BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General
BURDEN H. WALKER
Acting Deputy Assistant Attorney General

AMANDA N. LISKAMM
Director
LISA HSIAO
Senior Deputy Director
HILARY K. PERKINS
Assistant Director

NOAH T. KATZEN (D.C. Bar No. 1006053)
Trial Attorney
Consumer Protection Branch
U.S. Department of Justice
450 Fifth St., N.W.
Washington, DC 20530
Tele: 202-305-2428
Fax: 202-514-8742
Noah.T.Katzen@usdoj.gov

Attorney for Defendants Xavier Becerra, et al.

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF HAWAII

HEIDI PURCELL, *et al*., Plaintiffs, v. XAVIER BECERRA, *et al*., Defendants.	CIV. NO. 1:17-00493-JAO-RT **DEFENDANTS' COMBINED MEMORANDUM IN SUPPORT OF CROSS-MOTION FOR SUMMARY JUDGMENT AND IN OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT**

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INTRODUCTION

In 2000, the U.S. Food and Drug Administration approved mifepristone as safe and effective for medical termination of early pregnancy subject to certain restrictions to assure safe use.[1] Since 2008, those restrictions have been called "elements to assure safe use" (ETASU) and are part of a Risk Evaluation and Mitigation Strategy (REMS).

Among other things, the restrictions on mifepristone have always required that prescribers certify that they meet certain criteria and that patients sign a Patient Agreement Form disclosing risks of the drug. Until 2023, the restrictions also included a requirement—known as the "in-person dispensing requirement"—that mifepristone be dispensed only in certain healthcare settings by or under the supervision of a certified prescriber.

In 2021, FDA directed the sponsors[2] of mifepristone to submit a proposed modification to the REMS to eliminate the in-person dispensing requirement and add a pharmacy certification requirement. That directive followed FDA's

[1] This brief uses "mifepristone" as shorthand to refer to drug products that are approved for medical termination of early pregnancy. FDA has separately approved another manufacturer's drug, Korlym, which has mifepristone as its active ingredient and is approved for the treatment of Cushing's syndrome. This litigation does not affect Korlym.

[2] This brief uses "sponsor" to refer to a person who submits a new drug application, abbreviated new drug application, or supplemental application, or who holds an approved application.

comprehensive review of adverse event reports, literature, and other information available since an earlier modification in 2016. FDA approved the modified REMS on January 3, 2023. As a result, mifepristone may be dispensed in-person or by mail and must be dispensed by or under the supervision of a certified prescriber or by a certified pharmacy. In short, FDA made mifepristone's REMS less burdensome in response to evidence that an existing restriction (the in-person dispensing requirement) was no longer needed if pharmacy certification was added and the other ETASU were followed.

Indeed, the effect of the January 2023 REMS modification was to make mifepristone's REMS (including the ETASU) less burdensome than ever before. Yet in their Second Amended Complaint, Plaintiffs—one doctor (Dr. Purcell) and two organizations with healthcare provider members—challenge the January 2023 REMS modification as unjustified. They allege that mifepristone is safe without a REMS, even though FDA—the expert agency charged with reviewing drug safety—has not reached that conclusion. From there, Plaintiffs argue that FDA should have eliminated the REMS entirely, rather than approve modifications to the REMS that had the effect of making it less burdensome. The Court should reject these arguments, deny Plaintiffs' Motion for Summary Judgment, and grant summary judgment to Defendants.

First, Plaintiffs lack Article III standing. Their principal theory of injury is that

the REMS burdens patients and other unidentified healthcare providers. This theory cannot establish standing because Article III requires Plaintiffs to establish that *they* have been injured, which they fail to do. The lead Plaintiff, Dr. Purcell, relies on a speculative and attenuated theory of standing reminiscent of those the Supreme Court rejected in *FDA v. Alliance for Hippocratic Medicine*, 602 U.S. 367 (2024). The members of the plaintiff organizations rely on similarly flawed theories of standing. And the organizations attempt to establish standing in their own right by invoking their voluntary expenditure of resources—a theory the Supreme Court squarely rejected in *Alliance for Hippocratic Medicine*.

Second, on the merits, Plaintiffs' APA claims fail. FDA may not approve a modification to a REMS unless the agency determines that, with the change, the drug's benefits outweigh its risks. Here, applying that standard, FDA determined that there was insufficient evidence to eliminate the REMS entirely. Plaintiffs disagree, faulting FDA for supposedly failing to consider relevant statutory factors. But each statutory factor that Plaintiffs identify either was considered by FDA or was not relevant to the modification decision.

Nor do Plaintiffs' attacks on FDA's consideration of the evidence or the agency's reasoning have merit. Contrary to Plaintiffs' assertions, FDA did not ignore evidence based on its source. Instead, it considered all evidence before it relevant to whether the ETASU are necessary to maintain a favorable benefit/risk

(safety) profile for mifepristone. FDA found insufficient evidence to demonstrate that mifepristone would continue to have a favorable safety profile if the prescriber certification requirement or Patient Agreement Form were eliminated. But FDA found that there was sufficient evidence supporting removal of the in-person dispensing requirement, provided that all other REMS requirements were met and a pharmacy certification requirement was added.

Finally, Plaintiffs' constitutional claims also fail. Their argument that FDA's regulation of mifepristone denies Plaintiffs equal protection is subject to rational basis review. FDA's determination that the REMS is necessary to assure safe use of mifepristone supplies that rational basis. Plaintiffs do not contend they are entitled to summary judgment on these claims.

BACKGROUND

I. Statutory and Regulatory Background

The Federal Food, Drug, and Cosmetic Act (FDCA) generally prohibits the interstate distribution of new drugs that have not received FDA approval. 21 U.S.C. §§ 331(d), 355(a). FDA approves a new drug application if the drug is shown to be safe and effective for its intended use. *Id.* § 355(d); *see also* 21 C.F.R. §§ 314.50, 314.105(c). Similarly, when a drug's sponsor proposes changes to the drug's conditions of approval (such as changes to labeling or to restrictions relating to its distribution or use), FDA reviews the scientific evidence submitted in support

of the proposal to determine whether it should be approved. *See* 21 C.F.R. § 314.70. And in determining whether a drug is "safe," FDA examines whether the benefits of the drug outweigh the risks. *See* FDA Guidance for Industry, *Benefit-Risk Assessment for New Drug and Biological Products* (Oct. 2023) ("Because all drugs can have adverse effects, the demonstration of safety requires a showing that the benefits of the drug outweigh its risks.").[3]

