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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON

STATE OF WASHINGTON, et al.,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, et al.,

Defendants.

NO. 1:23-cv-03026-TOR

PLAINTIFF STATES' MOTION FOR SUMMARY JUDGMENT

With Oral Argument:
TBD (see ECF No. 153)

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I. INTRODUCTION

Mifepristone is an exceptionally safe medication; in the words of Defendant Becerra, it "is one of the safest and most effective medicines that we have seen over the last 20 years to help women with their health care[.]" https://tinyurl.com/5epfasmh. It is even safer than such well-known drugs as Tylenol, Viagra, and insulin. Yet unlike these drugs, mifepristone is subject to severe dispensing restrictions imposed by FDA. FDA has acknowledged that a key reason it imposed these restrictions on mifepristone and not other similarly safe drugs is that mifepristone is "controversial," because it is used for early-stage abortion. *Infra* at 6. But the statutes allowing FDA to restrict high-risk drugs do not include "political controversy" as a basis for doing so. Rather, Congress authorized FDA to impose special restrictions only when needed to ensure safety.

After extensive preliminary injunction briefing, this Court already concluded that "FDA did not assess whether mifepristone qualifies for [special restrictions] based on the criteria set forth under 21 U.S.C. § 355-1(a)(1), (f)(1)." *Washington v. FDA*, 668 F. Supp. 3d 1125, 1141 (E.D. Wash. 2023). On summary judgment, the administrative record confirms that conclusion. The record also shows that FDA failed to consider its restrictions' impact on patient access, violating Congress's express directive. This Court should again hold that FDA violated the law in imposing special restrictions on mifepristone, and should remand this matter to FDA for proper consideration of the statutory requirements and record evidence.

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II. RELEVANT FACTS

A. Statutory and Regulatory Background

Before a new drug may enter the U.S. market, it must undergo a rigorous approval process to determine its safety and efficacy. *See* 21 U.S.C. § 355. While all drugs have risks, for the vast majority of the 20,000 FDA-approved prescription medications, FDA manages those risks through "labeling." 21 C.F.R. § 201. Drug labeling includes "a summary of the essential scientific information needed for the safe and effective use of the drug," how it is administered, warnings, and potential adverse reactions. *Id.* §§ 201.56-57. FDA also often requires package inserts and medication guides to help patients avoid serious adverse events. *See id.* § 208.

After FDA approval, the provision of prescription drugs is subject to state regulations, malpractice laws, and professional and ethical rules—including requirements that prescriptions be issued only by licensed providers; providers only practice within their scope and the standard of care; and providers counsel patients on risks associated with the course of treatment. *See, e.g.*, AMA Principles of Medical Ethics, https://tinyurl.com/2dbl8oqd; Wash. Rev. Code § 18.71.002.

A tiny subset of FDA-approved drugs is subject to extra restrictions known as a Risk Evaluation and Mitigation Strategy (REMS). REMS may be imposed only when needed "to ensure that the benefits of the drug outweigh the risks . . . ." 21 U.S.C. § 355-1(a)(1). As FDA explains on its website: "While all medications have labeling that informs health care stakeholders about medication risks, only a few medications require a REMS." EAR324. This is because "REMS focus on

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preventing, monitoring and/or managing *a specific serious risk* by informing, educating and/or reinforcing actions to reduce the frequency and/or severity of the event." *Id.* (emphasis added).

The most restrictive and burdensome type of REMS are "Elements to Assure Safe Use" (ETASU), which FDA may impose only when a drug's "known serious risks" or "inherent toxicity or potential harmfulness" requires it. 21 U.S.C. § 355-1(f). ETASU apply only to drugs with serious side effects such as death, incapacity, or birth defects, and where the risk is so severe that the drug's approval "would be withdrawn" entirely without ETASU. *Id.* §§ 355-1(b)(5), (f)(1)(A). ETASU must be "commensurate with" the drug's risks, cannot be "unduly burdensome on patient access to the drug, considering in particular . . . patients who have difficulty accessing health care (such as patients in rural or medically underserved areas)," and must "minimize the burden on the health care delivery system" by conforming with ETASU for drugs with similar risks and "established distribution, procurement, and dispensing systems for drugs." *Id.* § 355-1(f)(2).

REMS and ETASU are rare. Of the 20,000 approved prescription drugs, EAR326, there are only 73 REMS programs, 69 with ETASU, EAR327-332. These cover high-risk drugs such as fentanyl and other opioids, certain risky cancer drugs, and sedatives used for patients with psychosis. *See* ECF No. 72 (high-risk drugs with point-of-dispensing restrictions include those associated with sudden death, organ failure, severe birth defects, addiction, and overdose); *see also* EAR324 (FDA, "REMS in Action: An Example").

