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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON

STATE OF WASHINGTON; STATE OF OREGON; STATE OF ARIZONA; STATE OF COLORADO; STATE OF CONNECTICUT; STATE OF DELAWARE; STATE OF ILLINOIS; ATTORNEY GENERAL OF MICHIGAN; STATE OF NEVADA; STATE OF NEW MEXICO; STATE OF RHODE ISLAND; and STATE OF VERMONT,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION; ROBERT M. CALIFF, in his official capacity as Commissioner of Food and Drugs; UNITED STATES

NO. 1:23-cv-03026

PLAINTIFF STATES' MOTION FOR PRELIMINARY INJUNCTION

03/27/2023
With Oral Argument at time and location to be determined by Court

DEPARTMENT OF HEALTH AND HUMAN SERVICES; and XAVIER BECERRA, in his official capacity as Secretary of the Department of Health and Human Services,

Defendants.

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I. INTRODUCTION

In approving and regulating drugs, the Food and Drug Administration is supposed to be guided by science alone. When FDA approved the drug mifepristone for early-stage abortion care in 2000, it properly followed the science, concluding, based on extensive evidence, that the drug is safe and effective. More than five million Americans have since used mifepristone, and the drug has proven incredibly safe—safer than many well-known over-the-counter drugs like Tylenol. But because mifepristone is used for abortion, FDA has imposed unnecessary, paternalistic restrictions on how it can be prescribed and dispensed. While FDA has loosened those restrictions somewhat over the years, it just imposed a new set in January that needlessly limits patient access to this vital, time-sensitive medication—harming patients, providers, and the states of Washington, Oregon, Arizona, Colorado, Connecticut, Delaware, Illinois, Michigan, New Mexico, Nevada, Rhode Island, and Vermont (Plaintiff States).

FDA's needless restrictions on mifepristone have no basis in science or statute, and they are both arbitrary and unconstitutional. Federal law allows FDA to impose additional restrictions on approved drugs only in narrow circumstances, none of which are present here given mifepristone's well-established safety record over the last two decades. In fact, the agency has approved a higher-dose, less safe form of mifepristone that is not used for abortion without any special restrictions. The difference in regulation can be explained only by the controversy surrounding abortion, not by science.

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FDA's illegal restrictions are causing immediate, irreparable harm. While pregnancy can be safely ended in various ways, a majority of Americans opt for mifepristone followed by misoprostol—the "gold standard" for early abortion care. Medication abortion is highly safe and effective, but it can only be used in the early stages of pregnancy, so time is of the essence. Yet FDA's unnecessary restrictions limit which providers are able and willing to prescribe mifepristone, restricting access to this time-sensitive medicine and imposing additional burdens on providers and pharmacies. FDA's restrictions also single mifepristone out for paper-trail requirements that create Orwellian dangers for patients and providers, potentially subjecting them to harassment, lawsuits, or even criminal prosecution by those intent on eliminating access to abortion nationwide at any cost.

This Court has the authority and responsibility to fix this problem by ordering FDA to follow the science and the law. This Court should enter an injunction affirming FDA's original conclusion that mifepristone is safe and effective, preserving the status quo by enjoining any actions by Defendants to remove this critical drug from the market, and enjoining the unnecessary and burdensome January 2023 restrictions. Such an order is crucial to protect the Plaintiff States' patients and providers, and the States themselves, from the harms that are already occurring—and growing worse—because of FDA's needless restrictions.

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II. FACTS

A. Statutory Background

Before a new drug may be introduced in the U.S. market, the Food, Drug and Cosmetic Act (FDCA) requires a rigorous approval process to determine that it is safe and effective. *See* 21 U.S.C. § 355. Following approval, prescription medications are subject to robust safeguards to ensure they are used safely and appropriately, including the requirement of a prescription by a licensed medical provider, patient informed-consent laws, scope of practice laws, professional and ethical guidelines, and state laws regulating medical and pharmacy practice, as well as additional warnings, indications, and instructions that FDA may impose specific to the medication. Compl. ¶ 55. FDA and the public rely on these safeguards to ensure the safe use of the vast majority of prescription drugs.

A tiny subset of FDA-approved drugs, however, are subject to an extra set of restrictions, known as a Risk Evaluation and Mitigation Strategy (REMS). FDA may impose a REMS only when it is "necessary to ensure that the benefits of the drug outweigh the risks of the drug." 21 U.S.C. § 355-1(a)(1). The most burdensome elements of a REMS are "Elements to Assure Safe Use" (ETASU), which FDA may impose only when necessary because of a drug's "inherent toxicity or potential harmfulness." *Id.* § 355-1(f)(1). By statute, FDA may impose an ETASU only for medications with demonstrated risks of serious side effects such as death, incapacity, or birth defects, and only where the risk is so severe that FDA could not approve, or would have to withdraw approval of, the

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medication absent the ETASU. *Id.* §§ 355-1(b)(5), (f)(1)(A). In addition, an ETASU cannot be "unduly burdensome on patient access to the drug, considering in particular . . . patients in rural or medically underserved areas," and must "minimize the burden on the health care delivery system." *Id.* §§ 355-1(f)(2)(C)–(D).

In light of these stringent statutory limitations, REMS, and in particular ETASU, are extremely rare: of the more than 20,000 FDA-approved drugs, only sixty are subject to a REMS: dangerous drugs like fentanyl and other opioids, certain risky cancer drugs, and high-dose sedatives used for patients experiencing psychosis. Compl. ¶ 6. This case is about whether mifepristone—an FDA-approved abortion medication that has been used over 5 million times with extremely low rates of serious complication—should be subject to the same restrictions as these dangerous drugs.

B. FDA Concludes—and Repeatedly Affirms—that Mifepristone Is Safe

The current FDA-approved regimen for the medical termination of early pregnancy involves two drugs: (1) *mifepristone*, which interrupts early pregnancy by blocking the effect of progesterone, a hormone necessary to maintain a pregnancy, and (2) *misoprostol*, which causes uterine contractions that expel the pregnancy from the uterus. Compl. ¶ 62. Shortly after taking mifepristone and then misoprostol, the patient will experience a miscarriage. *Id.*

FDA first approved mifepristone in 2000 under the name Mifeprex. *Id.*

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¶ 65.[1] In the 23 years since, there have only been 28 reported associated deaths out of 5.6 million uses—a rate of .00005%. Compl. ¶ 90. *None* of these deaths have been causally attributed to mifepristone; they include cases of homicide, drug overdose, and sepsis. *Id.* In its 2000 approval, "FDA extensively reviewed the scientific evidence and determined that the benefits of mifepristone outweigh any risks," and that it was safe and effective in terminating early pregnancies.[2] FDA considered clinical trials, a European post-market safety database, and chemical and manufacturing data to conclude there was "substantial evidence" of Mifeprex's safety and efficacy. Compl. ¶ 66. In 2013, FDA conducted a safety review and found that of the then 1.8 million uses of the medication, only .15% involved adverse events, and only .04% involved hospitalizations. *Id.*; Exs. D & E.

