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10 **UNITED STATES DISTRICT COURT**
 11 **EASTERN DISTRICT OF WASHINGTON**

12 STATE OF WASHINGTON;
 13 STATE OF OREGON; STATE OF
 ARIZONA; STATE OF
 14 COLORADO; STATE OF
 CONNECTICUT; STATE OF
 15 DELAWARE; STATE OF
 ILLINOIS; ATTORNEY GENERAL
 OF MICHIGAN; STATE OF
 16 NEVADA; STATE OF NEW
 MEXICO; STATE OF RHODE
 ISLAND; and STATE OF
 17 VERMONT,

18 Plaintiffs,

19 v.

20 UNITED STATES FOOD AND
 DRUG ADMINISTRATION;
 21 ROBERT M. CALIFF, in his official
 capacity as Commissioner of Food
 and Drugs; UNITED STATES
 22

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

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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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TABLE OF CONTENTS

I. INTRODUCTION 1

II. FACTS 3

 A. Statutory Background..... 3

 B. FDA Concludes—and Repeatedly Affirms—that Mifepristone Is Safe 4

 C. FDA Adopts Burdensome REMS for Mifepristone 6

 D. The 2023 REMS Unduly Burdens Access to Health Care 10

III. ARGUMENT 13

 A. Legal Standard 13

 B. The States’ Claims Are Likely to Succeed on the Merits 14

 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 14

 2. The 2023 REMS violates the APA..... 16

 a. The 2023 REMS is contrary to law..... 16

 b. The 2023 REMS is arbitrary and capricious 19

 C. The States Will Suffer Irreparable Harm Absent Injunctive Relief..... 26

 D. The Equities and Public Interest Weigh Strongly in the States’ Favor..... 33

IV. CONCLUSION 34

1 **I. INTRODUCTION**

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

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

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

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

21
22

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

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

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

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

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

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

22

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

13 In 2016, FDA’s Center for Drug Evaluation and Research (CDER)
14 conducted a comprehensive safety review in connection with a supplemental new
15 drug application. Compl. ¶¶ 72, 73, 86. By that point, Mifeprex had been used
16 2.5 million times for medication abortion in the U.S. Compl. ¶ 89. FDA
17 determined that serious adverse events following Mifeprex use are “exceedingly
18

19 ¹Citations to the Complaint incorporate the factual sources cited and linked
20 therein.

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

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

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

10 In the 23 years since its FDA approval, approximately 5.6 million patients
11 in the United States have used mifepristone. Compl. ¶ 3. According to FDA, this
12 medication “has been increasingly used as its efficacy and safety have become
13 well-established by both research and experience, and serious complications have
14 proven to be extremely rare.” *Id.*; Ex. B at 12. FDA has repeatedly confirmed
15 mifepristone’s safety and efficacy, and its periodic reviews of the post-marketing
16 data for mifepristone have not identified any new safety concerns. Compl. ¶ 125.

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

21 **C. FDA Adopts Burdensome REMS for Mifepristone**

22 Despite mifepristone’s undisputed safety and efficacy, FDA has long

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

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

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

15 *Third*, although the 2023 REMS for the first time allows mifepristone to
16 be dispensed by pharmacies (whereas prior REMS only allowed providers to
17 dispense it), the REMS unnecessarily requires dispensing pharmacies to be
18 “specially certified” by the drug distributor. *Id.* ¶ 98; Ex. L. Obtaining this
19 certification requires pharmacies to agree to an array of burdensome
20 communication and recordkeeping requirements, including verifying that every
21 prescription for mifepristone is written by a “specially certified” provider. *Id.*
22 ¶¶ 98–100; Ex. P.

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

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

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

1 **D. The 2023 REMS Unduly Burdens Access to Health Care**

2 The mifepristone REMS significantly impedes access to abortion care.
3 Even before *Dobbs v. Jackson Women’s Health Association*, 142 S. Ct. 2228
4 (2022), only a small fraction of counties in the United States had a clinician
5 providing surgical abortions. Compl. ¶ 136. Mifepristone offers the possibility of
6 vastly increased access to care by enabling primary care physicians to integrate
7 abortion care into their services. *Id.*; Gold Decl. ¶ 26; Godfrey Decl. ¶ 17; Janiak
8 Decl. ¶ 14. But the REMS significantly impedes mifepristone’s availability, and
9 as a result of these unnecessary restrictions, abortion care remains beyond the
10 reach of many—even in states like the Plaintiff States in which abortion is lawful
11 and protected. Gold Decl. ¶ 27; Godfrey Decl. ¶ 22; Shih Decl. ¶ 29; Colwill
12 Decl. ¶¶ 18–25; Nichols Decl. ¶¶ 25–27, 38; Compl. ¶ 136.

