No. 23-35294

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

UNITED STATES OF AMERICA ET AL.,
Plaintiff-Appellee,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, ET AL.,
Defendant-Appellees,

v.

STATE OF IDAHO, ET AL.
Movants-Appellants.

On Appeal from the United States District Court
for the Eastern District of Washington

No. 1:23-cv-03026-TOR
The Honorable Thomas O. Rice

MOVANTS-APPELLANTS' EXCERPTS OF RECORD INDEX VOLUME

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CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing Index Volume and Excerpts of Record Volumes 1–3 on this date with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit using the Appellate Electronic Filing system.

Description of Documents: State of Idaho's Excerpts of Record

s/ *Joshua N. Turner* August 9, 2023

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UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF WASHINGTON

STATE OF WASHINGTON, STATE OF OREGON, STATE OF ARIZONA, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, STATE OF ILLINOIS, ATTORNEY GENERAL OF MICHIGAN, STATE OF NEVADA, STATE OF NEW MEXICO, STATE OF RHODE ISLAND, STATE OF VERMONT, DISTRICT OF COLUMBIA, STATE OF HAWAII, STATE OF MAINE, STATE OF MARYLAND, STATE OF MINNESOTA, and COMMONWEALTH OF PENNSYVLANIA,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, ROBERT M. CALIFF, in his official capacity as Commissioner of Food and Drugs, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, and XAVIER BECERRA, in his official capacity as Secretary of the Department of Health and Human Services,

NO. 1:23-CV-3026-TOR

ORDER DENYING MOTION TO INTERVENE

Defendants.

BEFORE THE COURT are Proposed State Plaintiff-Intervenors' Motion to Intervene (ECF No. 76), Motion to Appear Pro Hac Vice re Attorney: Joshua N. Turner (ECF No. 77), Motion to Appear Pro Hac Vice re Attorney: Peter M. Torstensen, Jr. (ECF No. 79), Motion to Appear Pro Hac Vice re Attorney: Thomas T. Hydrick (ECF No. 85), Motion to Appear Pro Hac Vice re Attorney: Eric H. Wessan (ECF No. 87), Motion to Appear Pro Hac Vice re Attorney: Leif A. Olson (ECF No. 88),and Motion to Appear Pro Hac Vice re Attorney: Christopher A. Bates (ECF No. 89). These motions were submitted for consideration without oral argument. The Court has reviewed the record and files herein, the completed briefing, and is fully informed.

BACKGROUND

On March 3, 2023, Plaintiffs filed an Amended Complaint, seeking the following relief: (1) "Declare … that mifepristone is safe and effective and that Defendants' approval of mifepristone is lawful and valid;" (2) "Declare … that the mifepristone REMS violated the Administrative Procedures Act;" (3) "Declare … that the mifepristone REMS violated the United States Constitution;" (4) "Enjoin Defendants … from enforcing or applying the mifepristone REMS;" (5) "Enjoin Defendants … from taking any action to remove mifepristone from the market or

reduce its availability;" and (6) "Award such additional relief as the interests of justice may require." ECF No. 35 at 90.

On March 30, 2023, the Proposed State Plaintiff-Intervenors ("State Intervenors") filed the present Motion to Intervene, seeking to intervene as a matter of right, or alternatively, through permissive intervention. *See* ECF No. 76. State Intervenors seek to file a Complaint, claiming the following relief: (1) "Adjudge and declare … that the FDA's final agency action on January 3, 2023 modifying the mifepristone REMS violated the notice-and-comment requirements under the Administrative Procedure Act[;]" (2) "Adjudge and declare … that the FDA's final agency action on January 3, 2023 modifying the mifepristone REMS is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law under the Administrative Procedure Act;" (3) "Adjudge and declare … that the FDA's final agency action on January 3, 2023 modifying the mifepristone REMS exceeds the statutory authority granted to the FDA under the FDCA;" (4) "Enjoin Defendants … from enforcing or applying the January 3, 2023 mifepristone REMS;" (5) "Vacate the FDA's January 3, 2023 final agency action;" and (6) "Award [State Intervenors] such additional relief as the Court may deem just, proper, and necessary, including their attorneys' fees and costs associated with this litigation." ECF No. 76-1 at 20.

On April 7, 2023, this Court preliminarily enjoined Defendants from altering the status quo and rights as it relates to the availability of Mifepristone under the current operative January 2023 Risk Evaluation and Mitigation Strategy under 21 U.S.C. § 355-1 in Plaintiff States and the District of Columbia. ECF Nos. 80, 91.

Following this Court's preliminary injunction, the State Intervenors filed a Motion to Expedite the Court's consideration of the Motion to Intervene, which the Court granted. ECF Nos. 90, 96. Both parties oppose the Motion to Intervene. ECF Nos. 92, 93. State Intervenors timely filed a reply. ECF No. 103.

DISCUSSION

I. Intervention as of Right

"On timely motion, the court must permit anyone to intervene who… claims an interest relating to the property or transaction that is the subject of the action, and is so situated that disposing of the action may as a practical matter impair or impede the movant's ability to protect its interest, unless existing parties adequately represent that interest." Fed. R. Civ. P. 24(a)(2). Thus, the applicant seeking to intervene must show (1) timeliness, (2) a significantly protectable interest relating to the subject of the action, (3) that interest is subject to impairment by disposition of the case, and (4) the interest is not adequately represented by the parties. *W. Watersheds Project v. Haaland*, 22 F.4th 828, 835 (9th Cir. 2022). The requirements are interpreted broadly in favor of intervention and review "is guided

primarily by practical considerations, not technical distinctions." *Id.* (citation omitted). A failure to meet any element is fatal to mandatory intervention. *Perry v. Proposition 8 Official Proponents*, 587 F.3d 947, 950 (9th Cir. 2009).

"Whether an applicant for intervention as of right demonstrates sufficient interest in an action is a 'practical, threshold inquiry,' and '[n]o specific legal or equitable interest need be established.'" *Citizens for Balanced Use v. Montana Wilderness Ass'n*, 647 F.3d 893, 897 (9th Cir. 2011) (citation omitted). The interest must be "protectable under some law" with a "relationship between the legally protected interest and the claims at issue." *Id.* A relationship exists "if the resolution of the plaintiff's claims actually will affect the applicant." *Donnelly v. Glickman*, 159 F.3d 405, 410 (9th Cir. 1998) (citation omitted).

State Intervenors contend they have "significantly protectable interests related to the FDA's decision to modify mifepristone's REMS." ECF No. 76 at 4. Specifically, (1) "eliminating mifepristone's in-person dispensing requirement will harm women residents of the State Intervenors"; (2) "FDA's action …. undermines the State Intervenors' ability to enforce their laws"' and (3) "FDA's action violates the Administrative Procedures Act[.]" ECF No. 76 at 4–5.

It is not enough that both groups assert APA claims against the FDA relating to the 2023 Mifepristone REMS Program. *Donnelly v. Glickman*, 159 F.3d 405, 409 (9th Cir. 1998). As a practical matter, State Intervenors' claims are not at

issue in this case. *See* ECF No. 76-1. State Intervenors challenge the 2023 REMS on the grounds that the in-person dispensing requirement should not have been removed. *See id.* The in-person dispensing requirement is not at issue in this case, and will neither be eliminated nor reinstated as a result of this litigation. Moreover, this case will not impair State Intervenors' ability to enforce their own state laws regulating medication abortion. *See Am. Coll. Of Obstetricians & Gynecologists v. United States Food & Drug Admin.*, 467 F. Supp. 3d 282, 289 (D. Md. 2020) ("[T]he resolution of this case will not eliminate any state's ability to continue to regulate medication abortion, as they choose, above and beyond the FDA's requirements.").

Therefore, resolution of this case will not affect State Intervenors' claims that FDA should have more restrictive limitations than the 2023 REMS nor will this litigation impede State Intervenors' own laws. State Intervenors do not have a "significant protectable interest" that has a sufficient relationship to the claims at issue in this case. On this ground alone, intervention as a matter of right fails.

II. Permissive Intervention

"On timely motion, the court may permit anyone to intervene who… has a claim or defense that shares with the main action a common question of law or fact." Fed. R. Civ. P. 24(b)(1)(B). Even if satisfied, district courts have discretion to deny permissive intervention. *Cooper v. Newsom*, 13 F.4th 857, 868 (9th Cir.

2021), *cert. denied sub nom. San Bernardino Cnty. Dist. Att'y v. Cooper*, 143 S. Ct. 287 (2022).

State Intervenors assert their "APA claims are grounded in the same facts and the same laws as the existing Plaintiffs' action." ECF No. 76 at 7. However, in practical application, this is not true. The question in this case is whether the January 2023 REMS violates the APA by imposing patient agreement form, provider certification, and pharmacy certification requirements. *See* ECF No. 35. The question State Intervenors pose is whether the January 2023 REMS violates the APA by *not* imposing an in-person dispensing requirement. *See* ECF No. 76-1. As a result, the Court finds there is no common question of law or fact within the meaning of Rule 24(b). Moreover, the addition of State Intervenors who allege claims and relief not at issue would cause additional delay in this complex litigation. *Cooper*, 13 F.4th at 868.

As a result, the Court declines to permit State Intervenors to intervene in this case. Fed. R. Civ. P. 24(b). As the above findings are dispositive, the Court declines to address the remaining arguments. State Intervenors' Motion is denied.

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ACCORDINGLY, IT IS HEREBY ORDERED:

1. Proposed State Plaintiff-Intervenors' Motion to Intervene (ECF No. 76) is **DENIED**.
2. Motion to Appear Pro Hac Vice re Attorney: Joshua N. Turner (ECF No. 77) is **GRANTED**.
3. Motion to Appear Pro Hac Vice re Attorney: Peter M. Torstensen, Jr. (ECF No. 79) is **GRANTED**.
4. Motion to Appear Pro Hac Vice re Attorney: Thomas T. Hydrick (ECF No. 85) is **GRANTED**.
5. Motion to Appear Pro Hac Vice re Attorney: Eric H. Wessan (ECF No. 87) is **GRANTED**.
6. Motion to Appear Pro Hac Vice re Attorney: Leif A. Olson (ECF No. 88) is **GRANTED**.
7. Motion to Appear Pro Hac Vice re Attorney: Christopher A. Bates (ECF No. 89) is **GRANTED**.

The District Court Executive is directed to enter this Order and furnish copies to counsel.

DATED April 21, 2023.

