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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF HAWAII

HEIDI PURCELL, *et al*., Plaintiffs, v. ROBERT F. KENNEDY, JR., *et al*., Defendants.	CIV. NO. 1:17-00493-JAO-RT **DEFENDANTS' REPLY IN SUPPORT OF CROSS-MOTION FOR SUMMARY JUDGMENT**

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INTRODUCTION

For the near quarter century that mifepristone has been approved, the drug has been subject to restrictions, or "elements to assure safe use" (ETASU), to guard against risks relating to heavy bleeding, missed ectopic pregnancy, and other issues. In its most recent review, the Food and Drug Administration (FDA) found insufficient evidence to eliminate the Risk Evaluation and Mitigation Strategy (REMS) for mifepristone, including the ETASU, in its entirety.[1] Plaintiffs ask the Court to second-guess that determination. The Court should not reach the request because Plaintiffs lack standing to press the claim. But even if Plaintiffs could establish jurisdiction, their claims are meritless. Plaintiffs' opposition (ECF No. 230 (Pl. Opp'n)) fails to show otherwise.

For starters, Plaintiffs do not defend the theories of standing pleaded in the Second Amended Complaint. That alone should dispose of the case for lack of jurisdiction. In any event, Plaintiffs' new theories fail because they are insufficiently supported by Plaintiffs' declarations.

Even setting that aside, none of Plaintiffs' merits arguments survives scrutiny. *First*, Plaintiffs do not point to any relevant statutory factor that FDA failed to consider. Instead, they claim that FDA failed to apply six factors in 21

[1] As Defendants previously explained, since 2007, ETASU have been part of mifepristone's Risk Evaluation and Mitigation Strategy (REMS). ECF No. 228 (FDA MSJ) at 4-7.

U.S.C. § 355-1(a). Pl. Opp'n 22. But the text of that provision and the remainder of § 355-1 make clear that § 355-1(a) is inapplicable to a REMS modification decision.

Plaintiffs also wrongly contend that FDA failed to consider various factors in § 355-1(f). They allege that FDA failed to consider whether, without ETASU, the drug would be safe—that is, whether the drug's benefits would outweigh its risks. *Id.* 17-18 (citing 21 U.S.C. § 355-1(f)(1)(A)); *see also id.* 19 (arguing that FDA failed to assess whether the ETASU are "commensurate" with the risks) (citing 21 U.S.C. § 355-1(f)(2)(A)). The record, however, plainly demonstrates that FDA found insufficient evidence that the benefits of the drug would outweigh the risks if the ETASU were eliminated entirely. Plaintiffs also fault FDA's consideration of the alleged burdens of the ETASU. *Id.* 19-20 (citing 21 U.S.C. § 355-1(f)(2)(C)). But Plaintiffs do not explain how FDA could have further minimized burdens consistent with its determination that the drug has not been shown to be safe without a REMS with ETASU. Finally, Plaintiffs criticize FDA for not comparing mifepristone to other, unrelated drugs. *Id.* at 20-21, 27-28 (citing 21 U.S.C. § 355-1(f)(2)(D)(i)). That criticism misses the mark because, properly read, the statute does not require that comparison.

Second, Plaintiffs do not identify any relevant record evidence that FDA failed to consider. Focusing on the Canadian study, *see id.* 25-26, Plaintiffs neglect

that the study was not published until 2022, after FDA completed its literature review. Nor was the study subsequently cited to the agency in connection with its REMS review. Instead, the Canadian study was put before the agency as part of a citizen petition requesting a different agency action. And while Plaintiffs emphasize various kinds of other evidence (including advocacy statements), *see id.* 24-25, 27, they never squarely confront FDA's explanation that it was appropriate to focus on "objective safety data."

Third, as far as attacking FDA's judgment, Plaintiffs disregard how FDA did not write on a blank slate. The agency had already determined, several times over many years, that a REMS with ETASU is necessary. Plaintiffs challenge none of those earlier decisions. Rather, the sole final agency action they challenge is FDA's most recent review. 2d Am. Compl. ¶¶ 109, 212-22. And the narrow question before FDA then was whether evidence post-2016 warranted a departure from earlier assessments that certain ETASU are necessary. When that question is framed appropriately, the error of Plaintiffs' attacks on FDA's reasoning becomes clear.

The Court should grant Defendants' cross-motion for summary judgment.