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

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

12 These effects are only compounded by the serious and well-founded
13 concerns of many health care providers and pharmacists about creating a
14 documented association with abortion care, as required by seeking special
15 certification under the REMS. Compl. ¶ 156; Godfrey Decl. ¶ 27; Gold Decl.
16 ¶ 17; Janiak Decl. ¶ 20. Given the growing criminalization and penalization of
17 abortion following the *Dobbs* decision, these risks have grown significantly—
18 particularly for providers who hold licenses in multiple states, medical residents
19 who plan to practice in states that restrict or outlaw abortion, and providers and
20 pharmacists who treat patients from neighboring states like Idaho, Missouri, and
21 Texas, where draconian laws raise the specter of criminal or civil liability. Shih
22 Decl. ¶¶ 23–26; Prager Decl. ¶¶ 38–40; Godfrey Decl. ¶ 27; Janiak Decl. ¶ 20;

1 Gold Decl. ¶¶ 17–19.

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

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

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

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

17 III. ARGUMENT

18 A. Legal Standard

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

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

2 **B. The States’ Claims Are Likely to Succeed on the Merits**

3 **1. The States have standing based on their proprietary and**
4 **pecuniary interests as providers of health care, and based on**
5 **their interests in protecting their residents’ health**

6 As owners and operators of medical facilities that provide reproductive
7 health care services and pharmacies that dispense mifepristone, Compl. ¶¶ 14,
8 19, 26, 38, 42,151, most States are directly subject to the January 2023 REMS
9 and have standing to vindicate their proprietary interests in delivering high-
10 quality patient care. *See Washington v. Trump*, 847 F.3d 1151, 1159–61 (9th Cir.
11 2017) (states had standing where challenged law harmed proprietary work of
12 public universities); *City of Sausalito v. O’Neill*, 386 F.3d 1186, 1197 (9th Cir.
13 2004) (government entity’s proprietary interests “are not confined to protection
14 of its real and personal property” and “are as varied as [its] responsibilities,
15 powers, and assets”).

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

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

10 States likewise have a protectable interest in the health and well-being of
11 their residents. As this Court has confirmed, states have standing to vindicate
12 their “quasi-sovereign interest[s]” in “protection of the health and well-being of
13 [State] residents.” *Challenge v. Moniz*, 218 F. Supp. 3d 1171, 1180–82 (E.D.
14 Wash. 2016) (citing *Alfred L. Snapp & Son, Inc. v. Puerto Rico, ex rel., Barez*,
15 458 U.S. 592, 607 (1982)). The REMS negatively impact the health care choices
16 of millions of patients in the States each year, and the States have standing to
17 remedy those harms. And, as evidenced by recent studies documenting the
18 REMS’s direct impact on patient care, these harms are “fairly traceable” to the
19 2023 REMS and would be redressed by a ruling enjoining the enforcement of
20 these restrictions. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992)
21 (cleaned up).
22

1 **2. The 2023 REMS violates the APA**

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

15 **a. The 2023 REMS is contrary to law**

16 To be valid, agency actions “must be consistent with the statute under
17 which they are promulgated.” *United States v. Larionoff*, 431 U.S. 864, 873
18 (1977). The 2023 REMS is inconsistent with the FDCA, which permits ETASU
19 to be applied only in certain, limited circumstances not present here.

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

1 congenital anomaly or birth defect,” or if the medicine “may jeopardize the
2 patient and . . . require a medical or surgical intervention to prevent [such] an
3 outcome.” 21 U.S.C. §§ 355-1(f)(1)(A), (b)(4). And ETASU may be imposed
4 only where “required . . . to mitigate a specific risk” of a serious adverse drug
5 experience, and only where the risk is sufficiently severe that FDA would not
6 approve, or would withdraw approval of, the medication, absent ETASU. *Id.*
7 §§ 355-1(b)(5), (f)(1)(A). Moreover, ETASU must not be “*unduly burdensome*
8 on patient access to the drug, considering in particular . . . patients in rural or
9 medically underserved areas,” and must “minimize the burden on the health care
10 delivery system.” *Id.* §§ 355-1(f)(2)(C)–(D) (emphasis added).