THOMAS O. RICE
United States District Judge

No. 23-35294

UNITED STATES COURT OF APPEALS
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MOVANTS-APPELLANTS' EXCERPTS OF RECORD VOLUME 2 OF 3

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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' RESPONSE TO MOTION TO INTERVENE

I. INTRODUCTION

Seven states with restrictive abortion laws and policies—Idaho, Iowa, Montana, Nebraska, South Carolina, Texas, and Utah (the "Proposed Intervenors")—seek to intervene in this action addressing FDA's regulation of mifepristone, in spite of the abundant evidence of the drug's safety and efficacy. But the Proposed Intervenors' asserted interest in enforcing their own state laws is entirely divorced from the claims and issues raised in this lawsuit. Instead, as the Proposed Intervenors candidly admit in their Motion to Expedite (ECF No. 90), their interest is in appealing an order this Court has already issued, on a motion in which they did not seek to participate.

That falls far short of the requirements of Rule 24. The Proposed Intervenors have no protectable interest here, because this challenge to federal agency action will not affect the Proposed Intervenors' laws or ability to regulate abortion within their borders. Nor is it necessary or appropriate to expand the scope of this lawsuit to include their claims seeking to restore a previous FDA restriction on mifepristone that is not the subject of this case, but is already the subject of separate litigation elsewhere. The sparse and conclusory Motion to Intervene fails to establish any of the factors warranting either mandatory or permissive intervention. The Motion should be denied.

II. ARGUMENT

A. There Is No Right to Mandatory Intervention

The Proposed Intervenors do not meet their burden of demonstrating any

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of the four mandatory intervention factors. *Cooper v. Newsom*, 13 F.4th 857, 864–65 (9th Cir. 2021). "Failure to satisfy any one of the requirements is fatal . . . ." *Perry v. Proposition 8 Official Proponents*, 587 F.3d 947, 950 (9th Cir. 2009).

1. The Proposed Intervenors do not have a significantly protectable interest in the claims at issue in this litigation

As a threshold matter, the Proposed Intervenors' assertion that "practical considerations" drive the "significantly protectable interest" analysis and broadly favor intervention, ECF No. 76 at 2, 4–5, is incorrect. The Ninth Circuit recently held that, notwithstanding its prior "liberal policy in favor of intervention," if the two "core," "irreducible" elements of Rule 24(a)(2)'s "significantly protectable interest" analysis are not satisfied, "a putative intervenor lacks *any* interest under Rule 24(a)(2), *full stop*." *Cal. Dep't of Toxic Substances Control v. Jim Dobbas, Inc.*, 54 F.4th 1078, 1088 (9th Cir. 2022) (emphasis added). The Proposed Intervenors cannot satisfy this standard.

At its "irreducible minimum," those two core elements are that: (1) "the asserted interest be protectable under some law," and (2) "there exists a relationship between the legally protected interest and the claims at issue." *Id.* at 1088 (cleaned up). Seeking to pursue a similar claim to the existing lawsuit is not enough; a putative intervenor must establish that resolution of the lawsuit "actually will affect" its legally protected interest. *Donnelly v. Glickman*, 159 F.3d 405, 409–11 (9th Cir. 1998). In *Donnelly*, intervention was denied where

female plaintiffs raised sex discrimination claims and the putative intervenors sought to raise similar claims against the same employer on behalf of men. *Id*. The court held that the male employees' claims were "unrelated" to the plaintiffs' "*particular* claims of 'hostile-work-environment' discrimination" because none of the plaintiffs' remedies—aimed at ending harassment of women—would directly or necessarily affect the putative intervenors' claimed interest in preventing discrimination against men. *Id*.

The same is true here. The Proposed Intervenors' claims solely concern FDA's elimination of a prior in-person dispensing requirement. But this lawsuit challenges different REMS restrictions (*i.e.*, the patient agreement form, provider certification, and pharmacy certification). *See* ECF No. 35 ¶¶ 1–8. The in-person dispensing requirement is not at issue in this case and will neither be eliminated nor reinstated as a result of this suit. For this reason alone, intervention should be denied. *Donnelly*, 159 F.3d at 409–10 (for intervention, "[i]t is not enough that both groups assert [similar] claims against the same defendants"); *Ctr. for Biological Diversity v. Lubchenco*, No. 09-04087 EDL, 2010 WL 1038398, at *2 (N.D. Cal. Mar. 19, 2010) (denying intervention where Alaska's claimed interests in wildlife management were not "sufficiently related to" whether federal agency erred in not listing ribbon seal as endangered species).

The Proposed Intervenors' invocation of their own state abortion laws and the "health and well-being" of their residents, ECF No. 76 at 4, does not alter this conclusion. First, their concerns about the "ability to enforce" their *more*

restrictive abortion laws are illogical. *Id.* The Plaintiff States do not challenge any of the Proposed Intervenors' laws on abortion, which impose additional restrictions beyond FDA's REMS. *See, e.g.*, ECF No. 76-1 ¶¶ 52, 73, 75; *see also infra* at 6. Accordingly, "resolution of this case would not impair those States' ability to enforce their own laws regulating mifepristone." *See Am. College of Obstetricians & Gynecologists (ACOG) v. FDA*, 467 F. Supp. 3d 282, 286 (D. Md. 2020) (denying intervention to ten states in action challenging FDA's in-person dispensing requirement).

Further, the Proposed Intervenors "have not submitted evidence to support their fears" of any harm to their residents based on the 2023 REMS, "other than [their] speculative beliefs." *Standard Heating & Air Conditioning Co. v. City of Minneapolis*, 137 F.3d 567, 571 (8th Cir. 1998) (denying intervention because interests were too speculative to be "direct, substantial and legally protectable"); *see also United States v. Alisal Water Corp.*, 370 F.3d 915, 919 (9th Cir. 2004) (speculative interests insufficient to support a right to intervention); *Donnelly*, 159 F.3d at 411. Moreover, a core premise of their assertion of harm is factually mistaken. They highlight the "23-year requirement" that mifepristone be "administered in person in a clinical setting." ECF No. 76-1 ¶ 61. But since 2016, the REMS has allowed patients to take mifepristone "at a location of [their]

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choice." *See ACOG*, 467 F. Supp. 3d at 285. The 2023 REMS did not alter this.[1]

In any event, because "this case will not eliminate any state's ability to continue to regulate medication abortion," the Proposed Intervenors' "broader policy interests . . . cannot serve as a basis for mandatory intervention." *ACOG*, 467 F. Supp. 3d at 289.

2. Disposition of this suit will not impair the Proposed Intervenors' regulation of abortion within their borders

Because the Proposed Intervenors have failed to demonstrate a significantly protectable interest in the claims at issue in this case, "there can be no impairment of the ability to protect it." *Am. Ass'n of People with Disabilities v. Herrera*, 257 F.R.D. 236, 252 (D.N.M. 2008); *see also United States v. Arizona*, 2010 WL 11470582, at *3 (D. Ariz. Oct. 28, 2010). But even if they had such an interest, they still fail to establish impairment.

Fundamentally, the claims in this lawsuit are factually and legally distinct from the claims the Proposed Intervenors seek to assert against removal of the in-person dispensing requirement. And even if they could show this case might *affect* their interests, they cannot prove *impairment* because they have "other means by which [they] may protect" those interests. *Alisal Water Corp.*, 370 F.3d at 921. As discussed above, a ruling in this case does not affect the Proposed

[1] For these same reasons, Proposed Intervenors lack standing. *Jim Dobbas*, 54 F.4th at 1085 (intervenors seeking relief "that is broader than or different from the relief sought by existing parties" must "possess constitutional standing").

Intervenors' abilities to regulate abortion within their borders. *Supra* at 4. Just as in *ACOG*, "Plaintiffs do not seek the invalidation of the States' abortion laws." *ACOG*, 467 F. Supp. 3d at 289. Notably, many of the Proposed Intervenors have already imposed their own state-law restrictions on medication abortion, including REMS-like requirements. *See, e.g.*, Neb. Rev. Stat. § 28-335(2) (requiring physicians to be physically present during medication abortions); Utah Code 76-7-302(4) ("An abortion may be performed only in an abortion clinic or a hospital . . . ."); Idaho Code § 18-622 (banning abortions except in extremely limited circumstances); Tex. Health & Safety Code §§ 245.002, 170A.002 (criminalizing the provision of nearly all abortions, including medication abortion). This lawsuit requests no relief related to those state laws.

Further, the Proposed Intervenors can assert their purported interests via their own lawsuit, rather than seeking to commandeer this one. *See United States v. City of Los Angeles*, 288 F.3d 391, 402 (9th Cir. 2002) (denying intervention where it was "doubtful" that police reform advocates' "interests are impaired by" order relating to LAPD constitutional violations because "[t]he litigation does not prevent any individual from initiating suit against LAPD officers who engage in unconstitutional practices"); *Mi Pueblo San Jose, Inc. v. City of Oakland*, C06-4094VRW, 2007 WL 578987, at *7 (N.D. Cal. Feb. 21, 2007) ("[I]ntervention is also improper because alternative forums exist for Asociacion to vindicate its asserted interests."); *California v. Health & Hum. Servs.*, 330 F.R.D. 248, 254 (N.D. Cal. 2019) ("[T]his action will not impede or impair [Oregon's] ability to

protect [its] interests, because Oregon could adequately protect those interests by filing a separate suit . . . ."). Indeed, a separate lawsuit addressing the in-person dispensing requirement's legality is being actively litigated in Texas. Compl., *All. for Hippocratic Med. v. FDA*, No. 2:22-cv-00223-Z (N.D. Tex.), ECF No. 1 ¶ 394. For this reason, the Proposed Intervenors' reliance on *California ex rel. Lockyer v. United States*, 450 F.3d 436, 443 (9th Cir. 2006), is misplaced because there, the court determined the proposed intervenors would have been barred from bringing "a separate suit where they could argue" their position. By contrast, because the Proposed Intervenors have other ways to pursue their legal interests (including seeking intervention in the Texas litigation), they cannot show that this case will impair any significant protectable interest.[2]

3. If the Proposed Intervenors have a protectable interest in this suit, FDA can adequately represent it

The Proposed Intervenors have failed to demonstrate that FDA does not adequately represent their interests as they pertain to this lawsuit. As made clear by the proposed complaint (ECF No. 76-1), their claims solely concern FDA's elimination of the in-person dispensing requirement, not the restrictions challenged by the Plaintiff States. Of course, any nonparty can assert that existing parties will not raise and prosecute new claims on its behalf—but that is not the

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[2] Proposed Intervenors have asserted no protectable interest that could be impaired by this Court's preliminary injunction, which in any event is limited by its terms to the Plaintiff States and does not apply to Proposed Intervenors.

purpose of Rule 24. *See Piedmont Paper Prods., Inc. v. Am. Fin. Corp.*, 89 F.R.D. 41, 43–44 (S.D. Ohio 1980) (denying intervention because, although no "defendants have any interest in asserting the counterclaims advanced by the applicant . . . [w]ith regard to defense of *this action*, the applicant seeks relief identical to that requested by the current defendants") (emphasis added).