In 1992, FDA promulgated regulations (the Subpart H regulations) providing for the imposition of conditions "needed to assure safe use" of certain new drugs that satisfy the other requirements for approval under the FDCA. Final Rule, 57 Fed. Reg. 58,942, 58,958 (Dec. 11, 1992) (codified at 21 C.F.R. § 314.520). In the Food and Drug Administration Amendments Act of 2007 (FDAAA), Congress codified and expanded the Subpart H regulations by giving FDA authority to require a REMS when it determines that restrictions are necessary to ensure that the benefits of a drug outweigh the risks. *See* Pub. L. No. 110-85, tit. IX, § 901 (codified at, *inter alia*, 21 U.S.C. § 355-1). FDA may require that a REMS include ETASU if necessary to mitigate a serious health risk and if certain statutory criteria relating to ensuring safety and minimizing the burden of restrictions are satisfied. 21 U.S.C. § 355-1(f). ETASU may include requirements that a drug's prescribers have particular training or are specially certified, that a drug be dispensed only in

[3] Available at https://www.fda.gov/media/152544/download.

certain settings or by certified pharmacies, and that the drug be dispensed to patients only with evidence or other documentation of safe-use conditions. *See* 21 U.S.C. § 355-1(f)(3).

FDAAA expressly incorporated drugs with existing Subpart H restrictions to assure safe use into the new REMS framework. *See* Pub. L. No. 110-85, tit. IX, § 909 (21 U.S.C. § 331 note). Specifically, Congress "deemed" such drugs to have a REMS in effect, with the Subpart H restrictions serving as ETASU. *Id.* § 909(b). Thereafter, sponsors for such drugs were required to submit supplemental new drug applications with a proposed REMS, which FDA then reviewed. *See id.*

FDAAA also provided standards for modifying an existing REMS. *See* 21 U.S.C. § 355-1(g)(4). As relevant here, FDA may require a sponsor to "submit a proposed modification" to a REMS if the agency "determines that 1 or more goals or elements should be added, modified, or removed" from the approved REMS to "ensure the benefits of the drug outweigh the risks of the drug" or "minimize the burden on the health care delivery system of complying with the strategy." *Id.* § 355-1(g)(4)(B).

II. Factual Background

In 2000, FDA approved mifepristone (under the brand name Mifeprex) in a regimen with misoprostol for medical termination of intrauterine pregnancy through 49 days gestation. DCSF ¶ 1. At the same time, to assure mifepristone's

safe use, FDA placed restrictions under Subpart H on the distribution and use of the drug product. DCSF ¶ 2. These included requirements that (1) prescribers certify that (among other things) they have the ability to accurately date pregnancies and diagnose ectopic pregnancies, and will either provide surgical intervention or arrange for others to provide it if necessary; (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. FDA concluded based on a review of clinical trials and other scientific evidence that, under those conditions, mifepristone was safe and effective, in a regimen with misoprostol, to terminate early pregnancy. DCSF ¶ 4.

Because these restrictions under Subpart H were in place when FDAAA took effect, Mifeprex was "deemed to have in effect an approved [REMS]" that continued these restrictions as "elements to assure safe use." Pub. L. No. 110-85, § 909(b)(1); *see also* PCSF ¶ 27; DCSF ¶ 5. In 2011, in response to a supplemental application submitted by the sponsor, FDA approved the Mifeprex REMS after determining that restrictions remained necessary to ensure the benefits of mifepristone outweigh the risks. DCSF ¶ 6. In 2016, FDA approved modifications to the conditions of approval (including the REMS) for Mifeprex, to lower the dose of mifepristone, increase the gestational age limit from 49 to 70 days, reduce the

number of required in-person clinic visits from three to one, remove the requirement that mifepristone be taken at a clinic, and to allow mifepristone to be prescribed by non-physician healthcare providers licensed under state law to prescribe drugs. DCSF ¶ 7. When FDA approved a generic version of the drug in 2019, it approved a single, shared system REMS, known as the Mifepristone REMS Program, for both Mifeprex and the generic version. DCSF ¶ 8.

FDA has since reviewed and approved modifications to the Mifepristone REMS Program that are consistent with decades of experience reflecting that, with the REMS in effect, the benefits of mifepristone outweigh the risks. As relevant here, on May 7, 2021, FDA announced that it would review the elements of the Mifepristone REMS Program to determine whether those elements should be modified. DCSF ¶ 9. FDA's review encompassed "multiple different sources of information," including "published literature," "safety information," adverse event reports, a "REMS assessment report" submitted by the sponsors, and "information provided by advocacy groups, individuals, and the [sponsors]." DCSF ¶ 10. The time period for the agency's literature search was March 29, 2016 (the date of the 2016 REMS modification) and July 26, 2021, and the search included publications found on PubMed and Embase as well as those provided by "advocacy groups, individuals, plaintiffs in [*Chelius v. Becerra*, No. 1:17-493-JAO-RT (D. Haw.)]," the sponsors, and "healthcare providers and researchers." DCSF ¶ 11.

On December 16, 2021, FDA announced its conclusion that "mifepristone will remain safe and effective for medical abortion if the in-person dispensing requirement is removed, provided all the other requirements of the REMS are met, and pharmacy certification is added." DCSF ¶¶ 20. Specifically, because FDA found insufficient evidence to demonstrate that the drug would be safe without them, FDA determined that the prescriber certification and Patient Agreement Form requirements continued to be necessary components of the REMS to mitigate risks related to heavy bleeding, missed ectopic pregnancy, and other issues. DCSF ¶ 21.

At the same time, FDA determined that the REMS "must be modified" to remove the requirement that mifepristone be dispensed only in certain healthcare settings because this requirement is "no longer necessary to ensure that the benefits of the drug outweigh the risks." DCSF ¶ 36. FDA also determined that because the in-person dispensing requirement was being removed, it was necessary to add a new requirement that pharmacies that dispense the drug be certified. DCSF ¶ 37. FDA reasoned that "[a]dding 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." DCSF ¶ 39. "[M]ifepristone will remain safe and effective" with these REMS

modifications, FDA concluded, "provided all the other requirements of the REMS are met and pharmacy certification is added." DCSF ¶ 20.

FDA directed the mifepristone sponsors to submit supplemental applications proposing these modifications to the REMS. DCSF ¶ 42. The sponsors submitted their supplemental applications in 2022, and FDA approved them on January 3, 2023. DCSF ¶ 43. Plaintiffs challenge that decision.

