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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON

STATE OF WASHINGTON, et al.,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, et al.,

Defendants.

NO. 1:23-cv-03026-TOR

PLAINTIFF STATES' REPLY IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION

03/28/2023
With Oral Argument: 8:30 a.m.
Spokane Courtroom 902

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TABLE OF CONTENTS

I. INTRODUCTION 1

II. ARGUMENT 2

A. The Plaintiff States Are Likely to Succeed on the Merits 2

1. This challenge is ripe for judicial review 2

2. The States have established standing 5

3. The 2023 REMS is contrary to the REMS statute 9

4. The 2023 REMS is blatantly arbitrary and capricious 10

B. The Plaintiff States Are Irreparably Harmed 13

C. The Public Interest and Equities Favor Enjoining the REMS 15

D. Plaintiffs' Requested Relief Matches the Harm Shown: Eliminating Unnecessary Restrictions on Mifepristone in the Plaintiff States 16

III. CONCLUSION 17

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1 ## I. INTRODUCTION

2 FDA's response brief, like its decision to continue imposing REMS on
3 mifepristone, ignores the facts and the law. Correcting those errors makes clear
4 that the REMS are unlawful and should immediately be enjoined.

5 FDA first claims that the Plaintiff States cannot sue because they failed to
6 exhaust administrative remedies, but the Plaintiff States and many others have
7 repeatedly asked FDA to eliminate the mifepristone REMS, and FDA has serially
8 refused. These claims are amply exhausted.

9 FDA next asserts that the States can show no irreparable harm from the
10 REMS and no standing, but this ignores the well-documented financial costs
11 States are incurring to comply, and the irrefutable harms the REMS impose on
12 patients and State providers. Astonishingly, FDA's brief never mentions *Dobbs*,
13 which allowed states to criminalize abortion, led to an influx of out-of-state
14 patients coming to the Plaintiff States for care, and created grave new legal risks
15 for abortion patients and providers—risks that the REMS exacerbate. The States
16 and Court cannot ignore these harms, even if FDA might rather.

17 Finally, FDA claims that the REMS is lawful because FDA lacks evidence
18 that mifepristone is safe without the REMS. But this ignores the scientific
19 evidence and the legal standard FDA must apply. FDA imposes no similar
20 restrictions on vastly more dangerous drugs, or even on a higher dose of
21 mifepristone not used for abortion. The agency's actions are unlawful and
22 arbitrary, and the States have satisfied the standard for preliminary relief.

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II. ARGUMENT

A. The Plaintiff States Are Likely to Succeed on the Merits

1. This challenge is ripe for judicial review

The States' arguments that the mifepristone REMS is unsound, unsupported, and harmful have been serially raised to, and rejected by, FDA. These issues have been amply exhausted, and further petitioning would be futile.

The evidence demonstrating exhaustion is overwhelming. Most recently, the 2022 citizen petition submitted by ACOG and dozens of other medical professional and healthcare access organizations asked FDA to eliminate the REMS as medically unnecessary and unduly burdensome for *all* uses of the drug—not just miscarriage management. *See* Hughes Decl. Ex. A at 12–17; *contra* Resp. at 17. The petition made the same arguments the Plaintiff States make here, including citing the Canadian study and other evidence FDA now claims is "new." Hughes Decl. Ex. A at 17; ECF No. 35 ¶¶ 141 n.62, 143 n.66 (listing studies cited by ACOG petition); *contra* Resp. at 14, 25. Glaringly missing from FDA's argument is any suggestion that it would have reached a different decision if the States had joined ACOG's petition. And FDA cites no authority for the proposition that "plaintiffs in this case" must submit a new petition on the exact same subject. Resp. at 17. Its regulation instead requires the claims to "be the subject" of a petition. 21 C.F.R. § 10.45(b).[1]

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[1]Regardless, ACOG's membership includes over 90% of the nation's