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Further, a REMS is not permanent. REMS may be modified or removed to "ensure the benefits of the drug outweigh the risks" or "minimize the burden on the health care delivery system . . . ." 21 U.S.C. § 355-1(g)(4)(B). FDA must also "periodically evaluate" ETASU to assess if the elements are still needed to "assure safe use of the drug," "are not unduly burdensome on patient access," and "minimize the burden on the health care delivery system[.]" *Id.* § 355-1(f)(5)(B).

B. Mifepristone, Its Labeling, and Its Medication Guide

The FDA-approved regimen for first-trimester medication abortion involves two drugs: mifepristone and misoprostol. Taken alone, misoprostol (labeled as an ulcer drug) also acts as a safe and effective abortifacient, but it is less effective than the two-drug regimen. EAR105. In the current regimen, the patient first swallows one 200 mg mifepristone tablet. EAR319. Then, 24 to 48 hours later, she takes four misoprostol tablets. *Id.* Most women expel the pregnancy within 2 to 24 hours. *Id.*

As with all prescription drugs, the FDA-approved labeling for mifepristone warns of its potential risks. Specifically, the boxed warning on the Mifeprex label explains: "Serious and sometimes fatal infections and bleeding occur very rarely *following spontaneous, surgical, and medical abortions*, including following MIFEPREX use. No causal relationship between the use of MIFEPREX and misoprostol and these events has been established." EAR318, 321 (emphasis added); *see also* EAR65. Thus, labeling identifies the two rare risks associated with Mifeprex (infections and bleeding). But those are the same risks associated with miscarriage, abortion, and childbirth and are *not* risks inherent to mifepristone.

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See EAR318, 321; *see also* EAR47 ("the two serious risks described on the Mifeprex label—atypical infection and prolonged heavy vaginal bleeding—also may occur after many other common obstetrical and gynecological procedures," including vaginal birth); EAR32-33 (FDA acknowledgement that "the critical risk factor" for certain rare infections following mifepristone was "pregnancy itself").

C. FDA Long Ago Concluded That Mifepristone Is Safe and Effective

Since its FDA approval nearly a quarter-century ago, mifepristone has proven extraordinarily safe. As FDA's 2016 medical review (based on 2.5 million U.S. uses) concluded: "[Mifeprex] has been increasingly used as its efficacy and safety have become well established by both research and experience, and serious complications have proven to be extremely rare." EAR21; EAR22 (similar). Mifepristone's "associated" fatality rate is a miniscule 0.0005% for the 20-plus years it has been on the U.S. market, and not a single death from among the now 5.6 million uses can "be causally attributed to mifepristone." EAR271; EAR65.

Mifepristone's safety record has remained stable as FDA restrictions have been lifted over time. *See* EAR164 (FDA acknowledging safety profile is "well-characterized" and "has not changed over the period of surveillance"); EAR55. There is no evidence of any increase in adverse events after FDA stopped enforcing the in-person dispensing requirement during COVID-19 when it was distributed without pharmacy certification. EAR68. And in Canada, lifting all REMS-like restrictions resulted in no change to mifepristone's safety profile. EAR238, 239.

Mifepristone is also *far* safer than a pregnant person's alternative to

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abortion: giving birth, where the risk of death is "14 times higher" than with abortion, and which is far riskier to health. *See, e.g.*, EAR92-94; 100-01 (charts describing "pregnancy-related deaths"). Mifepristone is also safer than common drugs like Tylenol, Viagra, and penicillin—none of which have a REMS—as well as highly-addictive drugs like OxyContin and other opioids, which have no mandatory ETASU. *See, e.g.*, EAR144 ("acetaminophen, aspirin" have "higher complication rates"); EAR84 (600+ Tylenol-related deaths annually); EAR84 (Viagra fatality rate six times higher; penicillin's three times higher); EAR333-36.

Indeed, FDA approved mifepristone *without a REMS* when the very same drug is prescribed, in higher doses, for a less "controversial use" than abortion. Specifically, in 2012, FDA approved Korlym—mifepristone used to treat Cushing's disease—without a REMS, even though it is taken chronically and in much higher doses than one-time mifepristone for pregnancy termination. *See* EAR20, EAR2, EAR11. FDA openly admitted that the application for Korlym's approval presented a "challenge" **"because of the more controversial use of this active ingredient for medical termination of pregnancy[.]"** EAR13. Korlym has remained without a REMS even though it has consistently had significantly higher rates of adverse events (hundreds compared with a handful of abortion-related events). *See, e.g.*, EAR149, 270; *see also* EAR20.