LEGAL STANDARD

A court "shall grant 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). "[I]n the context of reviewing an administrative decision under the APA, 'there are no disputed facts that the district court must resolve.'" *Conservation Council for Haw. v. Nat'l Marine Fisheries Serv.*, 97 F. Supp. 3d 1210, 1218 (D. Haw. 2015) (quoting *Occidental Eng'g Co. v. INS*, 753 F.2d 766, 769 (9th Cir. 1985)). Thus, on summary judgment, "the function of the district court is 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." *Occidental Eng'g*, 753 F.2d at 769; *accord City & Cnty. of S.F. v. United States*, 130 F.3d 873, 877 (9th Cir. 1997).

That inquiry requires the Court to determine, based on the administrative record, *Camp v. Pitts*, 411 U.S. 138, 142 (1973), whether the challenged agency

action was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," 5 U.S.C. § 706(2)(A), or "in excess of statutory jurisdiction, authority, or limitations," *id.* § 706(2)(C). Review under the arbitrary-and capricious standard is "at its most deferential" with respect to an agency's scientific determinations within its area of expertise. *Balt. Gas & Elec., Co. v. Nat. Res. Def. Council, Inc.*, 462 U.S. 87, 103 (1982). In particular, "[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 from [courts]." *Schering Corp. v. FDA*, 51 F.3d 390, 399 (3d. Cir. 1995); *see also FDA v. Am. Coll. Of Obstetricians & Gynecologists*, 141 S. Ct. 578, 579 (2021) (Roberts, C.J., concurring in the grant of application stay) ("courts owe significant deference to the politically accountable entities with the background, competence, and expertise to assess public health") (internal quotation marks omitted); *Ipsen Biopharmaceuticals, Inc. v. Becerra*, 108 F.4th 836, 840 (D.C. Cir. 2024) (court "must be careful not to unduly second-guess an agency's scientific judgments") (citation omitted); *Cytori Therapeutics, Inc. v. FDA*, 715 F.3d 922, 925 (D.C. Cir. 2013) ("In Administrative Procedure Act cases alleging arbitrary or capricious agency action, courts must be careful not to unduly second-guess an agency's scientific judgments.") (Kavanaugh, J.).

Plaintiffs' equal protection claim is reviewed under the rational basis standard.

Montana Medical Ass'n v. Knudsen, 119 F.4th 618, 630 (9th Cir. 2024) (unless fundamental right or suspect class is involved, equal protection claims are reviewed under rational basis standard).

ARGUMENT

I. Plaintiffs Lack Standing

"The fundamentals of standing are well-known and firmly rooted in American constitutional law." *Alliance for Hippocratic Medicine*, 602 U.S. at 380. To meet the "irreducible constitutional minimum of standing," *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992), Plaintiffs "must show (i) that [they] suffered an injury in fact that is concrete, particularized, and actual or imminent; (ii) that the injury was likely caused by the defendant[s]; and (iii) that the injury would likely be redressed by judicial relief," *TransUnion LLC v Ramirez*, 594 U.S. 413, 423 (2021). "Those specific standing requirements constitute 'an essential and unchanging part of the case-or-controversy requirement of Article III.'" *Alliance for Hippocratic Medicine*, 602 U.S. at 380.

"In 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). Moreover, "standing is not dispensed in gross." *Lewis v. Casey*,

518 U.S. 343, 358 n.6 (1996). "Rather, a plaintiff must demonstrate standing for each claim he seeks to press and for each form of relief that is sought." *Davis v. FEC,* 554 U.S. 724, 734 (2008) (internal quotation marks omitted).

A. Dr. Purcell and the plaintiff organizations' members lack standing

Plaintiffs seek to establish their standing through Dr. Purcell, as well as other alleged members of the two plaintiff organizations, the Society of Family Planning and the California Academy of Family Physicians. But the various theories they offer to establish standing fail to satisfy Article III.

1. Primarily, Dr. Purcell and the organization members rely on alleged harm *to others* to establish their Article III standing. *See, e.g.*, 2d Am. Compl. ¶ 190 (alleging injuries to Dr. Purcell's patients); *id.* ¶¶ 192, 193, 195 (alleging injuries to other clinicians in Dr. McNeil's county health system); *id.* ¶ 194 (alleging injuries to inpatient pharmacy in Dr. McNeil's health system); *id.* ¶ 199 (alleging injuries to other prescribers); *id.* ¶ 200 (alleging injuries to Dr. Chen's patients); *id.* ¶ 202 (alleging injuries to Dr. Uzumcu's patients); *id.* ¶ 204 (alleging injuries to other doctors); Pl. Mem. 21-24 (alleging harms to patients, pharmacies, and other doctors and prescribers); PCSF ¶¶ 75-83 (alleging harms to "health centers," other clinicians and doctors, pharmacies, the healthcare system generally).

Such allegations are insufficient. "The relevant showing for purposes of Article III standing . . . is . . . injury *to the plaintiff*." *Friends of the Earth, Inc. v. Laidlaw*

Envt'l Servs. (TOC), Inc., 528 U.S. 167, 181 (2000) (emphasis added). Thus, "even when [courts] have allowed litigants to assert the interest of others, the litigants themselves must still have suffered an injury in fact, thus giving them a sufficiently concrete interest in the outcome of the issue in dispute." *Hollingsworth v. Perry*, 570 U.S. 593, 708 (2013). In short, the doctors cannot "shoehorn themselves into Article III standing simply by showing that their patients"—or others—"have suffered injuries or may suffer future injuries." *Alliance for Hippocratic Medicine*, 602 U.S. at 393 n.5.

2. For her own standing, Dr. Purcell relies exclusively on an attenuated theory stemming from the alleged limitations of the electronic medical system used in her practice. That system, she alleges, cannot house the Patient Agreement Form. As a result, she allegedly "had to involve administrative staff in creating a hard copy file" for a patient who later became a colleague. 2d Am. Compl. ¶ 190. This, in turn, "potentially reveal[ed] the patient's private medical decision to her future colleagues." *Id.* And that, in turn, "jeopardiz[ed] Dr. Purcell's relationship with someone who is both a patient and now also a colleague." *Id.* Dr. Purcell expressed "concern[] about potential HIPAA implications" if "similar situations occur in the future." *Id.*

Absent from this theory is any injury in fact. Her allegation that her relationship with her patient/colleague was "jeopardiz[ed]" (but not actually

harmed) is too abstract to show concrete injury. *See TransUnion*, 594 U.S. at 434 (holding that an inaccuracy in an internal credit file that is not actually disclosed "causes no concrete harm"). Moreover, Dr. Purcell does not explain what her "concern[s]" about HIPAA are, let alone show that they represent likely future injury to her.

