**IN THE UNITED STATES DISTRICT COURT**
**FOR THE WESTERN DISTRICT OF VIRGINIA**

| | |
|---|---|
| WHOLE WOMAN'S HEALTH ALLIANCE, *et al*.,<br><br>Plaintiffs,<br><br>v.<br><br>UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al*.,<br><br>Defendants. | Case No. 3:23-cv-00019-RSB |

**PLAINTIFFS' NOTICE OF SUPPLEMENTAL AUTHORITY**

Plaintiffs respectfully submit this Notice of Supplemental Authority regarding the Order Granting Plaintiffs' Motion for Summary Judgment and Denying Defendants' Cross-Motion for Summary Judgment issued in *Purcell v. FDA*, No. 17-00493 JAO-RT (D. Haw. Oct. 30, 2025), attached as Exhibit A. The 79-page opinion in the *Purcell* case holds that the same agency action at issue in this case—the 2023 REMS Decision—violated the APA in three different ways.

*First*, the district court held that the six statutory factors set out in 21 U.S.C. § 355-1(a)(1) "remain relevant even in the context of a [§ 355-1](g)(4)(B) modification because they define what the Agency must consider when deciding whether a drug's benefits outweigh its risks." Ex. A at 39. The district court held that FDA's failure to consider the mandatory § 355-1(a)(1) factors in the 2023 REMS Decision "renders it and the resulting ETASUs arbitrary and capricious." *Id*. at 52.

*Next*, the district court examined FDA's stated reasons for the mifepristone ETASUs and held that each one "demonstrates unexplained logical leaps and conflicts with evidence in the record." *Id*. at 63. FDA's flawed reasoning is yet another ground for the district court's finding that the 2023 REMS Decision is "arbitrary and capricious." *Id*.

*Finally*, the district court examined the record data and faulted FDA for its refusal "to address the Canadian study in any meaningful way coupled with the Agency's selective focus on objective safety data, and its inconsistent use of survey data." *Id*. at 76. The district court further held that when FDA "failed to consider relevant evidence," it acted "arbitrarily and capriciously." *Id*.

DATED: October 31, 2025

Respectfully submitted,

/s/ *Gail M. Deady*
Gail M. Deady
Virginia Bar Number: 82035
Linda C. Goldstein (*pro hac vice*)
CENTER FOR REPRODUCTIVE RIGHTS
199 Water Street, 22nd Floor
New York, New York 10038
Telephone: (917) 637-3600
Fax: (917) 637-3666
Email: gdeady@reprorights.org
Email: lgoldstein@reprorights.org

*Counsel for Plaintiffs*

**CERTIFICATE OF SERVICE**

I hereby certify that on this 31st day of October, 2025, I filed the foregoing document with the Clerk of Court using the CM/ECF system.

/s/ *Linda C. Goldstein*
Linda C. Goldstein (*pro hac vice*)
Gail M. Deady
Virginia Bar Number: 82035
CENTER FOR REPRODUCTIVE RIGHTS
199 Water Street, 22nd Floor
New York, New York 10038
Telephone: (917) 637-3600
Fax: (917) 637-3666
Email: gdeady@reprorights.org
Email: lgoldstein@reprorights.org

*Counsel for Plaintiffs*

# EXHIBIT A

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF HAWAII

| | |
|---|---|
| HEIDI PURCELL, ET AL.,<br><br>Plaintiffs,<br><br>vs.<br><br>ROBERT F. KENNEDY, JR., in his official capacity as SECRETARY, U.S. D.H.H.S., ET AL.,<br><br>Defendants. | CIV. NO. 17-00493 JAO-RT<br><br>ORDER GRANTING PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT (ECF NO. 221) AND DENYING DEFENDANTS' CROSS MOTION FOR SUMMARY JUDGMENT (ECF NO. 228) |

**ORDER GRANTING PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT (ECF NO. 221) AND DENYING DEFENDANTS' CROSS MOTION FOR SUMMARY JUDGMENT (ECF NO. 228)**

The Food and Drug Administration ("FDA" or "Agency") regulates prescription drugs to ensure their safe use. When approving drugs, the Agency sometimes requires a "risk evaluation and mitigation strategy" ("REMS") if it determines such a strategy "is necessary to ensure that the benefits of the drug outweigh the risks of the drug." 21 U.S.C. §§ 355-1(a)(1). In addition, when imposing a REMS, the FDA may further restrict the drug by imposing certain "elements as are necessary to assure safe use" ("ETASU"). *Id*. § 355-1(f). ETASUs must "be commensurate with the specific serious risk listed in the labeling of the drug" and cannot "be unduly burdensome on patient access to the

drug," especially considering "patients who have difficulty accessing health care (such as patients in rural or medically underserved areas)[.]" *Id.* § 355-1(f)(2)(A), (C).

This case involves a challenge to the FDA's regulation of mifepristone, a drug used as part of a regimen for medication abortion. Mifepristone is one of those rare drugs with a REMS and ETASUs. Plaintiffs[1]—a Kauai-based physician and two non-profit organizations—contend that the FDA's imposition of these burdensome conditions on the prescription of mifepristone are unwarranted relative to the drug's safety. In particular, Plaintiffs challenge the Agency's most recent decision to maintain the mifepristone REMS ("2023 REMS Decision"). Mifepristone's REMS includes three specific ETASUs, as summarized:

> (1) The Prescriber Certification condition, which requires providers to sign a form attesting that they possess certain qualifications and that they reviewed the Patient Agreement Form with the patient. Providers must then send this form to the drug's sponsors and prescribing pharmacies.

[1] Plaintiffs are Heidi Purcell, M.D., FACOG, Society of Family Planning ("SFP"), and the California Academy of Family Physicians. Defendants are the FDA; Robert F. Kennedy, Jr. in his official capacity as Secretary of the United States Department of Health and Human Services; and Martin A. Makary, M.D., M.P.H., in his official capacity as Commissioner of Food and Drugs.

(2) The Patient Agreement Form, which requires patients and providers to sign and agree that the provider explained the drug's risks to the patient. By signing the form, a patient attests that she has decided to end her pregnancy.

(3) The Pharmacy Certification requirement, which obligates pharmacies to confirm that the prescribing provider complied with the Prescriber Certification requirement, and that they can deliver the drug to the patient within four days of the prescription date.

Before the Court are the parties' cross-motions for summary judgment. *See* ECF No. 221 (Plaintiffs' Motion for Summary Judgment or "Plaintiffs' Motion"); ECF No. 228 (Defendants' Cross Motion for Summary Judgment or "Defendants' Cross Motion"). Plaintiffs ask the Court to declare the 2023 REMS Decision unlawful under the Administrative Procedure Act ("APA"), but do not currently seek vacatur of the restrictions. *See* ECF No. 221-1 at 9; ECF No. 221 at 4–6. Rather, Plaintiffs ask the Court to remand the matter to the FDA with instructions to address the statutorily-mandated factors and consider relevant evidence the Agency allegedly disregarded. *See* ECF No. 221 at 2, 4–6. Defendants respond that Plaintiffs lack standing, and that the 2023 REMS Decision satisfies the APA's requirements. *See* ECF No. 228-1 at 7–9. Defendants also move for summary judgment on Plaintiffs' constitutional claims. *See id.*

Ultimately, the Court concludes that the Agency violated the APA by failing to provide a reasoned explanation for its restrictive treatment of the drug, which was compounded by its decision to limit the scope of information it considered when evaluating the REMS. More specifically, the Agency neglected to consider certain required statutory factors and generally failed to sufficiently explain the logic behind any reasoning it did provide, rendering the 2023 REMS Decision arbitrary and capricious.

Thus, for the following reasons, the Court GRANTS Plaintiffs' Motion and DENIES Defendants' Cross Motion. By granting Plaintiffs' Motion, this Order maintains the current restrictions on mifepristone but remands the question of those requirements to the FDA for a review consistent with this Order.

# I. BACKGROUND

## A. Facts[2]

### 1. Mifepristone and its Regulation

The FDA first approved mifepristone[3] in a regimen with misoprostol for medication abortion in 2000. *See* ECF No. 239 at 13 (Defs. Concise Statement of Facts or "DCSF") ¶ 1. Mifepristone blocks the effect of a hormone necessary for pregnancy, while misoprostol causes contractions and bleeding that empty the uterus. *See* ECF No. 227 (Pls. Concise Statement of Facts or "PCSF") ¶ 3. Medication abortion serves as an alternative to procedural abortion, which is conducted in a clinical setting and comes with its own risks and burdens. *See id.* ¶¶ 1, 10. Mifepristone therefore can offer a "meaningful therapeutic benefit" over procedural abortion that may be "preferable and safer in [a patient's] particular situation." *Id.* ¶ 10. Indeed, patients may prefer to use mifepristone for a medication abortion to avoid the anesthesia or invasiveness of procedural abortion.

---

[2] As this is an APA action, the Court does not engage in any factfinding and instead derives these facts from the administrative record. *See Nw. Motorcycle Ass'n v. U.S.D.A.*, 18 F.3d 1468, 1472 (9th Cir. 1994).

[3] The FDA originally approved mifepristone under the brand name Mifeprex, but approved a generic version in 2019. DCSF ¶ 8; PCSF ¶ 43. The Court, like the parties, uses "mifepristone" as shorthand to refer to both the brand name and the generic, which are subject to the same regulations. *See* DCSF ¶8.

*Id.* ¶ 11. Between September 2000 and June 2022, approximately 5.6 million women used mifepristone for medication abortion in the United States. *Id.* ¶ 8.

Mifepristone carries some risks, with its label indicating, among others, serious and sometimes fatal infections or bleeding. *See id.* ¶ 14; ECF No. 240-5 at 545. Yet, such risks are also present in miscarriages and surgical abortions. *See* ECF No. 240-5 at 565. In fact, per mifepristone's FDA-approved label, "no causal relationship between the use of Mifepristone tablets . . . and misoprostol and these events [(i.e., serious or fatal infections and bleeding)] has been established." *Id.* And there is no dispute that major adverse events associated with mifepristone are "exceedingly rare, generally far below 0.1% for any individual adverse event." PCSF ¶ 13.

When the FDA initially approved mifepristone for termination of pregnancy twenty-five years ago, it imposed certain additional restrictions on the distribution and use of the drug under "Subpart H" of the Agency's regulations. DCSF ¶ 2; *see also* 21 C.F.R. § 314.520. The mifepristone restrictions *at that time* mandated that:

> (1) prescribers certify that (among other things) they can assess the duration of pregnancies and diagnose ectopic pregnancies,[4] and will either provide surgical intervention or arrange for others to provide it if necessary;

[4] Mifepristone is contraindicated—meaning it should not be used—for patients with ectopic pregnancies. *See* ECF No. 240-5 at 548.

> (2) the drug be dispensed only in certain healthcare settings, by or under the supervision of a specially certified prescriber (the in-person dispensing requirement); and
>
> (3) patients sign a patient agreement form.

DCSF ¶ 3. These three restrictions remained in effect until 2020/2021 (as explained below), albeit with some modifications to the exact requirements. *See* PCSF ¶¶ 32, 44; DCSF ¶ 7 (describing the changes).

In 2007, Congress passed the Food and Drug Administration Amendments Act of 2007, which codified the Subpart H regulations and gave the FDA the authority to require a REMS for a drug when it determines such an approach "is necessary to ensure that the benefits of the drug outweigh the risks of the drug." 21 U.S.C. § 355-1(a)(1); *see* DCSF ¶ 5. Because mifepristone's Subpart H restrictions were in effect at the passage of the statute, the drug was deemed to have a REMS in place that incorporated the initial restrictions as ETASUs. *See* DCSF ¶ 5; PCSF ¶ 27; *see also* 21 U.S.C. § 355-1(a)(1). The FDA retained the same basic ETASUs for mifepristone after REMS reviews in 2011 and 2013. PCSF ¶ 28.

The FDA again reviewed mifepristone's REMS in 2015 and 2016. *Id.* ¶ 30. During the review, the FDA received letters urging the elimination of the REMS, including from researchers and providers of medical abortion. *Id.* ¶ 33; *see also* ECF No. 240-2 at 36. These letters argued that evidence demonstrated that "some

of the restrictions placed on mifepristone at its initial approval are no longer necessary for the safe and effective use of the drug." ECF No. 240-2 at 36–37. For example, organizations contended that the Patient Agreement Form was medically unnecessary and interfered with the clinician-patient relationship. *Id.* at 48.

Significantly, as part of the 2016 review, the FDA's own scientific review team recommended eliminating the Patient Agreement Form ETASU because:

- The safety profile of [mifepristone] is well-characterized over 15 years of experience, with known risks occurring rarely; the safety profile has not changed over the period of surveillance.
- Established clinical practice includes patient counseling and documentation of informed consent and evidence shows that practitioners are providing appropriate patient counseling and education; the Patient Agreement Form is duplicative of these established practices.
- Medical abortion with [mifepristone] is provided by a small group of organizations and their associated providers. Their documents and guidelines are duplicated in the Patient Agreement Form.
- The Prescriber Agreement Form and the requirement that [mifepristone] be dispensed to patients only in certain healthcare settings, specifically, clinics, medical offices, and hospitals under the supervision of a certified prescriber, remain in place.