Moreover, even if the Proposed Intervenors asserted an interest that could be impaired by the current litigation, FDA adequately represents it. FDA has every incentive and ability to defend its own decision on the REMS requirements challenged here, and indeed is vigorously doing so. *See* ECF No. 51 (FDA Opp'n to Mot. for Prelim. Injun.); *see, e.g.*, *Cedars-Sinai Med. Ctr. v. Shalala*, 125 F.3d 765, 768 (9th Cir. 1997); *Am. Fed'n of State, Cty. & Mun. Emps. Council 79 v. Scott*, 278 F.R.D. 664, 670 (S.D. Fla. 2011) ("The [proposed intervenor's] interests . . . are impaired only if the [Executive Order] is ruled unconstitutional. However, the [defendant] Governor . . . has every reason to defend this policy."). For this reason too, mandatory intervention is inappropriate.

4. The Motion to Intervene is untimely

Finally, the Proposed Intervenors' motion is untimely under the circumstances. *See Alisal Water Corp.*, 370 F.3d at 921 ("Timeliness is a flexible concept; its determination is left to the district court's discretion."); *League of United Latin Am. Citizens v. Wilson*, 131 F.3d 1297, 1303 (9th Cir. 1997) ("[T]he timeliness inquiry demands a more nuanced, pragmatic approach."). In particular, they seek expedited consideration based on the deadline for appealing this

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Court's preliminary injunction—an injunction that does not affect any legitimate interest of the Proposed Intervenors, as it is expressly limited to the eighteen Plaintiff States. ECF No. 90 at 2; Beneski Decl. Ex. A (confirming that Proposed Intervenors seek to be "included with respect to any appeal rights that may run from the court's grant of preliminary relief"). And yet, they did not move to intervene until *after* the preliminary injunction was fully briefed and argued.

B. Permissive Intervention Should Be Denied

Permissive intervention is "not intended to allow the creation of whole new lawsuits by the intervenors." *S. Cal. Edison Co. v. Lynch*, 307 F.3d 794, 804 (9th Cir. 2002), *modified*, 307 F.3d 943 (9th Cir. 2002) (cleaned up). Because intervention will vastly complicate this case without any benefit, this Court should reject the Proposed Intervenors' bid for permissive intervention as well.

First, there is no "common question of law or fact" between the existing lawsuit and the elimination of the in-person dispensing requirement such that intervention under Rule 24(b)(1)(B) is warranted. Although the Proposed Intervenors assert their claims are "grounded in the same facts and the same laws" as the Plaintiff States', ECF No. 76 at 7, permissive intervention is not an appropriate vehicle to bring tangentially related claims that would "unnecessarily expand[] the lawsuit" beyond its original scope. *Van Hoomissen v. Xerox Corp.*, 497 F.2d 180, 182 (9th Cir. 1974) (denying EEOC intervention to bring claims alleging discriminatory hiring practices in a retaliation lawsuit); *see also Cooper*, 13 F.4th at 868 (denying intervention by district attorneys seeking to enforce

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execution protocol where they did not draft the protocol and were not authorized to defend its constitutionality, the issue in the "main action").

Permitting the Proposed Intervenors to inject tangential claims will also unduly delay and increase the complexity of this litigation. Fed. R. Civ. P. 24(b)(3); *Perry*, 587 F.3d at 955–56. As the *ACOG* court recognized, "permissive intervention is [] not advisable because it would result in the injection of issues relating to numerous different state laws into a case that . . . focuses squarely on federal regulations." 467 F. Supp. at 292 ("intervention would require the Court to grapple with issues of the laws of ten different states"); *see* Dkt. 76-1 ¶¶ 55, 71, 80, 85, 90, 100 (alleging FDA's elimination of the in-person dispensing requirement upset reliance interests baked into their state laws). In short, this Court should deny the Proposed Intervenors' request that the Court manage two, unrelated cases under one, unwieldy docket number. *See Stringfellow v. Concerned Neighbors in Action*, 480 U.S. 370, 380, (1987) ("[A] . . . judge's decision on how best to balance the rights of the parties against the need to keep the litigation from becoming unmanageable is entitled to great deference."); *Montgomery v. Rumsfeld*, 572 F.2d 250, 255 (9th Cir. 1978) (affirming denial of permissive intervention that would "unnecessarily delay and complicate the case"). Accordingly, permissive intervention should be denied.

III. CONCLUSION

For the foregoing reasons, the Plaintiff States respectfully request that the Court deny Proposed Intervenors' Motion to Intervene.

DATED this 13th day of April, 2023.

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**Applications for pro hac vice admission forthcoming*

CERTIFICATE OF SERVICE

I hereby certify that on April 13, 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 13th day of April, 2023, at Seattle, Washington.

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

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF WASHINGTON

STATE OF WASHINGTON, STATE OF OREGON, STATE OF ARIZONA, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, STATE OF ILLINOIS, ATTORNEY GENERAL OF MICHIGAN, STATE OF NEVADA, STATE OF NEW MEXICO, STATE OF RHODE ISLAND, STATE OF VERMONT, DISTRICT OF COLUMBIA, STATE OF HAWAII, STATE OF MAINE, STATE OF MARYLAND, STATE OF MINNESOTA, and COMMONWEALTH OF PENNSYVLANIA, Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, ROBERT M. CALIFF, in his official capacity as Commissioner of Food and Drugs, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, and XAVIER	NO. 1:23-CV-3026-TOR ORDER GRANTING IN PART PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

BECERRA, in his official capacity as Secretary of the Department of Health and Human Services,

Defendants.

BEFORE THE COURT are Plaintiffs' Motion for Preliminary Injunction (ECF No. 3), Third Parties' Unopposed Motion for Leave to File Amicus Curiae Brief (ECF No. 52), and Third Parties' Unopposed Motion for Leave to File Amicus Brief (ECF No. 69). The Motion for Preliminary Injunction was submitted for consideration with oral argument on March 28, 2023. Kristin Beneski, Colleen M. Melody, and Noah G. Purcell appeared on behalf of Plaintiffs. Noah T. Katzen, Aravind Sreenath, and Molly Smith appeared on behalf of Defendants. The Court has reviewed the record and files herein, and is fully informed. For the reasons discussed below, Plaintiffs' Motion for Preliminary Injunction (ECF No. 3) is **granted in part**, Third Parties' Unopposed Motion for Leave to File Amicus Curiae Brief (ECF No. 52) is **denied**, and Third Parties' Unopposed Motion for Leave to File Amicus Brief (ECF No. 69) is **denied**.

BACKGROUND

This case concerns federal regulation of mifepristone used in connection with the termination of early pregnancy. ECF No. 35. Plaintiffs seek a preliminary injunction, asking this Court to "affirm[] "FDA's original conclusion that mifepristone is safe and effective, preserv[e] the status quo by enjoining any

actions by Defendants to remove this critical drug from the market, and enjoin[] the unnecessary and burdensome January 2023 restrictions." ECF No. 3 at 5. The parties timely filed their respective response and reply. ECF Nos. 51, 60. The following facts are generally undisputed for purposes of resolving the instant motion.

In 1992, Subpart H regulations authorized the Food and Drug Administration ("FDA") to require conditions "needed to assure safe use" for certain drugs. Final Rule, 57 Fed. Reg. 58,942, 58,958 (December 11, 1992) (codified at 21 C.FR. § 314.520). In September 2000, FDA approved mifepristone[1] under Subpart H, concluding that mifepristone is safe and effective for medical termination of intrauterine pregnancy through 49 days' gestation when used in a regimen with the already-approved drug, misoprostol. ECF No. 35 at 21, ¶ 85. FDA's restrictions on mifepristone included requiring (1) an in-person dispensing requirement where the drug could only be dispensed in a hospital, clinic, or medical office, by or under the supervision of a certified provider who at the time could only be a physician, (2) providers attest to their clinical abilities in a

[1] As referenced herein, mifepristone is the drug used for early termination of pregnancy, such as Mifeprex and the generic drug. This Order does not impact mifepristone as used in Korlym, a drug used to treat Cushing's syndrome.

signed form kept on file by the manufacturer, and agree to comply with reporting and other REMS requirements, and (3) prescribers and patients review and sign a form with information about the regimen and risks and that the prescriber provide copies to the patient and patient's medical record. *Id.* at 24, ¶ 87.

From 1992 to February 2002, seven New Drug Applications ("NDA"), including Mifeprex, were approved subject to these conditions, in contrast to the 961 NDAs with no additional restrictions from January 1993 to September 2005. ECF No. 35 at 24–25, ¶ 88.

The Food and Drug Administration Amendments Act of 2007 effectively replaced Subpart H with the REMS statute codified at 21 U.S.C. § 355-1. Pub. L. No. 110-85, tit. IX, § 901. All drugs previously approved under Subpart H, including Mifeprex, were deemed to have a REMS in place. Pub. L. No. 110-85, tit. IX, § 909(b). Under the Federal Food, Drug and Cosmetic Act ("FDCA"), a new drug cannot be marketed and prescribed until it undergoes a rigorous approval process to determine that it is safe and effective. 21 U.S.C. § 355.

In 2011, FDA issued a new REMS for Mifeprex incorporating the same restrictions under which the drug was approved eleven years earlier. *Id.*, ¶ 90; ECF No. 51-2. In 2013, FDA reviewed the existing REMS and reaffirmed the restrictions in place. ECF No. 35 at 25, ¶ 91.

In 2015, Mifeprex's manufacturer submitted a supplemental NDA proposing to update the label to reflect evidence-based practices across the country – namely, the use of 200 mg of mifepristone instead of 600 mg. *Id.*, ¶ 92. In July 2015, the manufacturer submitted its REMS assessment, proposing minor modifications. *Id.* This submission prompted a review of the Mifeprex label and REMS by FDA. *Id.* at 26, ¶ 93. As part of the review, FDA received letters from more than 40 medical experts, researches, advocacy groups, and professional associations who asked, *inter alia*, that the REMS be eliminated in their entirety. *Id.* One letter asked FDA to "[e]liminate the REMS and ETASU (Elements to Assure Safe Use), including eliminating the certification and patient agreement requirements. *Id.* at 27, ¶ 95.