D. The Mifepristone REMS Has Long Been Opposed by Medical Experts

The mifepristone REMS program has long been opposed by medical experts and out of line with FDA's treatment of similarly safe drugs. *See, e.g.*, EAR36-37,

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34-35. Opposition has only grown as the medication's "effectiveness and safety have been definitively established" through millions of uses. *See* EAR48 (explaining how the "REMS no longer makes clinical sense" given the "data and experience" collected since 2000). As former FDA Commissioner Jane E. Henney, M.D., concluded: "The accumulated knowledge about mifepristone strongly suggests that the current restricted distribution system is not aligned with the limited risks that are now known to be posed by the drug." EAR85.

Indeed, over time, studies have proven that the REMS does nothing to promote patient safety, but does harm patients by artificially limiting access and delaying time-sensitive care. *See, e.g.*, EAR122-27, 128-32, 135-36, 47-48. Leading medical organizations, including the American College of Obstetricians and Gynecologists (ACOG), American Academy of Family Physicians, and American Medical Association (AMA), oppose the REMS as scientifically unfounded, an outlier that is "inconsistent with [requirements] for other medications with similar safety profiles," and harmful to patients because it interferes with evidence-based care and causes treatment delays "without supporting demonstrated improvements to patient safety or outcomes." EAR208; *see, e.g.*, EAR210-37, 246-251, 143-44, 59-61, 208-09, 56-58, 75, 43-44, 111-16.

Consistent with this medical consensus, in 2016 FDA's own scientific review team concluded that an element of the mifepristone REMS program is unnecessary. They found that ETASU D (the Patient Agreement Form) is duplicative of standard informed consent requirements and labeling, "does not add

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to safe use conditions," is burdensome, and should be removed. EAR18; *see also, e.g.*, EAR15-17, 26-27, 29-30. However, these scientific experts were overruled by Commissioner Robert M. Califf, a political appointee, and ETASU D remains in force today. EAR24.

E. FDA's Decision to Continue the Burdensome Mifepristone REMS

The current mifepristone REMS, approved in January 2023 (hereinafter the 2023 REMS) is a product of FDA's repeated failure to meaningfully consider the mountain of evidence of mifepristone's safety and efficacy. In 2020, fifteen Plaintiff States petitioned FDA to remove the REMS as "onerous and medically unnecessary." EAR69-74. And in 2022, ACOG and AMA petitioned FDA to (among other things) remove the REMS entirely. EAR210-37. FDA denied ACOG's petition, disregarding the scientific evidence cited therein, EAR240-243, and later admitted in this litigation that it did not consider the evidence at all for its 2023 REMS decision, *see* ECF No. 139 at 8. Notwithstanding continued opposition to the REMS from experts and FDA's own scientists, FDA nevertheless decided to impose the 2023 REMS with three ETASU elements: Prescriber Certification, Pharmacy Certification, and a Patient Agreement Form. *See* EAR150-98, 272-93.

ETASU A (Prescriber Certification): ETASU A mandates that mifepristone can only be prescribed by "certified" providers, who must attest to their qualifications and send their certification to *every* pharmacy to which they send a prescription. Regarding this element, FDA conceded that "[o]ur review of the literature did not identify any studies comparing providers who met these

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qualifications with providers who did not," but stated that "[i]n the absence of such studies, there is no evidence to contradict our 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 use of mifepristone in a regimen with misoprostol." *See* EAR162. FDA also stated that "the potential addition of new prescribers" once the in-person dispensing requirement was lifted further supported the requirement for prescriber certification. EAR163. In concluding that ETASU A "continues to be necessary," FDA provided *no explanation* for why the standard scope-of-practice and regulatory/ethical framework was insufficient to ensure that prescribers are appropriately qualified, nor did it analyze the burden imposed on providers by requiring them to send their certification form to every pharmacy to which they sent a prescription. *See* EAR185-86, 281, 290-91 (conclusory determination of no burden). FDA also ignored the *absence* of any evidence that "this restriction impacts the safety or quality of abortions." EAR64.

ETASU B (Pharmacy Certification): ETASU B requires that pharmacies must also be "certified," which entails designing and implementing a *sui generis* system to confidentially track prescriber certifications and fill prescriptions. FDA stated: "Adding pharmacy certification ensures that ETASU A 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* (ETASU D) is completed." EAR189. In short, ETASU B merely reinforces

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ETASUs A and D, while imposing enormous new burdens on pharmacies as a condition of dispensing, thereby "likely limit[ing]" the number of pharmacies willing to become certified dispensers. EAR285 (FDA concession). Further, in concluding that this new ETASU B was necessary, FDA ignored that pharmacies dispensed mifepristone with no pharmacy certification requirement for more than a year during the COVID-19 pandemic with no increase in adverse events. *See* EAR68; EAR107, 108 (zero adverse events "related to pharmacist dispensing").