*See* ECF No. 240-1 at 166; ECF No. 240-4 at 122–23.

One reviewer concurred, explaining that "the Patient Agreement Form, which requires a patient's signature, does not add to safe use conditions for the

patient for this REMS and is a burden for patients." ECF No. 240-1 at 167. That reviewer continued that it was "standard of care for patients undergoing pregnancy termination to undergo extensive counseling and informed consent," such that the Patient Agreement Form requirement is duplicative. *See id.* Nonetheless, the Commissioner of the FDA requested the requirement be maintained. *See* PCSF ¶ 41. The Director of the Center for Drug Evaluation and Research ("CDER") explained the Commissioner's rationale in a memorandum:

> After being briefed on the planned changes to the [new drug application] that the Center was considering, the Commissioner concluded that continuing the REMS requirement for a signed Patient Agreement Form would not interfere with access and would provide additional assurance that the patient is aware of the nature of the procedure, its risks, and the need for appropriate follow-up care. He requested that the Patient Agreement Form be retained as an element of the REMS.

ECF No. 240-1 at 282. That memorandum offered no further explanation as to why the Commissioner concluded as much.

The FDA also kept the two other ETASUs (again, at that time, the prescriber certification and the in-person dispensing requirements), *see* PCSF ¶ 32; ECF No. 240-1 at 289, but made changes to the REMS including (among other things), lowering the dose, increasing the gestational age to 70 days, and reducing the number of required in-person visits, *see* DCSF ¶ 7.

In 2019, FDA approved a generic version of mifepristone and approved a single, shared system REMS, known as the Mifepristone REMS Program, for both

Mifeprex and the generic version. DCSF ¶ 8; PCSF ¶ 43. It maintained the same three ETASUs. *See* PCSF ¶ 32.

The COVID-19 pandemic was a pivotal moment for the FDA's regulation of mifepristone. First, in July 2020, the United States District Court for the District of Maryland issued a preliminary injunction to bar enforcement of the in-person dispensing ETASU. *See id.* ¶ 44. While that injunction lasted only about six months, in April 2021, the FDA announced it would exercise enforcement discretion with regards to the in-person dispensing requirement during the COVID-19 public health emergency, and temporarily suspended that ETASU. *See id.* ¶¶ 44–45.

Meanwhile, although the instant case had been pending since 2017, in May 2021, the FDA announced that, in connection with this litigation, it would "undertake *a full review* of the Mifepristone REMS Program." *See* DCSF ¶ 9; ECF No. 240-4 at 112 (emphasis added). The result of that review, which occurred from mid-2021 to its culmination on January 3, 2023, is the subject of the parties' cross-motions.

**2. The 2021–2023 FDA Review**

During the 2021–2023 review, Plaintiffs submitted letters to the Agency arguing for the elimination of the Mifepristone REMS. *See* PCSF ¶ 48; ECF No. 240-4 at 7–12, 47–55. For example, they asserted that the REMS—and

specifically the prescriber certification and in-person dispensing requirements—"confers no benefit in terms of safety, efficacy, or acceptability of the drug mifepristone and instead creates barriers to use that negatively impact public health and equity in access to care." ECF No. 240-4 at 7. Plaintiffs also attacked the Patient Agreement Form requirement as unnecessary, noting that they:

> [A]gree[d] with the recommendation of FDA's scientific review team in 2016 to eliminate [the Prescriber Agreement Form ETASU], because [it] "is generally duplicative of information contained in the Medication Guide and of information and counseling provided to patients under standard informed consent practices for medical care and under professional practice guidelines."

*See id.* at 48 (quoting 2016 recommendation).

Plaintiffs also generally argued that mifepristone was significantly safer than other drugs with REMS. *See id.* at 48–49. They emphasized that less than 3% of FDA-regulated drugs have a REMS and that the majority that do are opioids. *See id.* at 48. The Agency agreed that since it initially approved mifepristone, no new safety concerns had arisen. *See id.* at 145.

Yet, on December 16, 2021, FDA announced in a memorandum ("2021 REMS Rationale Memo") that it would modify rather than eliminate the REMS. Specifically, the Agency would: (1) remove the in-person dispensing requirement, but (2) retain the Prescriber Certification and Patient Agreement Form restrictions, and (3) add a Pharmacy Certification condition. *See* DCSF ¶ 20; ECF No. 240-4 at

148. On January 3, 2023, the FDA issued another memorandum ("2023 REMS Rationale Memo), approving the mifepristone REMS modification with the three ETASUs. *See* PCSF ¶ 49. Thus, the current ETASUs require completion of (1) the Prescriber Certification, (2) the Patient Agreement Form, and (3) the Pharmacy Certification, prior to the dispensing of mifepristone.

As described in detail in Section III.B.1 below, the reasoning the Agency provided in the 2021 REMS Rationale Memo and 2023 REMS Rationale Memo was sparse. While the memos describe the historical regulation of mifepristone and the requirements of the ETASUs in some detail, the portions that discuss the Agency's justification for its decisions to retain two ETASUs and add a new one are relegated to a handful of paragraphs with repetitive and conclusory statements. *See, e.g.*, ECF No. 240-4 at 120–21 (describing in a couple paragraphs the conclusion that Prescriber Certification should be maintained).

***a. The Current Challenged REMS***

*i. The Prescriber Certification ETASU*

The Prescriber Certification ETASU requires health care providers who prescribe mifepristone to be specially certified. ECF No. 240-5 at 540. To become certified, the provider must review the prescribing information for the drug and sign the Prescriber Agreement Form. In the form, prescribers must attest that they are able to (1) assess the duration of pregnancy accurately, (2) diagnose ectopic

pregnancies, and (3) provide surgical intervention in cases of incomplete abortion or severe bleeding, or have made plans to provide such care through others. *See id.* Providers must also agree to the guidelines for the use of mifepristone, which include (1) reviewing the Patient Agreement Form with the patient and ensuring that both provider and patient sign, (2) providing the dispensing certified pharmacy with a signed copy of the Prescriber Agreement Form, and (3) assessing the appropriateness of dispensing the drug when contacted by a certified pharmacy about patients who will receive mifepristone more than four calendar days after the pharmacy received the subscription. *Id.* at 540–41.

*ii. The Patient Agreement Form ETASU*

This ETASU requires the patient and provider sign the Patient Agreement Form indicating that the patient has received, read, and been given a copy of the form, and that the patient received counseling "regarding the risk of serious complications associated with mifepristone." *Id.* at 543. In signing the form, the patient attests: "I have decided to take mifepristone and misoprostol to end my pregnancy[.]" *Id.* at 584. This is true even for patients who take mifepristone as prescribed by their providers for miscarriage treatment—an off-label use for the drug. *See* PCSF ¶ 4; *see also* ECF No. 240-4 at 25 ("All [ETASUs] apply even for off-label indications like [early pregnancy loss]."). Patients must additionally agree that they will (1) take the misoprostol 24 to 48 hours after taking

mifepristone *and* that they will (2) follow their "healthcare provider's advice about when to take each drug[.]" ECF No. 240-5 at 584. But many providers instruct their patients to follow a different timing regimen. *See* ECF No. 240-2 at 48.

*iii. The Pharmacy Certification ETASU*

The newly-added Pharmacy Certification requirement mandates that pharmacies must agree to (among other things): (1) verify that the prescriber of mifepristone is certified by confirming that the pharmacy received the Prescriber Agreement Form; (2) dispense mifepristone such that it is delivered to the patient within four calendar days of the date of the prescription; (3) contact the prescriber if the patient won't receive the drug within four calendar days; (4) maintain records of Prescriber Agreement Forms; (5) keep patients' and providers' identities confidential by limiting access only to those personnel necessary to dispense mifepristone; (6) designate an authorized individual to carry out the certification process; and (7) comply with audits. *See* ECF No. 240-5 at 542–43.

**B. Procedural History of this Litigation**

This case has been pending for over eight years, taking some twists and turns along the way, which the Court describes in only basic detail here. The original plaintiffs in this case filed suit on October 3, 2017 challenging the FDA's 2016 REMS. *See generally* ECF No. 1. Defendants moved to dismiss for lack of standing in February 2018, ECF No. 30, but eventually withdrew the motion, ECF

No. 40, after plaintiffs filed additional declarations with their opposition to the motion to dismiss, ECF No. 34. The parties then cross-moved for summary judgment in December 2019. *See* ECF Nos. 86, 89. Before resolving those motions, however, the Court stayed the action pending a Supreme Court case until March 2021. *See* ECF Nos. 107, 128. The Court thereafter reset a briefing schedule for cross-motions for summary judgment. ECF No. 130. Just before Defendants' due date for their motion and opposition to plaintiffs' motion, the FDA agreed to undertake the 2021 full REMS review, and the Court again stayed and administratively closed the case, ECF No. 149.

The case remained administratively closed for almost two years, until the Court reopened it in February 2023 after the parties indicated that Plaintiffs intended to seek leave to amend their complaint to challenge the 2023 REMS Decision. *See* ECF Nos. 157, 158. With leave of Court, Plaintiffs then filed the anticipated amended complaint. ECF No. 169. Before any new dispositive motions, Plaintiffs filed a motion to complete the administrative record to include materials related to a citizen petition submitted by the American College of Obstetricians and Gynecologists ("ACOG") and 48 other organizations, which asked the FDA to eliminate the mifepristone REMS, primarily for miscarriage management ("ACOG Petition"). *See* ECF No. 198. The Court granted the motion, ECF No. 207, which prompted Plaintiffs to file their second amended

complaint, ECF No. 209, and eventually their operative Corrected Second Amended and Supplemental Complaint ("SAC") in August 2024, ECF No. 212.

Briefing on the instant motions then spanned the better part of a year. Plaintiffs filed their Motion for Summary Judgment on October 2, 2024. ECF No. 221. Defendants filed their Cross Motion and opposition to Plaintiffs' Motion on December 3, 2024. ECF No. 228. Plaintiffs filed their reply and opposition to Defendants' Cross Motion on January 31, 2025. ECF No. 230. After an unopposed extension of time to file their reply because of the change in Presidential Administration, Defendants filed their reply on May 13, 2025. ECF No. 238.

The Court held a hearing on the Motions on August 22, 2025. After the hearing, the Court allowed Plaintiffs to file a supplemental declaration and set a deadline for Defendants to object to the declaration. *See* ECF No. 250. Plaintiffs filed the declaration, ECF No. 251, and Defendants timely objected, ECF No. 252.

## II. LEGAL STANDARD

A party is entitled to summary judgment "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "Summary judgment is a particularly appropriate tool for resolving claims challenging agency action," because "[i]n such cases the district court's role is not to resolve facts, but to determine whether

or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did." *Ctr. for Biological Diversity v. Haaland*, 562 F. Supp. 3d 68, 76 (D. Ariz. 2021) (internal quotation marks and citations omitted). In other words, "summary judgment is an appropriate mechanism for deciding the legal question of whether the agency could reasonably have found the facts as it did." *Occidental Eng'g Co. v. INS*, 753 F.2d 766, 769 (9th Cir. 1985).

Under the APA, a court may set aside an agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," or "in excess of statutory jurisdiction, authority, or limitations." 5 U.S.C. § 706(2)(A), (C). To survive a challenge under the APA's arbitrary and capricious standard, an "agency must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (internal quotation marks and citation omitted). An agency runs afoul of the arbitrary and capricious standard if it:

> [R]elied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

*Id.* In analyzing agency action, courts "'must be careful not to unduly second-guess an agency's scientific judgments,' and will affirm the FDA's decision so

long as it is 'reasonable and reasonably explained.'" *Ipsen Biopharms., Inc. v. Becerra*, 108 F.4th 836, 640 (D.C. Cir. 2024) (quoting *Cytori Therapeutics, Inc. v. FDA*, 715 F.3d 922, 923, 926 (D.C. Cir. 2013)).

## III. DISCUSSION

### A. Standing

Before turning to the merits of the APA claim, the Court addresses and rejects Defendants' argument that Plaintiffs lack standing to pursue their claims. *See* ECF No. 228-1 at 17–26; ECF No. 238 at 9–12. While Defendants articulated various attacks on standing in their briefs, Plaintiffs significantly narrowed the issues during the August 22, 2025 hearing when they conceded that they exclusively rely on one SFP member, Dr. Honor MacNaughton, to establish standing. Defendants maintain their standing attack, arguing that: (1) Plaintiffs impermissibly changed their theory of standing from the one alleged in the SAC; (2) Dr. MacNaughton's declaration does not establish she was a member of SFP at the filing of the SAC, and that her supplemental declaration was improper; and (3) Dr. MacNaughton cannot support standing in any event. ECF No. 238 at 9–11; ECF No. 252.