Nor can Dr. Purcell's theory satisfy the requirement of causation, which "is central to Article III standing." *Alliance for Hippocratic Medicine*, 602 U.S. at 383. She does not explain why she must generate a "hard copy" of the Patient Agreement Form, which may be signed electronically. DCSF ¶ 32. Nor does she explain how the Patient Agreement Form is different from other sensitive medical records handled by staff, housed in patient medical files, and required to be protected under HIPAA. *See generally* U.S. Department of Health and Human Services, Health Information Privacy, https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html. For example, she does not allege, let alone show, that there is no HIPAA-compliant way to protect the confidentiality of the Patient Agreement Form.

Moreover, as the Supreme Court explained in rejecting another challenge to FDA's actions with respect to mifepristone, a plaintiff cannot establish causation through "speculative links—that is, where it is not sufficiently predictable how third parties would react to government action or cause downstream injury to the

plaintiffs." *Alliance for Hippocratic Medicine*, 602 U.S. at 383. Nor, explained the Court, do "attenuated links" based on "distant (even if predictable) ripple effects" suffice. *Id.* Neither the limitations of Dr. Purcell's electronic medical system nor the happenstance that a patient to whom she prescribed mifepristone would become a colleague were predictable. Even assuming the chain of causation Dr. Purcell alleges were predictable, it—like the theories in *Alliance for Hippocratic Medicine*—is too attenuated to satisfy Article III.

3. Plaintiffs' attempt to establish associational standing through other members of the plaintiff organizations fares no better. *See Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977) ("[A]n association has standing to bring suit on behalf of its members when (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.").

a. Dr. McNeil alleges that she "spent tens of hours" on REMS compliance, 2d Am. Compl. ¶ 192, but she does not explain how that past injury would likely be redressed by prospective relief. *See Alliance for Hippocratic Medicine*, 602 U.S. at 381. To be sure, she vaguely alleges that her "work to surmount the REMS barriers is ongoing." 2d Am. Compl. ¶ 192. But the only examples she points to involve alleged burdens on others. *Id.* ¶¶ 193-95. Nor is it clear that those burdens result

from the REMS, rather than from the independent choices of still more third parties not before the Court. *See, e.g.*, *id.* ¶ 193 (alleging that "Dr. McNeil's health system requires" a burdensome process for clinicians to become credentialed); *id.* ¶ 194 (alleging that "Dr. McNeil's health system recently developed" a burdensome process for maintaining pharmacy records); *id.* ¶ 195 (alleging burdens to Dr. McNeil's healthcare system if uncertified clinicians attempt to prescribe mifepristone).

b. Dr. Jenkins alleges that, when she was obtaining her doctorate, she intended to complete a project related to mifepristone but "faced repeated REMS-related hurdles." *Id.* ¶ 197. She claims that "leadership at her academic institution" told her to seek Institutional Review Board (IRB) approval for this project "expressly because of" the REMS. *Id.* For reasons she does not specify, Dr. Jenkins alleges that she "was unable to complete [her] project." *Id.* She further alleges that she later had to explain this failure in a job interview and "ultimately did not get that job." *Id.*

Dr. Jenkins' theory of standing fails in multiple ways. For starters, any past injury to her job prospects is not redressable by prospective relief. Moreover, her theory is plainly too speculative and attenuated to support standing. Dr. Jenkins does not allege that the REMS itself required her to seek IRB approval—that advice was from "leadership at her academic institution." 2d Am. Compl. ¶ 197.

Nor does she explain why it was "predictable" that the leadership at her institution told her to seek such approval. She provides no evidence that her failure to complete her project was due to the REMS. Nor does she show—or even clearly allege—that her prospective employer did not hire her because of her failure to complete the research project. In any event, she cannot credibly claim that any loss of a job opportunity was a "predictable" downstream consequence of FDA's actions. And even if one assumes both that Dr. Jenkins has proven all the links in the chain of causation and that those links were predictable, her loss of a job opportunity was at most a "distant . . . ripple effect[]" of FDA's actions. *Alliance for Hippocratic Medicine*, 602 U.S. at 383.

c. Dr. Chen's theory is similarly speculative and attenuated. She alleges that some "colleagues within her institution and at the institution's satellite clinics" are unwilling to comply with the prescriber certification requirement and thus do not prescribe mifepristone. 2d Am. Compl. ¶ 199. This, in turn, purportedly causes them to refer patients to "Dr. Chen and her [other] colleagues." *Id.* To accommodate those referrals, Dr. Chen, other certified prescribers, and staff allegedly "try to squeeze these patients into already packed schedules." *Id.*

This theory mirrors one the Supreme Court rejected in *Alliance for Hippocratic Medicine*. There, doctors alleged that having to treat patients suffering adverse events would "divert[] resources and time from other patients." 602 U.S. at

390. The Court rejected this "doctrine of 'doctor standing,'" whereby doctors may "challenge general government safety regulations" on the theory that they cause "more individuals [to] show up" at their offices to seek treatment. *Id.* at 391. Dr. Chen therefore cannot base her claim to standing on the theory that more patients seek treatment from her as an indirect, downstream consequence of the REMS.

d. Dr. Uzumcu does not allege that the REMS impedes her ability to prescribe mifepristone for abortion in any way. Instead, she alleges that she does not prescribe mifepristone to manage miscarriage (an unapproved indication) because her clinic administration "is deeply concerned about having to require miscarriage patients to sign a form stating that they are having an abortion." 2d Am. Compl. ¶ 202. But any alleged injury related to mifepristone's use for an unapproved indication (miscarriage management) is simply too attenuated to establish standing to challenge restrictions related to the drug's approved use.

e. Dr. Lossy does not allege that the mifepristone REMS affects her in any way. Indeed, she admits that she has retired from the job in which she previously prescribed mifepristone. *Id.* ¶ 204. She attempts to predicate standing on her voluntary decision to consult with other doctors "who want to integrate mifepristone into *their* practices," claiming that these consultations "require time that she would otherwise spend on paid work or time with her family." *Id.* Article III standing cannot rest on such voluntarily assumed time-commitments. *See infra*

p. 21.[4]

4. Even if the Court found that one of these doctors had standing, that would not mean Plaintiffs may challenge, in gross, FDA's decision to retain the REMS. At most, they would have standing to challenge only those requirements that cause a redressable actual or imminent concrete injury to a plaintiff or member. *See Davis*, 554 U.S. at 734. Thus, Plaintiffs must provide evidence that each REMS requirement they wish to challenge causes such an injury. They have not met that burden for any REMS requirement.