ETASU D (Patient Agreement Form): This element requires patients to sign an agreement form that goes in their medical file, certifying that "I have decided to take mifepristone and misoprostol to end my pregnancy." EAR323. FDA's literature search "yielded no publications which directly addressed this element of the REMS." EAR165. Based again on this absence of evidence, FDA determined there was no evidence "that would support *removing* ETASU D." EAR166 (emphasis added). FDA stated that, given the potential increase in number of prescribers upon removal of the in-person dispensing requirement, "[t]he Patient Agreement Form is an important part of standardizing the medication information on the use of mifepristone that prescribers communicate to their patients, and also provides the information in a brief and understandable format for patients." EAR167. But in "conclud[ing] that maintaining the Patient Agreement Form remains necessary to assure safe use at this time," EAR186, FDA provided *no explanation* for why the medication's current "box label" and Medication Guide, which provide the same information, are insufficient. *Infra* at 8. Nor did it address

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the burden associated with this ETASU, even though the sponsors apprised FDA of this problem. *Infra* at 12; *see* EAR167 (conclusory determination of no burden). Nor did FDA offer any justification for requiring every patient to attest that they have "decided" to end their pregnancy, despite knowing that mifepristone is commonly used off-label as the "gold standard" of care for miscarriage, which more than half a million U.S. women experience each year. EAR52-53, 91, 341.

F. The Mifepristone REMS Unduly Burdens Access to Healthcare

As the administrative record shows, the REMS creates stigma, fear, and reluctance to prescribe a safe and essential medication, artificially limits the number of providers who can prescribe mifepristone and the number of pharmacies that can dispense it, endangers providers' and patients' safety, and negatively impacts access to and quality of care. These harms are more salient than ever amid what Defendant Becerra described as a "crisis in health care" following *Dobbs v. Jackson Women's Health Organization*, 142 S. Ct. 2228 (2022). EAR342. Despite being well aware of the REMS' detrimental impacts on access and care quality, FDA failed to consider or account for this when imposing the 2023 REMS.

In particular, in deciding to impose the 2023 REMS with ETASU, FDA *intentionally excluded* reams of relevant information from its review, including "survey studies or qualitative studies" on "satisfaction with medical abortion procedures from patients, pharmacists, clinic staff, or providers," including studies that *directly assessed REMS ETASUs*. EAR160-61. FDA likewise ignored "[d]ata on the logistics of accessing abortion care in general, such as time to appointment

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or the distance traveled to obtain care," which bears directly on patient burden and access, as well as "policy/advocacy statements" by AMA and ACOG. *Id.*; EAR193-97 (listing excluded data). Its rationale was that such information does not contain "objective safety data," EAR160, but in excluding these materials, it ignored information Congress *directed* it to consider, including the effect of the REMS and its burden on patient access. 21 U.S.C. §§ 355-1(f)(2), (f)(5), (g)(4).

Also before FDA was stakeholder feedback from experts and providers in a broad spectrum of health settings who "[u]niformly . . . advocated that any changes to the REMS must lessen—and not increase—the current burdens on [health care providers (HCPs)] and patients to ultimately increase patient access to mifepristone," that "most stakeholders—particularly HCPs—continue to request the removal of both the Prescriber Agreement and Patient Agreement to reduce the burden on them and their patients," and that "most advocates were highly supportive of expansion to all types of pharmacies without any restrictions." EAR266-68, 264. FDA failed to address any of this in imposing the 2023 REMS.

III. ARGUMENT

A. Legal Standard

At summary judgment in an APA case, "the Court does not ask whether there is a genuine dispute as to any material fact." *Washington v. Azar*, 426 F. Supp. 3d 704, 708 (E.D. Wash. 2019). "Rather, '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.'" *Id.* (citation omitted).

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Review is based on "the whole record," 5 U.S.C. § 706, which "consists of all documents and materials directly or *indirectly* considered by the agency decision-makers and includes evidence contrary to the agency's position." *Thompson v. U.S. Dep't of Lab.*, 885 F.2d 551, 555 (9th Cir. 1989) (quotation omitted).

B. The 2023 REMS with ETASU Violates the APA

The APA authorizes courts to hold unlawful a "final agency action" where it is, *inter alia*, "in excess of statutory jurisdiction, authority, or limitations," or "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law[.]" 5 U.S.C. §§ 706(2)(A), (C). The 2023 REMS is unlawful because FDA ignored the REMS statute's unambiguous criteria, and is arbitrary and capricious because it entirely failed to consider important aspects of the problem. The 2023 REMS violates the APA, and the matter should be remanded to FDA.

1. The 2023 REMS is contrary to law

To be valid, agency actions "must be consistent with the statute under which they are promulgated." *United States v. Larionoff*, 431 U.S. 864, 873 (1977). The reviewing court "must exercise [its] independent judgment in deciding whether [FDA] has acted within its statutory authority, as the APA requires." *Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2273 (2024). Here, FDA blatantly failed to consider whether mifepristone still qualifies for a REMS at all based on the factors Congress enumerated, much less the more demanding standards for ETASU. This error is dispositive and, on its own, warrants remand.