In 2016, FDA's Center for Drug Evaluation and Research (CDER) conducted a comprehensive safety review in connection with a supplemental new drug application. Compl. ¶¶ 72, 73, 86. By that point, Mifeprex had been used 2.5 million times for medication abortion in the U.S. Compl. ¶ 89. FDA determined that serious adverse events following Mifeprex use are "exceedingly

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[1]Citations to the Complaint incorporate the factual sources cited and linked therein.

[2]FDA's Opp'n to Pls.' Mot. for Prelim. Inj., *All. for Hippocratic Med. v. FDA*, No. 2:22-CV-00223-Z (N.D. Tex. Jan. 13, 2023), Dkt. 28 at 4.

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rare, *generally far below 0.1%* for any individual adverse event," and "the numbers of these adverse events appear to be stable or decreased over time." *Id.*

Following the 2016 comprehensive safety review, FDA increased the gestational age limit for mifepristone from 49 to 70 days (10 weeks) of pregnancy, covering a period in which the overwhelming majority (over 80%) of abortions occur. FDA also reduced the number of required in-person clinic visits from two to one and broadened the range of health care providers who could prescribe the drug. Compl. ¶ 81. In 2019, FDA approved a generic version of mifepristone. *Id.* ¶ 83.

In the 23 years since its FDA approval, approximately 5.6 million patients in the United States have used mifepristone. Compl. ¶ 3. According to FDA, this medication "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." *Id.*; Ex. B at 12. FDA has repeatedly confirmed mifepristone's safety and efficacy, and its periodic reviews of the post-marketing data for mifepristone have not identified any new safety concerns. Compl. ¶ 125.

Mifepristone is not just safe—it is considerably safer than many commonly used drugs, including blood thinners, erectile dysfunction medicines, penicillin, and over-the-counter medications like Tylenol and aspirin. *Id.* ¶¶ 108, 127, 129, 131. Unlike mifepristone, none of these drugs is subject to a REMS. *Id.* ¶ 131.

C. FDA Adopts Burdensome REMS for Mifepristone

Despite mifepristone's undisputed safety and efficacy, FDA has long

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imposed a REMS with ETASU that unduly restricts how the medication can be distributed, without any corresponding medical benefit. *See* Compl. ¶¶ 4, 93. The current REMS, adopted by FDA in January 2023, imposes three types of restrictions on access to mifepristone. *Id.* ¶¶ 93–95; Ex. L. at 60–61.

First, the 2023 REMS requires a Patient Agreement Form that is not required for other medications, and that creates a written record of the patient's certification that they "have decided to take mifepristone and misoprostol to end my pregnancy"—a requirement even if the patient is taking the medicine for miscarriage management, for which it is frequently prescribed. *Id.* ¶¶ 101–102; Ex. Q.

Second, mifepristone can only be prescribed by a health care provider who is "specially certified" to do so. *Id.* The certification attests that the provider can accurately date a pregnancy, diagnose an ectopic pregnancy, and provide surgical intervention or referral in the event of any complications. *Id.* ¶¶ 96–97; Ex. O.

Third, although the 2023 REMS for the first time allows mifepristone to be dispensed by pharmacies (whereas prior REMS only allowed providers to dispense it), the REMS unnecessarily requires dispensing pharmacies to be "specially certified" by the drug distributor. *Id.* ¶ 98; Ex. L. Obtaining this certification requires pharmacies to agree to an array of burdensome communication and recordkeeping requirements, including verifying that every prescription for mifepristone is written by a "specially certified" provider. *Id.* ¶¶ 98–100; Ex. P.

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FDA has maintained the REMS restrictions on mifepristone despite opposition from leading medical organizations, including the American College of Obstetricians and Gynecologists (ACOG), the American Academy of Family Physicians (AAFP), and the American Medical Association (AMA). By 2016, ACOG described the REMS as "no longer necessary for mifepristone, given its history of safe use. The REMS requirement is inconsistent with requirements for other drugs with similar or greater risks, especially in light of the significant benefit that mifepristone provides to patients." *Id.* ¶ 116. According to AAFP, "the REMS restrictions on mifepristone are not based on scientific evidence"; are overly burdensome on practitioners and impede patient access to care, particularly "for patients who might prefer to go to their own physician and for rural patients who have no other access points beyond their local physician"; cause "delays in care, thereby increasing second-trimester and surgical abortions, both of which have increased complication rates"; and create "a barrier to safe and effective off-label uses of mifepristone, such as for anti-corticoid treatment of Cushing's disease, term labor induction, and miscarriage management[.]" *Id.* ¶ 117. In a June 21, 2022, letter to FDA Commissioner Califf, ACOG and the AMA urged the agency to "eliminate the requirement for patients to sign a form to get the drug" and "lift the requirement that prescribers acquire a certification from the manufacturer," noting that "[b]arriers to accessing mifepristone do not make care safer, are not based on medical evidence, and create barriers to patient access to essential reproductive health care." *Id.* ¶ 118.

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In 2022, 49 organizations again petitioned FDA to remove the REMS entirely. *Id.* ¶ 119. This citizen petition maintained that "the Patient Agreement Form [should] be removed entirely because it is medically unnecessary and repetitive of informed consent, as a previous review conducted by CDER determined in 2016." *Id.* ¶ 120. Further, "the Certified Provider Requirement serves no benefit to patient safety" and is "redundant and unnecessary." *Id.* ¶ 121. The petition cited studies showing that the provider-certification requirement disproportionately burdens rural patients, as "clinicians who have already navigated mifepristone REMS compliance to provide abortion care . . . are almost always located in cities." *Id.* Making matters worse, "rural residents are more likely to lack access to OBGYNs, meaning that surgical management is also less likely to be an option." *Id.* Finally, the petition urged FDA not to include a pharmacy-certification requirement because "research . . . suggests that [this] is unnecessary to ensure that mifepristone's benefits outweigh its risks and unduly burden[s] access." *Id.* ¶ 122. Specifically, a study "conducted . . . in California and Washington state suggests that pharmacies are already equipped to dispense the drug without special certification." *Id.* "As with the certified provider requirement, the burdens associated with the certified pharmacy requirement will also fall disproportionately on poor and rural women, contrary to the REMS statute." *Id.*

FDA denied this petition, *id.* ¶ 124; Ex. S, and, wholly disregarding the scientific evidence cited therein, proceeded to implement the 2023 REMS.