ARGUMENT

I. Plaintiffs Lack Standing

At the outset, Plaintiffs have not met their burden of establishing Article III standing. The elements of standing—injury-in-fact, causation, and redressability—"are not mere pleading requirements but rather an indispensable part of the plaintiff's case." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992). Thus, "each element 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." *Id.* "In response to a summary judgment motion . . . the plaintiff . . . must 'set forth' by affidavit or other evidence 'specific facts'" demonstrating standing. *Id.* (quoting Fed. R. Civ. P. 56(e)).

Rather than support the theories of standing pleaded in the Second Amended Complaint, Plaintiffs offer new ones. Plaintiffs now attempt to establish standing through two previously unidentified members of the Society of Family Planning (SFP) and a novel theory of "direct" regulation. Pl. Opp'n 3-10; *see also* ECF No. 231, Ex. A. (MacNaughton Decl.); *id.*, Ex. B. (Nouhavandi Decl.). But the Second Amended Complaint contains no allegations of direct regulation. Nor does it suggest actual or threatened enforcement. Rather, Dr. Purcell and the members identified in the Second Amended Complaint allege (at most) indirect injuries through speculative and attenuated chains of causation. FDA MSJ 12-21.

The Court should reject this late effort to change the theories of standing. "[S]ummary judgment is not a procedural second chance to flesh out inadequate pleadings." *Waco Prods., Inc. v. Southwall Techs., Inc.*, 435 F.3d 989, 992 (9th Cir. 2006). A plaintiff "may not effectively amend its Complaint by raising a new theory of standing in response to a motion for summary judgment." *La Asociacion de Trabajadores de Lake Forest v. City of Lake Forest*, 624 F.3d 1083, 1089 (9th Cir. 2010). Accordingly, because Plaintiffs' current theories are not alleged in the operative complaint, Plaintiffs "cannot use them to escape summary judgment." *BMG Rights Mgmt. (US) LLC v. Joyy Inc.*, No. 2:22-cv-1578-MCS-RAO, 2025 WL 736576, at *2 (C.D. Cal. Jan. 23, 2025).

In any event, the gambit fails. To establish associational standing, an organization must show 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." *Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977). A plaintiff organization must "establish[] that at least one identified member ha[s] suffered or [will] suffer harm." *Summers v. Earth Island Inst.*, 555 U.S. 488, 498 (2009).

Neither organization Plaintiff establishes that it has a member whose alleged injuries can serve as a predicate for the organization's standing. The California

Academy of Family Physicians (CAFP) does not even attempt to meet this burden. Although SFP identifies two members, neither alleges that she was a member of SFP at the outset their challenge to the January 2023 REMS Modification—the relevant time for assessing standing. *See Friends of the Earth, Inc. v. Laidlaw Envt'l Servs. (TOC), Inc.*, 528 U.S. 167, 180 (2000); *see also Northstar Fin. Advisors Inc. v. Schwab Investments*, 779 F.3d 1036, 1044 (9th Cir. 2015) (looking assessing standing at the time of a supplemental complaint); 2d Am. Compl. ¶ 191 (alleging standing "as of March 30, 2023," the date Plaintiffs sought leave to challenge the January 2023 REMS Modification)

Moreover, even assuming Drs. MacNaughton and Nouhavandi were members of SFP at the relevant time, they fail to establish their own standing. Dr. MacNaughton repeatedly 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. Def. Resp. to Pl. Concise Stmt. of Supp. Facts ¶¶ 3-9. For her part, Dr. Nouhavandi alleges no injuries to herself. Instead, she asserts only injuries to Honeybee Health, Nouhavandi Decl. ¶¶ 8-22, a separate legal entity.[2] *See Erlich v. Glasner*, 418 F.2d

[2] Katzen Decl. Ex. A (https://bizfileonline.sos.ca.gov/search/business). Defendants respectfully request that the Court take judicial notice of Honeybee Health's status

226, 228 (9th Cir. 1969) (applying "the fundamental rule that even though a stockholder owns all . . . of the stock in a corporation, such fact of itself does not authorize him to sue as an individual").