In 2016, FDA found "no new safety concerns have arisen in recent years, and that the known serious risks occur rarely," and that "[g]iven that the number of … adverse events appear to be stable or decreased over time, it is likely that … serious adverse events will remain acceptably low." *Id.* at 30, ¶ 100. Following this review, FDA changed Mifeprex's indication, labeling, and REMS, including increasing the gestational age limit from 49 to 70 days, reducing the number of required in-person clinic visits to one, finding at-home administration of misoprostol safe, finding no significant differences in outcomes based on whether patients had a follow-up phone call or in person or based on the timing of those appointments, and allowing a broader set of healthcare providers to prescribe

mifepristone. *Id.*, ¶ 101. However, FDA still required that mifepristone be administered in a clinic setting. *Id.*

In 2019, FDA approved a different manufacturer's abbreviated NDA for a generic version of mifepristone and established the Mifepristone REMS Program, which covered both Mifeprex and the generic drug. *Id.* at 32, ¶ 103; ECF No. 51-3. In May 2020, American College of Obstetricians and Gynecologists ("ACOG") sued FDA, challenging the Mifepristone REMS Program's in-person dispensing requirement in light of the COVID-19 pandemic. ECF No. 35, ¶ 104. In that case, the district court temporarily enjoined FDA from enforcing the in-person dispensation requirements under the REMS in light of the COVID-19 pandemic. *American College of Obstetricians and Gynecologists v. United States Food and Drug Administration*, 47 2F. Supp. 3d 183 (D. Md. 2020).

In April 2021, FDA suspended the in-person dispensing requirement during the COVID-19 public health emergency because, during the six-month period in which the in-person dispensing requirement had been enjoined, the availability of mifepristone by mail showed no increases in serious patient safety concerns. *Id.*, ¶ 105.

On May 7, 2021, FDA announced it would review whether the Mifepristone REMS Program should be modified. ECF No. 51-4. FDA reviewed materials between March 29, 2016 and July 26, 2021, as well as publications found on

PubMed and Embase and those provided by "advocacy groups, individuals, plaintiffs in *Chelius v. Becerra*, 1:17-493-JAO-RT (D. Haw.), application holders, and healthcare providers and researchers. *Id.* at 10–11.

On December 16, 2021, FDA announced its conclusions regarding the Mifepristone REMS Program. ECF No. 51-5. On January 3, 2023, FDA accepted these conclusions by approving the supplemental applications proposing conforming modifications. ECF Nos. 51-8; 51-11. The 2023 REMS removed the in-person dispensing requirement and added a pharmacy-certification requirement. ECF Nos. 51-4, 51-5. The FDA maintained the Prescriber and Patient Agreement Form requirements. *Id.*

DISCUSSION

I. Preliminary Injunction Standard

Plaintiffs, on behalf of themselves and as *parens patriae* in protecting the health and well-being of its residents, moves for a preliminary injunction "affirming FDA's original conclusion that mifepristone is safe and effective, preserving the status quo by enjoining any actions by Defendants to remove this critical drug from the market, and enjoining the unnecessary and burdensome January 2023 restrictions." *See* ECF Nos. 3 at 5; 35.

Pursuant to Federal Rule of Civil Procedure 65, the Court may grant preliminary injunctive relief in order to prevent "immediate and irreparable

injury." Fed. R. Civ. P. 65(b)(1)(A). To obtain this relief, a plaintiff must demonstrate: (1) a likelihood of success on the merits; (2) a likelihood of irreparable injury in the absence of preliminary relief; (3) that a balancing of the hardships weighs in plaintiff's favor; and (4) that a preliminary injunction will advance the public interest. *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008); *M.R. v. Dreyfus*, 697 F.3d 706, 725 (9th Cir. 2012). Under the *Winter* test, a plaintiff must satisfy each element for injunctive relief.

Alternatively, the Ninth Circuit also permits a "sliding scale" approach under which an injunction may be issued if there are "serious questions going to the merits" and "the balance of hardships tips sharply in the plaintiff's favor," assuming the plaintiff also satisfies the two other *Winter* factors. *All. for the Wild Rockies v. Cottrell*, 632 F.3d 1127, 1131 (9th Cir. 2011) ("[A] stronger showing of one element may offset a weaker showing of another."); *see also Farris v. Seabrook*, 677 F.3d 858, 864 (9th Cir. 2012) ("We have also articulated an alternate formulation of the *Winter* test, under which serious questions going to the merits and a balance of hardships that tips sharply towards the plaintiff can support issuance of a preliminary injunction, so long as the plaintiff also shows that there is a likelihood of irreparable injury and that the injunction is in the public interest." (internal quotation marks and citation omitted)).

A preliminary injunction can either be prohibitory or mandatory. *Marlyn Nutraceuticals, Inc. v. Mucos Pharma GmbH & Co.*, 571 F.3d 873, 878 (9th Cir. 2009). A prohibitory injunction preserves the status quo which is the "last, uncontested status which preceded the pending controversy." *Id.* at 879. A mandatory injunction "orders a responsible party to take action." *Id.* at 878. Mandatory injunctions are disfavored and require a higher showing that the "facts and law clearly favor the moving party." *Garcia v. Google*, 786 F.3d 733, 740 (9th Cir. 2015).

Plaintiffs contend they are seeking a prohibitory injunction to maintain the "status quo." ECF Nos. 3, 78. Plaintiffs seek an "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." ECF No. 60 at 19. However, when addressing Defendants' argument that the 2023 REMS is less restrictive than any prior REMS, Plaintiffs contend they "seek to enjoin the application of *any* REMS, such that mifepristone can be prescribed just like the 20,000+ other drugs that don't have one." *Id.* at 10. At oral argument, Plaintiffs maintain they seek a prohibitory injunction.

The status quo, i.e., the last uncontested status preceding the pending controversy, were the REMS in place prior to the 2023 REMS. Considering the

conflicting requests, the Court will apply the prohibitory injunction standard to the extent Plaintiffs seek to maintain the status quo.

A. Likelihood of Success on the Merits

Plaintiffs assert they are likely to succeed on the success of the merits of the claim that the 2023 REMS violated the Administrative Procedures Act ("APA"). ECF No. 3 at 16–19. Defendants disagree and also contend that Plaintiffs lack standing and have not exhausted their administrative remedies. ECF No. 51.

1. Standing

Plaintiffs brings suit on behalf of themselves and as *parens patriae* in protecting the health and well-being of its residents. *See* ECF No. 35. Defendants argue Plaintiffs lack standing where the federal government is the ultimate *parens patriae* and the alleged economic interests are insufficient to establish standing. ECF No. 51.

The APA provides a cause of action to any "person … adversely affected or aggrieved by agency action." 5 U.S.C. § 702. A state qualifies as a "person" within the meaning of the APA. *See Maryland Dep't of Human Res. v. Dep't of Health & Human Servs.*, 763 F.2d 1441, 1445 n.1 (D.C. Cir. 1985). The APA allows a person to challenge agency action under various statutes. *See Block v. Cmty. Nutrition Inst.*, 467 U.S. 340, 345 (1984).

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a. *Parens Patriae* Suit

A *parens patriae* lawsuit allows a state to sue in a representative capacity on behalf of its citizens' interests. *Gov't of Manitoba v. Bernhardt*, 923 F.3d 173, 178 (D.C. Cir. 2019). In order to establish standing beyond Article III's minimum, the State must assert a quasi-sovereign interest "apart from the interests of particular private parties." *Alfred L. Snapp & Son, Inc. v. Puerto Rico, ex rel., Barez*, 458 U.S. 592, 607 (1982). A state has a quasi-sovereign interest "in the health and well-being – both physical and economic – of its residents" and "in not being discriminatorily denied its rightful status within the federal system." *Id.* at 607. Courts look to "whether the injury is one that the State, if it could, would likely attempt to address through its sovereign lawmaking powers." *Id.*

Under the *Mellon* bar, a state lacks standing as *parens patriae* to bring an action against the federal government. *Massachusetts v. Mellon*, 262 U.S. 447, 485–86 (1923). However, "courts must dispense with [the *Mellon* bar] if Congress so provides." *Maryland People's Couns. v. FERC*, 760 F.2d 318, 321 (D.C. Cir. 1985). "The cases on the standing of states to sue the federal government seem to depend on the kind of claim that the state advances. The decisions … are hard to reconcile." *Arizona State Legislature v. Arizona Indep. Redistricting Comm'n*, 576 U.S. 787, 802, n.10 (2015).

Courts have determined that the APA alone does not demonstrate congressional intent to authorize a state to sue the federal government as *parens patriae*. *See Bernhardt*, 923 F.3d at 181; *Am. Fed'n of Tchrs. v. Cardona*, No. 5:20-CV-00455-EJD, 2021 WL 4461187, at *5 (N.D. Cal. Sept. 29, 2021). However, states are not necessarily precluded from bringing a *parens patriae* suit against the federal government, including where the underlying statute forming the basis for the APA action authorizes a *parens patriae* suit. *See New York v. United States Dep't of Lab.*, 477 F. Supp. 3d 1, 9, n.6 (S.D.N.Y. 2020); *New York v. Biden*, No. 20-CV-2340(EGS), 2022 WL 5241880, at *7 (D.D.C. Oct. 6, 2022) (allowing *parens patriae* suit against federal government where "Plaintiffs' efforts to mitigate the spread of COVID-19 are aimed at protecting the public health of their respective jurisdictions as a whole."); *Louisiana v. Becerra*, No. 3:21-CV-04370, 2022 WL 4370448, at *5 (W.D. La. Sept. 21, 2022) (finding states have *parens patriae* and/or quasi-sovereign interest in APA claims on behalf of citizens).

Regardless of whether Plaintiffs have standing to assert claims on behalf of its citizens under the APA in this case, Plaintiffs allege direct injuries sufficient to confer standing. Therefore, the Court declines to resolve the *parens patriae* issue.

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b. Direct Suit

In a direct suit where a state seeks redress for its own injuries, the state must meet Article III's minimum requirements. *Bernhardt*, 923 F.3d at 178. A plaintiff "must allege that they have suffered, or will imminently suffer, a 'concrete and particularized' injury in fact." *City & Cnty. of San Francisco v. United States Citizenship & Immigr. Servs.*, 981 F.3d 742, 754 (9th Cir. 2020) (quoting *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992)).