B. The plaintiff organizations lack standing

For their part, the plaintiff organizations allege only that they "must divert resources from other organizational priorities to try to mitigate the burdens of the mifepristone REMS." 2d Am. Compl. ¶ 207; *see also id.* ¶¶ 208-09. They do not—and cannot plausibly—allege that the REMS itself requires this claimed diversion of resources. Nor do they assert that their diversion of resources is compelled by

[4] In previous motions, Plaintiffs relied on declarations by Dr. Chelius and other alleged members of plaintiff organizations to establish standing. ECF Nos. 34 (exhibits), 142 (exhibits). With respect to their Second Amended Complaint, however, they have not pleaded or attempted to show standing based on injury to these individuals. Nor could they. Dr. Chelius has withdrawn as a plaintiff and retired. Moreover, the declarations assert harm based on the in-person dispensing requirement, which has now been removed. To the extent those declarations sought to establish standing based on other ETASU that still apply, they suffer from flaws similar to those described above.

the need to avoid an injury in fact. Rather, their theory is that their *voluntary* decision about how to spend resources gives them Article III standing.

Alliance of Hippocratic Medicine rejected this theory. There, medical organizations likewise claimed "to have standing . . . based on their incurring costs to oppose FDA's actions" relating to mifepristone. 602 U.S. at 394. Rejecting that theory, the Court explained that "an organization that has not suffered a concrete injury caused by a defendant's action cannot spend its way into standing simply by expending money to gather information and advocate against the defendant's action." *Id.* So too here. Under *Alliance for Hippocratic Medicine*, organizations cannot generate standing to challenge FDA's actions with respect to mifepristone through their own voluntary allocation of resources.

II. Plaintiffs' APA Claims Are Meritless

A. FDA reasonably applied the statutory factors for REMS modifications

As explained above, FDA's decision to modify a REMS is governed by § 355-1(g)(4). That paragraph is titled "[m]odification" and, among other things, sets forth the factors that FDA considers when determining whether to require a sponsor to propose a REMS modification. FDA may require that a sponsor propose a modification to an existing REMS in a supplemental application to "ensure the benefits of [a] drug outweigh the risks of the drug" or to "minimize the burden on the health care delivery system." 21 U.S.C. § 355-1(g)(4)(B). FDA may not

approve a supplemental application modifying a REMS unless the agency is satisfied that the evidence shows that the drug will remain safe with the modification. *Id.* §§ 355-1(g)(4)(B), 355(d); 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).

Here, FDA appropriately applied the § 355-1(g)(4)(B) factors to determine that the REMS must be modified in certain respects and that, as modified, the drug would remain safe, while minimizing the burden of the REMS. In reaching that determination, FDA did not reassess information it already considered in coming to its then-existing safety determination. Rather, it based that determination on its 2021 review of information generated after the 2016 REMS modification. DCSF ¶¶ 10-14.

Specifically, FDA carefully examined hundreds of publications to determine whether they supported modifications to the REMS that would continue to assure safe use of the drug. DCSF ¶¶ 10-14. The agency also reviewed information from a wide variety of other sources, including healthcare providers, advocacy groups, and Plaintiffs. DCSF ¶¶ 10-11, 13-14. FDA also considered safety information from time periods in which the in-person dispensing requirement was not being enforced during the COVID-19 public health emergency, including information from the sponsors and adverse event reports. DCSF ¶ 10. Additionally, in assessing

whether to maintain the Patient Agreement Form, FDA considered the National Abortion Federation's 2020 Clinical Policy Guidelines for Abortion Care, as well as Practice Bulletins from the American College of Obstetricians and Gynecologists and the Society of Family Planning, and data relating to an increase in new providers for this care obtained from well-conducted surveys. DCSF ¶ 14.

Based on its review, FDA found evidence sufficient to support eliminating the in-person dispensing requirement, so long as pharmacy certification was added and the other existing REMS elements were retained. DCSF ¶ 20. FDA's determination with respect to each element was reasonable.

1. Prescriber certification. FDA explained that the evidence was insufficient to show that the benefits of mifepristone would continue to outweigh its risks if the prescriber certification requirement was removed. DCSF ¶ 22. Specifically, the agency's literature review did not identify any studies comparing providers who met these qualifications with providers who did not, and thus found "no evidence to contradict [its] previous finding that prescribers' ability to accurately date pregnancies, diagnose ectopic pregnancies, and provide surgical intervention or arrange for such care through others if needed, is necessary to mitigate the serious risks associated with" the drug. DCSF ¶ 23. In addition, by requiring prescribers to acknowledge that they "must report patient deaths associated with mifepristone to the manufacturer," the prescriber certification requirement "ensures that the

manufacturer receives all reports of patient deaths and, in turn, fulfills its regulatory obligations to report those deaths to the FDA." DCSF ¶ 24. Moreover, FDA anticipated a "potential for doubling" the number of prescribers due to the agency's removal of the in-person dispensing requirement. DCSF ¶ 25. In view of that potential, the agency determined that it was important to retain the prescriber certification to ensure that providers meet the necessary qualifications and adhere to the guidelines for use. DCSF ¶ 25.

FDA therefore concluded that prescriber certification "continues to be a necessary component of the REMS to ensure the benefits of mifepristone for medical abortion outweigh the risks." DCSF ¶ 26. At the same time, it noted that "[t]he burden of prescriber certification has been minimized to the extent possible" because each provider need only provide one certification to each of the two drug sponsors for mifepristone. DCSF ¶ 27.

2. Patient Agreement Form. FDA similarly concluded that the single-page Patient Agreement Form, which "ensures that patients are informed of the risks of serious complications associated with" use of mifepristone for this indication, "does not impose an unreasonable burden on providers or patients" and "remains necessary to assure the safe use of Mifepristone." DCSF ¶ 28. FDA explained that "literature that focused on the informed consent process" "d[id] not provide evidence that would support removing" the Patient Agreement Form requirement.

DCSF ¶ 29. Specifically, the agency found "no publications which directly addressed" the Patient Agreement Form. DCSF ¶ 30. Moreover, seven studies focusing on the informed consent process contained "no outcome data" or "other evidence demonstrating that informed consent made the Patient Agreement Form unnecessary." DCSF ¶ 31.

Moreover, as with prescriber certification, FDA found that the potentially significant increase in the number of medical abortion providers weighed in favor of retaining the Patient Agreement Form. DCSF ¶ 33. The agency noted the "continued need to ensure that patients are consistently provided patient education under the Mifepristone REMS Program regarding the use and risks of mifepristone." DCSF ¶ 34. The Patient Agreement Form, FDA explained, fulfills that need by "standardizing the medication information that prescribers communicate to their patients, including new prescribers." DCSF ¶ 34. It also provides that information in a "brief and understandable format," thus minimizing the burden of this requirement. DCSF ¶ 35.