"To have standing, Plaintiffs must have '(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision.'" *LA All. for Human Rights*

*v. Cnty. of Los Angeles*, 14 F.4th 947, 956 (9th Cir. 2021) (quoting *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016)). Standing "'must be supported in the same way as any other matter on which the plaintiff bears the burden of proof, *i.e.*, with the manner and degree of evidence required at the successive stages of the litigation.'" *Washington v. Trump*, 847 F.3d 1151, 1159 (9th Cir. 2017) (quoting *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992)). Thus, "[i]n order to have standing at the summary judgment stage, plaintiffs must 'set forth by affidavit or other evidence specific facts' . . . showing that they have suffered an 'injury in fact' that is fairly traceable to the action they seek to challenge." *Arakaki v. Hawaii*, 314 F.3d 1091, 1098 (9th Cir. 2002) (quoting *Lujan*, 504 U.S. at 561).

Organizations may assert standing based on their own injuries or on behalf of their members, which is known as associational or representational standing. *See Stavrianoudakis v. U.S. Fish & Wildlife Serv.*, 108 F.4th 1128, 1143 (9th Cir. 2024). To establish associational standing, an organization must demonstrate "that: (a) its members would otherwise have standing to sue in their own right; (b) the interests it seeks to protect are germane to the organization's purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Id.* (citation omitted). The third requirement may be fulfilled where plaintiffs seek only declaratory or injunctive relief, which does not require individualized proof. *See id.* (citing *Columbia Basin Apartment*

*Ass'n v. City of Pasco*, 268 F.3d 791, 799 (9th Cir. 2001)). Here, SFP "sues on behalf of its members and their patients," ECF No. 212 ¶ 29, rather than on its own behalf.

Turning to the instant case, the Court first addresses Defendants' argument that Plaintiffs deviated from the theory of standing they pled, before considering the issues related to Dr. MacNaughton.

**1. Plaintiffs' Theory of Standing**

First, Defendants argue that Plaintiffs now offer a different theory of standing from the one they alleged in the SAC. ECF No. 238 at 9–10. Specifically, Defendants claim that Plaintiffs did not allege in the SAC that they were directly regulated by the 2023 REMS Decision, but instead asserted only "indirect injuries through speculative and attenuated chains of causation." *See id.* at 9. The Court concludes that Plaintiffs sufficiently alleged direct regulation in the SAC and thus did not impermissibly switch theories.

While the SAC does contain long descriptions of administrative burdens that health centers bear to comply with the REMS, *see, e.g.*, ECF No. 212 ¶ 194,[5] it also alleges that the REMS requires Plaintiffs *to do* certain things (and thereby

[5] "[One SFP member's] health system recently developed a process for its inpatient pharmacy to maintain records of whether a clinician is certified to prescribe mifepristone, and to dynamically update the system's electronic health records to reflect that information—a substantial and ongoing investment of human labor."

directly regulates them). For example, the Prescriber Certification mandates that providers submit a form attesting to their qualifications and that they go over the Patient Agreement Form with patients, sign that Form along with the patient, and keep a copy of it in the patients' records. *See id.* ¶¶ 69, 144–46; *see also id.* ¶ 107 (noting that the FDA maintained Prescriber Certification and Patient Agreement ETASUs in 2023 REMS).

The SAC also outlines other allegations concerning direct regulation. Focusing on SFP, the SAC alleges that SFP "has members who are prevented from providing mifepristone to their patients because of the REMS," and that the REMS "undermines some of SFP's members' relationships with and counseling of their patients." *Id.* ¶ 29. Under the header, "The Impact of the Mifepristone REMS on Plaintiffs, Plaintiffs' Members, and Plaintiffs' Members' Patients," and a sub-header, "Harms Caused by the 2023 REMS," Plaintiffs also aver that the REMS "sends a false message about mifepristone's safety that complicates, delays, and derails efforts by health care providers to prescribe . . . mifepristone." *Id.* ¶ 170. They further assert that the REMS requires the involvement of many medical and non-medical staff "which can delay or altogether derail their ability to provide this medication to their patients." *Id.* ¶ 173. Moreover, they allege that the Prescriber Certification "reduce[s] the pool of qualified health care providers willing to prescribe mifepristone because many clinicians are fearful that they will face anti-

abortion violence and harassment if their registration as a mifepristone prescriber were ever exposed." *Id.* ¶ 176. This is all to say that Plaintiffs alleged they were directly subject to the REMS requirements and did not radically change their theory, as the Agency asserts.

Defendants' cited law is inapposite. It principally relies on *La Asociacion de Trabajadores de Lake Forest v. City of Lake Forest*, 624 F.3d 1083, 1089 (9th Cir. 2010), for the premise that a plaintiff "may not effectively amend its Complaint by raising a new theory of standing in its response to a motion for summary judgment." *Id.* In that case, however, the organizational plaintiff initially alleged only associational standing, but at the motion for summary judgment stage, appeared to submit evidence asserting standing on its own behalf. *Id*. No such sea change in standing theory occurred here though—SFP has always relied on associational standing to assert the claims of its members. *See* ECF No. 212 ¶ 29.

**2. Dr. MacNaughton's Supplemental Declaration**

The Court next addresses Defendants' contention that Plaintiffs failed to show that Dr. MacNaughton was a member of SFP at the initiation of Plaintiffs' challenge to the 2023 REMS, which is indeed required under caselaw. *See* ECF No. 238 at 10–11 (citing *Friends of the Earth, Inc. v. Laidlaw Envt'l Servs. (TOC), Inc.*, 528 U.S. 167, 180 (2000); *Northstar Fin. Advisors Inc. v. Schwab Invests.*, 779 F.3d 1036, 1044 (9th Cir. 2015)). Plaintiffs submitted Dr. MacNaughton's

declaration in their reply and opposition to Defendants' Cross Motion on January 31, 2025. *See* ECF No. 231-1 (Decl. of Dr. MacNaughton). In it, Dr. MacNaughton attests, "I *am* a member of [SFP]," without any discussion of when she became a member. *Id*. ¶ 4 (emphasis added). At the hearing, however, Plaintiffs' counsel clarified that Dr. MacNaughton was a member at the relevant time. To dispel any evidentiary concerns about accepting counsel's statement, the Court allowed Plaintiffs to file a supplemental declaration. *See* ECF No. 250 (citing *Alabama Legis. Black Caucus v. Alabama*, 575 U.S. 254, 268–71 (2015); *Warth v. Seldin*, 422 U.S. 490, 501–02 (1975); Fed. R. Civ. P. 56(e)(1)). Plaintiffs timely filed the supplemental declaration and confirmed what Plaintiffs' counsel represented about Dr. MacNaughton's membership history. *See* ECF No. 251 ¶ 3.

Yet Defendants object to the Court's consideration of Dr. MacNaughton's supplemental declaration. First, they argue that the Court's citations to *Alabama Legislative Black Caucus*, *Warth*, and Rule 56(e)(1) in its August 25, 2025 Entering Order, ECF No. 250, were misguided because Plaintiffs had sufficient opportunities to establish standing before the Court allowed them to supplement. *See* ECF No. 252 at 4–5. The Court, however, thinks that "it is relatively clear, rather than merely speculative, that one or more members" of the organizational Plaintiffs would have standing to challenge the 2023 REMS Decision. *See Nat'l Council of La Raza v. Cegavske*, 800 F.3d 1032, 1041 (9th Cir. 2015). Thus, rather

than dismiss the action on a narrow challenge to when exactly a member of SFP joined the organization, the Court concludes that in these circumstances, "elementary principles of procedural fairness," justified the Court's grant of leave for Plaintiffs to file a supplemental declaration. *Alabama Leg. Black Caucus*, 575 U.S. at 271.

Defendants next argue that consideration of the supplemental declaration would be futile because Dr. MacNaughton would lack standing in any event and Plaintiffs needed to have named her in the SAC. The Court addresses the former contention in detail below. But as to the latter, the FDA's citations to *Summers v. Earth Island Institute*, 555 U.S. 488, 499 (2009) and *National Council of La Raza*, 800 F.3d at 1041, fail to persuade the Court because neither stands for the premise that an organizational plaintiff must name a specific member in its complaint and then provide evidence of that *same* specific member's standing at summary judgment. As the Ninth Circuit commented in *National Council of La Raza, Summers* merely "refused to find standing based only on *speculation* that unidentified members would be injured by a proposed action of the National Forest Service." *Nat'l Council of Law Raza*, 800 F.3d at 1041 (citing *Summers*, 555 U.S. at 498–99) (emphasis added). Thus, the Ninth Circuit declined to read *Summers* to require that a complaint specifically name any harmed members. *See Nat'l Council of Law Raza*, 800 F.3d at 1041. And neither the FDA's briefing nor the

Court's own research uncovered a case requiring that an organizational plaintiff name the same member in the complaint and at summary judgment. Regardless, there's no doubt that SFP needed to identify a member now at summary judgment, *see Assoc. Gen. Contractors of Am., San Diego Chapter, Inc. v. Cal. Dep't of Transp.*, 713 F.3d 1187, 1194–95 (9th Cir. 2013), and it did so here, *see* ECF No. 231-1 (initial Declaration of Dr. MacNaughton); ECF No. 251 (supplemental declaration). The Court thus declines to find that SFP lacks standing because it did not name Dr. MacNaughton in the SAC.

**3. Dr. MacNaughton's Standing**

Finally, Defendants argue that even if Dr. MacNaughton was a member of SFP at the relevant time, and Plaintiffs did not change theories, Dr. MacNaughton's declaration still fails to establish her own standing because she "relies on (1) burdens imposed on her by her employer, (2) speculation about what pharmacies might fill prescriptions she writes if there were no pharmacy certification requirement, and (3) difficulties created by her own decision to prescribe mifepristone off-label for miscarriage management." ECF No. 238 at 11. The declaration itself belies Defendants' characterization and reveals that the REMS more directly burdens Dr. MacNaughton. *See generally* ECF No. 231-1.

Dr. MacNaughton is a board-certified family medicine physician and Associate Professor of Family Medicine at Tufts University School of Medicine.

*Id.* ¶ 2. She provides primary care and reproductive health services in a hospital system and is also part of a team overseeing the three reproductive health clinics within the system. *See id.* ¶¶ 2, 7. She is a certified prescriber of mifepristone under the REMS and regularly prescribes the drug for both abortion and miscarriage care. *See id.* ¶ 8. As part of her administrative duties, she also knows of more than eighty other colleagues who regularly prescribe mifepristone. *Id.* ¶ 9. She is thus well-placed to comment on her and her colleagues' experiences with the mifepristone REMS.

Regarding the impact of the REMS on her practice, Dr. MacNaughton states:

> The Mifepristone REMS directly imposes multiple, ongoing burdens on me and my colleagues by forcing us to comply with requirements that take considerable time and energy to navigate and that compromise our clinician-patient relationships and ability to practice our profession. These ongoing burdens include the time, labor, and health system resources necessary to navigate and fulfill the prescriber certification, pharmacy certification, and patient agreement requirements—burdens that would not exist but for the REMS. The REMS also routinely complicates and interferes with the counseling process for my medication abortion and miscarriage patients, by (1) creating administrative complexities that I'm forced to spend considerable time and effort navigating with my patients during each appointment, and (2) mandating the provision of duplicative and, for some patients, inaccurate counseling information.

*Id.* ¶ 10. She also describes how the Prescriber Certification's requirement that providers must send their certification forms to every individual pharmacy proves difficult to manage from an administrative perspective. *Id.* ¶ 12. In short, it's clear

that Dr. MacNaughton's practice is burdened by the ETASUs and that she has standing.

This all boils down to one principle—the mifepristone REMS indisputably requires Plaintiffs who prescribe mifepristone to do certain things and prevents them from doing other things, which goes a long way toward establishing standing. Defendants' citation to *FDA v. Alliance for Hippocratic Medicine*, 602 U.S. 367 (2024), demonstrates why.

Defendants rely on *Alliance for Hippocratic Medicine* for the premise that Plaintiffs' theories of standing are too removed from the alleged harms of the REMS to bring suit. ECF No. 228-1 at 19–21. In *Alliance for Hippocratic Medicine*, the Supreme Court unanimously held that doctors *who did not prescribe or use* mifepristone lacked standing to challenge the FDA's approval of and loosening of restrictions on the drug since its initial approval in 2000. *See* 602 U.S. at 385. The Supreme Court explained that it is more difficult for plaintiffs who assert others' harms to have the kind of stake in a case necessary to maintain suit. In doing so, the Supreme Court summarized the well-known standing requirements of injury in fact, causation, and redressability and commented that:

> The second and third standing requirements—causation and redressability—are often flip sides of the same coin. If a defendant's action causes an injury, enjoining the action or awarding damages for the action will typically redress that injury. So the two key questions in most standing disputes are injury in fact and causation.