Congress permits FDA to impose a REMS *only* when FDA determines that

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it is "necessary to ensure that the benefits of the drug outweigh [its] risks," 21 U.S.C. § 355-1(a)(1), which must be based on consideration of six factors: (1) the size of the population likely to use the drug; (2) the seriousness of the condition treated with the drug; (3) the expected benefit of the drug with respect to the condition; (4) the duration of the treatment with the drug; (5) 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; and (6) whether the drug is a new molecular entity. *Id.* And ETASU may be imposed only where a drug has such "inherent toxicity or potential harmfulness" that, without ETASU, it would be banned outright. *Id.* § 355-1(f)(1).

Once imposed, REMS are to be modified or removed as needed to "ensure the benefits of the drug outweigh the risks of the drug" or to "minimize the burden on the health care delivery system of complying with the [REMS.]" *Id.* § 355-1(g)(4)(B); *see also id.* § 355-1(f)(5)(B). "Implicit in this assessment is whether the drug's risks require REMS and/or ETASU." *Washington*, 668 F. Supp. 3d at 1140-41 (citation omitted). "Thus," as this Court previously held, "it would be contrary to the plain language of the statute that the agency need not consider arguments that mifepristone's REMS and ETASU should be removed in whole or part based on criteria under 21 U.S.C. § 355-1(a)(1), (f)(1)." *Id.* And the Court was exactly right—the statute requires FDA to determine that REMS and ETASU are necessary *each time it imposes them*; the agency cannot simply assume that once a REMS has been imposed on a drug, it will be automatically justified going forward

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regardless of new data and evidence. By January 2023, mifepristone did not come close to meeting the stringent standards for a REMS with ETASU—and FDA never determined otherwise. It simply imposed the 2023 REMS anyway.

First, FDA failed to consider the relevant statutory criteria in determining whether a REMS with ETASU remained necessary to "ensure that the benefits of the drug outweigh the risks of the drug[.]" 21 U.S.C. §§ 355-1(a)(1), (g)(2)(C)(i). Notably absent from FDA's analysis is *any* discussion of Congress's six statutory benefit/risk factors, *see id.* § 355-1(a)(1), making it anyone's guess what the FDA's benefit/risk analysis was based upon. *See* EAR150-98, 277-310. Importantly, if FDA had considered these statutory factors, it would have had to account for the record demonstrating: (1) that more than 5.6 million patients had safely used mifepristone since its U.S. approval in 2000, *supra* at 5; (2) the adverse physical and mental health impacts associated with a lack of abortion access, *infra* at 22-23; (3) the continued efficacy of the two-drug regimen for medication abortion; (4) that only one dose of mifepristone is prescribed for medication abortion (as opposed to the daily, higher dose of REMS-free Korlym); (5) additional reporting confirming FDA's previous determination that adverse events remain "extremely rare" and much lower than for Korlym, *supra* at 5; and (6) the continuing rise in U.S. maternal mortality rates, making the background risk of pregnancy-related death dramatically higher than the mifepristone-related mortality rate, *infra* at 22-23. FDA, however, considered none of this in conducting its 2023 REMS review. Indeed, this review stands in stark contrast to the type of risk/benefit analysis FDA

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conducted for Korlym, where FDA walked through the statutory factors and considered how a REMS would "burden" patients and "impede access." EAR3-10.

Beyond requiring consideration of all six REMS factors, Congress also unambiguously mandated that any ETASU be "necessary . . . to mitigate a specific serious risk listed in the labeling of the drug," 21 U.S.C. § 355-1(f), and be "commensurate with" any such risk, *id.* § 355-1(f)(2)(A). Here, FDA did not make the statutorily required conclusion that mifepristone is so dangerous that FDA would "withdraw[]" its approval absent ETASU. *Id.* § 355-1(f)(1)(A). Such a conclusion would be impossible: the two risks listed on the labeling of mifepristone are infection and heavy bleeding, but the labeling clearly states that "[n]o causal relationship between the use of MIFEPREX and misoprostol and these events has been established." *Supra* at 4. Moreover, FDA has concluded that serious adverse events following mifepristone use are "extremely rare." *Id.* at 5. And the drug's *associated* fatality rate (which, of course, is not causation) is 0.0005% for the entire time it has been available. *Id.* FDA did not even attempt to justify the ETASU in light of the mandatory statutory elements—because it cannot.

Additionally, any ETASU must "not be unduly burdensome on patient access," particularly for patients in "rural or medically underserved areas," and must "minimize the burden on the health care delivery system[.]" 21 U.S.C. §§ 355-1(f)(2)(C), (D). Although FDA determined it was necessary to remove the in-person dispensing element due to its impact on patient access, FDA otherwise ignored this statutory mandate in imposing the 2023 REMS ETASU elements.