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D. The 2023 REMS Unduly Burdens Access to Health Care

The mifepristone REMS significantly impedes access to abortion care. Even before *Dobbs v. Jackson Women's Health Association*, 142 S. Ct. 2228 (2022), only a small fraction of counties in the United States had a clinician providing surgical abortions. Compl. ¶ 136. Mifepristone offers the possibility of vastly increased access to care by enabling primary care physicians to integrate abortion care into their services. *Id.*; Gold Decl. ¶ 26; Godfrey Decl. ¶ 17; Janiak Decl. ¶ 14. But the REMS significantly impedes mifepristone's availability, and as a result of these unnecessary restrictions, abortion care remains beyond the reach of many—even in states like the Plaintiff States in which abortion is lawful and protected. Gold Decl. ¶ 27; Godfrey Decl. ¶ 22; Shih Decl. ¶ 29; Colwill Decl. ¶¶ 18–25; Nichols Decl. ¶¶ 25–27, 38; Compl. ¶ 136.

Specifically, the REMS unnecessarily reduces the number of providers who can prescribe mifepristone and the number of ways to fill a mifepristone prescription in the Plaintiff States, sharply curtailing access to medication abortion. As multiple studies have shown, the REMS is "a barrier to" family physicians providing this type of care. Compl. ¶ 137; *see also* Godfrey Decl. ¶ 18; Janiak Decl. ¶ 20; Nichols Decl. ¶ 38. This is because "[t]he complexity of navigating the REMS results in physicians and clinic administration . . . viewing medication abortion as not worth the effort," and because it requires "substantial involvement of clinic administration, who can be unsupportive" of abortion access. Compl. ¶ 137; *see also id.* ¶ 138 (concluding that the REMS is the

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"linchpin of a cycle of stigmatization that continues to keep mifepristone out of primary care practice"). The REMS creates a similar effect for pharmacies. Downing Decl. ¶ 17 (2023 REMS "present[s] a series of burdens . . . that are stigmatizing, administratively burdensome, confusing, expensive, and legally risky"). "The REMS will cause Washington pharmacies to opt out of dispensing mifepristone," particularly "smaller pharmacies, which are . . . more likely to serve rural, minority, or poor communities." *Id.*; *see also id.* ¶¶ 9–16. The costly administrative burdens imposed by the REMS deter hospitals, clinics, and pharmacies from prescribing or dispensing mifepristone altogether, to patients' detriment. Henry Decl. ¶¶ 6–8; Downing Decl. ¶¶ 14–17; Godfrey Decl. ¶ 20; Lazarus Decl. ¶ 17; Colwill Decl. ¶¶ 19-20.

These effects are only compounded by the serious and well-founded concerns of many health care providers and pharmacists about creating a documented association with abortion care, as required by seeking special certification under the REMS. Compl. ¶ 156; Godfrey Decl. ¶ 27; Gold Decl. ¶ 17; Janiak Decl. ¶ 20. Given the growing criminalization and penalization of abortion following the *Dobbs* decision, these risks have grown significantly—particularly for providers who hold licenses in multiple states, medical residents who plan to practice in states that restrict or outlaw abortion, and providers and pharmacists who treat patients from neighboring states like Idaho, Missouri, and Texas, where draconian laws raise the specter of criminal or civil liability. Shih Decl. ¶¶ 23–26; Prager Decl. ¶¶ 38–40; Godfrey Decl. ¶ 27; Janiak Decl. ¶ 20;

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Gold Decl. ¶¶ 17–19.

In turn, reducing the number of physicians and pharmacies able to provide and dispense medication abortion negatively impacts patients' access to care. Under the REMS, a person who turns to their trusted health care provider—often a family doctor or primary care physician—for a medication abortion cannot obtain that care unless that particular clinician is certified and either has arranged to stock the drug or can refer the patient to a nearby pharmacy that is also already "specially certified." This is so even though that same provider can simply write the same patient a prescription for misoprostol, the second drug in FDA's approved regimen for medication abortion, or virtually any other prescription drug that the clinician deems medically appropriate—and a pharmacy can simply dispense it—without the need for any special certifications.

Forcing patients to go to "specially certified" providers, as opposed to their primary care or family physicians, can require patients to travel long distances, disrupts continuity of care, stigmatizes routine health care, and discourages patients from making the best health care choices for themselves and their families. Janiak Decl. ¶¶ 24–26; Godfrey Decl. ¶¶ 15–16, 19, 24–25; Lazarus Decl. ¶ 16; Colwill Decl. ¶¶ 24–25. This burden is especially harsh for patients whose access to health care is already threatened by poverty, language barriers, lack of transportation, racial discrimination, or other factors. Gold Decl. ¶ 23; Janiak Decl. ¶¶ 25–29; Downing Decl. ¶ 17. And it is particularly burdensome given the limited time window in which medication abortion is available.

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Godfrey Decl. ¶ 28; Gold Decl. ¶¶ 15–16.

All of this results in worse health outcomes for patients who might otherwise rely on mifepristone to safely terminate their pregnancies, but who are unable to obtain a medication abortion given the limited number of REMS-certified prescribers and pharmacies. This restricted access means some patients will ultimately be unable to end their unwanted or dangerous pregnancies and will continue to carry them, suffering any related physical, psychological, or economic consequences. Compl. ¶¶ 141–42. Still others will opt for surgical abortion, which FDA itself acknowledges is a more "invasive medical procedure that increases health risks for some patients and that may be otherwise inaccessible to others." *Id.* ¶ 143. Procedural abortion comes with additional risks, especially for patients with pre-existing health problems that make surgery risky, such as allergy to anesthesia, or pre-existing trauma from abuse or rape that may be exacerbated by an invasive vaginal procedure. *Id.* ¶ 144. By unduly burdening patients' access to mifepristone through the 2023 REMS, FDA deprives patients of the drug's therapeutic benefits without any scientific basis.

III. ARGUMENT

A. Legal Standard

A party seeking a preliminary injunction must show (1) a likelihood of success on the merits, (2) a likelihood of suffering irreparable harm in the absence of preliminary relief, (3) that the balance of hardship tips in the movant's favor, and (4) that a temporary restraining order in is in the public interest. Fed. R. Civ.

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P. 65(c); *Winter v. Nat. Res. Def. Council, Inc*., 555 U.S. 7, 20 (2008).