1 The same issues were also raised repeatedly prior to 2022. FDA performed
2 a "full review" of the REMS in 2021 after being sued in federal court in Hawaii.
3 ECF No. 51-4 at 6. The 2021 review, prompted by litigation where FDA did not
4 even raise exhaustion, covered all the same points: the REMS, while medically
5 useless, trigger unnecessary costs and erect significant obstacles to patient care.
6 *See* Hughes Decl. Exs. B, C. Similarly, as FDA acknowledges (Resp. at 15–16),
7 fifteen Plaintiff States asked the FDA in 2020 to eliminate the REMS, identifying
8 the patient agreement and certification requirements as "onerous and medically
9 unnecessary"—but received only a form response. Hughes Decl. Ex. D at 2–3;
10 ECF No. 51-11. The States' letter there was part of a chorus of contemporaneous
11 letters and litigation urging FDA to abandon the REMS, just as the States urge
12 here. *See, e.g.*, ECF Nos. 1-9, 1-10, 1-12; Hughes Decl. Exs. B–M; *Am. Coll. of*
13 *Obstetricians & Gynecologists v. FDA*, 472 F. Supp. 3d 183 (D. Md. 2020).
14 These recent appeals to FDA occurred against the backdrop of the agency's
15 2016, full-scope review of the REMS (ECF No. 1-3), in which FDA ignored or
16 minimized the absence of evidence supporting the REMS, failed to consider
17 evidence of the burdens they impose in practice, and departed from its own
18 internal experts' recommendation (as the 2022 citizen petition pointed out).
19 Hughes Decl. Ex. A; ECF No. 35 ¶¶ 93–102; ECF No. 1-11 at 25 (unanimous
20

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21 OBGYNs, including several state-employee declarants in this case. Colwill Decl.
22 Ex. A; Nichols Decl. Ex. A; Prager Decl. Ex. A.

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1 conclusion of CDER clinical team). The 2016 review squarely considered the
2 same issues the States raise here, which were also presented earlier in 2016 and
3 twice in 2015. Schreiber Decl. ¶ 43; ECF No. 1-9; Hughes Decl. Exs. E, F; ECF
4 1-10 at 27. Simply put, if this record does not satisfy exhaustion, nothing does.
5 This record also demonstrates why raising the same issues yet again would
6 be futile, distinguishing this case from those on which FDA relies. Resp. at 15;
7 *see El Rescate Legal Servs., Inc. v. EOIR*, 959 F.2d 742, 747 (9th Cir. 1991)
8 ("[T]here is no requirement of exhaustion where resort to the agency would be
9 futile."); *McCarthy v. Madigan*, 503 U.S. 140, 146, 148–49 (1992) (futility
10 "weigh[s] heavily against requiring administrative exhaustion"). Here, it is clear
11 that FDA's position is "already set[.]" *El Rescate*, 959 F.2d at 747. On this point,
12 FDA asserts only that its form response to the States' 2020 letter did not, standing
13 alone, demonstrate futility. Resp. at 16 n.3. But this ignores FDA's rejection of
14 successive requests to eliminate the REMS—even from its own internal experts.
15 FDA claims this case involves "technical and factual assertions" that it has
16 had no opportunity to consider. Resp. at 14. This is wrong, as all three of FDA's
17 examples demonstrate. *First*, FDA complains about "studies that were not before
18 the agency at the time of" its December 2021 review. *Id.* at 14, 25. But as noted
19 above, FDA was able to consider these studies for purposes of the 2023 REMS,
20 because ACOG cited them in its 2022 petition. FDA "cannot credibly argue" that
21 *another* "formal application" from the States with identical information would
22 make any difference. *Chinook Indian Nation v. Zinke*, 326 F. Supp. 3d 1128, 1144

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1 (W.D. Wash. 2018). *Second*, FDA claims this lawsuit newly raises "safety
2 comparisons of mifepristone to other drugs[.]" Resp. at 14. But during its 2021
3 "full review" of the REMS, FDA considered information about comparator
4 drugs. ECF No. 51-5 at 7; Hughes Decl. Ex. B at 3. The States raised the same
5 issues in their 2020 letter to FDA. *Id.* Ex. D at 3 (noting mifepristone "is *four*
6 *times* safer than Viagra and *fourteen times* safer than carrying a pregnancy to
7 term"). *Third*, FDA claims this lawsuit newly raises "unique burdens" arising
8 from the REMS. Resp. at 14. But the mifepristone REMS have been unique since
9 the day they were implemented—no other drug has anything remotely like
10 them—and this point has been made ad nauseam to FDA. *See, e.g.*, Hughes Decl.
11 Ex. C at 41–42, 65–75, 86–87; *id.* Ex. A at 12–17; ECF No. 35 ¶¶ 96–98.