*Id.* at 380–81 (internal quotation marks and citation omitted). It continued that, "[g]overnment regulations that *require or forbid some action by the plaintiff* almost invariably satisfy both the injury in fact and causation requirements. So in those cases, standing is usually easy to establish." *Id.* at 382 (emphasis added); *see also Lujan*, 504 U.S. at 561–62.

Here, the Court concludes that Plaintiffs sufficiently alleged and have now sufficiently established through Dr. MacNaughton's declaration that they are directly regulated under the mifepristone REMS, which requires and forbids some actions by them. Because the Court finds that Dr. MacNaughton would have standing to pursue this case, and because she is and was a member of SFP, that organization has established standing.[6] And because at least one party has standing, the Court proceeds to the merits of Plaintiffs' claims. *See, e.g.*, *Brown v. City of Los Angeles*, 521 F.3d 1238, 1240 n.1 (9th Cir. 2008) ("[T]he presence in a suit of even one party with standing suffices to make a claim justiciable." (citing *Dep't of Commerce v. U.S. House of Representatives*, 525 U.S. 316, 330 (1999)).

[6] Defendants do not dispute that SFP satisfies the other two requirements of associational standing, i.e., that the interests at stake are germane to SFP's purpose and that the case does not require individual participation of members. *See generally* ECF Nos. 228-1 at 21–24. The Court is satisfied that both requirements are met. *See* ECF No. 212 ¶ 28 (describing SFP's organizational purpose).

## B. APA

Plaintiffs pursue their APA claims on two different theories: (1) that the Agency's 2023 REMS Decision was arbitrary and capricious and/or (2) that the Agency exceeded its statutory authority. *See* ECF No. 221-1 at 30. As to the arbitrary and capricious argument, Plaintiffs present two different broad lines of attack, alleging that the Agency failed to: (1) consider relevant evidence and (2) provide a reasoned explanation for the 2023 REMS Decision. The Court addresses the latter first but recognizes the interconnectedness of the arguments and analysis.

### 1. Arbitrary and Capricious – Failure to Provide Reasoned Explanation

Plaintiffs contend that the FDA failed to provide a reasoned explanation for the 2023 REMS Decision because it: (1) did not analyze mandatory statutory factors; (2) ignored key arguments and evidence contrary to its decision; (3) neglected to explain its inconsistent regulation of mifepristone relative to comparable and less safe drugs; and (4) provided unreasonable rationales for its conclusions. *See* ECF No. 221-1 at 36. Defendants dispute which statutory factors controlled the FDA's review of the 2023 REMS Decision and argues the Agency reasonably assessed the required factors and explained its conclusions. *See* ECF No. 228-1 at 26–39. The Court first addresses the dispute about the statutory factors and ultimately agrees with Plaintiffs that the FDA failed to consider

relevant statutory factors or otherwise provide a reasoned explanation for its 2023 REMS decision.

***a. The Statutory Factors***

Failure to consider a statutorily-mandated factor renders an agency's decision arbitrary and capricious because such a factor, "by definition, is an important aspect of any issue before an administrative agency, as it is for Congress in the first instance to define the appropriate scope of an agency's mission." *Pub. Citizen v. Fed. Motor Carrier Safety Admin.*, 374 F.3d 1209, 1216 (D.C. Cir. 2004). Because the parties dispute which factors applied to the 2021–2023 REMS review/modification, the Court starts with that question.

There are three potentially relevant subprovisions in the REMS statute: 21 U.S.C. §§ 355-1(a)(1) ("Initial Approval Factors"), (f)(1)–(2) ("ETASU Factors"), and (g)(4)(B) ("Modification Provision"). The parties broadly agree that the ETASU Factors and Modification Provision governed the Agency's REMS review, but debate the meanings of those sections, and the extent to which the FDA considered them. *See* ECF No. 221-1 at 36–37; ECF No. 228-1 at 26, 36–38. By contrast, the parties fiercely dispute whether the Initial Approval Factors applied. *See* ECF No. 228-1 at 34–36; ECF No. 230 at 29; ECF No. 238 at 13–14. To make sense of the arguments, the Court outlines the subprovisions below.

*i. Initial Approval Factors (21 U.S.C. § 355-1(a)(1))*

To approve a new drug, the FDA must conclude that it is safe and effective. 21 U.S.C. § 355(d). This safety and effectiveness determination remains relevant to subsequent modifications to approved drug applications. *See* 21 C.F.R. §§ 314.1 (new drug application requirements apply to supplemental applications), 314.105(c) (approval contingent on meeting statutory standards for safety and effectiveness). In other words, the Agency cannot approve a modification without at least implicitly finding that the drug remains safe and effective with the change.

Within the REMS regimen, § 355-1(a)(1) is captioned "Initial Approval" and provides that "[i]f the Secretary . . . determine[es] that a [REMS] is necessary to ensure that *the benefits of the drug outweigh the risks of the drug*," then the Secretary may require a drug sponsor to submit a proposed REMS. 21 U.S.C. § 355-1(a)(1) (emphasis added). To determine whether a REMS is necessary to ensure that the benefits of the drug outweigh its risks, the FDA must consider the following factors:

> (A) The estimated size of the population likely to use the drug involved.
>
> (B) The seriousness of the disease or condition that is to be treated with the drug.
>
> (C) The expected benefit of the drug with respect to such disease or condition.

> (D) The expected or actual duration of treatment with the drug.
>
> (E) The 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.
>
> (F) Whether the drug is a new molecular entity.

*Id*.

*ii. ETASU Factors (21 U.S.C. § 355-1(f)(1)–(2))*

In addition to a REMS, the FDA may also—but need not—impose ETASUs. Subsection (f)(1) describes when a REMS may include such conditions:

> The Secretary . . . may require that the [REMS] for a drug include such elements as are necessary to assure safe use of the drug, because of its inherent toxicity or potential harmfulness, if the Secretary determines that—
>
> (A) the drug, which has been shown to be effective, but is associated with a serious adverse drug experience, 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.* ¶ 355-1(f)(1)(A). Still, the statute requires that ETASUs meet certain conditions to "assur[e] access and minimiz[e] burden." *Id.* ¶ 355-1(f)(2). ETASUs must:

> (A) be commensurate with the specific serious risk listed in the labeling of the drug;
>
> (B) within 30 days of the date on which any element under paragraph (1) is imposed, be posted publicly by the Secretary with an explanation of how such elements will mitigate the observed safety risk;

> (C) considering such risk, not be unduly burdensome on patient access to the drug, considering in particular—
>
> > (i) patients with serious or life-threatening diseases or conditions;
> >
> > (ii) patients who have difficulty accessing health care (such as patients in rural or medically underserved areas); and
> >
> > (iii) patients with functional limitations; and
>
> (D) to the extent practicable, so as to minimize the burden on the health care delivery system—
>
> > (i) conform with elements to assure safe use for other drugs with similar, serious risks; and
> >
> > (ii) be designed to be compatible with established distribution, procurement, and dispensing systems for drugs.

21 U.S.C. § 355-1(f)(2).

*iii. Modification Provision (21 U.S.C. § 355-1(g)(4)(B))*

Finally, § 355-1(g)(4)(B) addresses REMS modifications and states:

> After the approval of a [REMS] by the Secretary, the Secretary may, at any time, require a responsible person to submit a proposed modification to the strategy . . . if the Secretary . . . determines that 1 or more goals or elements should be added, modified, or removed from the approved strategy to—
>
> > (i) ensure *the benefits of the drug outweigh the risks of the drug*; [or]
> >
> > (ii) minimize the burden on the health care delivery system of complying with the strategy.

21 U.S.C. § 355-1(g)(4)(B) (emphasis added).

***b. Consideration of the Statutory Factors***

With the relevant language articulated, the Court turns to the heart of the matter—which factors did the FDA need to consider when rendering its 2023 REMS Decision and did it consider them? As explained below, the Court concludes that the Initial Approval Factors remain relevant at REMS modification or review because the Modification Provision effectively incorporates the Initial Approval Factors by using the identical phrase that mandates a REMS at the initial approval stage (i.e., "to ensure that the benefits of the drug outweigh the risks of the drug"). Because the Agency failed to consider the Initial Approval Factors, the 2023 REMS Decision violates the APA. And, even if the Agency alludes to some relevant factors, the Court finds that the 2023 REMS Decision's analysis of the ETASU Factors was insufficient.

By concluding that the Agency violated the APA based on this failure to analyze the factors, the Court is not holding the Agency accountable for some technical mistake or elevating form over substance. Rather, the Court finds the failure to discuss the factors in any significant way violates the APA's requirement that an agency show its work. *See Nat'l Parks Conservation Ass'n v. EPA*, 788 F.3d 1134, 1145 (9th Cir. 2015) (finding an APA violation where the agency failed to explain *how* it reached the challenged decision).

*i. Initial Approval Factors (21 U.S.C. § 355-1(a)(1))/Modification Provision (§ 355-1(g)(4)(B)(i))*

First, Plaintiffs argue that the Agency completely ignored the six Initial Approval Factors. *See* ECF No. 221-1 at 36–37; ECF No. 230 at 29. One might ask why the Initial Approval Factors remain relevant after the mifepristone REMS was approved in the first instance. Defendants' answer to that question is that they do not. The Court disagrees, however, and concludes that because 21 U.S.C. § 355-1(a)(1) and the Modification Provision in 21 U.S.C. § 355-1(g)(4)(B)(i) use the same language about ensuring the benefits of the drug outweigh the risks, the Modification Provision effectively incorporates the Initial Approval Factors.

Some of Defendants' support for their position is certainly reasonable. They stress that subsection (a)(1) is titled "initial approval" whereas (g)(4) is titled "modification" and states that "*[a]fter* the approval of a [REMS]," the Secretary may require a proposed modification. *Compare* 21 U.S.C. § 355-1(a)(1), *with id.* § 355-1(g)(4). *See* ECF No. 228-1 at 35; ECF No. 238 at 13. Defendants also highlight that (g)(4) does not explicitly cross-reference (a)(1) and that some of the language in (a)(1) appears directed at drugs that haven't yet been marketed. *See id.* at 35–36. For example, the Initial Approval Factors require the Secretary to consider the *estimated* population of users or the *expected* benefit, referring to hypothetical future effects of the drug. Finally, Defendants argue that 21 U.S.C. §

355-1(h) establishes different resolution procedures for disputes that arise in initial approvals and modifications. *See* ECF No. 228-1 at 35 (citing § 355-1(h)(3), (4)).

Yet the reasonableness of Defendants' position wavers in light of the fact that the Initial Approval Factors define how the Secretary must "determine[] that a risk evaluation and mitigation strategy is necessary to *ensure that the benefits of the drug outweigh the risks of the drug*," 21 U.S.C. § 355-1(a)(1), and that the Secretary may trigger a modification under (g)(4)(B)(i) if it considers such modification necessary to meet that same goal. In short, the Initial Approval Factors tell the Secretary *how* to determine whether the "benefits outweigh the risks," and the Modification Provision uses the identical phrase.

The Agency's suggestion that the statute requires the Secretary to consider different factors to make the same determination thereby runs afoul of the statutory construction presumption "that identical words used in different parts of the same act are intended to have the same meaning." *Gustafson v. Alloyd Co.*, 513 U.S. 561, 598 (1995) (internal quotation marks omitted). Admittedly, this presumption "is not rigid and readily yields" when the words are used in such different contexts that they evince different intent. *Env't Def. v. Duke Energy Corp.*, 549 U.S. 561, 574 (2007) (quoting *Atl. Cleaners & Dyers, Inc. v. United States*, 286 U.S. 427, 433 (1932)). But none of Defendants' arguments about purported distinctions

between the subprovisions convince the Court to depart from the presumption of consistent meaning.

Indeed, the lack of an explicit cross-reference between the provisions could just as easily be read as evidence of Congress' recognition that the identical term would mean the same thing in different provisions. Defendants' cite to *Russello v. United States*, 464 U.S. 16 (1983), fails to persuade the Court otherwise. *See* ECF No. 238 at 13–14. In that case the Supreme Court "refrain[ed] from concluding . . . that the *differing language* in the two subsections" meant the same thing. *See Russello*, 464 U.S. at 23 (emphasis added). Here, the statutory directive to the Agency uses the same language in both sections—the Agency must ensure the benefits of the drug outweigh the risks. Similarly, that the subprovisions are titled differently is not dispositive, *cf. California Independent System Operator Corp. v. FERC*, 372 F.3d 395, 399 (D.C. Cir. 2004), or particularly persuasive here. Subsection (g) of the statute simply provides that REMS will be assessed and modified when required. Likewise, the difference in dispute resolution procedures at the different stages doesn't speak to the substance of the Agency's duty at those different stages. If anything, it suggests a recognition that there could be a different relationship between the Agency with the sponsor of a new drug and with the sponsor of an approved drug.