B. The States' Claims Are Likely to Succeed on the Merits

1. The States have standing based on their proprietary and pecuniary interests as providers of health care, and based on their interests in protecting their residents' health

As owners and operators of medical facilities that provide reproductive health care services and pharmacies that dispense mifepristone, Compl. ¶¶ 14, 19, 26, 38, 42,151, most States are directly subject to the January 2023 REMS and have standing to vindicate their proprietary interests in delivering high-quality patient care. *See Washington v. Trump*, 847 F.3d 1151, 1159–61 (9th Cir. 2017) (states had standing where challenged law harmed proprietary work of public universities); *City of Sausalito v. O'Neill*, 386 F.3d 1186, 1197 (9th Cir. 2004) (government entity's proprietary interests "are not confined to protection of its real and personal property" and "are as varied as [its] responsibilities, powers, and assets").

By creating substantial administrative burdens for the States' hospitals, clinics, and pharmacies, the 2023 REMS also subjects the States to pecuniary harms. *See, e.g.*, *Dep't of Commerce v. New York*, 139 S. Ct. 2551, 2565 (2019) (loss of federal funds was a "sufficiently concrete and imminent injury to satisfy Article III); *Hawai'i v. Trump*, 241 F. Supp. 3d 1119, 1129–30 (D. Haw. 2017) (state had standing based on loss of tuition and damage to state's tourism industry). To date, the University of Washington alone has expended hundreds of hours implementing the 2023 REMS, with many outstanding tasks left to

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complete. Compl. ¶ 152; DasGupta Decl. ¶¶ 15–18; Godfrey Decl. ¶ 35; Prager Decl. ¶¶ 25–36; Reed Decl. ¶¶ 16–17; Singh Decl. ¶¶ 20–21. And there are direct costs to States each time the REMS causes a patient insured by a state Medicaid program to undergo a procedural abortion instead of a medication abortion. In Washington, for example, each procedural abortion provided through the Medicaid program costs the State an average of $270 more than a medication abortion, meaning this type of care is both more expensive to the State and less accessible to patients—particularly those living in rural areas. Birch Decl. ¶¶ 6–9; Harris Decl. ¶¶ 5–11, Ex. 1.

States likewise have a protectable interest in the health and well-being of their residents. As this Court has confirmed, states have standing to vindicate their "quasi-sovereign interest[s]" in "protection of the health and well-being of [State] residents." *Challenge v. Moniz*, 218 F. Supp. 3d 1171, 1180–82 (E.D. Wash. 2016) (citing *Alfred L. Snapp & Son, Inc. v. Puerto Rico, ex rel., Barez*, 458 U.S. 592, 607 (1982)). The REMS negatively impact the health care choices of millions of patients in the States each year, and the States have standing to remedy those harms. And, as evidenced by recent studies documenting the REMS's direct impact on patient care, these harms are "fairly traceable" to the 2023 REMS and would be redressed by a ruling enjoining the enforcement of these restrictions. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992) (cleaned up).

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2. The 2023 REMS violates the APA

Under the Administrative Procedure Act (APA), a court "shall . . . hold unlawful and set aside agency action" that is "arbitrary [and] capricious," "not in accordance with law," or "in excess of statutory . . . authority . . . or limitations." 5 U.S.C. §§ 706(2)(A), (C). As explained above—and as repeatedly confirmed by FDA—mifepristone is safe and effective. Indeed, under any objective view of the evidence, it is safer than common prescription drugs such as Viagra and blood thinners, and is even safer than common over-the-counter medications like Tylenol and aspirin. Because mifepristone does not come close to meeting the FDCA's stringent statutory requirements for imposing a REMS, much less ETASU, the 2023 REMS is contrary to the law and in excess of statutory authority. Similarly, because there is no medical or scientific basis for restricting access to this safe and effective medication via the REMS, FDA's decision to impose the REMS is arbitrary and capricious.

a. 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 2023 REMS is inconsistent with the FDCA, which permits ETASU to be applied only in certain, limited circumstances not present here.

Congress permits FDA to impose ETASU only if a medication is "associated with a serious adverse drug experience," like "death," "immediate risk of death," "hospitalization," "persistent or significant incapacity," "a

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congenital anomaly or birth defect," or if the medicine "may jeopardize the patient and . . . require a medical or surgical intervention to prevent [such] an outcome." 21 U.S.C. §§ 355-1(f)(1)(A), (b)(4). And ETASU may be imposed only where "required . . . to mitigate a specific risk" of a serious adverse drug experience, and only where the risk is sufficiently severe that FDA would not approve, or would withdraw approval of, the medication, absent ETASU. *Id.* §§ 355-1(b)(5), (f)(1)(A). Moreover, ETASU must not be "*unduly burdensome* on patient access to the drug, considering in particular . . . patients in rural or medically underserved areas," and must "minimize the burden on the health care delivery system." *Id.* §§ 355-1(f)(2)(C)–(D) (emphasis added).

Mifepristone does not meet these stringent standards. First, far from being "associated with a serious adverse drug experience," FDA itself has concluded that serious adverse events following mifepristone use are "exceedingly rare." Compl. ¶ 89. Mifepristone's associated fatality rate is a miniscule .00005% for the almost quarter-century it has been on the U.S. market—and not a single death can "be causally attributed to mifepristone." *Id.* ¶ 90; Ex. A. Indeed, FDA found that the "critical risk factor" for infection deaths is not mifepristone but "pregnancy itself." *Id.* ¶ 91. By any measure, mifepristone is among the safest drugs on the market—demonstrably far safer than many drugs that are *not* subject to a REMS.

Second, the restrictions here are not "required . . . to mitigate a specific risk" of a serious adverse drug experience. *Id.* §§ 355-1(b)(5), (f)(1)(A). To the

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contrary, ETASU's burdensome administrative requirements—requiring patients to sign a form and providers and pharmacies to seek special certification—are *unrelated* to any medical risk, let alone required to mitigate it. Compl. ¶¶ 93–104. Moreover, ETASU is appropriate only where the drug is so "inherent[ly] toxic[] or potential[ly] harmful[]" that—as a medical or scientific matter—FDA otherwise could not approve it. *Cf.* 21 U.S.C. § 355-1(f)(1). This clearly is not the case here, as shown by the agency's approval without restrictions of a higher-dose, less safe form of mifepristone that is not used for abortion. Compl. ¶ 126.