Under the APA, a claimant must also establish that their interests are "arguably within the zone of interests to be protected or regulated by the statute." *Match-E-Be-Nash-She-Wish Band of Pottawatomi Indians v. Patchak*, 567 U.S. 209, 224 (2012) (quoting *Ass'n of Data Processing Serv. Orgs., Inc. v. Camp*, 397 U.S. 150, 153 (1970)). This test is not "especially demanding" and requires only that the interest is "sufficiently congruent with those of the intended beneficiaries that the litigants are not more likely to frustrate than to further the statutory objectives." *City & Cnty. of San Francisco*, 981 F.3d at 755 (citations omitted).

Plaintiffs assert the following direct harm: (1) unrecoverable costs on the States' Medicaid and other state-funded health care programs from increased surgical abortions and pregnancy care, (2) practice restrictions on providers and pharmacists, including state employees, and (3) unrecoverable costs in implementing systems to comply with the 2023 REMS' patient agreement and

licensure requirements. ECF Nos. 3 at 29–30; 60 at 7–10 (citations to the record omitted).

Plaintiffs have shown a reasonably probable threat to their economic interests in the form of unrecoverable costs that are fairly traceable to the 2023 REMS, which are allegedly in violation of the APA. *See California v. Azar*, 911 F.3d 558, 571–73 (9th Cir. 2018) (finding state had standing due to economic interests where state was responsible for reimbursing women who will seek contraceptive care through state-run programs). Therefore, Plaintiffs have established standing.

2. Administrative Exhaustion

Defendants contend Plaintiffs failed to exhaust their administrative remedies by not filing a citizen petition under the 2023 REMS. ECF No. 51 at 14–19. Plaintiffs maintain that a new citizen petition would be futile where FDA had the same information and arguments prior to the January 2023 REMS decision. ECF No. 60 at 4–7.

Under the APA, "[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof." 5 U.S.C. § 702. However, the APA requires a plaintiff to "exhaust available administrative remedies before bringing their grievances to federal court." *Idaho Sporting Congress, Inc. v.*

Rittenhouse, 305 F.3d 957, 965 (9th Cir. 2002) (citing 5 U.S.C. § 704). Administrative exhaustion allows "the administrative agency in question to exercise its expertise over the subject matter and to permit the agency an opportunity to correct any mistakes that may have occurred during the proceeding, thus avoiding unnecessary or premature judicial intervention into the administrative process." *Buckingham v. Secretary of U.S. Dept. of Agr.*, 603 F.3d 1073, 1080 (9th Cir. 2020) (internal citation omitted). While the APA does not mandate a process by which a plaintiff must exhaust remedies, the APA provides for exhaustion "to the extent that it is required by statute or by agency rule as a prerequisite to judicial review." *Darby v. Cisneros*, 509 U.S. 137, 153 (1993).

As relevant here, the FDA created a regulatory mechanism by which interested persons may challenge agency activities under the Food, Drug, and Cosmetic Act ("FDCA"). *See* 21 C.F.R. §§ 10.1(a), 10.25(a), 10.45(b). "An interested person may petition the Commissioner to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action …. in the form of a citizen petition." 21 C.F.R. § 10.25(a). "A request that the Commissioner take … administrative action must first be the subject of a final administrative decision based upon a petition submitted under § 10.25(a) … before any legal action is filed in a court complaining of the action or failure to act." 21 C.F.R. § 10.45(b). The purpose of administrative exhaustion is

to prevent "premature interference with agency processes, so that the agency may function efficiently and so that it may have an opportunity to correct its own errors, to afford the parties and the courts the benefit of its experience and expertise, and to compile a record which is adequate for judicial review." *Tamosaitis v. URS Inc.*, 781 F.3d 468, 478 (9th Cir. 2017).

Under exceptional circumstances, administrative exhaustion of an APA claim is not required. *See Anderson v. Babbitt*, 230 F.3d 1158, 1164 (9th Cir. 2000). Exceptional circumstances include where there is "objective and undisputed evidence" of administrative bias rendering pursuit of an administrative remedy futile. *Id.* (brackets omitted); *see also SAIF Corp./Oregon Ship v. Johnson*, 908 F.2d 1434, 1441 (9th Cir. 1990). Thus, where it appears the agency's position is "already set" and it is "very likely" what the result would be, such recourse is futile. *El Rescate Legal Servs., Inc. v. Exec. Off. of Immigr. Rev.*, 959 F.2d 742, 747 (9th Cir. 1991) (citation omitted); *see also Chinook Indian Nation v. Zinke*, 326 F. Supp. 3d 1128, 1144 (W.D. Wash. 2018) ("There is virtually no chance that requiring Plaintiffs to go through [agency's] formal request process will make any difference.").

In 2020, fifteen Plaintiff States asked FDA to eliminate the REMS patient agreement and certification requirements as "onerous and medically unnecessary" and received a form response from FDA. ECF No. 60 at 5. In 2021, FDA

conducted a "full review" of REMS, including information about comparator drugs with mifepristone. ECF No. 60 at 7. In 2022, the ACOG and other medical and professional healthcare access organizations petitioned FDA to, in part, eliminate the REMS as medically unnecessary and unduly burdensome for uses of mifepristone, primarily for miscarriage management. ECF Nos. 35 at 47, ¶ 139; 60 at 4; 61-1. FDA rejected ACOG's citizen petition. ECF No. 35 at 51, ¶ 144.

Based on the information and requests already put forth before FDA, FDA cannot credibly argue that its decision on the Mifepristone REMS Program would change upon another citizen petition. *See, e.g.*, ECF Nos. 51-5 at 22–23 (assessing whether to retain Mifeprex REMS); 61-13 at 2 (chronology of FDA communications). Thus, the Court finds that administrative exhaustion through a citizen petition on the January 2023 REMS would be futile.

3. APA Claim

Plaintiffs assert they are likely to succeed on the merits of the claim that the 2023 REMS is contrary to law and arbitrary and capricious under the APA. ECF No. 3 at 19–29.

To obtain injunctive relief, Plaintiff must show that there are "serious questions going to the merits" of its claims or that it is "likely to succeed on the merits." *Cottrell*, 632 F.3d at 1131; *Farris*, 677 F.3d at 865. Under the APA, a court shall "hold unlawful and set aside agency action, findings, and conclusions

found to be … arbitrary [and] capricious … or otherwise not in accordance with law [or] in excess of statutory … authority, or limitations." 5 U.S.C. § 706(2)(A), (C). Courts must uphold an agency action unless it (1) "relied on factors which Congress has not intended it to consider," (2) "entirely failed to consider an important aspect of the problem," (3) "offered an explanation for its decision that runs counter to the evidence before the agency," or (4) the "decision is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Turtle Island Restoration Network v. U.S. Dep't of Commerce*, 878 F.3d 725, 732–33 (9th Cir. 2017) (internal quotation marks omitted). Additionally, a decision is arbitrary and capricious if it is internally inconsistent with the underlying analysis. *Nat'l Parks Conservation Ass'n v. EPA*, 788 F.3d 1134, 1141 (9th Cir. 2015). Review is "at its most deferential" regarding an agency's scientific determinations within its area of expertise. *Baltimore Gas & Elec., Co. v. Nat. Res. Def. Council, Inc.*, 462 U.S. 87, 103 (1982).

Regulations are valid if they are "consistent with the statute under which they are promulgated." *United States v. Larionoff*, 431 U.S. 864, 873 (1977). Under the FDCA, a new drug cannot be marketed and prescribed until it undergoes a rigorous approval process to determine that it is safe and effective. 21 U.S.C. § 355. For certain drugs, a risk evaluation and mitigation strategy (REMS) is required when the agency determines, after considering six factors, 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). An existing REMS may be modified or removed to "ensure the benefits of the drug outweighs the risks of the drug [or] minimize the burden on the health care delivery system of complying with the strategy." 21 U.S.C. § 355-1(g)(4)(B).

Moreover, a REMS may include elements that are necessary to assure safe use [ETASU] due to a drug's "inherent toxicity or potential harmfulness" if the drug has "been shown to be effective, but is associated with a serious adverse drug experience, can be approved only if, or would be withdrawn unless, such elements are required as part of such strategy to mitigate a specific serious risk listed in the labeling of the drug." 21 U.S.C. § 355-1(f)(1)(A). A "serious adverse drug experience" is one that results in:

> death; an adverse drug experience that places the patient at immediate risk of death…; inpatient hospitalization or prolongation of existing hospitalization; a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions; or a congenital anomaly or birth defect; or based on appropriate medical judgment, may jeopardize the patient and may require a medical or surgical intervention to prevent [such] an outcome.

21 U.S.C. § 355-1(b)(4)(A).

If the FDA determines ETASU is required, the ETASU shall:

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> not be unduly burdensome on patient access to the drug, considering in particular – patients with serious or life-threatening diseases or conditions; patient who have difficulty accessing health care (such as patients in rural or medically underserved areas); and patients with functional limitations; and to the extent practicable, so as to minimize the burden on the health care delivery system – conform with [ETASU] for other drugs with similar, serious risks; and be designed to be compatible with established distribution, procurement, and dispensing systems from drugs.

21 U.S.C. § 355-1(f)(2)(C)–(D).

Plaintiffs contend that mifepristone no longer requires a REMS program with ETASU. ECF Nos. 3 at 19–21, 23–24; 60 at 11. Plaintiffs assert that (1) FDA acknowledges that serious adverse events are "exceedingly rare", (2) mifepristone's associated fatality rate is .00005%, with not a single death "casually attributed to mifepristone"(3) "all the data shows the 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", and (4) "there is no reasoned scientific basis for subjecting it to additional burdens that are not applied to other, riskier medications." *See id.* Defendants do not address whether mifepristone qualifies for ETASU, asserting it need only determine whether modifications are appropriate under 21 U.S.C. § 355-1(g)(4)(B). *See* ECF Nos. 51 at 25; 78 at 22.

The FDA may modify or remove an approved REMS, including ETASU, if it determines "1 or more goals or elements should be … modified, or removed from the approved strategy [in part] to ensure the benefits of the drug outweigh the

risks of the drug." 21 U.S.C. § 355-1(g)(4)(B). Implicit in this assessment is whether the drug's risks require REMS and/or ETASU. 21 U.S.C. § 355-1(a)(1), (f)(1). Thus, it would be contrary to the plain language of the statute that the agency need not consider arguments that mifepristone's REMS and ETASU should be removed in whole or part based on criteria under 21 U.S.C. § 355-1(a)(1), (f)(1).