By contrast, plain meaning, context, and common sense suggest that the Initial Approval Factors remain relevant to the modification of a REMS. For one, Defendants admit that in determining whether to modify a REMS, the Secretary must assess whether the drug's risks require a REMS at all. *See* ECF No. 238 at 15. The question is *how* the Agency must do so. The Modification Provision explicitly states that the Agency may trigger a modification if it decides that a change should be made to "ensure the benefits of the drug outweigh the risks of the drug." 21 U.S.C. § 355-1(g)(4)(B)(i). This plainly asks whether the good effects of the drug are greater than the potential bad effects. The Initial Approval Factors distill that essential calculation: they command the Secretary to consider things such as the potential population likely to use the drug, the seriousness of the condition to be treated, the benefits of the drug with respect to the condition, and the seriousness of the potential adverse effects when considered against the background incidence of such events in the population likely to use the drug. *See id.* § 355-1(a)(1)(A), (B), (C), (F). That those considerations would become immaterial after initial approval of a REMS strikes the Court as illogical, particularly where greater, more recent data is likely to be useful. And significantly, the Agency's REMS Rationale Memos do not offer much guidance on the matter. Neither the 2021 nor 2023 memo specifically cites the Initial Approval Factors or Modification Provision, but both repeat the "benefits outweigh

the risks" language throughout. *See, e.g.*, ECF No. 240-4 at 121; ECF No. 240-5 at 483.

Defendants' argument that the language of the Initial Approval Factors is hypothetical or forward looking doesn't persuade the Court either. Even at the modification stage, the Agency would consider the *possible* effect of its change. Presumably a new *estimate* of the *likely* population would need to be considered in determining whether and how to make a drug more accessible. In the same vein, new research could reveal new data about the *expected* benefits or risks of a drug. The statute's use of hypothetical or future language thus suggests not only pre-approval considerations, but also the fact that scientific judgments are often estimates or projections. They do not speak in certainties. *See* ECF No. 240-4 at 120, 121, 125 (discussing *potential* complications, increase in providers, and burden on providers and patients in the 2021 REMS Rationale Memo).

In sum, the Court concludes that the Initial Approval Factors remain relevant even in the context of a (g)(4)(B) modification because they define what the Agency must consider when deciding whether a drug's benefits outweigh its risks. The Court also determines that the Agency failed to explicitly address those factors and that its conclusory repetition of the phrases "necessary to ensure the benefits outweigh the risks," in the 2021 and 2023 REMS Rationale Memos does not suffice to explain its reasoning.

For this reason, the Court also rejects Defendants' contention that, because the REMS was necessary to ensure the safety of mifepristone, the failure to explicitly consider any factor would constitute harmless error. *See* ECF No. 228-1 at 38–39 (harmless error argument); *see also id.* at 10 ("[I]n determining whether a drug is 'safe,' FDA examines whether the benefits of the drug outweigh the risks." (citation omitted)). But this is a circular proposition because, as Defendants argue, to determine whether a drug is safe, the Agency must conclude that the drug's benefits outweigh the risks. *See* ECF No. 238 at 7. Thus, to conclude that a drug is safe, the Agency must consider the factors that define whether the benefits outweigh the risks. And even if the Agency did not need to go through each of the Initial Approval factors one-by-one to determine whether the benefits outweigh the risks, as discussed below, its general justification for the REMS with ETASUs demonstrates logical gaps and inconsistencies and doesn't pass muster under the APA.

*ii. ETASU Factors (21 U.S.C. § 355-1(f)(1)–(2))*

Defendants' treatment of the ETASU Factors bolsters the Court's conclusion. As Plaintiffs note, Defendants implicitly concede that the ETASU Factors remain relevant in the context of a REMS modification. *See* ECF No. 230 at 24; ECF No. 228-1 at 36–37 (addressing the factors). Indeed, during the REMS review, the Agency believed the ETASU Factors applied, as evidenced by the fact

it cites 21 U.S.C. § 355-1(f)(2) in the 2021 REMS Rationale Memo. *See* ECF No. 240-4 at 125, 144. Plaintiffs contend that the Agency nonetheless failed to consider the factors in "four discrete ways." ECF No. 230 at 24. The Court evaluates each below and finds Plaintiffs' third and fourth arguments compelling.

1. Whether the FDA Considered if Mifepristone Presented Such a Serious Risk that Approval Would be Withdrawn without ETASUs

First, Plaintiffs argue that the Agency failed to make the threshold finding under subsection (f)(1)(A) that mifepristone is associated with such a serious risk that the Agency would "withdraw" the drug's approval without the ETASUs. *See* ECF No. 230 at 24–25. They contend that this withdrawal requirement is above and beyond the REMS standard that requires the Agency to ensure the benefits of the drug outweigh its risks. *See id.* at 25.

As a basic matter of statutory interpretation, the Court agrees that subsection (f)(1)(A) must mean *something* different than the benefit outweighing the risk language in (a)(1) and (g)(4)(B), but Plaintiffs fail to explain precisely what more the Agency needed to do in this regard, and it is not obvious to the Court. Plaintiffs' arguments about this withdrawal requirement are broad anyway, and the Court thus considers them more relevant to Plaintiffs' generalized contention that the Agency failed to provide a reasonable explanation for its retention and addition of the ETASUs. And because the Court concludes that the Agency otherwise

violated the APA, the Court need not reach this precise issue. The Court will nonetheless address Plaintiffs' arguments below in its "Unreasonable Explanations" discussion in Section III.B.1.c.

2. Whether the FDA Failed to Explain How the ETASUs are Commensurate with Mifepristone's Specific Risks

Second, Plaintiffs attack the FDA's purported failure to explain how the ETASUs are "commensurate" with the specific risks identified on mifepristone's label under (f)(2)(A). ECF No. 230 at 26. Like their first argument though, Plaintiffs don't quite explain what the "commensurate" determination requires and how their argument here would be different from their challenge to the REMS and ETASUs in general. The Court thus again declines to decide the matter, but will address the generalized arguments below.

3. Whether the FDA Failed to Consider if the ETASUs were Consistent with Those of Other Drugs with Similar Risks

Whereas the first two ETASU factors that Plaintiffs claim the Agency failed to consider are somewhat broad, the third and fourth describe specific and discrete obligations on the Agency. Namely, Plaintiffs argue that the Agency completely failed to consider whether the mifepristone ETASUs conformed with those of other drugs with similar, serious risks under subsection (f)(2)(D)(i). *See* ECF No. 230 at 27–28. The Agency responds that Plaintiffs' chosen comparator drugs are not relevantly similar to mifepristone and that Plaintiffs misread the statute in any

event. *See* ECF No. 228-1 at 37–38. The Court addresses both arguments in turn and ultimately concludes that while the Agency may not have needed to compare the mifepristone ETASUs to the Agency's regulation of any other specific drug, the total absence of any discussion of the factor evinces an APA violation.

Beginning with the interpretation of the statute, the Court notes that it could be read at least two different ways. The entire relevant subprovision (cleaned up) states, "such ETASUs shall, to the extent practicable, so as to minimize the burden on the health care delivery system, conform with ETASUs for other drugs with similar, serious risks." 21 U.S.C. § 355-1(f)(2)(D)(i). One possible reading is that the Agency must only compare the mifepristone ETASUs to other drugs *with* ETASUs that present similar, serious risks. Another interpretation is that the FDA must compare the mifepristone ETASUs with the regulation *or lack thereof* of *any* drug that presents similar, serious risks, even if that drug does not have an ETASU. In the latter reading, presumably the lack of ETASUs for the similar drug would cast doubt on the need for the conditions on mifepristone. Unsurprisingly, Defendants apply the first interpretation; Plaintiffs, the latter.

In support of their contention that the FDA ignored the factor, Plaintiffs include some examples of possible comparators (that can allegedly present similar serious risks) like "Tylenol, Viagra, aspirin, penicillin, blood thinners, antibiotics, insulin, and multiple drugs used for purely cosmetic purposes, none of which are

subject to a REMS." *See* ECF No. 221-1 at 39. They also highlight that Korlym—a different manufacturer's drug, which has mifepristone as its active ingredient, and which is used to treat Cushing's syndrome—doesn't have a REMS. *See id.* at 25; PCSF ¶¶ 65–67. Defendants respond that such drugs are not valid comparators. *See* ECF No. 228-1 at 37.

Here, the Court need not definitively say whether the Agency was required to consider these specific drugs because there is no evidence in the record that the Agency considered subsection (f)(2)(D)(i) under any interpretation. In their briefing, Defendants seem to suggest that silence constitutes evidence that the REMS review *must have* concluded that there were no relevantly similar comparators, but if that were the case, the Agency should have said so. The statute sets forth a clear and specific directive, but without any discussion of the factor, there is no way to know whether the Agency considered it.

4. Whether the FDA Failed to Sufficiently Address the Question of Burden on Patient Access or Health Care System

Fourth, Plaintiffs argue that the FDA failed to address whether the ETASUs unduly burden patient access or the health system under subsections (f)(2)(C)(ii) and (g)(4)(B)(ii). ECF No. 230 at 26–27. Defendants do not dispute that burden considerations are relevant to the REMS decision, *see* ECF No. 228-1 at 32–34,

but contend that the FDA sufficiently considered the factors. *See* ECF No. 228-1 at 32–34. The Court disagrees with Defendants.

Both the 2021 and 2023 REMS Rationale Memos nod to consideration of burden with statements like: "[t]he burden of prescriber certification has been minimized to the extent possible by requiring prescribers to certify only one time for each applicant," *see* ECF No. 240-4 at 121, and "[the Patient Agreement Form] does not impose an unreasonable burden on providers or patients," *see id.* at 125. But there's not much more. Digging into the Agency's treatment of the burdens of each ETASU reveals the extent of the failure to explain its reasoning.

*a. The Burden of the Prescriber Certification*

As to the Prescriber Certification, the 2021 REMS Rationale Memo included only the line about burden being minimized by "requiring prescribers to certify only one time for each applicant." ECF No. 240-4 at 121. This conclusory statement does not explain *how* the burden was minimized or the supposedly minimal burden assessed.

There is no doubt that this requirement prevents some potential prescribers from becoming certified and may thus burden patient access. One study in the administrative record considering an earlier version of the ETASU demonstrates that nine percent of potential prescribers declined to prescribe mifepristone based on the Prescriber Certification requirement. *See Id.* at 21–22. And one reason that

prescribers hesitate to become certified is that they are worried they'll face violence or harassment if the information becomes public. ECF No. 240-5 at 483–84 (citing patients' and providers' fear of facing violence as support for adopting requirement that pharmacies maintain confidentiality of records); *see also* PCSF ¶ 76; ECF No. 240-4 at 51 (letter to agency noting that the Prescriber Certification deters would-be prescribers because of history of anti-abortion violence and fear that abortion opponents would gain access to the certification agreements). As such, even under the previous ETASU, providers were concerned about privacy despite the fact that distributors had to maintain confidential records. *See* ECF No. 240-4 at 51.

Yet the current challenged Prescriber Certification ETASU is likely even more burdensome than the earlier version because of the adoption of the *Pharmacy* Certification ETASU, as it saddles prescribers with new obligations. For example, the statement about prescribers only needing to certify "once" obscures the fact that prescribers must send the certification form to each pharmacy they seek to use, raising privacy concerns and exacerbating administrative issues. *See* ECF No.

240-5 at 479–80. The Agency recognized that this created additional burdens,[7] but never really assessed how much the privacy concerns would burden access (despite recognizing the gravity of the concern as evidenced by the fact that it redacted its own employees' names in the 2021 and 2023 REMS Rationale Memos to protect them). *See* PCSF ¶ 77.

Specifically, when discussing the Pharmacy Certification's requirement that participating pharmacies keep patient and provider records confidential, the Agency did recognize that "confidentiality concerns may unduly burden patient access by limiting the number of prescribers who are willing to send prescriptions to certified pharmacies." ECF No. 240-5 at 484. But it concluded the requirement on the pharmacies to maintain confidentiality "avoid[ed] unduly burdening patient access." *Id.* at 483. Again, though, there is no explanation as to why the

[7] More specifically, the 2023 REMS Rationale memo stated:

> The burden of providing the Prescriber Agreement Form prior to or when the prescription is provided to a certified pharmacy does not create unreasonable burden for prescribers. The burden of prescriber certification has been minimized to the extent possible. The Prescriber Agreement Form is designed to require minimal time to complete and requires that the prescriber submit it to the authorized distributor once, and if the prescriber chooses to use a certified pharmacy to dispense mifepristone, they will need to submit the form to the certified pharmacy.

*Id.* at 480.

confidentiality requirement sufficiently addressed the concern about patient access. Indeed, as noted above, under the previous REMS, nearly one in ten potential prescribers cited the requirement to sign the Prescriber Agreement with the distributor of mifepristone as their reason for not prescribing the drug. ECF No. 240-4 at 21–22. It follows that by requiring prescribers to submit their Prescriber Agreement Forms to additional and disparate parties—i.e., multiple pharmacies as opposed to just the distributor or sponsor—such confidentiality concerns would increase, and patient access may suffer. This is not to say that any of that would render the ETASU unduly burdensome, it is only to highlight the Agency's lack of explanation.