3. Pharmacy certification. FDA determined that the benefits of mifepristone for medical termination of early pregnancy would continue to outweigh the risks if the in-person dispensing requirement was removed, provided all other requirements of the REMS were met and a pharmacy certification requirement was added. DCSF ¶¶ 20, 37. The pharmacy certification requirement permits

pharmacies to dispense mifepristone upon prescription by a certified prescriber if the pharmacies become certified. DCSF ¶ 38. FDA explained that, with the removal of the in-person dispensing requirement, the pharmacy certification requirement is necessary to ensure that pharmacies are aware of and agree to follow applicable REMS requirements and that only prescriptions from certified prescribers are filled. DCSF ¶ 39.

B. Plaintiffs fail to identify any relevant statutory factor that FDA did not reasonably consider

1. Plaintiffs ultimately disagree with how FDA weighed the § 355-1(g)(4)(B) considerations, but they fail to identify any way in which FDA's consideration was unreasonable. Congress assigned FDA the responsibility to determine the conditions under which drugs are safe. 21 U.S.C. § 355(d). Based on the evidence before it, FDA concluded that the evidence remains insufficient to find that mifepristone would be safe without the requirements for the prescriber certification, the Patient Agreement Form, and pharmacy certification. That determination is entitled to the utmost deference. *Balt. Gas & Elec., Co.*, 462 U.S. at 103; *Schering Corp.*, 51 F.3d at 399; *Ipsen*, 108 F.4th at 840; *Cytori Therapeutics*, 715 F.3d at 925 (Kavanaugh, J.); *see also Am. Coll. Of Obstetricians & Gynecologists*, 141 S. Ct. at 579 (Roberts, C.J., concurring in the grant of application stay) (explaining that the "significant deference" owed to FDA's judgments weighed against "compel[ling] the FDA to alter the regimen for medical

abortion").

First, Plaintiffs do not dispute that prescribers should have the qualifications that the prescriber certification requirement ensures. Instead, they argue at length that physicians may have the qualifications without so certifying. Pl. Mem. 39-41. But FDA did not rest its decision solely on the need for prescribers to have these qualifications. FDA also invoked (1) the absence of new evidence demonstrating a reason to depart from the agency's earlier determination that prescriber certification was necessary to ensure the safe use of mifepristone, (2) the prescriber certification's role in ensuring that patient deaths are reported to FDA, and (3) the potential for a significant increase in the number of prescribers following elimination of the in-person dispensing requirement. DCSF ¶¶ 23-25. Given these considerations, it was reasonable for FDA to find that the evidence did not support eliminating this requirement.

Plaintiffs also wrongly contend that FDA found the prescriber certification requirement imposes "no burden" by supposedly ignoring evidence that prescribers fear it will cause their identities to be exposed. Pl. Mem. 41-42. In fact, FDA acknowledged that the prescriber certification requirement imposes a burden, but it concluded that this burden "has been minimized to the extent possible by requiring prescribers to certify only one time for each [sponsor]." DCSF ¶ 27. Additionally, FDA acknowledged prescriber (and patient) confidentiality concerns, and

emphasized those concerns as part of the basis for requiring pharmacy certification in light of the elimination of the in-person dispensing requirement. DCSF ¶ 40. As evidenced by the record, FDA did consider the confidentiality concerns raised by Plaintiffs.

Second, Plaintiffs argue that the Patient Agreement Form should be eliminated because informed consent provides sufficient protection for patients and because the information in the Patient Agreement Form is also contained in the Medication Guide required to be provided to patients. Pl. Mem. 36-38. But FDA considered the relevant evidence and rejected this argument. DCSF ¶¶ 29, 31. Plaintiffs appear to fault FDA for failing to point to evidence that mifepristone would be unsafe without a Patient Agreement Form. But that flips the burden: under subsection (g)(4)(B), FDA determines if an existing REMS should be modified to, among other things, "ensure the benefits of the drug outweigh the risks of the drug." *See supra* pp. 21-22.

Third, Plaintiffs note that FDA acknowledged that the pharmacy certification requirement would likely limit the types of pharmacies that would choose to dispense mifepristone. Pl. Mem. 42. That acknowledgement refutes Plaintiffs' suggestion that FDA ignored the burdens of this requirement. Plaintiffs also argue that FDA made the pharmacy certification requirement more burdensome than necessary by "mandating that pharmacies ensure delivery within four days of

receiving the prescription or make contact with the prescriber to confirm that another timeline is sufficient." Pl. Mem. 43. They reason that two-day shipping may not always be affordable. *Id.* But FDA reasonably explained that the purpose of the four-day requirement is to help ensure that the drug is received in time, in light of the labeled indication and gestational age. DCSF ¶ 41. Plaintiffs do not explain why the pharmacist cannot contact the provider, who can agree to another timeline (as the requirement permits) if appropriate under the circumstances. In light of the time-sensitive nature of mifepristone's use, this aspect of the pharmacy certification requirement is reasonable.

2. Plaintiffs also err by emphasizing the specific factors listed in 21 U.S.C. § 355-1(a)(1) that they claim FDA failed to consider. That subsection simply does not apply to a REMS modification decision. As its title ("Initial Approval") suggests, § 355-1(a)(1) governs FDA's decision to require an applicant seeking *initial approval* of a new drug for a particular use to propose a REMS. 21 U.S.C. § 355-1(a)(1). It provides that FDA may require the applicant to propose a REMS if the agency determines that one is "necessary to ensure that the benefits of the drug outweigh the risks of the drug." *Id.* In making that determination, FDA must consider (1) "[t]he estimated size of the population likely to use the drug involved," (2) "[t]he seriousness of the disease or condition that is to be treated with the drug," (3) "[t]he expected benefit of the drug with respect to such disease

or condition," (4) "[t]he expected or actual duration of treatment with the drug," (5) "[t]he 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," and (6) "[w]hether the drug is a new molecular entity." *Id.*

These factors do not apply here. Plaintiffs are not challenging FDA's "initial approval" of the mifepristone REMS. 21 U.S.C. § 355-1(a)(1). Instead, they challenge only the January 2023 REMS modification,[5] a decision governed by § 355-1(g). As discussed above, § 355-1(g)(4)(B) sets out distinct considerations relevant to an agency decision to modify a REMS. Moreover, it does not cross-reference or incorporate the factors enumerated in § 355-1(a)(1). Indeed, § 355-1 recognizes an initial determination under subsection (a)(1) as distinct from a later determination to modify the REMS under subsection (g). *See* 21 U.S.C. § 355-1(h)(1) (distinguishing between a "proposed [REMS] for a drug submitted under subsection (a)" and a "proposed modification to an approved [REMS] for a drug submitted under subsection (g)"); *id.* § 355-1(h)(3), (4) (establishing different dispute resolution procedures for decisions under subsections (a)(1) and (g)).