II. Plaintiffs' APA Claims Are Meritless

If the Court reaches the merits, Plaintiffs' APA claims are unavailing. As an initial matter, Plaintiffs wrongly accuse FDA of making the "remarkable assertion that the Court cannot consider anything in the administrative record beyond the agency's own findings." Pl. Opp'n 10. FDA merely observed that, in an APA case, the Court does not resolve disputes of fact or make its *own* factual findings based on the evidence in the administrative record; it reviews *the agency's* findings in light of that record under the applicable APA standard. *See* ECF No. 227 (FDA Opp'n Statement of Fact) at 2-3.

In any event, Plaintiffs' response does not demonstrate that FDA exceeded its statutory authority, 5 U.S.C. § 706(2)(C), or failed to "consider all relevant factors and offer an explanation for its conclusion that is grounded in the evidence." *San Luis & Delta-Mendota Water Auth. v. Locke*, 776 F.3d 971, 998 (9th Cir. 2014) (citing *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)).

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as a separate entity. *Bralich v. Sullivan*, 17-cv-00547-ACK-RLP, 2018 WL 11260505, at *9 n.12 (D. Haw. Apr. 10, 2018) (taking judicial of records in California Business Entities database).

A. FDA reasonably considered all relevant statutory factors

As FDA explained in its opening brief, 21 U.S.C. § 355-1(g)(4)(B) sets forth the applicable REMS modification standard. FDA MSJ 29-31. Plaintiffs, however, accuse FDA of failing to consider factors that either are irrelevant or were in fact considered by FDA.

The § 355-1(a)(1) factors. FDA's initial decision to require the sponsor of a pending application to propose a REMS is governed by 21 U.S.C. § 355(a)(1), which lists six specific factors for FDA to consider. But "[a]fter the approval of a" REMS, the operative framework is supplied by 21 U.S.C. § 355-1(g)(4)(B). This section provides that FDA "may" require the sponsor of the drug to "submit a proposed modification" if, as relevant here, FDA "determines that 1 or more goals or elements should be added, modified, or removed" to (1) "ensure the benefits of the drug outweigh the risks of the drug" or (2) "minimize the burden on the health care delivery system of complying with the strategy." 21 U.S.C. § 355-1(g)(4)(B).

On its face, 21 U.S.C. § 355-1(g)(4)(B) neither cross-references nor contains the factors from 21 U.S.C. § 355-1(a)(1). "[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." *Russello v. United States*, 464 U.S. 16, 23

(1983). Thus, contrary to Plaintiffs' contentions, *see* Pl. Opp'n 22, the § 355-1(a)(1) factors do not apply to REMS modifications.

In arguing otherwise (Pl. Opp'n 22), Plaintiffs ignore the many textual signs that point against reading the subsection (a)(1) factors into subsection (g)(4)(B). For one thing, the only cross-reference to subsection (a)(1) anywhere in § 355-1 repeats the language in subsection (a)(1)'s heading. *See* 21 U.S.C. § 355-1(h)(3) (referring to a REMS "submitted under subsection (a)(1) in an application for initial approval"). For another, subsection (g)(4)(B) expressly applies "*[a]fter the approval* of a [REMS]." 21 U.S.C. § 355-1(g)(4)(B) (emphasis added). By contrast, subsection (a)(1) applies *before* approval, when the REMS is still "*proposed*." *Id.* § 355-1(a) (emphasis added). What is more, the dispute resolution procedures for reviewing determinations under subsection (a)(1) are different from the dispute resolution procedures for reviewing determinations under subsection (g)(4)(B). *See* 21 U.S.C. § 355-1(h)(3)-(4). Finally, the factors in subsection (a) are crafted in language that more naturally applies to drugs that have not previously been marketed for a particular use subject to a REMS. FDA MSJ 30-31 (discussing 21 U.S.C. § 355-1(a)(1)(A)-(F)).

Nonetheless, Plaintiffs insist that "it would make no sense" for Congress to require FDA to consider certain factors when deciding to impose a REMS without requiring the agency to consider the same factors in deciding whether to modify or

retain it. Pl. Opp'n 22. However, it is hardly irrational for different criteria to govern different decisions, such as modification rather than imposition of a REMS. Indeed, that reflects a decision by Congress not to require FDA to perpetually revisit *de novo* its original decision to impose restrictions on a drug's distribution.

To be clear, FDA does not dispute that, in determining whether to modify the REMS, FDA must make an "assessment" of whether evidence supports departing from the agency's conclusion that "the drug's risks require [a] REMS." *Washington v. FDA*, 668 F. Supp. 3d 1125, 1140 (E.D. Wash. 2023). But in so doing, FDA need not consider factors nowhere mentioned in 21 U.S.C. § 355-1(g)(4)(B).