It is not the Court's role to review the scientific evidence and decide whether mifepristone's benefits outweigh its risks without REMS and/or ETASU. That is precisely FDA's role. However, based on the present record, FDA did not assess whether mifepristone qualifies for REMS and ETASU based on the criteria set forth under 21 U.S.C. § 355-1(a)(1), (f)(1). *See* ECF No. 51-4. Even under a deferential review, it appears FDA failed to consider an important aspect of the problem. *Turtle Island*, 878 F.3d at 732. Moreover, the record demonstrates potentially internally inconsistent FDA findings regarding mifepristone's safety profile. *Nat'l Parks Conservation*, 788 F.3d at 1141; *see, e.g.*, ECF Nos. 51-5 at 8–9 ("Serious adverse events … are rare" [and] mifepristone "is safe and effective through 70 days gestation."); 51-9 (approving mifepristone for Cushing's syndrome without a REMS considering risks of fetal loss).

Therefore, the Court finds there are serious issues going to the merits of Plaintiffs' APA claims. *Cottrell*, 632 F.3d at 1131. The Court emphasizes this finding is not binding at a trial on the merits. *Univ. of Texas v. Camenisch*, 451

U.S. 390, 395 (1981). Given this determination, the Court finds it unnecessary to address the other arguments regarding the individual ETASU currently in place. *See* ECF No. 3 at 21.

B. Irreparable Harm

Plaintiffs assert they will suffer irreparable harm from the 2023 REMS in at least three ways: (1) financial costs on Plaintiffs that cannot be compensated, (2) burdens on Plaintiffs' institutions and providers who provide abortion care, and (3) harm to the health and well-being of patients and providers "by aggravating the ongoing crisis of reduced access to abortion care." ECF No. 3 at 29.

A plaintiff seeking injunctive relief must "demonstrate that irreparable injury is *likely* in the absence of an injunction." *Winter*, 555 U.S. at 22 (emphasis in original). "Issuing a preliminary injunction based only on a possibility of irreparable harm is inconsistent with [the Supreme Court's] characterization of injunctive relief as an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief." *Id.* "Irreparable harm is traditionally defined as harm for which there is no adequate legal remedy, such as an award of damages." *Arizona Dream Act Coalition v. Brewer*, 757 F.3d 1053, 1068 (9th Cir. 2014). A court may imply a lack of irreparable harm where there is no "speedy action" and a plaintiff sleeps on its rights. *Lydo Enters. v. City of Las Vegas*, 745 F.2d 1211, 1213 (9th Cir. 1984).

Plaintiffs assert that the Mifepristone REMS Program imposes costs that are not compensable where the restriction of access to mifepristone causes patients to miss the window for medication abortion, leaving patients with procedural abortion or carrying a pregnancy to term, options that impose higher costs on Plaintiffs' state-run health care programs. ECF No. 3 at 29–30. Plaintiffs also contend the ongoing implementation of the 2023 REMS modifications impose costs on Plaintiffs. *Id.* at 33. Economic costs that may not be recovered through the ordinary course of litigation satisfy the irreparable harm standard. *Idaho v. Coeur d'Alene Tribe*, 794 F.3d 1039, 1046 (9th Cir. 2015); *see also California v. U.S. Health & Human Servs.*, 390 F. Supp. 3d 1061, 1065 (N.D. Cal. 2019). The Court finds that the alleged unrecoverable economic costs in this case is sufficient to demonstrate irreparable harm. The Court need not reach Plaintiffs' other bases of irreparable harm.

Defendants argue Plaintiffs fail to show irreparable harm on two grounds: (1) the 2023 REMS loosen restrictions and (2) Plaintiffs delayed in filing this action. ECF No. 51 at 30. First, even taking Defendants' argument that the "net effect" of the 2023 REMS lessens restrictions, Plaintiffs continue to assert that *no* restrictions are necessary and the 2023 REMS impose new restrictions that Plaintiffs are still working to implement. *See* ECF No. 3 at 33. Second, as to any delay, Plaintiffs contend they did not know FDA would approve the 2023 REMS

in light of the *Dobbs* decision[2] until January 2023. ECF No. 60 at 15–16; *see also* ECF No. 78 at 9. This is a complex case with 18 Plaintiffs. The Court finds Plaintiffs' less than two-month delay from the FDA approval minimal considering the record and issues in this case. *Lydo*, 745 F.2d at 1213. Accordingly, these are not bases to deny preliminary relief based on the lack of irreparable harm. Plaintiffs have satisfied this element.

C. Balancing of Equities and Public Interest

Plaintiffs assert that the equities and public interest weigh strongly in their favor where the public's health is at stake. ECF No. 3 at 36.

When the government is a party to a case in which a preliminary injunction is sought, the balance of the equities and public interest factors merge. *Drakes Bay Oyster Co. v. Jewell*, 747 F.3d 1073, 1092 (9th Cir. 2014). The public's interest in health care favors a preliminary injunction where the agency's action likely "results in worse health outcomes." *New York v. U.S. Dep't of Homeland Sec.*, 969 F.3d 42, 87 (2d Cir. 2020).

Plaintiffs contend the public has an interest in access to safe and effective medicine for those who terminate their pregnancies. ECF No. 3 at 36. Defendants contend the public interest is "best served by deferring to FDA's judgments about

[2] *Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228 (2022).

what restrictions are necessary to ensure drugs are safe." ECF No. 51 at 32. The Court agrees with this general premise, but the allegations in this case are that FDA made findings (or failed to make findings) that the Court does not defer to, i.e. those contrary to law and those that are arbitrary and capricious. Thus, this argument does not strongly favor Defendants. Based on the public health and administrative considerations at issue in this case, Plaintiffs have shown the balance of the equities sharply tip in their favor and the public interest favors a preliminary injunction.

The Court finds Plaintiffs have satisfied the "alternative" *Cottrell* test. At this point, the Court will issue a status quo preliminary injunction but not a mandatory preliminary injunction.

D. Relief

The Court turns to Plaintiffs' remedy. Defendants contend that Plaintiffs' requested relief exceeds any permissible scope where Plaintiffs seek an order enjoining "any action to remove mifepristone from the market or otherwise cause the drug to become less available." ECF No. 51 at 33–36. Plaintiffs counter that an order enjoining Defendants from the following is appropriate: "(1) enforcing the 2023 REMS, and (2) changing the status quo to make mifepristone less available in the Plaintiff States." ECF No. 60 at 19.

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1. Type of Relief

When the Court determines a preliminary injunction is warranted, "injunctive relief should be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs." *Califano v. Yamasaki*, 442 U.S. 682, 702 (1979). "The purpose of such interim equitable relief is not to conclusively determine the rights of the parties but to balance the equities as the litigation moves forward." *California v. Azar*, 911 F.3d 558, 582 (9th Cir. 2018). In crafting a remedy, courts "need not grant the total relief sought by the applicant but may mold its decree to meet the exigencies of the particular case." *Trump v. Int'l Refugee Assistance Project*, 137 S. Ct. 2080, 2087 (2017) (citation omitted).

"Ordinarily when a regulation is not promulgated in compliance with the APA, the regulation is invalid." *Paulsen v. Daniels*, 413 F.3d 999, 1008 (9th Cir. 2005) (citation omitted). "The effect of invalidating an agency rule is to reinstate the rule previously in force." *Id.* (citation omitted). "The scope of an injunction is within the broad discretion of the district court." *TrafficSchool.com, Inc. v. Edriver Inc.*, 653 F.3d 820, 829 (9th Cir. 2011).

First, the relief Plaintiffs seek by enjoining FDA from enforcing REMS is inconsistent. *Compare* ECF Nos. 3 at 37 (enjoining 2023 REMS) *with* 3-1 at 3 (enjoining REMS entirely). Enjoining REMS from mifepristone entirely is well beyond the status quo. Indeed, enjoining the 2023 REMS and returning to the

status quo would eliminate the ability of pharmacies to provide the drug, thereby reducing its availability. This runs directly counter to Plaintiffs' request.

Second, the relief Plaintiffs seek by enjoining FDA from reducing mifepristone's availability does not exceed the permissible scope of relief. In preserving the status quo, it is fair and equitable for FDA to not act with respect to the Mifepristone REMS Program until a determination is made on the merits. *See Boardman v. Pac. Seafood Grp.*, 822 F.3d 1011, 1024 (9th Cir. 2016) (finding court's prohibition on taking any further action "effectively preserved the parties' last uncontested status"); *Bracco Diagnostics, Inc. v. Shalala*, 963 F. Supp. 20, 30 (D.D.C. 1997) (enjoining "FDA from proceeding with any approval or review proceedings"). This is consistent with the APA authorizing courts to stay agency action "to preserve status or rights pending conclusion of the review proceedings." 5 U.S.C. § 705.

Accordingly, Defendants are preliminary enjoined from altering the status or rights of the parties under the operative Mifepristone REMS Program until a determination on the merits.

2. Scope of Relief

As a final matter, the Court notes Plaintiffs appear to seek a nationwide injunction. *See* ECF No. 3-1.

Generally, there is no "requirement that an injunction affect only the parties in the suit." *Bresgal v. Brock*, 843 F.2d 1163, 1169 (9th Cir. 1987). While courts have the authority to issue nationwide preliminary injunctions, the Ninth Circuit cautions they are for "exceptional cases" and that have proof of "an articulated connection to a plaintiff's particular harm." *E. Bay Sanctuary Covenant v. Barr*, 934 F.3d 1026, 1029 (9th Cir. 2019). "District judges must require a showing of nationwide impact or sufficient similarity to the plaintiff states to foreclose litigation in other districts." *Azar*, 911 F.3d at 584; *see also City & Cnty. of San Francisco v. Trump*, 897 F.3d 1225, 1244 (9th Cir. 2018) (noting record must be developed on nationwide impact).

First, the Court finds a nationwide injunction inappropriate where the record does not demonstrate a nationwide impact of sufficient similarity to Plaintiffs' situation. *Azar*, 911 F.3d at 584. Abortion restrictions vary state-by-state and Plaintiffs allege harm not shared nationwide. For example, Plaintiffs allege harm from the 2023 REMS in light of the influx of patients from states who do not have similar services available. Second, the Court finds a nationwide injunction inappropriate where there is the potential for competing litigation.[3] *Id.* at 583

[3] *See, e.g.*, *All. For Hippocratic Med. v. FDA*, No. 2:22-cv-00223-Z (N.D. Tex. Jan. 13, 2023).

(noting courts should consider "the equities of non-parties who are deprived the right to litigate in other forums.").

Under these circumstances, the Court declines to issue a nationwide injunction and will enter the preliminary injunction as it applies to Plaintiff States.