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Most glaringly, FDA *expressly declined to consider* "[d]ata on the logistics of accessing abortion care in general, such as time to appointment or the distance traveled to obtain care," as well as information from ACOG, AMA, and others that would have allowed it to analyze burdens on patients and the health care system as required. *See supra* at 11-12. FDA's refusal to consider evidence on this issue despite Congress's express direction is dispositive on its own.

In sum, the 2023 REMS is a product of FDA's stark failure to consider the statutory elements Congress required. Where an agency action is "inconsistent with the statutory mandate," it is the Court's "clear duty . . . to reject" it. *S.E.C. v. Sloan*, 436 U.S. 103, 118-19 (1978). Thus, the 2023 REMS should be remanded.

2. The 2023 REMS is arbitrary and capricious

The 2023 REMS is also arbitrary and capricious. An agency acts arbitrarily and capriciously if it "has relied 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." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). An agency must "pay[] attention to the advantages *and* the disadvantages of [its] decisions." *Michigan v. E.P.A.*, 576 U.S. 743, 753 (2015). It must also demonstrate that it "examine[d] the relevant data and articulate[d] a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs.*, 463 U.S. at

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42-43 (cleaned up). In multiple respects, the 2023 REMS fails this test.

a. FDA failed to consider how the 2023 REMS burden patient access, particularly in rural & medically underserved areas

First, FDA failed to consider substantial record evidence of how the REMS burdens patient access, an issue Congress directed FDA to consider. 21 U.S.C. §§ 355-1(f)(2)(C)-(D); *see Ctr. for Biological Diversity v. Nat'l Highway Traffic Safety Admin.*, 538 F.3d 1172, 1206 (9th Cir. 2008) ("An agency may not ignore factors Congress explicitly required be taken into account.") (citation omitted).

For example, a study examining the REMS' impact on patient access found that institutional resistance to prescribing mifepristone is driven by fears and misconceptions about its REMS classification and requirements; that disallowing routine access in primary care disrupts continuity of care, delays or impedes access, and creates stigma; that more costly and invasive aspiration (surgical) abortion accordingly becomes some patients' only realistic option (and for many is out of reach entirely); and that other countries' experience has confirmed that REMS-like restrictions are medically unjustified. *See, e.g.*, EAR122-27 (study concluding that the REMS reflects and perpetuates stigma that creates systematic barriers to care); EAR112 ("the REMS creates barriers to incorporation of mifepristone into practice by creating administrative burdens that clinical champions cannot overcome"); EAR18-24 (FDA analysis describing "burden for patients" of the "duplicative" Patient Agreement Form, which "does not add to safe use conditions"); EAR42.

For instance, ETASU A (prescriber certification) results in mifepristone

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being excluded from the primary care setting with no scientific justification. As reflected in the record, abortion with mifepristone is "well within the scope of primary care in the United States, as it involves patient assessment and health education for which primary care providers are extensively trained." EAR128; *see, e.g.*, EAR66 ("Prescribing medication abortion is no different from prescribing other medications"); EAR105, 106 ("Any clinician with the skills to screen patients for eligibility for medication abortion and to provide appropriate follow-up can provide medication abortion."); EAR39 ("Fulfilling these [provider-certification] criteria requires no specialized medical expertise."). Indeed, all that providers must do to become certified under ETASU A is attest that they possess these "minimal" primary care skills—an "empty formality." EAR147, 48. As ACOG explained to FDA, the "redundant and unnecessary" provider-certification requirement "serves no benefit to patient safety" because providers *must always* possess the skills necessary to prescribe any given medication. EAR210-37; *see also* EAR39 (noting provider certification is not required to prescribe other "drugs that require careful patient screening to ensure safety," such as "powerful cardiovascular drugs," antibiotics, and antipsychotics). Still, because of the stigma, administrative hurdles, and privacy concerns created by the REMS, **only 1%** of medication abortions occur in the primary care setting. EAR128; *see also* EAR146, 147. When mifepristone is unavailable in primary care, patients suffer the consequences: "disrupted continuity of care, medically-unnecessary appointments, and undesired aspiration procedures." EAR122; *see also* EAR255-56; EAR37.