Finally, even where ETASU satisfies these stringent requirements, it nonetheless violates the law if it is "*unduly burdensome* on patient access to the drug, considering in particular . . . patients in rural or medically underserved areas[.]" *Id.* § 355-1(f)(2)(C)–(D) (emphasis added). Here, the ETASU fails on both counts: it creates a medically unnecessary burden and that burden falls disproportionately on rural patients.

Agency actions that are "inconsistent with the statutory mandate or that frustrate the policy that Congress sought to implement" are invalid. *Fed. Election Comm'n v. Democratic Senatorial Campaign Comm.*, 454 U.S. 27, 32 (1981).[3]

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[3]Likewise, agency actions that violate the Constitution are invalid. FDA's imposition of the 2023 REMS irrationally treats providers, pharmacists, and patients who prescribe, dispense, and take mifepristone differently from similarly situated providers, pharmacists, and patients who prescribe, dispense, and take

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The 2023 REMS violates the FDCA's plain language and undermines the statute's goals of protecting public health and providing access to safe and effective medicines. By dissuading primary care providers and other health care professionals from prescribing mifepristone, the REMS puts abortion care out of reach for many patients. These concerns are heightened now that the criminalization of abortion and the threat of "bounty" lawsuits—including in nearby states like Idaho, Missouri, and Texas—have made providers more wary of becoming "certified" abortion-care providers, even in states where abortion is a protected right. *See* Shih Decl. ¶¶ 23–26; Prager Decl. ¶¶ 38–39; Gold Decl. ¶¶ 18–19. The 2023 REMS is invalid because it is squarely contrary to the FDCA.

b. The 2023 REMS is arbitrary and capricious

The 2023 REMS is also arbitrary and capricious. A regulation is arbitrary and capricious if the agency "relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem,

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similar or less safe drugs, in violation of equal protection and the Fifth Amendment. *See Plyler v. Doe*, 457 U.S. 202, 216 (1982) (quoting *F.S. Royster Guano Co. v. Virginia*, 253 U.S. 412, 415 (1920)) (the constitutional principle of equal protection "directs that 'all persons similarly circumstanced shall be treated alike'"). Further, "the deprivation of constitutional rights 'unquestionably constitutes irreparable injury.'" *Melendres v. Arpaio*, 695 F.3d 990, 1002 (9th Cir. 2012) (quoting *Elrod v. Burns*, 427 U.S. 347, 373 (1976)).

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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 v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). To comply with the APA, an agency must "pay[] attention to the advantages *and* the disadvantages of [its] decisions." *Michigan v. Env't Prot. Agency*, 576 U.S. 743, 753 (2015).

Though FDA's legitimate expertise warrants some deference, courts "do not hear cases merely to rubber stamp agency actions. To play that role would be 'tantamount to abdicating the judiciary's responsibility under the Administrative Procedure Act.'" *Nat. Res. Def. Council, Inc. v. Daley*, 209 F.3d 747, 755 (D.C. Cir. 2000) (citation omitted). Rather, to survive judicial review, the agency must demonstrate that it "examined the relevant data and articulated 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 42–43 (cleaned up).

The arbitrary and capricious nature of the 2023 REMS is threefold: it (1) is not justified by science, (2) fails to improve patient safety, and (3) harms patients by needlessly restricting the availability of a safe and effective drug.

1. The 2023 REMS restrictions are not supported by science. Mifepristone is safe and effective, and there is no reasoned scientific basis for subjecting it to additional burdens that are not applied to other, riskier medications. The mifepristone REMS has long been opposed by leading medical organizations, including ACOG, AAFP, and the AMA, each of which has urged

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FDA to withdraw the REMS restrictions in light of the scientific consensus that it unnecessarily burdens access to health care without improving patient safety. Compl. ¶¶ 115–123. Most recently, the 2022 citizen petition submitted by the nation's leading health care professional organizations conclusively demonstrated that the 2023 REMS restrictions is not backed by science. *Id.* ¶ 119. But FDA disregarded these concerns and retained the medically unfounded REMS restrictions, renewing them in 2016, 2019, 2021, and yet again in 2023. *Id.* ¶ 125.

To be clear, the superior safety profile of mifepristone is not *because of* the REMS. Data from countries without REMS-like restrictions shows similarly low rates of complications. For example, "[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." *Id.* ¶ 123. FDA knows the mifepristone REMS is unsupported by science, and its own approval of other drugs confirms it. Even as mifepristone for pregnancy termination has remained subject to the highly burdensome REMS, a *less safe*, higher-dosage mifepristone product not used for abortion has been available for over a decade *with no similar restrictions*. In 2012, FDA approved Korlym (mifepristone) tablets, 300 mg, as treatment for Cushing's syndrome *without* a REMS. *Id.* ¶ 126. FDA gave its blessing for normal prescribing despite acknowledging that Korlym "is taken in higher doses, in a chronic, daily fashion unlike the single 200 mg dose of Mifeprex . . . [and]

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the rate of adverse events with Mifeprex is much lower." *Id.* FDA's decision to restrict 200 mg tablets of mifepristone more stringently than 300 mg tablets underlines the arbitrary and capricious nature of the REMS. *See Nat'l Parks Conservation Ass'n v. Env't Prot. Agency*, 788 F.3d 1134, 1141 (9th Cir. 2015) ("[I]nternally inconsistent analysis is arbitrary and capricious.").

While there may be extraneous pressures contributing to FDA's decision to adopt and then maintain the REMS, "[t]he FDA is an expert scientific agency charged with making scientific and medical decisions within the boundaries set by the FDCA. Nothing in that statute suggests that scientific decisions may bend to political winds." *Tummino v. Hamburg*, 936 F. Supp. 2d 162, 185 (E.D.N.Y. 2013). "The standards are the same for aspirin and for contraceptives." *Id.* at 169. Because FDA arbitrarily subjects mifepristone to more stringent restrictions than other, riskier medications, despite acknowledging mifepristone's thoroughly proven safety, the 2023 REMS violates the APA.

2. Compounding the problem, none of the strategies in the 2023 REMS actually enhance patient safety. FDA's *own team* of expert reviewers at CDER unanimously recommended in 2016 that the Patient Agreement Form be eliminated because it is duplicative of informed consent laws and standards, "does not add to safe use conditions . . . and is a burden for patients." Compl. ¶ 82; *see also id.* ¶ 120 (citizen petition stating that the Form is "medically unnecessary and repetitive of informed consent," citing FDA's 2016 findings). However, the 2023 REMS maintains this useless requirement, which has become

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even more burdensome post-*Dobbs*, as many states threaten to criminalize or impose liability on abortion providers nationwide.