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

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

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

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

15 Agency actions that are “inconsistent with the statutory mandate or that
16 frustrate the policy that Congress sought to implement” are invalid. *Fed. Election*
17 *Comm’n v. Democratic Senatorial Campaign Comm.*, 454 U.S. 27, 32 (1981).³

18
19 ³Likewise, agency actions that violate the Constitution are invalid. FDA’s
20 imposition of the 2023 REMS irrationally treats providers, pharmacists, and
21 patients who prescribe, dispense, and take mifepristone differently from similarly
22 situated providers, pharmacists, and patients who prescribe, dispense, and take

1 The 2023 REMS violates the FDCA’s plain language and undermines the
2 statute’s goals of protecting public health and providing access to safe and
3 effective medicines. By dissuading primary care providers and other health care
4 professionals from prescribing mifepristone, the REMS puts abortion care out of
5 reach for many patients. These concerns are heightened now that the
6 criminalization of abortion and the threat of “bounty” lawsuits—including in
7 nearby states like Idaho, Missouri, and Texas—have made providers more wary
8 of becoming “certified” abortion-care providers, even in states where abortion is
9 a protected right. *See* Shih Decl. ¶¶ 23–26; Prager Decl. ¶¶ 38–39; Gold Decl.
10 ¶¶ 18–19. The 2023 REMS is invalid because it is squarely contrary to the FDCA.

11 **b. The 2023 REMS is arbitrary and capricious**

12 The 2023 REMS is also arbitrary and capricious. A regulation is arbitrary
13 and capricious if the agency “relied on factors which Congress has not intended
14 it to consider, entirely failed to consider an important aspect of the problem,
15

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

1 offered an explanation for its decision that runs counter to the evidence before
2 the agency, or is so implausible that it could not be ascribed to a difference in
3 view or the product of agency expertise.” *Motor Vehicle Mfrs. Ass’n v. State*
4 *Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). To comply with the APA, an
5 agency must “pay[] attention to the advantages *and* the disadvantages of [its]
6 decisions.” *Michigan v. Env’t Prot. Agency*, 576 U.S. 743, 753 (2015).

7 Though FDA’s legitimate expertise warrants some deference, courts “do
8 not hear cases merely to rubber stamp agency actions. To play that role would be
9 ‘tantamount to abdicating the judiciary’s responsibility under the Administrative
10 Procedure Act.’” *Nat. Res. Def. Council, Inc. v. Daley*, 209 F.3d 747, 755 (D.C.
11 Cir. 2000) (citation omitted). Rather, to survive judicial review, the agency must
12 demonstrate that it “examined the relevant data and articulated a satisfactory
13 explanation for its action including a rational connection between the facts found
14 and the choice made.” *Motor Vehicle Mfrs.*, 463 U.S. at 42–43 (cleaned up).

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

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

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

9 To be clear, the superior safety profile of mifepristone is not *because of*
10 the REMS. Data from countries without REMS-like restrictions shows similarly
11 low rates of complications. For example, “[a]fter Canada removed all restrictions
12 on prescribing mifepristone for abortion, thereby allowing it to be prescribed and
13 dispensed like any other drug (‘normal prescribing’), there was no increase in
14 complications from mifepristone use.” *Id.* ¶ 123. FDA knows the mifepristone
15 REMS is unsupported by science, and its own approval of other drugs confirms
16 it. Even as mifepristone for pregnancy termination has remained subject to the
17 highly burdensome REMS, a *less safe*, higher-dosage mifepristone product not
18 used for abortion has been available for over a decade *with no similar restrictions*.
19 In 2012, FDA approved Korlym (mifepristone) tablets, 300 mg, as treatment for
20 Cushing’s syndrome *without* a REMS. *Id.* ¶ 126. FDA gave its blessing for
21 normal prescribing despite acknowledging that Korlym “is taken in higher doses,
22 in a chronic, daily fashion unlike the single 200 mg dose of Mifeprex . . . [and]

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

6 While there may be extraneous pressures contributing to FDA’s decision
7 to adopt and then maintain the REMS, “[t]he FDA is an expert scientific agency
8 charged with making scientific and medical decisions within the boundaries set
9 by the FDCA. Nothing in that statute suggests that scientific decisions may bend
10 to political winds.” *Tummino v. Hamburg*, 936 F. Supp. 2d 162, 185 (E.D.N.Y.
11 2013). “The standards are the same for aspirin and for contraceptives.” *Id.* at 169.
12 Because FDA arbitrarily subjects mifepristone to more stringent restrictions than
13 other, riskier medications, despite acknowledging mifepristone’s thoroughly
14 proven safety, the 2023 REMS violates the APA.