II. Amici Briefs

The Court has broad discretion to grant or refuse a prospective amicus participation. *See Hoptowit v. Ray*, 682 F.2d 1237, 1260 (9th Cir. 1982), *abrogated on other grounds by Sandin v. Conner*, 515 U.S. 472 (1995). Amicus may be either impartial individuals or interested parties. *See Funbus Sys., Inc. v. Cal. Pub. Utils. Comm'n*, 801 F.2d 1120, 1125 (9th Cir. 1986). In deciding whether to grant leave to file an amicus brief, courts should consider whether the briefing "supplement[s] the efforts of counsel, and draw[s] the court's attention to law that escaped consideration." *Miller-Wohl Co., Inc. v. Comm'r of Labor & Indus. Mont.*, 694 F.2d 203, 204 (9th Cir. 1982). "An amicus brief should normally be allowed when . . . the amicus has an interest in some other case that may be affected by the decision in the present case, or when the amicus has unique information or perspective that can help the court beyond the help that the lawyers for the parties are able to provide. . . . Otherwise, leave to file an amicus curiae brief should be denied." *Cmty. Ass'n for Restoration of Env't (CARE) v. DeRuyter*

Bros. Dairy, 54 F. Supp. 2d 974, 975 (E.D. Wash. 1999) (internal citations omitted).

While these motions are unopposed, the proposed briefs offer no additional legal or substantive information that is particularly helpful to the Court's findings on the present motion. The briefs may be more useful during a trial on the merits. Therefore, the motions are denied.

ACCORDINGLY, IT IS HEREBY ORDERED:

1. Plaintiffs' Motion for Preliminary Injunction (ECF No. 3) is **GRANTED in part**.
2. Pursuant to Federal Rule of Civil Procedure 65(a), Defendants and their officers, agents, servants, employees, attorneys, and any person in active concert or participation, are **PRELIMINARILY ENJOINED** from:

   "altering the status quo and rights as it relates to the availability of Mifepristone under the current operative January 2023 Risk Evaluation and Mitigation Strategy under 21 U.S.C. § 355-1 in Plaintiff States."
3. No bond shall be required. Fed. R. Civ. P. 65(c).
4. Third Parties' Unopposed Motion for Leave to File Amicus Curiae Brief (ECF No. 52) is **DENIED.**

5. Third Parties' Unopposed Motion for Leave to File Amicus Brief (ECF No. 69) is **DENIED**.

The District Court Executive is directed to enter this Order and furnish copies to counsel.

DATED April 7, 2023.

THOMAS O. RICE
United States District Judge

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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,

STATE OF IDAHO; STATE OF IOWA; STATE OF MONTANA; STATE OF NEBRASKA; STATE OF SOUTH CAROLINA; STATE OF TEXAS; STATE OF UTAH,

Plaintiffs-Intervenors,

Case No. 1:23-cv-03026

MOTION TO INTERVENE

Pursuant to Federal Rule of Civil Procedure 24(a), Plaintiffs State of Idaho, State of Iowa, State of Montana, State of Nebraska, State of South Carolina, State of Texas, and State of Utah (the "State Intervenors") respectfully move the Court for an order permitting them to intervene as a matter of right in the above-captioned matter as plaintiffs. The State Intervenors' proposed Complaint is attached to this motion. *See* Exhibit 1. Alternatively, State Intervenors move for permissive intervention pursuant to Federal Rule of Civil Procedure 24(b).

ARGUMENT

Rule 24(a)(2) provides a nonparty the right to intervene when it "(i) timely moves to intervene; (ii) has a significantly protectable interest related to the subject of the action; (iii) may have that interest impaired by the disposition of the action; and (iv) will not be adequately represented by existing parties." *Western Watersheds Project v. Haaland*, 22 F.4th 828, 835 (9th Cir. 2022) (citation omitted). The State Intervenors bear the burden of showing that these four elements are met, but the Ninth Circuit has instructed courts to "interpret these requirements broadly in favor of intervention." *Id.* (citation omitted). Additionally, this Court's review should be "guided primarily by practical considerations, not technical distinctions." *Citizens for Balanced Use v. Mont. Wilderness Ass'n*,

647 F.3d 893, 897 (9th Cir. 2011) (citation omitted). The State Intervenors easily satisfy each of the four requirements.

Timeliness. The State Intervenors bring this motion just five weeks after this case was commenced. Defendants have not answered the Amended Complaint. And the Court has not even issued a scheduling order in the case. *Kachess Cmty. Ass'n v. U.S. Dep't of Interior*, 2019 WL 10744937, at *1 (E.D. Wash. Dec. 11, 2019) (holding that intervention motion filed before scheduling order was issued was timely and at an "early stage of the case"). This case is just getting started, and no party will suffer prejudice from the grant of intervention. Nor will intervention cause any disruption or delay in the proceedings. The Ninth Circuit has found that far greater delays still satisfied the timeliness requirement. *See, e.g., Mont. Wilderness Ass'n*, 647 F.3d at 897 (finding motion was timely when it was brought "less than three months after the complaint was filed and less than two weeks after the Forest Service filed its answer to the complaint"); *Idaho Farm Bureau Fed'n v. Babbitt*, 58 F.3d 1392, 1397 (9th Cir. 1995) (noting that motion to intervene was filed "at a very early stage" even where intervenor waited four months after complaint was filed).

Protectable Interest. As detailed in their Complaint, *see* Exhibit 1, the State Intervenors have significantly protectable interests related to the FDA's decision to modify mifepristone's REMS. The FDA's action harms the State Intervenors' sovereign and quasi-sovereign interests. As alleged in the Complaint, eliminating mifepristone's in-person dispensing requirement will harm women residents of the State Intervenors. The Supreme Court has long recognized that "a State has a quasi-sovereign interest in the health and well-being—both physical and economic—of its residents in general." *Alfred L. Snapp Son, Inc. v. Puerto Rico ex rel. Pedro Barez*, 458 U.S. 592, 607 (1982). The FDA's action jeopardizes those quasi-sovereign interests, and the State Intervenors seek to protect them by intervening here. It also undermines the State Intervenors' ability to enforce their laws, which is another classic protectable state interest. *Id.* at 601 (identifying the "power to create and enforce a legal code" as an important state interest).

As a practical matter—which is Rule 24's guiding star—the State Intervenors' interests are strong proof that they should be part of this litigation. *See United States v. City of Los Angeles*, 288 F.3d 391, 398 (9th Cir. 2002). The "interest" analysis is a practical guide that "directs courts" involve "as many apparently concerned persons as is compatible

with efficiency and due process." *Id.* Permitting intervention here allows efficient resolution of a common concern with the FDA's action.

Finally, because the FDA's action violates the Administrative Procedure Act, the State Intervenor's interests are legally protected and can be remedied by the claims they assert. *See Mont. Wilderness Ass'n*, 647 F.3d at 897.

Impairment of Interest. Once an intervenor has shown that it has a significant protectable interest, courts will "have little difficulty concluding that the disposition of this case may, as a practical matter, affect it." *California ex rel. Lockyer v. United States*, 450 F.3d 436, 442 (9th Cir. 2006). Here, that is clearly the case. The existing Plaintiffs are seeking to eliminate mifepristone's REMS altogether. The State Intervenors are seeking to restore and strengthen mifepristone's REMS. If the existing Plaintiffs prevail, the State Intervenors' interests will be impaired. Put another way, "[t]he same evidence that bolsters the [existing Plaintiffs'] standing to sue also bolsters the case for intervention." *Id.*

Inadequate Representation. The State Intervenors' interests are not, and will not, be adequately represented by the existing parties. "The most important factor in determining the adequacy of representation is how the interest compares with the interests of existing parties." *Arakaki*

v. Cayetano, 324 F.3d 1078, 1086 (9th Cir. 2003), as amended (May 13, 2003) (citation omitted). The existing Plaintiffs' interests do not align with the State Intervenors' interests. That much is plain from the face of the Amended Complaint and the State Intervenors' Complaint.

None of the existing parties "will undoubtedly" make all of the State Intervenors' arguments. *See California v. Tahoe Reg'l Plan. Agency*, 792 F.2d 775, 778 (9th Cir. 1986). The FDA believes its action was lawful, and the existing Plaintiffs want to wholly eliminate mifepristone's REMS, not restore the in-person dispensing requirement.

The State Intervenors' burden here is "minimal." *Arakaki*, 324 F.3d at 1086. They've more than carried it, and intervention should be granted as of right.

* * * * *

Rule 24(b) also provides the State Intervenors with a path to intervention. All the Ninth Circuit requires for permissive intervention is "(1) an independent ground for jurisdiction; (2) a timely motion; and (3) a common question of law and fact between the movant's claim or defense and the main action." *Freedom from Religion Found., Inc. v. Geithner*, 644 F.3d 836, 843 (9th Cir. 2011) (citation omitted). Each of these

grounds is satisfied here. In federal-question cases, like this one, the jurisdictional requirement is only relevant "where a proposed intervenor seeks to bring new state-law claims." *Id.* That's not at issue here. As discussed above, the motion is timely. And the State Intervenor's APA claims are grounded in the same facts and the same laws as the existing Plaintiffs' action.

Permissive intervention is thus also well supported.

CONCLUSION

For the foregoing reasons, the State Intervenors respectfully request the Court to grant their motion to intervene.

Dated: March 30, 2023

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CERTIFICATE OF SERVICE

I hereby certify that, on March 30, 2023, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

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Case No. 1:23-cv-03026

COMPLAINT

INTRODUCTION

1. On September 28, 2000, the U.S. Food and Drug Administration (FDA) determined that mifepristone was unsafe for marketing and use without important restrictions that were designed to mitigate the serious dangers posed by the drug.

2. For 23 years, one of those restrictions was that a certified health care provider needed to dispense mifepristone to patients in person in a clinical setting.

3. This common-sense safety measure was deemed necessary by the FDA to protect women from the drug's deadly potential.

4. Yet the FDA under the Biden administration has suddenly determined that mifepristone no longer needs to be dispensed in person. On January 23, 2023, the FDA eliminated mifepristone's in-person dispensing requirement.

5. The FDA made this substantive change without providing the notice and opportunity to comment required by the Administrative Procedure Act, 5 U.S.C. § 553.

6. The FDA also did not sufficiently justify its drastic decision. Nor could it. Nothing about the drug's danger has changed. And nothing else relevant has changed that would alter the risk-benefit profile the FDA has consistently determined requires in-person dispensing.