Similarly, the provider-certification requirement provides no additional safety benefit. "Abortion with mifepristone is safe and effective" and "falls 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." Compl. ¶ 138. Health care providers are already subject to numerous ethical and legal obligations, as well as potential malpractice liability, ensuring that they practice only within their competency. *See, e.g.*, AMA Principles of Medical Ethics, Principle I, https://code-medical-ethics.ama-assn.org/principles#:~:text=I.,for%20human%20dignity%20and%20rights (adopted June 1957, last revised June 2001) (last visited Feb. 23, 2023) ("A physician shall be dedicated to providing competent medical care[.]"); Wash. Rev. Code § 18.71.002 (2023) (Washington Medical Commission "regulate[s] the competency and quality of professional health care providers . . . by establishing, monitoring, and enforcing qualifications for licensing, consistent standards of practice, continuing competency mechanisms, and discipline"). Requiring providers to attest to their competency provides no added guarantee that they will stay within the scope of their competence; it just adds burden. It is also out of step with how FDA regulates other, less safe medications. Providers are allowed to prescribe countless drugs without first attesting to their competency to make an accurate diagnosis or provide care in the event of a complication—including, again, *a*

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higher dose of mifepristone itself. The decision to single out the lower dose of mifepristone used for medication abortion is baseless.

The requirement that pharmacies be "specially certified" through the drug's distributor before they can dispense mifepristone is similarly unjustifiable. A 2021 pilot study at Washington and California clinics found *zero* serious adverse events related to pharmacy dispensing. Compl. ¶ 122. Like prescribers, pharmacies and pharmacists are subject to extensive regulation, and to discipline if they fail to adhere to established standards. *See, e.g.*, Wash. Rev. Code §§ 69.41.040, 69.50.308(h) (2023); Wash. Admin. Code §§ 246-945-011(1), -305(1)–(2), -415(2) (2023). Against this backdrop, additional paperwork does nothing to enhance patient safety. It merely singles out mifepristone for burdens that are completely out of sync with how pharmacies are required to treat nearly every other drug they stock.

3. The 2023 REMS is arbitrary and capricious not only because it is useless, but because it is actively harmful: evidence shows the restrictions *worsen* health outcomes by impeding access to abortion care. *See Michigan*, 576 U.S. at 753 (an agency must "pay[] attention to the advantages *and* the disadvantages of [its] decisions"). Multiple studies show the REMS acts as "a barrier to providing medication abortion," most notably by dissuading primary care providers from offering it. Compl. ¶¶ 137–38. For those patients unable to access medication abortion, surgical abortion may be an option (depending on where they live and their resources), but it is an option that FDA describes as more invasive,

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potentially risky for patients with certain medical issues, and traumatizing for many. *Id.* ¶ 143. And for those patients unable to obtain an abortion at all, the health risks are severe. Mifepristone use is far safer than continuing an unwanted pregnancy. A person who carries a pregnancy to term is at least fourteen times more likely to die than a person who uses mifepristone to end a pregnancy. *Id.* ¶ 133. The landmark Turnaway Study shows that patients denied abortion are more likely to: experience serious complications from the end of pregnancy, including eclampsia and death; stay tethered to abusive partners; suffer anxiety and loss of self-esteem in the short term after being denied abortion; and experience poor physical health for years after the pregnancy, including chronic pain and gestational hypertension. *Id.* ¶ 142.

Racial and class inequities in the health care system exacerbate these risks. Black women, for instance, are three to four times more likely than white women to die a pregnancy-related death in the U.S. *Id.* ¶ 133. And for patients whose access to health care is already diminished by poverty, language barriers, lack of transportation, or other factors, the burden is especially harsh. For example, as ACOG explained in its 2022 citizen petition, the provider certification requirement disproportionately affects rural patients because REMS-certified providers "are almost always located in cities." *Id.* ¶ 122. "As with the certified provider requirement, the burdens associated with the certified pharmacy requirement will also fall disproportionately on poor and rural women, contrary to the REMS statute," ACOG noted. *Id.*; *cf.* 21 U.S.C. § 355-1(f)(2)(C) (ETASU

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must not be "unduly burdensome on patient access to the drug, considering in particular . . . patients in rural or medically underserved areas."). And none of this is justified by the science. FDA has repeatedly determined that mifepristone is exceedingly safe. By limiting access to mifepristone through the 2023 REMS, FDA deprives patients of the therapeutic benefit of the drug, leading to worse outcomes without any scientific basis.

C. The States Will Suffer Irreparable Harm Absent Injunctive Relief

For purposes of a preliminary injunction, the harm analysis "focuses on irreparability, irrespective of the magnitude of the injury." *California v. Azar*, 911 F.3d 558, 581 (9th Cir. 2018) (cleaned up). The Plaintiff States are irreparably harmed in at least three ways. The 2023 REMS: (1) imposes uncompensable financial costs on the States, (2) burdens State institutions and providers who provide abortion care and dispense mifepristone (or could absent the REMS), and (3) harms the health and well-being of State patients and providers by aggravating the ongoing crisis of reduced access to abortion care.

First, the 2023 REMS is harming the States economically, and there is no mechanism by which the States could recover damages from the United States. Uncompensable economic harm, such as that caused by unlawful federal agency action, satisfies the irreparable harm standard. *Id.* at 581; *Idaho v. Coeur d'Alene Tribe*, 794 F.3d 1039, 1046 (9th Cir. 2015); *Texas v. United States*, 809 F.3d 134, 186 (5th Cir. 2015); *Cent. Bancorp, Inc. v. Cent. Bancompany, Inc.*, 385 F. Supp. 3d 1122, 1145 (D. Colo. 2019). The REMS imposes unrecoverable costs on the

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States' Medicaid and other state-funded health care programs where patients who would otherwise use mifepristone instead must choose expensive procedural abortions—or even more expensive maternal care. *See California v. U.S. Health & Human Servs*., 390 F. Supp. 3d 1061, 1065 (N.D. Cal. 2019) (concluding HHS rule would "inflict irreparable harm" on Oregon by forcing patients to turn to "state [run] programs, imposing unrecoverable costs on the state").

As detailed above, restricting access to mifepristone pushes many patients toward costlier procedural abortions. Additionally, delays in treatment—whether caused by a lack of "specifically certified" providers (Godfrey Decl. ¶ 30) or pharmacies (Shih Decl. ¶ 27), lack of access to technology required to e-sign the Patient Agreement Form (Shih Decl. ¶ 17), lagging or incomplete REMS-required paperwork (DasGupta Decl. ¶ 10), or some other reason—may cause patients to miss their window for medication abortion. Shih Decl. ¶ 17 ("[D]elaying the process even by a few days may make [some patients] ineligible to select medication abortion."); Colwill Decl. ¶ 24. In these cases, patients may have to choose between procedural abortion or carrying an unwanted pregnancy to term.