12 Finally, under well-established case law, exhaustion is not required in light
13 of the irreparable harm caused by the REMS amid an ongoing crisis of access to
14 reproductive health care. Mot. at 29–33; *see Bd. of Trs. of Constr. Laborers'*
15 *Pension Tr. for S. Cal. v. M.M. Sundt Constr. Co.*, 37 F.3d 1419, 1421 (9th Cir.
16 1994) (exhaustion excused where necessary to avoid irreparable harm).

17 **2. The States have established standing**

18 None of FDA's generalized objections to the States' standing erases the
19 clear harms the States are suffering and will suffer absent an injunction. In terms
20 of costs, while not disputing that procedural abortions and pregnancy care are
21 costlier than medication abortions, FDA argues the States "provide no evidence"
22 that the REMS causes increased numbers of surgical abortions. Resp. at 18–19.

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1 But the States' evidence shows just that. The REMS reduces the number of
2 providers of medication abortion, which delays treatment and makes some
3 patients ineligible for medication abortion altogether. Mot. at 10–11 (citing
4 multiple declarations and evidence incorporated into the complaint). This lack of
5 timely access to medication abortion forces some patients to choose either
6 procedural abortions or carrying unwanted pregnancies to term. *Id.* at 12–13, 27;
7 Nelson Decl. ¶ 13. This "causal chain" has exactly two links—hardly the sort of
8 leap that renders Plaintiffs' harms speculative. *Wash. Env't Council v. Bellon*,
9 732 F.3d 1131, 1141–42 (9th Cir. 2013) (citing cases); *see also City & Cnty. of*
10 *San Francisco v. U.S. Citizenship & Immigr. Servs.*, 981 F.3d 742, 754 (9th Cir.
11 2020) (finding alleged financial harm to states resulting from federal rule were
12 not speculative); *see also infra* II.B (discussing growth in abortion demand in the
13 Plaintiff States following the *Dobbs* decision).

14 Nor are the REMS like the "tax policy" at issue in *Simon v. E. Ky. Welfare*
15 *Rts. Org.*, 426 U.S. 26, 42–43 (1976). They are very real restrictions that directly
16 restrict providers and pharmacists—including the multiple declarants who
17 practice *as state employees*—from prescribing and dispensing mifepristone as
18 they do other medications. *See* ECF No. 4-1: Decls. of Colwill, DasGupta,
19 Godfrey, Henry, Hedenstrom, Schwartzkopf, Nichols, Prager, Shih. These
20 restrictions particularly impact patients in rural areas, causing some pregnant
21 patients in the Plaintiff States to "miss the very limited window in which to have
22 a safe and effective medication abortion," resulting in increased costs to the

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1 States. Godfrey Decl. ¶¶ 31–32. Because the REMS apply directly to State
2 employees, and "inflict[] a financial burden on the states" through their impacts
3 on patients, the States have standing. *See, e.g.*, *California v. Azar*, 911 F.3d 558,
4 571 (9th Cir. 2018) (states' allegation of economic harm sufficient to support
5 standing to challenge rule related to contraception coverage); *New York v. U.S.*
6 *Dep't of Agric.*, 454 F. Supp. 3d 297, 310 (S.D.N.Y. 2020) (states' allegation of
7 increased healthcare costs was sufficient injury for standing).

8 What is more, as the operators of facilities that prescribe and dispense
9 mifepristone, the States submitted evidence detailing how implementing the 2023
10 REMS has been a significant (and costly) undertaking. *See* Mot. at 30. FDA does
11 not dispute that such harm is sufficient to confer standing, but instead argues that
12 some of the steps necessary to implement the REMS "do not reflect burdens
13 imposed by the REMS itself." Resp. at 19. This argument reflects FDA's total
14 unwillingness to contend with the way the REMS operates *in the real world*. FDA
15 argues, for instance, that changes to and testing of information technology (IT)
16 systems is not a REMS requirement. *Id.* at 19–20. But of course it is. In a time of
17 electronic patient and medication records, state medical institutions and
18 pharmacies must obviously undertake IT work to implement and ensure
19 compliance with the REMS; indeed, FDA has pointed to telehealth as a reason
20 why the REMS is supposedly *not burdensome*. ECF No. 51-4 at 38, note w.
21 FDA's failure to so much as consider or account for IT burdens does not mean
22 that they do not exist. And even if IT work were not necessary to comply, FDA

1 does not dispute that the numerous other burdensome tasks being undertaken by
2 state institutions—including identifying providers who would like to become
3 REMS-certified; ensuring provider certifications are completed and provided to
4 certified pharmacies; developing secure systems to store lists of certified
5 prescribers; and training pharmacy staff on REMS requirements—*are* necessary
6 to comply. *See, e.g.*, ECF No. 4-1: Prager Decl. ¶¶ 32–37; Shih Decl. ¶¶ 15–19;
7 Reed Decl. ¶¶ 3–17; Godfrey Decl. ¶¶ 34–35; DasGupta Decl. ¶¶ 15–18. These
8 expensive burdens establish standing.