*b. The Burden of the Patient Agreement Form*

The 2021 REMS Rationale Memo explains that the purpose of the Patient Agreement Form ETASU is to counsel patients about mifepristone and that the requirements "to provide the patient with the Patient Agreement Form, and to have the healthcare provider and patient sign the Patient Agreement Form, ensures that" purpose. ECF No. 240-4 at 125. It continues that a copy of the Form must be given to the patient and that the Form must be placed in the patient's record to document the patient's acknowledgment of receiving the information. *See id.* The memo then states simply, "[w]e determined consistent with [21 U.S.C. § 355-1(f)(2)], that [the Patient Agreement Form ETASU] does not impose an

unreasonable burden on providers or patients," and repeats, "after considering potential burden on healthcare providers and patients . . . we conclude that the Patient Agreement Form should remain a safe use condition in the REMS." *Id*. The Agency neglects to describe the basis for its determination, however, and such a bare assertion is insufficient under the APA. *See Los Padres ForestWatch v. United States Forest Service*, 25 F.4th 649, 657 (9th Cir. 2022) (noting that a bare assertion without supporting analysis does not constitute a satisfactory explanation under the APA).

The Agency also fails to square its position on whether the Patient Agreement Form unduly burdens access with the 2016 scientific review team's analysis that it does. Before the 2016 REMS recommendation reached the Commissioner, the scientific review team noted that the Patient Agreement Form "is a burden for patients," because "[i]t is standard of care for patients . . . to undergo extensive counseling and informed consent." *See* ECF No. 240-1 at 167. Thus, the review team concluded that the Form was duplicative. *See id.* Granted, the Commissioner ultimately rejected the recommendation to remove the ETASU, but all he said about burden was that keeping the requirement "would not interfere with access." *Id.* at 282. Lacking from that one sentence conclusion is any explanation regarding why he disagreed with the scientific review team. As discussed in more detail below, the Commissioner's 2016 failure to explain the

decision remained relevant in the 2023 REMS Decision because the Agency in effect endorsed the Commissioner's decision in the absence of any data to the contrary. *See* ECF No. 240-4 at 123–25. But what that means is that the Agency has never explained *why* it disagreed with the scientific team's recommendation regarding the burden and ultimately concluded the opposite both then and now. *See NRDC v. EPA*, 38 F.4th 34, 51 (9th Cir. 2022) ("Inconsistent reasoning is, absent explanation, the hallmark of arbitrary action." (internal quotation marks and citations omitted)).

*c. The Burden of Pharmacy Certification*

The Agency did engage with the burden question a bit more in the context of Pharmacy Certification. In addition to noting that confidentiality concerns may dissuade some prescribers from participating in the REMS, the FDA "acknowledge[d] that the provision in the REMS related to pharmacies' verification of prescriber enrollment will likely limit the types of pharmacies that will choose to certify in the REMS." ECF No. 240-5 at 484. The Agency argues that this acknowledgment refutes Plaintiffs' position that the Agency ignored the burdens of the Pharmacy Certification ETASU. *See* ECF No. 228-1 at 33. But the basic recognition of an effect is different than a sufficient consideration of the likely burden on patient access, and the Court concludes that the statute requires more from the Agency. *See Los Padres ForestWatch*, 25 F.4th at 657.

The Court finds the Agency's treatment of the burden question in the context of the Pharmacy Certification particularly notable because it was a new ETASU. As such, the Agency's failure to consider the ETASU Factors—and specifically those related to burden in subsection (f)(2)(C)(i)–(iii)—is unreasonable. For example, the Agency doesn't describe how the limiting effect on the types of pharmacies that may opt to dispense mifepristone would affect patients who have difficulty accessing health care—an acute concern here in Hawai'i. *See* 21 U.S.C. § 355-1(f)(2)(C)(ii). It is not enough to say that a new ETASU might burden patient access and leave it at that.

Defendants' arguments that the Agency sufficiently addressed the burden factors, or didn't need to, fail to persuade the Court. Throughout its briefing, Defendants repeat that Plaintiffs haven't explained how the ETASUs could have been modified to make them less burdensome. *See* ECF No. 228-1 at 37; ECF No. 238 at 17. But it is the Agency's duty to consider factors and provide a reasoned explanation for its decisions, *see Motor Vehicle Mfrs. Ass'n of U.S., Inc.*, 463 U.S. at 42–43, not Plaintiffs' job to propose alternatives. Defendants also argue that Plaintiffs' suggestion that the ETASUs could be eliminated entirely is inconsistent with the Agency's conclusion that the ETASUs are necessary for safety. *See* ECF No. 228-1 at 37. Yet, that contention is beside the point—because the Agency imposed the ETASUs, it also needed to ensure that the ETASUs were not "unduly

burdensome on patient access to the drug." 21 U.S.C. § 355-1(f)(2)(C). And, as Plaintiffs point out, subsection (g)(4)(B)(ii) makes burden evidence relevant because the Secretary may remove one or more REMS goals or elements to "minimize the burden on the health care delivery system." ECF No. 230 at 27 (citing 21 U.S.C. § 355-1(g)(4)(B)(ii)). In short, the Agency was required to consider the burden of the REMS and ETASUs and explain its consideration of them. It failed to do so, or at least neglected to provide a reasoned explanation of how it did so.

In sum, the Court concludes that the Initial Review Factors applied to the REMS review, and the Agency's failure to consider them in the 2023 REMS Decision renders it and the resulting ETASUs arbitrary and capricious. Likewise, as to the ETASU Factors, the Agency ignored the comparison with other drugs requirement and failed to sufficiently assess the ETASUs' burden on patients and providers. As such, the Court concludes that the Agency has not sufficiently justified its imposition of the ETASUs.

***c. Unreasonable Explanations***

Separate from the Agency's lack of explicit consideration of the REMS factors, Plaintiffs also argue that the Agency's explanations as to why the ETASUs are necessary are "implausible, speculative, incomplete, and contradicted by the record." ECF No. 221-1 at 41. The Court concludes that the justifications for the

ETASUs are indeed illogical and fail to address obvious inconsistencies or assumptions.

The Court addresses one overarching issue before turning to the individual ETASUs. Throughout its briefing, Defendants argue that the Agency was not "writ[ing] on a blank slate," *see* ECF No. 238 at 8, or conducting a de novo review of the REMS, *see id.* at 22, but instead reviewing new information since the approval of the 2016 REMS. In support, Defendants cite the Modification Provision (§ 355-1(g)(4)(B)), but that section doesn't explicitly address the scope of the Agency's review and, as explained above, the Court disagrees that such provision excludes the Initial Approval Factors.[8]

In any event, Plaintiffs do not directly dispute the contention. Instead, they seem to suggest that the Agency's previous reasoning may inform the current challenged REMS, which makes sense to the Court. *See* ECF No. 230 at 20–24. If the Agency wasn't writing on a blank slate, then its previous rationales still animate the current decision. As described below, though, the prior reasoning,

[8] The Court also sees some tension between Defendants' agreement with Plaintiffs to conduct a *full* REMS review and their assumption that previous iterations of the REMS were correct.

coupled with the current decisions' rationales don't suffice to proffer a reasonable explanation.

*i. Prescriber Certification*

The Agency primarily justifies the continuation of the requirement that prescribers sign a form attesting that they have certain qualifications by pointing to the lack of "any studies comparing providers who met these qualifications with providers who did not." ECF No. 240-4 at 120. This explanation exhibits several flaws.

First, as discussed more thoroughly below, the type of study that the Agency is looking for to consider changing the ETASU is unlikely to exist in the United States, because American prescribers have always been required to have the relevant qualifications. If the Agency required such a study to consider eliminating the ETASU, the ETASU would be self-perpetuating.

Further, there is a difference between requiring prescribers to have certain qualifications and making prescribers sign a form swearing to the fact. *See* ECF No. 240-4 at 143. In other words, even if there was a study that compared patient outcomes based on whether the prescriber had the listed qualifications, the study would fail to get at the heart of the Prescriber Certification requirement—the form signing. To this point, Plaintiffs emphasize that Defendants do not dispute that all licensed clinicians are able to read prescribing information and assess whether they

are qualified to prescribe a certain drug. *See* PCSF ¶ 36; *see also Motor Vehicle Mfrs. Ass'n of U.S., Inc.*, 463 U.S. at 43 (explaining that an agency must explain its action with a "rational connection between the facts found and the choice made" (internal quotation marks and citation omitted)).

The requirement to sign the form is an additional step purportedly to assure that prescribers have the necessary qualifications, but what is the problem the Agency is trying to address with it? Does it believe that prescribers of mifepristone are ignoring the medication information and their professional ethics and prescribing it despite being unqualified? Certainly, there is no discussion about such a concern in the Agency's 2021 REMS Rationale Memo. Alternatively, is the FDA concerned that the requisite qualifications are so specialized that most clinicians lack them, and that the requirement to sign the form in effect flags the issue for prescribers? If so, it did not say so or examine any evidence about what percentage of potential providers lack the qualifications, e.g., are unable to diagnose ectopic pregnancies. In short, the Agency's reliance on the non-existence of a hypothetical study that would only be semi-related to the requirements of the Prescriber Certification does not sufficiently explain the retention of the challenged ETASU. *Cf. Greater Yellowstone Coalition, Inc. v. Servheen*, 665 F.3d 1015, 1028 (9th Cir. 2011) (explaining that an agency may not

rely solely on "scientific uncertainty" to justify its action without discussing why the uncertainty matters).

In its briefing, Defendants argue the FDA sufficiently explained its decision to maintain the Prescriber Certification requirement because the ETASU also informs prescribers that they must report patient deaths associated with mifepristone. *See* ECF No. 228-1 at 28–29. In the 2021 REMS Rationale Memo, the Agency states simply that the ETASU forces prescribers to acknowledge the reporting requirement to "ensure[] that the manufacturer receives all reports of patient deaths and, in turn, fulfills its regulatory obligations to report those deaths to the FDA." ECF No. 240-4 at 121. But Plaintiffs persuasively note that it is undisputed that adverse events from mifepristone, including deaths, are exceedingly rare. *See* PCSF ¶ 13; ECF No. 239 (Pls. Supplemental Concise Statement of Facts or "Supp. PCSF") ¶ 24. The Agency fails to address this contradiction in the reporting requirement. In effect, the Agency tries to justify the Prescriber Certification by citing a requirement to do something for a situation that almost never arises. And, as Plaintiffs point out, Korlym—which includes mifepristone as its active ingredient—has a higher rate of adverse events but does not have a REMS at all, let alone any ETASUs. *See* PCSF ¶ 66 (undisputed that mifepristone's adverse events rate is "much lower" than Korlym's); *see also id.* ¶

64 (providing record cites to other drugs without REMS than have serious potentially fatal effects).

Defendants next argue that the potential doubling of providers with the removal of the in-person dispensing requirement sufficiently explains the Agency's decision to maintain the Prescriber Certification ETASU. *See* ECF No. 228-1 at 29. But, if the Agency has failed to justify the ETASU in the first place, *see supra* Section III.B.1.b.ii, subjecting more people to it does not make the requirement more valid. And the argument runs into the same issue discussed above about the disconnect between having qualifications and signing a form—it assumes providers would neglect their professional and ethical obligations when it comes to mifepristone, but that they comply with those requirements as to any other new drug that comes on the market that doesn't have a REMS. Such speculation cannot support an Agency's action. *See Sorenson Commc'ns Inc. v. F.C.C.*, 755 F.3d 702, 708 (D.C. Cir. 2014) (noting that deference to agency judgment "must be based on some logic and evidence, not sheer speculation[.]" (citation omitted)).

*ii. Patient Agreement Form*

The Agency's explanation for the retention of the Patient Agreement Form exhibits similar deficiencies, especially given that certain segments within the FDA had previously recommended eliminating the ETASU. *See* PCSF ¶ 40. As outlined above, *see supra* Section I.A.1, during the 2016 REMS review, the

scientific review team recommended that the FDA eliminate the Patient Agreement Form, describing it as unnecessarily burdensome because: (1) the form was duplicative of standard informed consent practices and (2) the drug's risks rarely occur.[9] *See* ECF No. 240-1 at 166; ECF No. 240-4 at 122–23. One reviewer concurred, and summed it up: "the Patient Agreement Form, which requires a patient's signature, does not add to safe use conditions for the patient for this REMS and is a burden for patients." ECF No. 240-1 at 167. Nonetheless, the Commissioner of the FDA kept the requirement, concluding without elaboration that maintaining the ETASU "would not interfere with access and would provide additional assurance that the patient is aware of the nature of the procedure, its risks, and the need for appropriate follow-up care." *See id.* at 282. The FDA thus retained the requirement, but the conclusory nature of the Commissioner's determination stands out as particularly unsupported.