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Further, despite its appropriately low threshold for providers to qualify for certification, ETASU A "deters many qualified clinicians from becoming mifepristone prescribers," in part due to stigma associated with a REMS as well fear that registration could expose them to threats of violence by anti-abortion extremists. EAR42; EAR88 (certification makes "some clinicians uneasy because they fear they will be identified publicly" and creates a provider shortage that is "particularly pronounced in rural communities"); EAR8 (in rejecting a REMS for Korlym, FDA said "[p]rivacy may be better maintained if there are no systems in place to track formally prescribers and patients"); EAR142 (noting that FDA itself strictly shields the identities of its personnel involved in reviewing mifepristone); *see also* EAR41, 39, 82, 200-01, 202-204, 205-207. These "extreme risks" are all too real, as reflected by the "long history of harassment and violence" experienced by abortion providers in the U.S. EAR245, 47, 312-13; *see also* EAR110. Keeping mifepristone out of the primary care setting exposes patients to risks of violence as well, because at specialized clinics, they may encounter harassment that can turn violent. *See* EAR389-90, 314-16 (homicides and arson at abortion clinics); EAR284 (discussing concerns about patients' exposure to "intimidation, threats, or acts of violence"); EAR245 (acknowledging the "ever-present risk of anti-abortion violence"). While the FDA appropriately acknowledged abortion violence in structuring ETASU B (pharmacy certification), it continued to ignore evidence as to how the other ETASU create stigma and fear, and in turn barriers to access.

FDA's refusal to consider highly relevant data went much further, with FDA

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ignoring stakeholder feedback "request[ing] the removal of both the Prescriber Agreement and Patient Agreement to reduce the burden on them and their patients." EAR267. Even worse, FDA intentionally decided to exclude *all* studies about patient access and provider experience that "did not include objective safety data related to outcomes of medical abortion." EAR160-61; *see supra* at 11-12. But Congress did not limit FDA to objective drug-safety data in reviewing whether ETASU are "unduly burdensome on patient access . . . ." *See* 21 U.S.C. § 355-1(f). FDA's decision to ignore the effects of stigma, reduced drug availability, and violence, which are directly relevant to an issue Congress directed it to consider, was arbitrary and capricious. *See Rancheria v. Jewell*, 776 F.3d 706, 714 (9th Cir. 2015) ("An agency's decision is arbitrary and capricious if it ignores important considerations or relevant evidence on the record.") (citing cases); *see also Motor Vehicle Mfrs.*, 463 U.S. at 43 (requiring the agency to "examine the relevant data and articulate a satisfactory explanation for its action . . . ").

What's more, to justify retaining ETASU D (patient agreement form), FDA relied on a survey of OBGYNs showing that eliminating in-person dispensing would lead to new mifepristone prescribers, EAR166-67 (Grossman study)—yet ignored that *same study's* finding that prescriber certification prevents *nearly 1 in 10* OBGYNS from prescribing mifepristone. EAR120-21. FDA's decision "to rely on portions of studies in the record that support its position, while ignoring [information] in those studies that do[es] not," was arbitrary and capricious. *Genuine Parts Co. v. E.P.A.*, 890 F.3d 304, 313 (D.C. Cir. 2018).

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Likewise, in adding ETASU B, FDA did not address how limiting the number of pharmacies that can dispense mifepristone negatively impacts patients' access, particularly those who "are not digitally literate." EAR225. Although FDA admitted that imposing this ETASU would "likely limit" the number of pharmacies that would choose to become certified, EAR285, it did not consider how that would impact "patients in rural or medically underserved areas" with far fewer pharmacies, 21 U.S.C. § 355-1(f), an issue specifically raised by ACOG. EAR225; *see In re NTE Conn., LLC*, 26 F.4th 980, 989 (D.C. Cir. 2022) (unless the agency "answers objections that on their face seem legitimate, its decision can hardly be classified as reasoned") (citation omitted). That, too, was arbitrary and capricious.

In sum, FDA failed to consider extensive evidence on the burdens of the REMS, and its "generic statements" to the contrary are insufficient. *Los Padres ForestWatch v. U.S. Forest Serv.*, 25 F.4th 649, 657 (9th Cir. 2022) (cleaned up).

b. FDA arbitrarily failed to consider evidence on maternal mortality and mifepristone's safety without REMS

Further, in making its conclusory determination that the 2023 REMS was necessary, FDA failed to consider significant evidence on the "seriousness of the disease or condition that is to be treated with the drug." 21 U.S.C. § 355-1(a)(1)(B). Notably absent from FDA's REMS review is any acknowledgment of—much less consideration of—the fact that pregnant women are not taking mifepristone in a vacuum; instead, **they are pregnant** and experiencing a serious medical condition with limited alternatives. As reflected in the record, the U.S. has the highest rates

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of maternal mortality in the developed world. EAR248 (discussing EAR257-61); *see also* EAR262 ("[s]lightly less than two pregnant or postpartum women die *each day* in the U.S.") (emphasis added); EAR100-01 (discussing causes of pregnancy related deaths). In 2020, the most recent year for which data is in the record, there were 23.8 deaths per 100,000 live births, up from 20.1 in 2019. EAR248. Alarmingly, the maternal mortality rate for Black women was 55.3 deaths per 100,000 live births. *Id.* At just 0.3 deaths per 100,000 abortions performed at or before 8 weeks, the mortality rate associated with abortion is vastly lower than the mortality rate associated with childbirth. *Id.*; *see supra* at 6. Moreover, the landmark Turnaway Study shows that patients denied abortion are more likely to suffer anxiety and loss of self-esteem in the short term after being denied abortion. EAR263. But FDA ignored the serious and sometimes deadly risks associated with pregnancy—risks that are exacerbated by restricting mifepristone. That is arbitrary and capricious. *See Michigan*, 576 U.S. at 753 (agency must "pay[] attention to the advantages *and* the disadvantages of [its] decisions").