15 2. Compounding the problem, none of the strategies in the 2023 REMS
16 actually enhance patient safety. FDA’s *own team* of expert reviewers at CDER
17 unanimously recommended in 2016 that the Patient Agreement Form be
18 eliminated because it is duplicative of informed consent laws and standards,
19 “does not add to safe use conditions . . . and is a burden for patients.” Compl.
20 ¶ 82; *see also id.* ¶ 120 (citizen petition stating that the Form is “medically
21 unnecessary and repetitive of informed consent,” citing FDA’s 2016 findings).
22 However, the 2023 REMS maintains this useless requirement, which has become

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

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

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

3 | The requirement that pharmacies be “specially certified” through the
4 | drug’s distributor before they can dispense mifepristone is similarly unjustifiable.
5 | A 2021 pilot study at Washington and California clinics found *zero* serious
6 | adverse events related to pharmacy dispensing. Compl. ¶ 122. Like prescribers,
7 | pharmacies and pharmacists are subject to extensive regulation, and to discipline
8 | if they fail to adhere to established standards. *See, e.g.*, Wash. Rev. Code
9 | §§ 69.41.040, 69.50.308(h) (2023); Wash. Admin. Code §§ 246-945-
10 | 011(1), -305(1)–(2), -415(2) (2023). Against this backdrop, additional paperwork
11 | does nothing to enhance patient safety. It merely singles out mifepristone for
12 | burdens that are completely out of sync with how pharmacies are required to treat
13 | nearly every other drug they stock.

14 | **3.** The 2023 REMS is arbitrary and capricious not only because it is
15 | useless, but because it is actively harmful: evidence shows the restrictions *worsen*
16 | health outcomes by impeding access to abortion care. *See Michigan*, 576 U.S. at
17 | 753 (an agency must “pay[] attention to the advantages *and* the disadvantages of
18 | [its] decisions”). Multiple studies show the REMS acts as “a barrier to providing
19 | medication abortion,” most notably by dissuading primary care providers from
20 | offering it. Compl. ¶¶ 137–38. For those patients unable to access medication
21 | abortion, surgical abortion may be an option (depending on where they live and
22 | their resources), but it is an option that FDA describes as more invasive,

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

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

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

7 **C. The States Will Suffer Irreparable Harm Absent Injunctive Relief**

8 For purposes of a preliminary injunction, the harm analysis “focuses on
9 irreparability, irrespective of the magnitude of the injury.” *California v. Azar*,
10 911 F.3d 558, 581 (9th Cir. 2018) (cleaned up). The Plaintiff States are
11 irreparably harmed in at least three ways. The 2023 REMS: (1) imposes
12 uncompensable financial costs on the States, (2) burdens State institutions and
13 providers who provide abortion care and dispense mifepristone (or could absent
14 the REMS), and (3) harms the health and well-being of State patients and
15 providers by aggravating the ongoing crisis of reduced access to abortion care.

16 *First*, the 2023 REMS is harming the States economically, and there is no
17 mechanism by which the States could recover damages from the United States.
18 Uncompensable economic harm, such as that caused by unlawful federal agency
19 action, satisfies the irreparable harm standard. *Id.* at 581; *Idaho v. Coeur d’Alene*
20 *Tribe*, 794 F.3d 1039, 1046 (9th Cir. 2015); *Texas v. United States*, 809 F.3d 134,
21 186 (5th Cir. 2015); *Cent. Bancorp, Inc. v. Cent. Banccompany, Inc.*, 385 F. Supp.
22 3d 1122, 1145 (D. Colo. 2019). The REMS imposes unrecoverable costs on the

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

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

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

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

12 *Second*, federal action that undermines a state program and impedes its
13 purpose causes irreparable harm. *Washington v. Trump*, C17-0141JLR, 2017 WL
14 462040, at *2 (W.D. Wash. Feb. 3, 2017) (concluding states suffered irreparable
15 harm “by virtue of the damage . . . inflicted upon the operations and missions of
16 their public universities and other institutions of higher learning, as well as injury
17 to the States’ operations”); *County of Santa Clara v. Trump*, 250 F. Supp. 3d 497,
18 537 (N.D. Cal. 2017) (finding irreparable harm where executive action
19 “interfere[d] with the Counties’ ability to operate [and] to provide key services”);
20 *see also League of Women Voters of U.S. v. Newby*, 838 F.3d 1, 8 (D.C. Cir.
21 2016) (“An organization is harmed if the actions taken by [the defendant] have
22 ‘perceptibly impaired’ the [organization’s] programs.”) (cleaned up).