The necessity of the ETASU. Contrary to Plaintiffs' assertion, *see* Pl. Opp'n 17-18, FDA considered whether mifepristone "can be approved only if, or would be withdrawn unless" ETASU remained part of the drug's conditions of approval. 21 U.S.C. § 355-1(f)(1)(A). FDA has approved mifepristone only *with* restrictions to assure safe use. The relevant question for modifying the Mifepristone REMS Program, therefore, was whether the agency could now modify the conditions of mifepristone's approval to be *without* ETASU. But the agency may not approve an application to modify the conditions of approval for a drug unless the agency is satisfied that the evidence shows the drug will be safe (i.e., its benefits will outweigh its risks) with the modification. *Id.* §§ 355-1(g)(4)(B), 355(d); 21 C.F.R. §§ 314.1 (providing that new drug application requirements apply to supplemental

applications), 314.105(c); *see also* FDA Guidance for Industry, *Benefit-Risk Assessment for New Drug and Biological Products* (Oct. 2023) (explaining that in determining safety FDA examines whether "the benefits of the drug outweigh its risks"); FDA MSJ 4-5, 21-22.[3]

Here, FDA found insufficient evidence to demonstrate that mifepristone's benefits would outweigh its risks if the REMS with ETASU were eliminated—as would have been needed for FDA to depart from its prior conclusion. DCSF ¶¶ 21-35; 2021 REMS 001574, 1578, 1597. Plaintiffs believe this is not enough to justify the maintenance of ETASU. Pl. Opp'n 18. But they fail to explain how, given that determination, FDA could approve a supplemental application eliminating the REMS with ETASU. Under the REMS modification and drug approval standards of § 355-1(g)(4)(B) and § 355, it could not. For the same reason, Plaintiffs' related contention that FDA failed to consider whether the ETASU were "commensurate" with specific risks (Pl. Opp'n 19) should receive no traction.

Burdens on patients. Plaintiffs' argument that FDA failed to consider burdens on patients (Pl. Opp'n 19-20) is fundamentally misconceived. Nothing in § 355-1 requires FDA to reduce the burden of ETASU on patients when FDA determines that it cannot be done safely. FDA had already minimized the burden on

[3] Available at https://www.fda.gov/media/152544/download (accessed May 13, 2025).

the prescriber certification requirement, DCSF ¶ 27, and Plaintiffs identify no way that FDA could have further minimized the burden on patients in a manner consistent with the agency's finding that the evidence was insufficient to show that the drug's benefits would outweigh its risks without a REMS with ETASU.

Comparison to other drugs. Plaintiffs contend that FDA ignored the requirements of 21 U.S.C. § 355-1(f)(2)(D)(i). Pl. Opp'n 20-21. That provision contemplates comparing mifepristone to drugs with ETASU intended to mitigate against risks that are not only "serious" but "similar" to those of mifepristone. 21 U.S.C. § 355-1(f)(2)(D)(i). Plaintiffs' contention fails because they do not explain how any of the drugs FDA allegedly did not consider (none of which have ETASU) have risks "similar" to those of mifepristone.

B. FDA reasonably considered all relevant evidence

During the 2021 REMS review, FDA assessed whether evidence since 2016 demonstrated that the ETASU could be eliminated. DCSF ¶ 7; 2021 REMS 001570, 1573, 1577. FDA considered all relevant evidence in its REMS review. Plaintiffs have not proved that FDA failed to consider any relevant evidence that was before the agency.

The Canadian study. As FDA explained (FDA MSJ 36-38), the Canadian study (2022 CP 000099-109) was not before FDA at the time that FDA conducted its comprehensive literature review. Nor did anyone urge FDA to consider that

study in connection with the decision under review in this case. Instead, the Canadian study was submitted to FDA after the close of its literature review as part of a citizen petition that requested a different agency action and made arguments outside the scope of this case. Plaintiffs cite no authority supporting their contention that FDA was required to pluck this study out of the record for that separate action and consider it *sua sponte* here.