Nor would it make sense to apply the § 355-1(a)(1) factors to a REMS modification decision. Several of those factors are described in language directed

[5] *See, e.g.*, Pl. Mem. 4 ("Plaintiffs respectfully ask the Court to declare that FDA's 2023 REMS Decision violated the [APA] and remand to FDA to reconsider the mifepristone REMS and its ETASU.").

at drugs that have not yet been marketed for a particular use subject to a REMS. *See, e.g., id.* § 355-1(a)(1)(A) ("*estimated* size of the population *likely* to use the drug") (emphasis added); *id.* § 355-1(a)(1)(B) ("seriousness of the disease or condition that is *to be treated* with the drug") (emphasis added); *id.* § 355-1(a)(1)(C) ("*expected* benefit of the drug") (emphasis added); *id.* § 355-1(a)(1)(E) (referring to "the population *likely* to use the drug") (emphasis added); *id.* § 355-1(a)(1)(F) ("*new* molecular entity") (emphasis added). If Congress intended to require FDA to apply the subsection (a)(1) factors when assessing drugs already marketed subject to a REMS, it would have used language more amenable to that assessment.

3. Plaintiffs also argue that FDA failed to apply the factors in § 355-1(f)(1)-(3), which governs FDA's decision whether to require a REMS to include ETASU. But subsection (f), like subsection (g), looks to whether ETASU are "necessary to assure safe use of the drug" and are not unduly burdensome. *See id.* § 355-1(f)(1), (2); *accord id.* § 355-1(g)(4)(B)(i) and (ii); *see also id.* § 355-1(f)(1)(A) (permitting FDA to require elements to assure safe use if the drug "can be approved only if, or would be withdrawn unless, such elements are required"). And here, FDA weighed precisely those factors. As discussed, based on its review of the evidence, FDA concluded that (1) there was insufficient evidence to demonstrate that mifepristone would continue to have a favorable safety profile if the prescriber

certification requirement or the Patient Agreement Form were eliminated, but (2) there was sufficient evidence supporting removal of the in-person dispensing requirement, provided that all other REMS requirements were met and a pharmacy certification requirement was added.

Plaintiffs argue that FDA failed to reasonably account for burdens on access, but Plaintiffs do not explain how any of the ETASU could have been modified in a way to make them less burdensome while ensuring the drug's safety. *See, e.g.*, Pl. Mem. 26, 29, 30, 32, 34, 42-43. While Plaintiffs contend that FDA should have eliminated the ETASU entirely, that approach is inconsistent with FDA's determination that prescriber certification, the Patient Agreement Form, and pharmacy certification were *necessary* for safety. DCSF ¶¶ 20, 26, 28, 37, 42.

Misreading the statute, Plaintiffs fault FDA for not specifically comparing mifepristone to a diverse array of other drugs. Section 355-1(f)(2)(D)(i) does not require FDA to compare apples to oranges. Several of the drugs that Plaintiffs mention are over-the-counter drugs with vastly different conditions of use, indications, and risks. And opioids are controlled substances that are subject to other regulatory regimes that may affect the healthcare delivery system and patient access.[6] There is no basis in the statute for requiring FDA to use these different

[6] For example, § 1263 of the Consolidated Appropriations Act of 2023 requires opioid prescribers to complete training. Pub. L. 117-328, § 1263, 136 Stat. 4459,

drugs as a template for the regulation of mifepristone.

Contrary to Plaintiffs' suggestion (Pl. Mem. 20), the lack of a REMS for Korlym (a different drug product with mifepristone as its active ingredient, *see supra* n.1) does not support a different conclusion. In deciding whether to require a REMS for a particular drug, FDA makes a case-by-case determination that involves weighing the drug's risks and benefits in light of its particular conditions of use and other factors. *See* 21 U.S.C. § 355-1(a)(1). Indeed, FDA conducted this case-by-case inquiry for Korlym, explicitly considering the REMS for Mifeprex. FDA explained why Korlym does not require a REMS to assure safe use of the drug to treat Cushing's syndrome. Among other things, FDA noted that women with Cushing's syndrome are "unlikely to be pregnant" due to the underlying disease, and that the sponsor voluntarily distributes Korlym exclusively through specialty pharmacies. DCSF ¶ 44. Because Mifeprex and its generic and Korlym have different approved uses—and different benefits and risks in light of those uses—FDA was not compelled to reach the same decision regarding a REMS for those drugs.

4. In any event, even if Plaintiffs were right that FDA did not fully consider particular statutory factors relevant to REMS modification, any such error would

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5683 (Dec. 29, 2022). Plaintiffs fail to account for this in noting that FDA's Opioid Analgesics REMS does not contain a prescriber certification requirement. Pl. Mem. 4.

be harmless. *See* 5 U.S.C. § 706 ("due account shall be taken of the rule of prejudicial error"). Here, FDA determined that the REMS with ETASU is necessary to ensure mifepristone's safe use. Because FDA cannot approve a drug for use under conditions that the agency has not determined are safe, 21 U.S.C. § 355(d), none of the factors Plaintiffs identify could have changed the agency's conclusion.

C. FDA considered all relevant evidence

Plaintiffs' attack on FDA's consideration of the evidence likewise fails. Pl. Mem. 26-30. As explained above, FDA reviewed evidence from a wide variety of sources, including "advocacy groups," "healthcare providers and researchers," and Plaintiffs themselves. FDA did not ignore relevant evidence.

1. As noted, published literature was only one of several types of information that FDA considered. With respect to that literature, the agency's decision to focus on objective safety data when considering whether the evidence supported modifying the REMS with regard to the prescriber certification and in-person dispensing requirements was plainly reasonable. To determine whether to modify an existing REMS, FDA must assess whether the evidence before it shows that the drug would remain safe with the contemplated modification. Objective safety data, which here included, among other things, data regarding safety outcomes during the period in which in-person dispensing was not being enforced, was the evidence

most relevant to these modifications, and Plaintiffs do not contend otherwise.

Plaintiffs appear to misunderstand the import of FDA's focus on such evidence. They contend that FDA "expressly refused to consider statements by the nation's leading medical groups" and "excluded qualitative studies and stakeholder narratives" from consideration. Pl. Mem. 26. To the contrary, "[FDA's] review also included an examination of literature references provided by plaintiffs in the *Chelius v. Becerra* litigation." DCSF ¶ 10. Rather than exclude evidence based on *its source*, FDA generally focused on "objective safety data" because that was the *kind* of evidence most germane to its safety analysis.