9 FDA further argues that the States lack *parens patriae* standing because, it
10 claims, only the United States acts as *parens* vis-à-vis individuals' relations with
11 the federal government. But this court has rejected such a "blanket prohibition."
12 *Washington v. U.S. Dep't of Homeland Sec.*, 598 F. Supp. 3d 1051, 1061 (E.D.
13 Wash. 2020). This is particularly true when state residents' health is involved.
14 *See New York v. Biden*, ---F.3d---, 2022 WL 5241880, at *7 (D.D.C. Oct. 6, 2022)
15 (rejecting argument that states cannot bring *parens* claims against federal
16 government where state jurisdictions' public health was at issue).

17 Lastly, FDA argues that a preliminary injunction would not redress the
18 States' injuries because the 2023 REMS is less restrictive than prior REMS. Resp.
19 20–21. But the Plaintiff States seek to enjoin the application of *any* REMS, such
20 that mifepristone can be prescribed just like the 20,000+ other drugs that don't
21 have one. Because an injunction "could reduce or eliminate those regulatory
22 restrictions, causation and redressability are satisfied." *Barnum Timber Co. v.*

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U.S. E.P.A., 633 F.3d 894, 901 (9th Cir. 2011).

3. The 2023 REMS is contrary to the REMS statute

FDA begins with the premise that it is owed near-total deference, but no deference is owed when the agency violates its governing statute and fails to meet the standards Congress prescribed. The FDCA authorizes ETASU only when they are "commensurate with" a "specific serious risk" such as "death" or "hospitalization." 21 U.S.C. §§ 355-1(f)(2)(A), (f)(1)(A), (b)(4)(A). FDA may implement ETASU only for drugs so "inherent[ly] toxic[] or potential[ly] harmful[]" that—as a medical or scientific matter—FDA otherwise could not approve them. *Id.* (f)(1). FDA does not even cite this statutory language in its brief, and certainly makes no effort to meet it. Nor could it, when all the data shows that mifepristone is among the safest drugs in the world, and safer than the vast majority of drugs for which FDA has never attempted to impose a REMS.

FDA's response—that it "has found mifepristone to be safe *with* the REMS requirements" (Resp. at 24)—is a tautology. A safe drug without REMS will *always* be a safe drug with REMS. A safe drug is a safe drug. FDA cannot rely on the REMS to prove the REMS is necessary. And FDA cannot credibly claim a REMS is justified for mifepristone when it has approved a higher dose of the same drug—Korlym—without a REMS. FDA's response that Korlym is used to treat a different condition (Resp. at 24–25) only proves Plaintiffs' point. The ETASU provisions require "inherent toxicity or potential harmfulness" of a "drug" itself. 21 U.S.C. § 355-1(f)(1). FDA may not apply a heightened standard

1 when a drug is used for abortion, but not other purposes. *Cf. Bracco Diagnostics,*
2 *Inc. v. Shalala*, 963 F. Supp. 20, 28 (D.D.C. 1997) ("The disparate treatment of
3 functionally indistinguishable products is the essence of the meaning of arbitrary
4 and capricious."); *Tummino v. Hamburg*, 936 F. Supp. 2d 162, 169 (E.D.N.Y.
5 2013) ("The standards are the same for aspirin and for contraceptives."). Because
6 mifepristone does not meet the requirements of the REMS statute, the 2023
7 REMS is invalid as a matter of law.