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

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

1 to REMS compliance. As reflected in the testimony of multiple UW employees,
2 UW physicians, pharmacists, and staff have had to divert hundreds of hours of
3 time away from treating patients, teaching clinical medicine, conducting
4 research, or attending to other critical job functions in order to work on REMS
5 implementation. *See* Singh Decl. ¶¶ 20–21; Prager Decl. ¶¶ 32–37; Shih Decl.
6 ¶¶ 15–19; Reed Decl. ¶¶ 3–17; Godfrey Decl. ¶¶ 34–36; DasGupta Decl. ¶¶ 15–
7 18. Moreover, this work is not yet done, with additional time to be spent on
8 further REMS implementation work in the coming months. *See* Singh Decl. ¶ 21;
9 Reed Decl. ¶ 16; DasGupta Decl. ¶ 17; *see also* Colwill Decl. ¶¶ 38–40
10 (describing ongoing time wasted by REMS requirements). This diversion of time
11 from patient care, medical education, and research is irreparable harm. *Cf. Cent.*
12 *Bancorp, Inc.*, 385 F. Supp. 3d at 1145 (recognizing “time spent having to deal
13 with confused potential or purported customers is an irreparable harm” because
14 of the “opportunity cost” of the time that employees could not spend with other
15 “current or potential customers”).

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

1 preliminary injunctions are appropriate to prevent. *See, e.g., California v. Health*
2 *& Human Servs.*, 281 F. Supp. 3d 806, 830 (N.D. Cal. 2017), *aff'd in pertinent*
3 *part sub nom. California v. Azar*, 911 F.3d 558 (9th Cir. 2018) (states
4 demonstrated irreparable injury based on “what is at stake: the health of
5 Plaintiffs’ citizens and Plaintiffs’ fiscal interests”); *Rodde v. Bonta*, 357 F.3d 988,
6 999 (9th Cir. 2004) (recognizing irreparable harms of “delayed and/or complete
7 lack of necessary treatment, and increased pain and medical complications”);
8 *Beltran v. Myers*, 677 F.2d 1317, 1322 (9th Cir. 1982) (“Plaintiffs have shown a
9 risk of irreparable injury, since enforcement of the [challenged] rule may deny
10 them needed medical care. That is a sufficient showing.”); *Pennsylvania*, 351
11 F.3d at 828 (finding irreparable harm where “[d]isruptions in contraceptive
12 coverage will lead to women suffering unintended pregnancies and other medical
13 consequences”).

14 The unnecessary restrictions the 2023 REMS places on mifepristone are
15 harming the States by aggravating the ongoing crisis of reduced access to
16 abortion care. Dillon Decl. ¶¶ 4–14, 23; Colwill Decl. ¶ 39. More than half of all
17 abortions in Washington in 2021—59%—were medication abortions using
18 mifepristone. Rolland Decl. ¶ 6. Mifepristone is also widely used for the medical
19 management of miscarriage. Prager Decl. ¶¶ 4, 7, 9, 15; Shih Decl. ¶ 13. But the
20 2023 REMS has hindered providers from prescribing, pharmacies from
21 dispensing, and patients from obtaining this critical drug—stymieing the States’
22 efforts to adhere to best practices in patient care and diminishing the health and

1 safety of our residents. Prager Decl. ¶ 37–40; Shih Decl. ¶ 20–28; Janiak Decl.
2 ¶ 17–23; Downing Decl. ¶¶ 9–17; Henry Decl. ¶¶ 6–8; Lazarus Decl. ¶¶ 16–20.

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

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

7 **D. The Equities and Public Interest Weigh Strongly in the States’ Favor**

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

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

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

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

12 IV. CONCLUSION

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

18 DATED this 24th day of February 2023.

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**Application for pro hac vice admission
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**Application for pro hac vice admission
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**Applications for pro hac vice admission
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**Application for pro hac vice admission
forthcoming*

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**Application for pro hac vice admission
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**Application for pro hac vice admission
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**Application for pro hac vice admission forthcoming*

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**Application for pro hac vice admission
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**Application for pro hac vice admission
forthcoming*

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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