Insisting that FDA "possessed the Canadian study" before approving the modified REMS in January 2023 (Pl. Opp'n 25-26), Plaintiffs miss the point. FDA reasonably imposed a cut-off date for its literature review for administrability purposes. Otherwise, a final decision could be subject to endless delays while FDA refreshed the literature review to account for new studies published in the year-long interval between directing sponsors to propose modifications to the REMS and approving those modifications. *Cf. Vt. Yankee Nuclear Power Corp. v. Nat. Res. Def. Council, Inc.*, 435 U.S. 519, 554–55 (1978) ("there would be little hope that the administrative process could ever be consummated" if an agency were required to consider any evidence that arrives in the "gap between the time the record is closed and the time the administrative decision is promulgated") (quoting *ICC v. Jersey City*, 322 U.S. 503, 514 (1944)).

To be sure, FDA reviewed certain materials after the cut-off date when those materials came to its attention *in connection with its review of the proposed*

modifications. For example, when FDA became aware of a new study published on the date of its final agency action, it reviewed the study to determine whether it contained objective safety data that might affect its decision. Def. Resp. to Pl. Concise Stmt. of Supp. Facts ¶ 21. FDA also reviewed materials attached to the November 2022 complaint in *Alliance for Hippocratic Medicine v. FDA*, 22-cv-223-Z (N.D. Tex.) (now *Missouri v. FDA*), in which plaintiffs claimed, among other things, that the in-person dispensing requirement remained necessary—an issue that went to FDA's forthcoming January 2023 REMS Modification. *Id.* The published Canadian study, by contrast, was not cited in any challenge to that forthcoming action.

Rather, the Canadian study was cited in a citizen petition submitted in October 2022. The primary request of that petition was that FDA direct the sponsor of Mifeprex to submit a supplemental application seeking approval of mifepristone for miscarriage management. DCSF ¶ 16. The study was referenced in connection with a secondary request to modify the REMS so as not to be unduly burdensome *for that new indication*. 2022 CP 000081, 87. And ultimately, the citation proved irrelevant to FDA's disposition of the petition: FDA determined that it was up to the sponsor to decide what indications to seek approval for. DCSF ¶ 17.

Other evidence. FDA appropriately considered the remaining evidence, focusing primarily on "objective safety data," FDA MSJ 34-35—that is,

"publications containing safety data related to the outcomes of medical abortion," 2021 REMS 001571. Plaintiffs do not contest FDA's point that "objective safety data" is most germane. Likewise, they identify no "objective safety data" that FDA did not review. Instead, Plaintiffs allege that FDA failed to consider various "medical association' statements opposing the REMS," qualitative studies on burdens, and "stakeholder objections." Pl. Opp'n 24, 27. But as FDA previously explained, the agency considered the material but generally found it not informative to the safety analysis. FDA MSJ 34-35; *cf. FCC v. Prometheus Radio Project*, 592 U.S. 414, 426 (2021) ("The FCC did not ignore the Free Press studies. The FCC simply interpreted them differently.").

Plaintiffs suggest that FDA had to specifically respond to "statements by expert medical societies" advocating against the REMS with ETASU, Pl. Opp'n 27, as if FDA's REMS review were a form of notice-and-comment rulemaking. Even in such rulemaking, an agency has a particular obligation to respond to only "relevant" and "significant" public comments. *Catholic Legal Immigration Network, Inc. v. Executive Office for Immigration Review*, 513 F. Supp. 3d 154, 173 (D.D.C. 2021) (quoting *Home Box Office, Inc., v. FCC*, 567 F.2d 9, 35 & n.58 (D.C. Cir. 1977)). A REMS modification decision is an adjudication, not a rulemaking, and Plaintiffs cite no authority requiring FDA to respond to particular

submissions and comments. It is enough that FDA considered them and explained that they did not provide objective evidence of safety.

C. FDA reasonably explained its decision

FDA's decision not to eliminate the ETASU—and its explanation for that decision—was eminently reasonable considering the context. The 2021 REMS review occurred against the backdrop of prior determinations that mifepristone's benefits had not been shown to outweigh its risks without ETASU. Those include FDA's approval decision in 2000; Congress's decision in 2007 to "deem" existing restrictions on drugs such as mifepristone to be a REMS with ETASU; and FDA's affirmation in 2011 and 2016 that ETASU on mifepristone could not be eliminated.[4]