[9] It is true that the 2016 recommendation to eliminate the Patient Agreement Form was also based in part on the decision to retain the in-person dispensing requirement. *See* ECF No. 240-1 at 166; ECF No. 240-4 at 122–23. But, as discussed below, the Agency's explanation that the Patient Agreement Form should be retained due to a potential influx of new providers resulting from the elimination of the in-person requirement relies on unsupported assumptions about how those new providers will act. Thus, if the elimination of the in-person requirement is the reason for maintaining the Patient Agreement Form, the Agency failed to provide a logical explanation as to why that's the case.

That internal FDA conflict of course affects the REMS review at issue in this case because the 2021 REMS Rationale Memo assumed the validity of the previously-imposed ETASUs unless new objective safety data demonstrated otherwise. Basically, the Commissioner's 2016 conclusory decision serves as the basis for the current REMS, and the Agency assumed it was sufficient despite the lack of support.

Turning to the 2021 REMS Rationale Memo itself, the Court first notes that while the memo describes the reasoning behind the 2016 scientific review team's recommendation to eliminate the Patient Agreement Form, the memo never confronts that reasoning head-on. Rather, the Agency reviewed literature that focused on informed consent, but ultimately concluded that the publications did not address the Patient Agreement Form directly, nor did they include outcome data, and so "did not provide evidence that would support removing" the ETASU. *See* ECF No. 240-4 at 123–24. In other words, the Agency cited a lack of objective safety data to explain its decision not to eliminate the Patient Agreement Form, instead of addressing the duplicative nature of the requirement and prior internal recommendation that it did not enhance safe use conditions. The Court finds it notable though that neither the 2016 scientific team nor the Commissioner mentioned objective safety data when considering the Patient Agreement Form in 2016.

In fact, contrary to the 2016 scientific team's approach, the Agency appeared to cite abortion providers' stringent informed consent guidelines as justification to keep the Patient Agreement Form, rather than as evidence of duplicativeness. Specifically, the 2021 REMS Rationale Memo states, "[a]lthough . . . informed consent in medicine is an established practice, the National Abortion Federation's 2020 Clinical Policy Guidelines for Abortion Care continue to include a detailed section on patient education, counseling, and informed consent." *Id.* at 124 (footnote omitted). But the Agency provides no commentary on why the "established clinical practice" of extensive patient counseling, documentation, and informed consent would serve both as support for the scientific review team's recommendation to remove the ETASU in 2016, and as justification to retain the requirement in 2021.

That failure to explain its citation to the clinical policy guidelines appears more glaring considering that the Agency noted that one study "reveal[ed] strong adherence to evidence-based guidelines," i.e., clinicians following the profession's ethical standards and guidelines. *See id.*; PCSF ¶ 35. The Agency thus in effect agreed that practitioners (1) set stringent guidelines about informing patients, and (2) follow those guidelines. But rather than try to explain *why* the Patient Agreement Form requirement must be retained despite the redundancy with the practitioner guidelines, the Agency just stated in conclusory fashion that the

ETASU "remains necessary to assure the safe use of Mifepristone." ECF No. 240-4 at 125. Here, the Court sees the influence of the Commissioner's unexplained 2016 rejection of the scientific review team's recommendation to eliminate the ETASU. *See* ECF No. 240-1 at 282.

The Agency's explanation that the increase in providers justifies the retention of the Patient Agreement Form also fails to persuade. As discussed more below, the Agency deviated from its reliance on objective safety data to consider survey data that suggested the number of medication abortion providers could double with the elimination of the in-person dispensing requirement. *See* ECF No. 240-4 at 124–25. Based on this, the FDA concluded that the Patient Agreement Form ETASU "ensures that each provider, *including new providers*, informs each patient of the appropriate use of mifepristone, risks associated with treatment, and what to do if the patient experiences symptoms that may require emergency care." *See id.* at 125 (emphasis added). But to the extent this attempts to explain why an increase in providers would justify the retention of the ETASU, it rests on the assumption that new providers will shirk their professional and ethical responsibilities and not comply with practitioner guidelines. The data that showed "strong adherence to evidence-based guidelines" belies that assumption though and demonstrates the unreasonableness of the Agency's conclusion.

*iii. Pharmacy Certification*

In addition to removing the in-person dispensing requirement, and retaining the Prescriber Certification and Patient Agreement Form ETASUs, the 2023 REMS Decision added the Pharmacy Certification ETASU. To a large extent, the Agency imposed the new requirement to ensure compliance with the other ETASUs, mostly the Prescriber Certification condition. The Agency explained that based on the removal of the in-person dispensing requirement:

> [I]t is necessary to add a requirement for certification of pharmacies . . . Adding the pharmacy certification requirement incorporates pharmacies into the REMS, ensures that pharmacies are aware of and agree to follow applicable REMS requirements, and ensures that mifepristone is only dispensed pursuant to prescriptions that are written by certified prescribers. Without pharmacy certification, a pharmacy might dispense product that was not prescribed by a certified prescriber. Adding pharmacy certification ensures that [the Prescriber Certification] is met prior to dispensing the product to a patient; certified prescribers, in turn, have agreed to meet all the conditions of the REMS, including ensuring that the Patient Agreement Form . . . is completed.

ECF No. 240-4 at 147; *see also* ECF No. 240-5 at 483. But because the Court has concluded that the Agency has failed to justify the other ETASUs, the Agency's explanation about this new requirement necessarily falters.

Additionally, the FDA neglected to discuss the implications of the fact that, during the COVID-19 timeframe when the FDA declined to enforce the in-person dispensing requirements, pharmacies dispensed mifepristone without a Pharmacy

Certification ETASU. The Agency itself, in eliminating the in-person dispensing requirement, noted that *there did not appear to be an increase in adverse safety events during that time*. *See* PCSF ¶ 46.

As such, and independent of Agency's failure to consider the statutorily-mandated factors, the Court also concludes that the 2023 REMS Decision violates the APA for failure to provide a reasoned explanation. The Agency's rationale for maintaining the ETASUs demonstrates unexplained logical leaps and conflicts with evidence in the record. The Court finds it arbitrary and capricious. *See Motor Vehicle Mfrs. Ass'n of U.S., Inc*, 463 U.S. at 43.

**2. Arbitrary and Capricious – Failure to Consider Relevant Evidence**

Separate from, although interrelated with, their argument that the FDA failed to provide a reasoned explanation, Plaintiffs also assert that the Agency arbitrarily excluded certain categories of evidence from its 2021 REMS review, including statements from "preeminent medical societies urging elimination of the mifepristone REMS," qualitative studies and physician narratives especially as they pertained to the burdens on patient access to the drug, and a Canadian study examining the effects of the country's removal of REMS-like restrictions on mifepristone. ECF No. 221-1 at 31–35. Defendants respond that the Agency considered all relevant evidence, including the sources Plaintiffs highlight, and that its focus on "objective safety data" was reasonable. *See* ECF No. 228-1 at 39–41.

As to the Canadian study, the FDA concedes it didn't consider the data but only because the study was published after the cut-off date for the Agency's literature search. *See id.* at 41–43.

Based on the Court's review, the FDA appears to have selectively cabined its review of certain types of information and its explanation for doing so doesn't withstand examination. While the Agency's focus on "objective safety data" sounds scientific, neutral, and authoritative in the abstract, the Agency departs from this focus in a non-systematic manner and offers insufficient explanations for excluding various materials that Plaintiffs submitted. Based on this selective examination, the Court concludes that the Agency neglected to consider all relevant evidence.

***a. Selective Focus on Objective Safety Data***

In its 2021 REMS Rationale Memo, the FDA described the scope of its evaluation of the evidence:

> We reviewed multiple different sources of information, including published literature, safety information submitted to the Agency during the COVID-19 [Public Health Emergency], FDA Adverse Event Reporting System (FAERS) reports, the first REMS assessment report for the Mifepristone REMS Program, and information provided by advocacy groups, individuals, and the Applicants. Our review also included an

> examination of literature references provided by plaintiffs in the *Chelius v. Becerra* litigation.[10]

ECF No. 240-4 at 117. Regarding the published literature, the Agency explained it conducted a search for reports published "between March 29, 2016 (when the [mifepristone] labeling and REMS were last substantially revised) through July 26, 2021." *Id.* The Agency also supplemented its literature search with "an examination of literature references provided by advocacy groups, individuals, plaintiffs in the *Chelius* litigation . . . as well as letters from healthcare providers and researchers." *Id.*

Despite noting that it compiled all these sources of information, the FDA still "excluded" certain of those materials from its review. The Agency explained that it "focused on publications containing safety data related to outcomes of medical abortion (objective safety data) obtained from [its] literature search and from the references provided to [it]." *Id.* at 118. Because of the focus on objective safety data, the FDA "excluded" other materials, including "[i]nformation from survey studies or qualitative studies that evaluated perspectives on and/or satisfaction with medical abortion procedures from patients, pharmacists, clinic

[10] I.e., this litigation.

staff, or providers, even if the study assessed REMS ETASUs," and "[o]pinions, commentaries, or policy/advocacy statements."[11] *Id.*

From this, Plaintiffs argue that the Agency's focus on what it deemed "objective safety data" drew an arbitrary line and eliminated plainly relevant "statements from preeminent medical societies" that the FDA may consider.[12] *See* ECF No. 221-1 at 32. The Court agrees.

As an example of why the Agency's focus on objective safety data at the expense of all other information makes little sense in practice, the FDA retained the Prescriber Certification ETASU almost solely because its "review of the literature did not identify any studies comparing providers who met [the] qualifications [required under the REMS] with providers who did not." *See* ECF No. 240-4 at 120. But, as mentioned above, the REMS has always required prescribers to have those qualifications. Thus, at least in the United States, there

[11] The Agency applied these same criteria to the evidence Plaintiffs submitted. *See* ECF No. 240-4 at 118. To wit, in "Appendix A" to the 2021 Rationale Memo, the FDA lists the sources Plaintiffs submitted, the majority of which the Agency "excluded from the REMS review." *See id.* at 151–55. For those sources it excluded, the Agency provided a rationale for the exclusion like "Policy/advocacy statement," "Abstract," or "Focused on logistics of accessing abortion care," to name a few. *See id.*

[12] Plaintiffs also argue that the Agency "expressly refused to consider" or "reviewed none" of the evidence they submitted, ECF No. 221-1 at 31–32, but as evidenced by the Agency's brief rationales for excluding the documents, ECF No. 240-4 at 151–55, it's clear that the Agency at least looked at the materials.

has never been and cannot be a set of providers prescribing mifepristone without those qualifications to compare against a set who has them. Requiring such a study is therefore basically a self-fulfilling prophecy to maintain the Prescriber Certification.

There is also a difference between requiring providers to *possess* those qualifications and mandating that they sign a form attesting to the fact. The Agency, however, made no discernible attempt to assess whether providers that would prescribe mifepristone but for the REMS already have the necessary qualifications, *see* PCSF ¶¶ 38–39, such that signing a form would be redundant and burdensome. Certainly, objective safety data would not get at those types of issues. The Agency, in fact, recognized that it needed to depart from its emphasis on objective safety data to include surveys about provider volume. ECF No. 240-4 at 119. But it did so only selectively.

Again, the FDA "excluded" most of the sources Plaintiffs submitted because they did not include objective safety data. *See id.* at 118. But Plaintiffs argue that such qualitative or survey-based information was clearly relevant, especially considering that part of the Agency's statutory mandate is to assess burdens on patient access and the health care delivery system. *See* ECF No. 221-1 at 34–35 (citing 21 U.S.C. § 355-1(f)(2)(C)(ii), (f)(2)(D), (g)(4)(B)(ii)). And the Court

again notes that the 2016 scientific review team did not require "objective safety data" to recommend the removal of the Patient Agreement Form requirement.

Defendants offer little in response beyond reiterating that it was reasonable to focus on objective safety data, and that in any event, the Agency did rely on some practice guidelines and survey data. *See* ECF No. 228-1 at 40–41; ECF No. 238 at 19–20. Indeed, the 2021 REMS Rationale explicitly states:

> One exception to the above literature search criteria was the inclusion . . . of publications that discussed changes in provider volume. The data discussed in relation to provider volume was obtained from surveys. This data was included because changes in provider volume could only be obtained from well-conducted survey studies.

ECF No. 240-4 at 119. But an exception to an exclusion suggests some informational gerrymandering rather than a principled process. In other words, it appears the Agency cherry-picked which qualitative studies and surveys it relied on to render its decision.