Here, context makes plain that FDA's statements that it "excluded" certain types of evidence meant only that it concluded that such evidence did not bear on evaluation of some of the modifications it was considering. DCSF ¶ 13. The APA's requirement that an agency consider all relevant evidence before it does not oblige it to agree that any particular type of evidence should be given weight in its determination.

Indeed, "Appendix A" to FDA's 2021 REMS review memo is entitled "References Cited in Letters from Plaintiffs" and contains a chart that lists the references that FDA "excluded" from the review. The chart describes the contents of the listed references and briefly notes the reason that FDA did not give the item weight in making its determination. DCSF ¶ 13. The very existence of the chart

belies Plaintiffs' contention that FDA did not "consider" the references in the APA sense.

Nor are Plaintiffs correct that FDA refused to consider anything but objective safety data. The 2021 REMS review memo makes equally clear that FDA did not "categorically" refuse to consider qualitative data, such as practice guidelines and data from practitioner surveys regarding provider volume. To the contrary, FDA reviewed and considered practice guidelines and survey data in evaluating the Patient Agreement Form ETASU because of the relevance of the practice guidelines, the quality of the survey data, and the relevance of likely changes in provider volume. DCSF ¶ 14.

2. The only evidence Plaintiffs point to (Pl. Mem. 27-28, 33-34) that FDA did not consider is a Canadian study that was not published *until 2022*—that is, *after* FDA completed its 2021 REMS review and directed the sponsors of mifepristone to propose a modified REMS. DCSF ¶ 15.

FDA reasonably imposed a cut-off date of July 2021 for its systematic review of the literature. DCSF ¶ 11. Indeed, had FDA declined to establish a cut-off date, it would never have been able to complete its review. *See Ferguson v. Dep't of Educ.*, No. 09-cv-10057-FM, 2011 WL 4089880, at *10 (S.D.N.Y. Sept. 13, 2011) (holding that "it was reasonable" for an agency "to restrict the temporal scope" of its inquiry so as to avoid "a 'never-ending process.'") (quoting *Coven v. OPM*, No.

07-cv-1831-PHX-RCB, 2009 WL 3174423, at *7 (D. Ariz. Sept. 29, 2009)).

Perhaps Plaintiffs mean to suggest that FDA was required to review any evidence that was published before the actual *approval* of the proposed modification. But that would open the door to the same "never-ending process." The statute provides that a sponsor has 120 days or a "reasonable time[]" to propose a modified REMS after being directed to do so. 21 U.S.C. § 355-1(g)(4)(B). FDA then generally has 180 days to act on that proposal. *Id.* § 355-1(h)(2)(A). If the agency had to reevaluate its decision to request a modification every time a new, potentially relevant study is published in that long gap and notify the sponsor to amend its pending request for modification based on that study, the evaluation would never be completed.

In any event, FDA was never asked to consider the Canadian study in connection with the January 2023 REMS modification. Rather, the study was cited to FDA in a citizen petition asking FDA to request that the sponsor of Mifeprex submit a supplemental new drug application proposing to (1) add miscarriage management as an approved indication and (2) eliminate or modify the REMS so that it would not be unduly burdensome for *that* use. DCSF ¶ 16. FDA denied the citizen petition because it is up to the sponsor to decide whether to seek approval for a new indication. DCSF ¶ 17.

Citing the Canadian study, that petition also urged FDA to exercise

enforcement discretion with respect to the REMS requirements as they pertain to miscarriage management, while such a supplemental new drug application was being considered. DCSF ¶ 18. FDA denied this request because the management of miscarriage is not a currently approved indication for mifepristone, and it would be premature for FDA to consider the impact that the addition of this indication would have, if any, on the REMS so that it is not unduly burdensome for that use. DCSF ¶ 19. This disposition of the petition made it unnecessary for the agency to consider the Canadian study.[7]

III. Defendants Are Entitled To Summary Judgment On Plaintiffs' Constitutional Claims

Finally, even Plaintiffs do not contend that they are entitled to summary judgment on Counts I and II of their Second Amended Complaint. These counts allege that FDA's January 2023 REMS modification violates the Fifth Amendment. Those claims are meritless.

Plaintiffs assert that the January 2023 REMS modification treats them and their patients "differently from other similarly situated parties without a sufficient state interest," in violation of the equal protection component of the Fifth

[7] Nor is it a foregone conclusion that the Canadian study would support the result Plaintiffs seek. Were FDA to consider the study, it would have to determine (among other things) the extent to which findings concerning the use of mifepristone in Canada can support conclusions about the use of mifepristone in the United States, taking account of differences between the two countries' healthcare systems.

Amendment's Due Process Clause. 2d Am. Compl. ¶ 211. But it is unclear what "similarly situated parties" they are referring to. Plaintiffs do not claim that the Mifepristone REMS Program treats them or their patients differently than any other prescriber or user of mifepristone for termination of early pregnancy.

In any event, Plaintiffs' claims are subject to rational-basis review. *Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215, 300 (2022). The Court must therefore reject Plaintiffs' constitutional claims if the January 2023 REMS modification "furthers any legitimate governmental purpose and is rationally related to that goal." *Raidoo v. Moylan*, 75 F.4th 1115, 1121 (9th Cir. 2023). The government has a legitimate interest in protecting public health. *Seaplane Adventure, LLC v. Cnty. of Marin*, 71 F.4th 724, 730 (9th Cir. 2023). For the reasons explained above, FDA's decision to approve modification but not elimination of the Mifepristone REMS Program is rationally related to that interest. Therefore, FDA is entitled to summary judgment on Plaintiffs' constitutional claims.

CONCLUSION

For the foregoing reasons, the Court should grant Defendants' Cross-Motion for Summary Judgment and deny Plaintiffs' Motion for Summary Judgment.

Dated: December 3, 2024

Respectfully submitted,

/s/ Noah T. Katzen
NOAH T. KATZEN
Consumer Protection Branch
U.S. Department of Justice

Attorney for Defendants Xavier Becerra, in his official capacity as Secretary, U.S. Department of Health and Human Services; U.S. Food and Drug Administration; and Robert M. Califf, in his official capacity as Commissioner of Food and Drugs

Certificate of Compliance

I hereby certify that this document complies with the word-count limits set by the Court in Dkt. 82 and 211 because, excluding parts of the document exempted by Local Rule 7.4(d), it contains 9,098 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.

Dated: December 3, 2024

/s/ Noah T. Katzen
NOAH T. KATZEN
Consumer Protection Branch
U.S. Department of Justice

Attorney for Defendants Xavier Becerra, in his official capacity as Secretary, U.S. Department of Health and Human Services; U.S. Food and Drug Administration; and Robert M. Califf, in his official capacity as Commissioner of Food and Drugs