8 **4. The 2023 REMS is blatantly arbitrary and capricious**

9 All agencies—including FDA—must engage in "reasoned decision-
10 making." *Cigar Ass'n of Am. v. FDA*, No. 16-cv-01460 (APM), 2022 WL
11 2438512, at *7 (D.D.C. Jul. 5, 2022). Courts have overruled FDA's actions when
12 the agency has, for example, failed to consider relevant evidence, *id.*; held
13 comparable drugs to different standards, *Braeburn Inc. v. FDA*, 389 F. Supp. 3d
14 1, 28–32 (D.D.C. 2019); failed to consider statutory requirements or how a drug
15 would likely be used in the real world, *Bayer HealthCare, LLC v. FDA*, 942 F.
16 Supp. 2d 17, 24–25 (D.D.C. 2013); or imposed restrictions that were
17 "unnecessary" based on the evidence before the agency, *ACOG*, 472 F. Supp. 3d
18 at 223 (quotation omitted).

19 All of those things happened here. Most glaringly, the 2021 review that
20 FDA holds up as evidence of its expertise does not mention—even once—the
21 statutory requirement that a REMS only be imposed for medications associated
22 with a "serious adverse drug experience" like hospitalization or death. 21 U.S.C.

1 § 355-1(f)(1)(A). Nor does FDA ever once consider the REMS' impacts on
2 "patients in rural or medically underserved areas," even though it is statutorily
3 required to do so. *Id.* §§ 355-1(f)(2)(C)–(D). Indeed, FDA expressly "excluded"
4 from its consideration "the logistics of accessing abortion care," including "time
5 to appointment or the distance traveled to obtain care." ECF No. 51-4 at 12–13.
6 "[B]ecause the agency neglected to consider [these] statutorily mandated
7 factor[s]," and provided no evidence-backed analysis, its decision was arbitrary
8 and capricious. *Pub. Citizen v. Fed. Motor Carrier Safety Admin.*, 374 F.3d 1209,
9 1216 (D.C. Cir. 2004).

10 FDA also disregarded evidence that undermines the REMS. *See, e.g.*, ECF
11 No. 51-4 at 22 (dismissing, without discussion, evidence finding "no adverse
12 events" from dispensing by "non-certified healthcare providers"); ECF No. 35
13 ¶¶ 143–44 (FDA summarily dismissed Canadian study showing no increase in
14 adverse events after removal of REMS-like restrictions). "Where, as here, an
15 agency speaks in absolute terms that there is no evidence, it acts arbitrarily and
16 capriciously when there is in fact pertinent record evidence and the agency
17 ignores or overlooks it." *Cigar Ass'n of Am.*, 2022 WL 2438512, at *7.

18 FDA also ignored evidence about *why* mifepristone is safe. Its safety is
19 inherent *in the drug itself*, not because of the REMS:

20 > Mifepristone's chemical structure itself supports the conclusion that
21 > mifepristone is extremely safe. It is chemically similar to
> norethindrone, which was the original progestin formulation used in
> early oral contraceptive pills and which is still widely used today.
22 > Because it is so similar in structure to a widely used progestin,

1 mifepristone is unlikely to be toxic to patients.
2 Schreiber Decl. ¶ 22. FDA knows mifepristone is fundamentally safe without a
3 REMS: it approved Korlym without one. But when it came to mifepristone for
4 abortion, FDA not only failed to consider evidence of its inherent safety, it
5 expressly "excluded" such evidence from its review. ECF No. 51-4 at 12–13
6 (FDA's analysis "excluded . . . [i]nformation pertinent to molecular or other
7 basic science aspects of mifepristone").
8 Lastly, FDA wholly failed to consider the patient harms caused by the
9 REMS. *See Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins.*
10 *Co.*, 463 U.S. 29, 43 (1983) (agency action is "arbitrary and capricious if the
11 agency . . . entirely failed to consider an important aspect of the problem"). There
12 is, for example, no discussion whatsoever in FDA's 2021 memo about the REMS
13 reducing medication abortion's availability or deterring providers. Rather, the
14 memo makes clear that FDA *decided to disregard* studies showing the REMS
15 acts as a barrier to patient care. ECF No. 51-4 at 12 (noting that FDA's analysis
16 "excluded" . . . "[i]nformation from survey studies or qualitative studies that
17 evaluated perspectives on and/or satisfaction with medical abortion procedures
18 from patients, pharmacists, clinic staff, or providers, even if the study assessed
19 REMS ETASUs"). Indeed, FDA explicitly excluded one of the studies it now
20 faults the States for not bringing to its attention via a citizen petition. *Id.* at 49
21 (noting that FDA disregarded Calloway D et al. Contraception 2021; 104(1): 24–
22 28 because it "[p]rimarily addresses provider stigma around abortion care").