FDA also ignored evidence that mifepristone is equally safe without the REMS. This includes evidence that "[a]fter Canada removed all restrictions on prescribing mifepristone for abortion, thereby allowing it to be prescribed and dispensed like any other drug ('normal prescribing'), there was no increase in complications from mifepristone use." EAR226, 237. Based on the 10-month period in Canada when mifepristone was distributed under "REMS-like restrictions" and the 28-month period when it was distributed without such

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restrictions, the study found "no difference" in the rates of complications or serious adverse events. *Id.* (citing Laura Schummers, et al., *Abortion Safety and Use with Normally Prescribed Mifepristone in Canada*, 386 N. Engl. J. Med. 57-67 (2022)); EAR238; *see also* EAR117-18, 133, 134. Although this study was cited in ACOG's 2022 citizen petition, FDA ignored it. *See* ECF No. 139 at 13-14. It likewise ignored the U.S.'s own experience demonstrating no increase in adverse safety events when pharmacies distributed mifepristone without certification during the pandemic. *See supra* at 10. FDA's failure to "examine the relevant data" is arbitrary and capricious. *Motor Vehicle Mfrs.*, 463 U.S. at 42-43.

c. FDA's differential treatment of Korlym is arbitrary and capricious

Finally, that FDA does not impose a REMS for Korlym is determinative. It is nonsensical that mifepristone's labeling and Medication Guide are insufficient to mitigate the exceedingly low risks associated with mifepristone when used for the "controversial" treatment of abortion, but are sufficient to convey the risks for a chronic, higher dose when used daily for a non-controversial condition. *See supra* at 6. "[T]he FDA is not free to . . . treat [similar products] dissimilarly and to permit two sets of similar products to run down two separate tracks, one more treacherous than the other, for no apparent reason." *Bracco Diagnostics, Inc. v. Shalala*, 963 F. Supp. 20, 28 (D.D.C. 1997); 21 U.S.C. § 355-1(f)(2)(D)(i) (requiring ETASU to "conform" to restrictions "for other drugs with similar, serious risks"). Social "controversy" is not a factor Congress authorized FDA to consider. *Motor Vehicle*

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Mfrs., 463 U.S. at 42-43 (agency acts arbitrarily and capriciously when it "relie[s] on factors which Congress has not intended it to consider"). Indeed, "[t]he disparate treatment of functionally indistinguishable products is the essence of the meaning of arbitrary and capricious." *Bracco Diagnostics*, 963 F. Supp. at 28.[1]

C. The Court Should Remand This Matter to FDA

The most appropriate remedy for FDA's failures is to remand to FDA without vacatur. Although vacatur is the standard remedy, "when equity demands, the regulation can be left in place while the agency follows the necessary procedures to correct its action." *Cal. Cmties. Against Toxics v. E.P.A.*, 688 F.3d 989, 992 (9th Cir. 2012) (cleaned up). Here, remand is appropriate to allow FDA to address its errors without the potentially disruptive consequences of vacatur. *Id.* On remand, the Court should order FDA to consider *each* of the statutory requirements for REMS and ETASU, and *all* relevant portions of the record.

IV. CONCLUSION

The Court should grant summary judgment for the States and remand this matter to FDA for consideration consistent with this Court's Order.

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[1] The irrationality of FDA's action also renders the restrictions on pregnant patients unconstitutional. ECF No. 35 at 89-90; *City of Cleburne v. Cleburne Living Ctr.*, 473 U.S. 432, 446 (1985) (constitutional guarantee of equal protection violated by "arbitrary or irrational" governmental classifications). Because the Court should remand under the APA, it need not resolve the constitutional claim.

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CERTIFICATE OF SERVICE

I hereby certify that on October 10, 2024, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF System, which in turn automatically generated a Notice of Electronic Filing (NEF) to all parties in the case who are registered users of the CM/ECF system. The NEF for the foregoing specifically identifies recipients of electronic notice.

I declare under penalty of perjury under the laws of the State of Washington and the United States of America that the foregoing is true and correct.

DATED this 10th day of October 2024, at Seattle, Washington.

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