One clear result is that the Plaintiff States that are payors for abortion services covered by Medicaid and other state-funded health care programs are required to pay the higher costs for procedural abortions. Fotinos Decl. ¶¶ 5, 7–10. Between 2015 and 2022, for example, Washington's Medicaid program, Apple Health, covered over 32,000 medication abortions, at an average cost to

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the State of about $340 each. Birch Decl. ¶ 6. Over the same period, Apple Health covered over 42,000 procedural abortions, at an average cost of around *$610* each. *Id.* ¶ 9. Thus, for each Medicaid patient the REMS pushes from medication to procedural abortion, the direct cost to the State is around $270 unrecoverable dollars. This cost disparity is even higher for those patients Washington covers through the School Employee Benefits Board and Public Employees Benefits Board. Birch Decl. ¶¶ 11–14. And for Medicaid patients denied access to mifepristone who ultimately give birth: "on average for each delivery, the State pa[ys] about $11,200 for prenatal care and delivery for Apple Health clients." *Id.* ¶ 18; *see also* Fotinos Decl. ¶¶ 10–12 (describing additional potential costs to the State caused by the REMS). These unrecoverable costs are irreparable harm.

Second, federal action that undermines a state program and impedes its purpose causes irreparable harm. *Washington v. Trump*, C17-0141JLR, 2017 WL 462040, at *2 (W.D. Wash. Feb. 3, 2017) (concluding states suffered irreparable harm "by virtue of the damage . . . inflicted upon the operations and missions of their public universities and other institutions of higher learning, as well as injury to the States' operations"); *County of Santa Clara v. Trump*, 250 F. Supp. 3d 497, 537 (N.D. Cal. 2017) (finding irreparable harm where executive action "interfere[d] with the Counties' ability to operate [and] to provide key services"); *see also League of Women Voters of U.S. v. Newby*, 838 F.3d 1, 8 (D.C. Cir. 2016) ("An organization is harmed if the actions taken by [the defendant] have 'perceptibly impaired' the [organization's] programs.") (cleaned up).

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The 2023 REMS undermines state-run health facilities' mission of improving the health of the public. Compl. ¶ 151. For those state institutions that prescribe and dispense mifepristone, the REMS interferes with patient care in multiple ways. For example, the REMS has already "delayed telehealth access to medication abortions by over two months for patients seeking this care from UW." Reed Decl. ¶ 7; *see also* Singh Decl. ¶ 19. Further, the Patient Agreement Form, which requires all patients to acknowledge they are choosing an abortion, "makes patient counseling much harder," particularly for patients using mifepristone for miscarriages who must nevertheless attest that they have "*decided* . . . to end [their] pregnancy." Compl. ¶ 101 (emphasis added); Shih Decl. ¶ 14; *see also* Godfrey Decl. ¶ 14; Lazarus Decl. ¶ 18; Nichols ¶ 35 (Patient Agreement Form causes patients "concern" that mifepristone is "inherently risky"); Prager Decl. ¶¶ 18, 31 ("the Patient Agreement Form acts to unnecessarily heighten patient worry and stress"). The REMS also negatively impacts UW's training of medical residents by discouraging residents from receiving training in medication abortion—particularly if they fear violence or harassment as a result of providing abortion care, or plan to practice in states where abortion is illegal and penalized. Shih Decl. ¶¶ 25–26, 33; Prager Decl. ¶ 39; *see also* Dillon Decl. ¶¶ 24–33 (discussing threats to abortion providers).

And compliance with the 2023 REMS has created *tremendous* administrative burdens for state institutions like UW, further undermining their missions by diverting time from patient care, research, and other core functions

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to REMS compliance. As reflected in the testimony of multiple UW employees, UW physicians, pharmacists, and staff have had to divert hundreds of hours of time away from treating patients, teaching clinical medicine, conducting research, or attending to other critical job functions in order to work on REMS implementation. *See* Singh Decl. ¶¶ 20–21; Prager Decl. ¶¶ 32–37; Shih Decl. ¶¶ 15–19; Reed Decl. ¶¶ 3–17; Godfrey Decl. ¶¶ 34–36; DasGupta Decl. ¶¶ 15–18. Moreover, this work is not yet done, with additional time to be spent on further REMS implementation work in the coming months. *See* Singh Decl. ¶ 21; Reed Decl. ¶ 16; DasGupta Decl. ¶ 17; *see also* Colwill Decl. ¶¶ 38–40 (describing ongoing time wasted by REMS requirements). This diversion of time from patient care, medical education, and research is irreparable harm. *Cf. Cent. Bancorp, Inc.*, 385 F. Supp. 3d at 1145 (recognizing "time spent having to deal with confused potential or purported customers is an irreparable harm" because of the "opportunity cost" of the time that employees could not spend with other "current or potential customers").

Third, patients in the States are harmed by the 2023 REMS because it restricts their access to safe and effective medical care, leading to worse health outcomes. Injury to residents' health and well-being irreparably harms the States themselves. *See Pennsylvania v. Trump*, 351 F. Supp. 3d 791, 828 (E.D. Pa. 2019) ("the States also stand to suffer injury to their interest in protecting the safety and well-being of their citizens"). Reductions in health care access—and the negative patient outcomes that result—are precisely the sorts of irreparable harms that

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preliminary injunctions are appropriate to prevent. *See, e.g.*, *California v. Health & Human Servs.*, 281 F. Supp. 3d 806, 830 (N.D. Cal. 2017), *aff'd in pertinent part sub nom. California v. Azar*, 911 F.3d 558 (9th Cir. 2018) (states demonstrated irreparable injury based on "what is at stake: the health of Plaintiffs' citizens and Plaintiffs' fiscal interests"); *Rodde v. Bonta*, 357 F.3d 988, 999 (9th Cir. 2004) (recognizing irreparable harms of "delayed and/or complete lack of necessary treatment, and increased pain and medical complications"); *Beltran v. Myers*, 677 F.2d 1317, 1322 (9th Cir. 1982) ("Plaintiffs have shown a risk of irreparable injury, since enforcement of the [challenged] rule may deny them needed medical care. That is a sufficient showing."); *Pennyslvania*, 351 F.3d at 828 (finding irreparable harm where "[d]isruptions in contraceptive coverage will lead to women suffering unintended pregnancies and other medical consequences").