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1 FDA cannot cherry-pick evidence to justify singling out an extremely safe
2 drug for disfavored treatment. Its decision to do so was arbitrary and capricious.

3 **B. The Plaintiff States Are Irreparably Harmed**

4 FDA does not provide a single witness declaration in support of its
5 response, and offers no rebuttal to the hundreds of pages of declarations attesting
6 to the harms suffered by the States and their residents as a result of the 2023
7 REMS, *see* Mot. at 26–31. Instead, FDA argues that the States should have
8 challenged an earlier version of the REMS. Resp. at 27.

9 This argument completely ignores the unprecedented crisis in abortion
10 access following *Dobbs*. The harms caused by the 2023 REMS must be analyzed
11 in this context, which Defendant Becerra himself described as "a moment of
12 crisis in health care." Hughes Decl. Ex. G. Since *Dobbs*, the States have
13 experienced a tidal wave of out-of-state patients seeking abortions. ECF No. 4-1:
14 Cantrell Decl. ¶¶ 5, 7; Dillon Decl. ¶¶ 8–13; *see also* Nelson Decl. ¶ 10. For
15 example, in January 2023, Planned Parenthood of Greater Washington and
16 Northern Idaho saw a ***75% increase*** in Idaho patients, compared with January
17 2022, including a "***90% increase*** for medication abortion visits from Idaho."
18 Dillon Decl. ¶ 10 (emphasis added). This increased patient volume has led to
19 delays in abortion care and other consequences, including higher risks of
20 complications, increased costs, and unnecessary trauma and stress for patients, as
21 well as increasing burdens on an already overtaxed healthcare system. *Id.* ¶¶ 14–
22 22; Godfrey Decl. ¶¶ 28, 31. FDA concedes all of this. [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), ECF No. 28 at 48–49.

The 2023 REMS exacerbates these growing harms. On top of the challenges caused by increased patient volumes from anti-abortion states, the REMS restrictions themselves make mifepristone harder to prescribe, dispense, and obtain. ECF No. 4-1: Gold Decl. ¶¶ 15–16, 27; Godfrey Decl. ¶¶ 17–22; Shih Decl. ¶¶ 21–29; Colwill Decl. ¶¶ 18–25; Nichols Decl. ¶ 38; Janiak Decl. ¶¶ 15–20; Downing Decl. ¶¶ 9–16; Henry Decl. ¶¶ 6–8; Lazarus Decl. ¶¶ 17–20; ECF No. 35 ¶¶ 136–138. There are no two ways about it: delayed treatment causes patients to miss the narrow window for medication abortion altogether, resulting in more-expensive procedural abortion or maternity care. Mot. at 24–33; Dillon Decl. ¶¶ 18, 14; Godfrey Decl. ¶ 30; Shih Decl. ¶ 27. All of this imposes unrecoverable costs on the States, an irreparable harm.

As FDA also well knows, the post-*Dobbs* environment is a minefield of risks for abortion patients and providers. As medical expert Marji Gold, M.D., explains, post-*Dobbs* legislation in anti-abortion states works in concert with the 2023 REMS to limit access to abortion even in the Plaintiff States:

> In the current hostile environment surrounding abortion care, which includes states passing bills that empower ordinary citizens to sue anyone they deem has "aided and abetted" a person seeking an abortion, clinicians may be reluctant to become certified and thus be identified as a person who prescribes mifepristone. Since the REMS requires certified prescribers to send their signed forms to *each* certified pharmacy at which they intend to prescribe, clinicians who wish to provide this care have reason to be concerned that an anti-abortion staff or pharmacist at a pharmacy might leak the

confidential list and expose them to possible violence and/or civil or criminal liability.

Gold Decl. ¶ 18; *see also* Prager Decl. ¶¶ 38–40; Shih Decl. ¶¶ 23–25. Effects of the REMS were vastly different pre-*Dobbs*, when abortion was a constitutional right nationwide. But by re-imposing the REMS post-*Dobbs*, FDA compounded the very access problems Secretary Becerra committed to ameliorating.