For example, to support its decision to retain the Patient Agreement form in part because of the potential increase in new providers, the FDA cites one survey "which suggested that the number of obstetrician/gynecologists providing medical abortion care may be increasing and that uptake might increase if mifepristone were dispensed by pharmacies instead of being dispensed in-person." *See id.* at 125 (citing ECF No. 240-4 at 17–23). That same paper, however, also notes that nine percent of providers that declined to offer medication abortion attributed the

decision to the Prescriber Certification requirement. *See* ECF No. 240-4 at 21–22. Yet, the Agency doesn't discuss *that* survey data regarding the effect of the Prescriber Certification in the 2021 REMS Rationale Memo. The Court notes the absence not to suggest that the Agency needed to address every point in every study, but to highlight that its limited review of survey data raises questions. If survey data alone could provide information about provider volume, why did the Agency only discuss data about the potential increase in providers and not address other data suggesting the depressive effect of the ETASUs on provider volume? The Agency's reliance on some limited sources of survey data also casts some doubt on the genuineness of the Agency' commitment to objective safety data over other sources of information.

***b. The Canadian Study***

Regardless, there is one source of objective safety data that the Agency acknowledges it didn't consider, but argues it had no obligation to do so. *See* ECF No. 228-1 at 41–42. That source is a Canadian study that compared safety data before and after Canada's elimination of REMS-like requirements for prescribing mifepristone for use in medication abortions. *See* ECF No. 240-5 at 35; Schummers, L., et al., *Abortion Safety and Use with Normally Prescribed Mifepristone in Canada*, New England Journal of Medicine. It concluded that "[a]fter Mifepristone became available as a normal prescription, . . . the proportion

of abortions provided by medication increased rapidly, and adverse events and complications remained stable." *Id.*; *see also* PCSF ¶ 48. Yet, without challenging the potential relevance of the study, Defendants argue (1) that it was published after the FDA closed its literature search and (2) that it was only raised in a separate petition pending before the Agency. *See* ECF No. 228-1 at 42–43. Both contentions fail: the accumulation of circumstantial evidence suggests that the Agency was aware of the Canadian study at some point early enough in its REMS review process that it should have at least considered its relevance.

The Agency issued its 2021 REMS Rationale Memo on December 16, 2021 and noted that its literature search for the review spanned from March 29, 2016 to July 26, 2021. ECF No. 240-4 at 108, 117. In August and September 2021, prior to the issuance of the 2021 REMS Rationale Memo, Plaintiffs submitted to the FDA the abstract for the (at that point) forthcoming Canadian study. *See* PCSF ¶¶ 48, 57; ECF No. 240-4 at 13–14 (abstract); *id.* at 7–12 & 47–55 (Plaintiffs' letters). The abstract itself suggests that the study contained exactly the type of objective safety data that the Agency elevated over other sources of information. *See* ECF No. 240-4 at 13–14. But this was one of the sources of information that the Agency "excluded" from its review because it was only an abstract. ECF No. 240-4 at 118, 151, 154. The Agency explained that it didn't include abstracts in its literature search because they do not enable the Agency "to conduct a full review

of the methods or results." *Id.* at 118. While on its face that seems like a reasonable enough justification, it ignores the exact context here where the Agency agreed to undertake a full REMS review based on the litigation, and Plaintiffs heavily cited this forthcoming Canadian Study. In other words, circumstances suggests that the Agency was at least on notice about the pending data. But, to be clear, the Court doesn't fault the Agency for not considering the abstract; rather, the Court faults the Agency for not considering the full Canadian Study.

The actual study was published in the New England Journal of Medicine on December 8, 2021, prior to the issuance of the 2021 REMS Rationale Memo.[13] The Agency diminishes the significance of that fact, arguing that it was reasonable to impose the July 2021 cut-off date for its literature review. *See* ECF No. 228-1 at 41. The Agency says that, without the deadline, and if it were required to

[13] The parties state that the study was published in January 2022, *see* DCSF ¶ 15, but a review of the article and the New England Journal of Medicine website both say December 8, 2021, with an update on January 6, 2022. *See* ECF No. 240-5 at 35; *see also* https://www.nejm.org/doi/full/10.1056/NEJMsa2109779 (last visited October 29, 2025).

reevaluate based on every newly published study, it would be stuck in a perpetual cycle of review.[14] *See id.* at 41–42.

That argument only rings somewhat true here where (1) the Canadian study was published before the issuance of the memo and (2) the Agency's treatment of other studies it learned about after the submission deadline was inconsistent with its treatment of the Canadian study. As to (2), the Agency addressed in two "Memorandums to File" other studies that it came across after the July 2021 cut-off. *See* ECF No. 230 at 33; ECF No. 240-5 at 467–69, 519–20. In those memos to file—dated December 30, 2022 and January 3, 2023 (which is also the date the Agency issued the 2023 REMS Rationale Memo)—the Agency reported it reviewed the studies for the "limited purpose" of determining whether they were relevant to the proposed REMS modifications, and in both instances concluded that they were not. ECF No. 240-5 at 467–69, 519–20. That the Agency continued to read studies and to write memos up until the date of its 2023 REMS decision suggests that it considered timing alone to be an insufficient reason not to review a

[14] The Agency's Freedom of Information Act ("FOIA") caselaw in support of the argument is non-binding and distinguishable. *See Ferguson v. Dep't of Educ.*, 2011 WL 4089880, at *10–12 (S.D.N.Y. Sept. 13, 2011) (rejecting argument that agency had duty to supplement FOIA production with documents created after agency began search); *Coven v. U.S. Office of Pers. Mgmt.*, 2009 WL 3174423, at *9–10 (D. Ariz. Sept. 29, 2009) (rejecting plaintiff's request for a daily feed of job vacancy announcements).

potentially relevant study. And, significantly, if the Agency was assessing whether the studies were relevant, presumably a pertinent study published after the close of the search period could be factored into the Agency's decision. As such, the absence of a similar memo about the Canadian study is notable.

Defendants attribute the absence of any consideration of the full Canadian Study to the fact that it never "came to [the Agency's] attention *in connection with its review of the proposed [REMS] modifications*." ECF No. 238 at 18–19 (emphasis in original). Rather, the petition the American College of Obstetricians and Gynecologists submitted to the Agency on October 4, 2022 ("ACOG Petition"), which asked the FDA to eliminate the mifepristone REMS primarily for miscarriage management, cited the full Canadian Study. *See* DCSF ¶ 16; ECF No. 240-5 at 7–34. As the Court previously recognized, the ACOG Petition was "more singularly focused" on the elimination of the REMS for miscarriage management, but as to "each element of the REMS, the ACOG Petition also argued they were unnecessary more generally, regardless of whether mifepristone was being prescribed for miscarriage or abortion care." ECF No. 207 at 5; *see also* ECF No. 240-5 at 18–22. The FDA denied the ACOG Petition because it concluded that only the holder of the approved drug application may request the addition of an indication for a drug, and "[b]ecause the management of miscarriage is not a currently approved indication for mifepristone, 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." *See* ECF No. 240-5 at 48–49; DCSF ¶ 17. The Director of the Center for Drug Evaluation and Research ("CDER") signed the denial of the ACOG Petition on January 3, 2023, the same date as the 2023 REMS Decision. ECF No. 240-5 at 49.

Despite the overlap between the REMS review and the ACOG Petition, Defendants contend the Agency had no duty to review the Canadian study here because, in effect, the ACOG Petition and 2023 REMS modification were entirely unrelated or siloed matters. But the Court finds this difficult to accept. As the Court has already noted, CDER denied the ACOG Petition and signed off on the 2023 REMS Decision on the same day, suggesting coordinated action. *See* ECF No. 207 at 12–13. Even accepting that individuals other than the Director prepared the REMS modification, "it seems implausible that the Director of the CDER was not involved in the REMS." *Id.* at 13; *see also* ECF No. 240-4 at 116 (noting that in November 2021 "senior CDER leadership concurred with removing the in-person dispensing and adding pharmacy certification.").

Further, one of the memos to file about a different study written on the same day as the 2023 REMS Decision casts doubt on the Agency's assertion that it would only consider new information specifically raised in connection with the REMS review. That memo reflected that an individual with CDER "received

notification through a weekly email listing the table of contents for the Annals of Internal Medicine" that a potentially relevant study had been published that day. ECF No. 240-5 at 519–20. As such, that new study was not raised in connection with any particular review or petition, but was rather learned of by happenstance. Yet, the Agency still addressed that new study's potential relevance to the mifepristone REMS review in a memo to file written the same day as the 2023 REMS Decision. Similarly, the earlier memo to file also addressed studies cited in *separate litigation*, i.e., not directly connected to this REMS review. *Id.* at 468. This suggests to the Court that *how* the Agency learned of a study—be it through a serendipitously timed email newsletter, separate litigation, or a different petition before the agency—does not alone govern whether the Agency would consider the study's relevance to the REMS review, so long as the Agency knew of such a study. Put simply, Defendants' explanation for why the Agency didn't write at least a similar memo to file about the Canadian Study conflicts with the Agency's treatment of other studies it became aware of outside its literature search for this REMS review.

To recap: Plaintiffs cited the abstract of the Canadian study, which showed that objective safety data related to REMS-like restrictions would become available soon. The actual study was published on December 8, 2021, before the issuance of the 2021 REMS Rationale Memo. It did not appear in some obscure

publication, but rather the New England Journal of Medicine. And its potential relevance was hardly masked—"Mifepristone" and "[a]bortion safety" are in the title of the study. Separately, in the distinct but related ACOG Petition, a group of organizations cited the results of the full Canadian study. CDER oversaw both the REMS review and the ACOG Petition, with the Director of CDER denying the ACOG Petition on the same day the entity issued the 2023 REMS Rationale Memo. The Agency also considered whether other similarly-timed studies were relevant. Meanwhile, this is all set against the context of long-running contentious litigation all around the country concerning the Mifepristone REMS.

In sum, based on the failure to address the Canadian study in any meaningful way coupled with the Agency's selective focus on objective safety data, and inconsistent use of survey data, the Court concludes that the Agency failed to consider relevant evidence, and so it acted arbitrarily and capriciously.

**3. Exceeded Statutory Authority**

Because the Court concludes that the 2023 Mifepristone REMS Decision is arbitrary and capricious, it need not reach the question of whether the FDA also exceeded its statutory authority.

## C. Constitutional Claims

Defendants move for summary judgment on Plaintiffs' equal protection constitutional claims, arguing that Plaintiffs' claims are subject to rational basis

review, and that Plaintiffs or their patients are not treated any differently than any other prescriber or user of mifepristone. *See* ECF No. 228-1 at 43–44. On that last contention, Plaintiffs respond that the relevant comparison is not to other prescribers of mifepristone but to prescribers of other drugs with a similar risk profile to mifepristone that are not regulated as severely. *See* ECF No. 230 at 37. Plaintiffs also effectively argue that a finding that the Agency's treatment of mifepristone was arbitrary and capricious would necessarily be sufficient to survive summary judgment even on rational basis review. *See id.* Defendants' reply doesn't address Plaintiff's proposed classification, and merely repeats that the Agency did not violate the APA. *See* ECF No. 238 at 23.

Logically, Plaintiffs have the better of the argument but neither side devotes much attention to the issue, and both seem to end up arguing that the constitutional claim rises and falls with the APA claim. *See* ECF No. 230 at 37; ECF No. 238 at 23–24. Because the Court has concluded that the Agency's action was arbitrary and capricious, the Court cannot say at this point that the distinctive treatment of those who prescribe mifepristone for medication abortion passes rational basis review. *Cf. San Antonio Indep. Sch. Dist. v. Rodriguez*, 411 U.S. 1, 60 (1973) (Stewart, J., concurring) ("It has long been settled that the Equal Protection Clause is offended only by laws that are invidiously discriminatory—only by

classifications that are wholly arbitrary or capricious."). The Court denies Defendants' Cross Motion as to Plaintiffs' constitutional claim.

## IV. CONCLUSION

For the foregoing reasons, the Court GRANTS Plaintiffs' Motion for Summary Judgment and DENIES Defendants' Cross Motion for Summary Judgment. The Court declares the 2023 REMS Decision unlawful under the APA and remands the matter to the Agency to reconsider the mifepristone REMS in accordance with this order and the law. Because Plaintiffs did not seek vacatur of the REMS and its ETASUs in their Motion, the mifepristone REMS and ETASUs will remain in place pending the outcome of the Agency remand.

As Plaintiffs did not move for summary judgment on their constitutional claims, and because the Court denies Defendants' Cross Motion on the claims, they technically remain pending at this time. However, as they appear to be coextensive with Plaintiffs' successful APA challenge to the 2023 REMS Decision, the Court questions what becomes of the constitutional claims now. The Court thus DIRECTS the parties to file a joint status report of no more than ten pages within 14 days of this order setting forth their positions on how this case will proceed.

IT IS SO ORDERED.

DATED: Honolulu, Hawai‘i, October 30, 2025.

Jill A. Otake
United States District Judge

CIV. NO. 17-00493 JAO-RT, *Purcell, et al. v. Kennedy, et al.*; Order Granting Plaintiffs' Motion for Summary Judgment (ECF No. 221) and Denying Defendants' Cross Motion for Summary Judgment (ECF No. 228)