In 2021, FDA simply addressed whether evidence generated since the last review in 2016 justified the elimination of all ETASU. DCSF ¶ 11. After all, FDA cannot approve a supplemental application modifying the conditions of approval for a drug if the information before FDA is "insufficient" to show that the drug is safe and effective under those modified conditions. 21 U.S.C. § 355(d); *see also* 21

[4] Earlier in this litigation, Plaintiffs challenged the 2016 REMS Modification. However, the APA claims in the current operative complaint target only FDA's January 2023 REMS Modification. 2d Am. Compl. ¶¶ 213, 216, 219. In any event, the 2016 REMS Modification, like the January 2023 REMS Modification, was not based on a *de novo* review of FDA's original decision in 2000 to impose restrictions to assure safe use. At no point in this litigation have Plaintiffs challenged the 2000 decision.

C.F.R. §§ 314.50, 314.105(c). Here, in a 40-page memorandum, 2021 REMS 001561-1608, FDA explained that the required showing had not been made because the evidence—primarily "objective safety data"—did not provide the agency with the assurance it would need to change its baseline assessment and remove all restrictions. Proceeding ETASU by ETASU, FDA discussed the rationale for its decision to require pharmacy certification and maintain the prescriber certification and Patient Agreement Form ETASU. *See* FDA MSJ 21-26.

Plaintiffs' brief spends several pages (Pl. Opp'n 13-17) disagreeing with FDA's reasoning, but their critiques incorrectly put the onus on FDA to re-justify the ETASU as if this were a *de novo* assessment. For example, they argue that FDA was required to eliminate the Patient Agreement Form in 2021-2023 because FDA reviewers recommended doing so in connection with the 2016 review. Pl. Opp'n 13-14. But in 2016, "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." FDA 674.[5]

[5] As noted, Plaintiffs no longer challenge the 2016 REMS modification. In any event, "[e]ven assuming that [an agency's internal] communications are the proper subject of [judicial] review . . . 'the existence of internal disagreements . . . does not render the agency's ultimate decision arbitrary and capricious. Scientific conclusions reached by the agency need not reflect the unanimous opinion of its experts.'" *Rivers v. Bureau of Land Mgmt.*, 815 F. App'x 107, 109 n.3 (9th Cir. 2020) (quoting *Nat'l Mining Ass'n v. Zinke*, 877 F.3d 845, 868 (9th Cir. 2017)).

Here, FDA's explanation that it decided not to depart from its prior determination because objective safety information did not justify doing so satisfied the agency's obligation to engage in reasoned decision-making. Plaintiffs disagree with FDA's assessments, but disagreement alone will not suffice to invalidate agency action under the APA. *Alaska Cntr. for the Envt. v. West*, 157 F.3d 680, 685 (9th Cir. 1998). "It is well-established that FDA's 'judgments as to what is required to ascertain the safety and efficacy of drugs fall squarely within the ambit of the FDA's expertise and merit deference.'" *Cumberland Pharm. Inc. v. FDA*, 981 F. Supp. 2d 38, 48 (D.D.C. 2013) (quoting *Schering Corp. v. FDA*, 51 F.3d 390, 399 (3d Cir. 1995)). As the Chief Justice admonished the last time a district court ordered FDA not to enforce a mifepristone ETASU, the "significant deference" due to the agency in this area should make courts reluctant to "compel the FDA to alter the regimen for medical abortion." *FDA v. Am. Coll. of Obstetricians & Gynecologists*, 141 S. Ct. 578, 579 (2021) (Roberts, C.J., concurring in the grant of application for stay).

III. Plaintiffs' Constitutional Claim Fails

Finally, Plaintiffs attempt to avoid summary judgment on their equal protection claim (Count I) by recasting their APA claims in constitutional terms. In essence, they concede that rational-basis review applies but deny that FDA has a rational basis for requiring ETASU. For the reasons explained above, that is wrong.

CONCLUSION

For the foregoing reasons, the Court should grant Defendants' cross-motion for summary judgment.

May 13, 2025

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CERTIFICATE OF COMPLIANCE

I hereby certify that this document complies with the word-count limits set by the Court in ECF No. 82 and 211 because, excluding parts of the document exempted by Local Rule 7.4(d), it contains 4,246 words. In compliance with Local Rules 7.4(e) and 10.2(a), I further certify that this document has been prepared using Microsoft Word in 14-point Times New Roman font.

/s/ Noah T. Katzen
NOAH T. KATZEN