FDA's argument that the Plaintiff States "delay[ed] in seeking relief" fares no better. Resp. at 27–29. While some state healthcare institutions began taking steps prior to January 2023 to prepare for what they expected to be contained in the forthcoming REMS, Defendants' public statements post-*Dobbs* signaled that they might finally follow the medical science, comply with their statutory obligation to reduce burdens on access, and get rid of the REMS once and for all. Secretary Becerra insisted that FDA would take steps to *protect* mifepristone access, noting: "*Working to increase access to this drug is a national imperative and in the public interest*." Hughes Decl. Ex. G. It was not until FDA took final agency action on January 3, 2023, that the States knew the agency had nevertheless decided to continue to restrict access to mifepristone. Taking seven weeks to assemble a multi-state coalition and gather evidence following this final agency action hardly evinces a "lack of urgency," Resp. at 29—and does nothing to negate the States' mountain of evidence demonstrating irreparable harm.

C. The Public Interest and Equities Favor Enjoining the REMS

The REMS restrict access to abortion at a time when abortion rights are

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1 under unprecedented attack. Tellingly, Defendants are silent on the effect of an
2 injunction on patients. Rather, they rely entirely on self-preservation concerns
3 about the need to "defer[] to FDA's judgments." Resp. at 30. But that rationale
4 for deference evaporates here, where FDA has acted contrary to law and abused
5 its discretion by re-imposing arbitrary and unfounded restrictions on medication
6 abortion. The public interest and equities weigh strongly in the States' favor.

7 **D. Plaintiffs' Requested Relief Matches the Harm Shown: Eliminating Unnecessary Restrictions on Mifepristone in the Plaintiff States**

8 Defendants argue that an injunction prohibiting them from reducing
9 mifepristone's availability is "untethered to any actual claim for relief[.]" Resp.
10 at 31–34. But the States prayed for exactly this relief, ECF No. 35 ¶¶ IX(a), (e),
11 which is a necessary condition precedent to their request that FDA remove the
12 REMS so that access to mifepristone can be expanded, *id.* ¶¶ IX(b)–(d). Both
13 components of relief are plainly necessary. Given the irreparable harm Plaintiffs
14 have shown from the REMS, it would *a fortiori* unleash devastating harm if
15 Defendants were permitted to restrict mifepristone yet further, for example by re-
16 implementing previous REMS or withdrawing the drug from the market. Under
17 these circumstances, the *minimum* relief Plaintiffs require is an order "freez[ing]
18 the positions of the parties"—here, mifepristone's current baseline of availability
19 in the Plaintiff States—"until the court can hear the case on the merits." *Heckler*
20 *v. Lopez*, 463 U.S. 1328, 1333 (1983). Such an order can, and should, enjoin
21 Defendants from "chang[ing] this status quo" until the case concludes. *Ariz.*
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Dream Act Coal. v. Brewer, 757 F.3d 1053, 1061 (9th Cir. 2014).[2]

Nor do the Plaintiff States' requests violate Rule 65(d)'s specificity requirement. "[T]he scope of an injunction or restraining order may be broad but at the same time be drafted in a manner that is not vague . . . There is no inherent inconsistency between the two characteristics." 11A Charles A. Wright & Arthur R. Miller, *Fed. Prac. & Proc. Civ.* § 2955 (3d ed. 2022). Here, Plaintiffs request a specific order enjoining Defendants from doing two things: (1) enforcing the 2023 REMS, and (2) changing the status quo to make mifepristone less available in the Plaintiff States. Injunctions of similar specificity have been entered against FDA before, and this Court should enter one here. *See, e.g.*, *Cook v. FDA*, 733 F.3d 1, 5 (D.D.C. 2013) (affirming injunction against FDA's "permitting the entry of, or releasing any future shipments of" drugs used for lethal injection); *Bracco Diagnostics*, 963 F. Supp. at 31 ("enjoin[ing] the FDA from proceeding with any approval or review proceedings relating to any of plaintiffs' products" until FDA had responded to citizen review petition).

III. CONCLUSION

The Plaintiff States' motion for a preliminary injunction should be granted.

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[2]Defendants' strained hypothetical about contaminated drugs, Resp. at 33–34, is irrelevant. Plaintiffs seek an order preserving the status quo. Contaminated drugs are already illegal under the status quo. 21 U.S.C. §§ 331(a), (c).

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**Applications for pro hac vice admission forthcoming*

CERTIFICATE OF SERVICE

I hereby certify that on March 24, 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.

DATED this 24th day of March 2023, at Seattle, Washington.

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