The unnecessary restrictions the 2023 REMS places on mifepristone are harming the States by aggravating the ongoing crisis of reduced access to abortion care. Dillon Decl. ¶¶ 4–14, 23; Colwill Decl. ¶ 39. More than half of all abortions in Washington in 2021—59%—were medication abortions using mifepristone. Rolland Decl. ¶ 6. Mifepristone is also widely used for the medical management of miscarriage. Prager Decl. ¶¶ 4, 7, 9, 15; Shih Decl. ¶ 13. But the 2023 REMS has hindered providers from prescribing, pharmacies from dispensing, and patients from obtaining this critical drug—stymieing the States' efforts to adhere to best practices in patient care and diminishing the health and

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safety of our residents. Prager Decl. ¶ 37–40; Shih Decl. ¶ 20–28; Janiak Decl. ¶ 17–23; Downing Decl. ¶¶ 9–17; Henry Decl. ¶¶ 6–8; Lazarus Decl. ¶¶ 16–20.

Forcing patients in the States to go to "specifically certified" providers reduces the availability of abortion care, disrupts continuity of care, stigmatizes routine health care, and in many cases likely discourages patients from making the best health care choices for themselves and their families. *See, e.g.*, Janiak Decl. ¶¶ 24–26; Godfrey Decl. ¶¶ 15–16, 19, 24; Shih Decl. ¶¶ 20–29; Prager Decl. ¶¶ 37–40. As one example, Washington State University's student health center does not have any "specially certified" mifepristone providers. Students are therefore referred out for medication abortion care, which "often creates an undue amount of stress for [WSU] student[s] while they are attempting to access services." Henry Decl. ¶ 5; *see also id.* ¶ 6 ("[T]he REMS program requirements act as a barrier to the ability of WSU students to receive comprehensive reproductive health care services in a rural area."). As for pharmacies, while mail order delivery can lessen the burden of finding a certified pharmacy, mail-order prescriptions are not an option for many patients in the Plaintiff States, including people experiencing housing insecurity, those for whom receipt of the prescription is particularly time-sensitive (i.e., for patients close to the gestational limit), those in rural areas dependent on P.O. boxes for mail delivery (which are ineligible for mail-order prescriptions), or those for whom receipt of abortion medication at their home may trigger domestic violence or housing loss. Reed Decl. ¶ 15; Janiak Decl. ¶¶ 27–29; Colwill Decl. ¶ 21.

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To be sure, FDA well knows that a lack of access to mifepristone results in "worse health outcomes for patients who rely on the availability of mifepristone to safely and effectively terminate their pregnancies."[4] By imposing unrecoverable costs on the States, interfering with the missions of State health care institutions, and restricting residents' access to safe and appropriate care, the REMS irreparably harms the Plaintiff States.

D. The Equities and Public Interest Weigh Strongly in the States' Favor

When the government is a party, the final two *Winter* factors merge. *Drakes Bay Oyster Co. v. Jewell*, 747 F.3d 1073, 1092 (9th Cir. 2014). Here, the balance of the equities and public interest strongly favor an injunction. "There is clearly a robust public interest in safeguarding prompt access to health care." *Whitman-Walker Clinic, Inc. v. U.S. Dep't of Health & Human Servs.*, 485 F. Supp. 3d 1, 61 (D.D.C. 2020). Thus, "the public interest . . . favors a preliminary injunction" when agency action "will likely result in worse health outcomes." *New York v. U.S. Dep't of Homeland Sec.*, 969 F.3d 42, 87 (2d Cir. 2020) (cleaned up). The 2023 REMS unlawfully and unreasonably restricts access to a safe and effective medicine for those who wish to terminate their pregnancies. The "potentially dire public health . . . consequences" of the 2023 REMS undermines the public interest and support issuance of an injunction to protect access to

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[4]FDA's Opp'n to Pls.' Mot. for Prelim. Inj., *All. for Hippocratic Med. v. FDA*, No. 2:22-CV-00223-Z (N.D. Tex. Jan. 13, 2023), Dkt. 28 at 38.

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mifepristone by both enjoining the REMS and ensuring that Defendants do not taken any action to remove mifepristone from the market or limit its accessibility. *Azar*, 911 F.3d at 582.

By contrast, FDA has no legitimate interest in maintaining its unlawful, irrational REMS. "There is generally no public interest in the perpetuation of unlawful agency action." *League of Women Voters of U.S.*, 838 F.3d at 12 (cleaned up). And there is no safety-based public interest in maintaining the REMS. Mifepristone is exceedingly safe and the 2023 REMS does absolutely nothing to enhance patient safety, but in fact endangers it. Now more than ever, with the right to abortion under increasing attack, it is imperative to protect patient access to this critically important, safe medication.

IV. CONCLUSION

For the foregoing reasons, the Plaintiff States respectfully request that this Court enter an order protecting access to mifepristone by preliminarily enjoining FDA from (1) enforcing or applying the 2023 REMS, and (2) taking any action to remove mifepristone from the market or otherwise cause the drug to become less available.

DATED this 24th day of February 2023.

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**Application for pro hac vice admission forthcoming*

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**Application for pro hac vice admission forthcoming*

CERTIFICATE OF SERVICE

I hereby certify that on February 24th, 2023, 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 hereby certify that I have mailed by United States Postal Service, and sent via electronic mail, the document to the following non-CM/ECF participants:

United States Food and Drug Administration
Chief Counsel, Food and Drug Administration
ATTENTION: LITIGATION
White Oak Building 31, Room 4544
10903 New Hampshire Ave., Silver Spring, MD 20993-0002
OC-OCC-FDA-Litigation-Mailbox@fda.hhs.gov

Robert M. Califf, Commissioner
Chief Counsel, Food and Drug Administration
ATTENTION: LITIGATION
White Oak Building 31, Room 4544
10903 New Hampshire Ave., Silver Spring, MD 20993-0002
OC-OCC-FDA-Litigation-Mailbox@fda.hhs.gov

I hereby certify that I have mailed by United States Postal Service the document to the following non-CM/ECF participants:

Department of Health and Human Services
c/o General Counsel
200 Independence Avenue, S.W.
Washington, D.C. 20201

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

Xavier Becerra, Secretary
c/o General Counsel
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

I hereby certify that I have caused the document to be served by hand-delivery to the following non-CM/ECF participants:

U.S. Attorney Vanessa R. Waldref
United States Attorney's Office
Eastern District of Washington
920 W. Riverside Avenue, Suite 340
Spokane, WA 99201

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 24th day of February 2023, at Seattle, Washington.

/s/ Kristin Beneski
KRISTIN BENESKI, WSBA #45478
First Assistant Attorney General

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