7. This final agency action harms women in Idaho, Iowa, Montana, Nebraska, South Carolina, Texas, and Utah; it will undermine state law; and it is a violation of federal law. The FDA's unilateral decision to eliminate mifepristone's in-person dispensing requirement did not provide required notice and an opportunity for public comment, was arbitrary and capricious, and exceeded the FDA's authority under the Food,

Drug, and Cosmetic Act, all in violation of the APA.

JURISDICTION AND VENUE

8. This Court has jurisdiction pursuant to 28 U.S.C. § 1331 because this action raises federal questions under the Administrative Procedures Act, 5 U.S.C. §§ 551(13), 702, and 704, and the Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.*

9. This Court also has jurisdiction to declare the law, enjoin the FDA's unlawful final action, invalidate the FDA's final action, and provide further necessary or proper relief pursuant to 28 U.S.C. §§ 2201 and 2202. There is a real and present controversy between the parties regarding the lawfulness of the FDA's final action.

10. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(e)(1)(C) because Defendants are agencies of the United States or officers or employees of the United States acting in their official capacities and Plaintiff State of Washington resides in this district.

PARTIES

11. Plaintiffs State of Idaho, State of Iowa, State of Montana, State of Nebraska, State of South Carolina, State of Texas, and State of Utah, by and through their Attorneys General, bring this suit to assert their rights as Sovereign States and on behalf of their citizens. *See* Idaho Const. art. IV, § 1; Idaho Code §67-1401(1), (2), and (15); Iowa Const. art. V, § 12; Iowa Code Ann. § 13.2; Mont. Const. art. VI, § 4(4); Mont. Code Ann. § 2-15-501; Neb. Const. art. V, § 1; Neb. Rev. Stat. § 84-203 S.C. Const. art. V, § 24; S.C. Code § 1-7-40; Tex. Const. art. IV, § 22; Tex. Gov't Code Ch. 402; Utah Const. art. VII, § 16; Utah Code § 67-5-1.

12. Separate Plaintiffs Washington, Oregon, Arizona, Colorado,

Connecticut, Delaware, Illinois, Nevada, New Mexico, Rhode Island, Vermont, and the Michigan Attorney General are existing Plaintiffs in this suit.

13. Defendant United States Food and Drug Administration is an agency within the United States Department of Health and Human Services (HHS). The FDA is responsible for administering the provisions of the FDCA for approving new drug applications and authorizing a Risk Evaluation and Mitigation Strategy (REMS) for drugs, like mifepristone, that pose serious safety concerns.

14. Defendant Robert M. Califf, Commissioner of the FDA, is responsible for administering the FDA and overseeing its duties under the FDCA, including the issuance and modification of REMS. Plaintiffs sue him in his official capacity.

15. Defendant HHS is a federal agency that has statutory authority under the FDCA and has delegated that authority to Defendant FDA to administer the provisions of the FDCA that are relevant to this Complaint.

16. Defendant Xavier Becerra, Secretary of HHS, is responsible for the operations of HHS, including overseeing the FDA. Plaintiffs sue him in his official capacity.

BACKGROUND

The History of Mifepristone and Its Marketing Requirements

17. Before a drug can be approved for marketing, the FDA must determine that the drug is "safe for use," meaning that the drug's expected benefits outweigh its potential risks. 21 U.S.C. § 355; *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 140 (2000).

18. Some drugs are so risky, and pose significant enough dangers, that the FDA requires drug makers to develop programs for their safe use. *See* 21 U.S.C. § 355-1.

19. For these drugs to receive FDA approval, the FDA requires a REMS "to ensure that the benefits of the drug outweigh the risks of the drug." 21 U.S.C. § 355-1(a)(1).

20. In September 2000, the FDA determined that mifepristone could not be approved for marketing without "restrictions to assure safe use" under Subpart H of the FDCA (which later were deemed to be an approved REMS under the Food and Drug Administration Amendments Act).

21. Mifepristone is an endocrine disruptor that blocks progesterone receptors in the uterus. Progesterone is necessary for the development of an unborn child and the normal maintenance of a pregnancy. Thus, when ingested by a pregnant woman, mifepristone blocks nutrition to the unborn child and starves it.

22. Mifepristone, however, does not work alone. Another drug, misoprostol, is needed to induce uterine contractions and expel the dead or dying unborn child from the womb.

23. The FDA requires mifepristone to be used in a regimen with misoprostol.

24. Mifepristone's FDA-approved label warns—in large, bolded text—that "[s]erious and sometimes fatal infections and bleeding occur very rarely following" use of mifepristone.

25. This "black box warning" was necessary because the FDA determined that mifepristone poses "special problems, particularly those that may lead to death or serious injury."

26. Due to these "special problems," the FDA approved the drug only with the following restrictions:

a. Mifepristone regimen must be dispensed and administered in person in a hospital, clinic, or medical office by, or under the supervision of, a certified provider.

b. Mifepristone regimen must be prescribed by a certified health care provider.

c. Mifepristone regimen must be dispensed to patients with evidence or other documentation of safe use conditions as ensured by the certified prescriber in signing the Prescriber Agreement Form and by the patient signing the Patient Agreement Form.

27. These restrictions are referred to as Elements to Assure Safe Use (ETASUs).

28. Initially, mifepristone was approved for use only up to 49 days' gestation. In 2016, the FDA increased the gestational age limit to 70 days.

29. The increased period of use, however, made the in-person dispensing requirement even more important and necessary.

30. Hence, the FDA continued to require the in-person dispensing of the drug in an appropriate clinic setting, prescribed by a certified

health care provider, with evidence, through execution of the Prescriber Agreement Form and Patient Agreement Form, that the patient was properly informed of the risks.

31. On January 3, 2023, the FDA made major modifications to mifepristone's REMS by eliminating the in-person dispensing requirement. It nevertheless determined that mifepristone remains a dangerous drug requiring a REMS and ETASUs.

32. The FDA made this substantive change without following the APA's notice and comment procedures.

33. The FDA also failed to adequately explain or support eliminating the in-person dispensing requirement, which it had previously determined was required for safe use. Instead, in its December 16, 2021 letter noticing the modification, the FDA simply parroted the statutory language that the mifepristone REMS program "must be modified to minimize the burden on the health care delivery system of complying with the REMS and to ensure that the benefits of the drug outweigh the risks." (Ex. 1.)

34. This conclusory assertion provides no explanation of how eliminating the in-person dispensing requirement would minimize the burden on the health care delivery system or how it would ensure that the drug's benefits outweigh its risks. The FDA letter cites no studies, contains no data, identifies no factors or considerations relevant to its determination, and fails to explain what scientific, medical, or other changes justify eliminating the in-person dispensing requirement that it had insisted upon for the first 23 years of the drug's existence.

35. On the same day that the FDA conclusorily noticed eliminating the in-person dispensing requirement for mifepristone, it responded

by letter to a citizen petition submitted to the FDA on March 29, 2019. The citizen petition specifically requested the FDA to retain the in-person dispensing requirement. The FDA's response was lengthy but devoid of the necessary support to justify elimination of the in-person dispensing requirement. In fact, the FDA admitted in its response letter that eliminating the in-person dispensing requirement was shown by studies to result in "an increase in ED/urgent care visits." The FDA further acknowledged that there was "insufficient data" to "determine the safety and efficacy of dispensing from a retail pharmacy, by courier, or by a partner organization." (Ex. 2.)

36. The FDA's December 16, 2021 response to the citizen petition—and specifically its rejection of the citizen petition's request to retain the in-person dispensing requirement—demonstrates that the FDA's position on eliminating the in-person dispensing requirement was "already set" and "very likely" that any petition by the States opposing the elimination would be rejected by the FDA. *El Rescate Legal Servs., Inc. v. EOIR*, 959 F.2d 742, 747 (9th Cir. 1991) (citation omitted). Thus, resorting to agency administrative remedies would have been futile. *Id.*

37. The bottom line is that the FDA failed to consider relevant data, such as scientifically acceptable studies or relevant sources of information, and it identified no change to the risk profile of mifepristone.

38. In fact, nothing relevant has changed to justify the FDA's elimination of the in-person dispensing requirement. The FDA's action is attributable to the change to the new Biden administration, not new medical or scientific evidence.

The FDA's Action Harms Idaho and its Residents

39. Idaho is principally responsible for ensuring the safety of its citizens.

40. Idaho also has "legitimate interests" in the "respect for and preservation of prenatal life at all stages of development." *Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228, 2284 (2022).

41. The FDA's decision to eliminate mifepristone's in-person dispensing requirement will harm Idaho women and prenatal life.

42. As the FDA readily acknowledges, mifepristone is a dangerous drug that can cause death or serious bodily harm.

43. The 23-year requirement that mifepristone be prescribed and administered in person in a clinical setting by a certified health care provider was a sensible, necessary requirement to assure the drug's safe use.

44. Taking mifepristone—even as prescribed—can cause death or serious bodily harm requiring immediate medical attention.

45. Without the in-person dispensing requirement, women in Idaho will be exposed to the dangerous complications caused by the drug and will be left without any professional medical oversight or prompt medical assistance.

46. Taking mifepristone when contraindicated increases the likelihood of death or serious bodily harm.

47. Without the in-person dispensing requirement, women in Idaho who do not meet the indications for use will be able to take mifepristone. In other words, the in-person dispensing requirement is a necessary feature to ensure that women with contraindications don't take mifepristone.

48. For example, women with ectopic pregnancies cannot be prescribed mifepristone. But in-person medical care and in-person dispensing are crucial safety measures to accurately diagnose an ectopic pregnancy. It is particularly dangerous for a woman with an ectopic pregnancy to take mifepristone because the drug masks the symptoms of a ruptured ectopic pregnancy.

49. Taking mifepristone beyond the approved-for-use 70-day gestational period increases the likelihood of death or serious bodily harm.

50. Without the in-person dispensing requirement, important safeguards will no longer protect women in Idaho from being administered the drug outside of the 70-day gestational limitation.

51. The in-person dispensing requirement is the safest and surest way to protect women from being administered mifepristone beyond the 70-day gestational period.

52. Idaho also has a sovereign interest in ensuring that its laws are enforced and not undermined. *See Alfred L. Snapp Son, Inc. v. Puerto Rico ex rel. Pedro Barez*, 458 U.S. 592, 601 (1982). Idaho law protects women and prenatal life from abortion-inducing drugs like mifepristone. *See* Idaho Code §§ 18-602 (recognizing "[t]hat children have a special place in society that the law should reflect"), 18-617 (defining "Abortifacient" to mean "mifepristone, misoprostol and/or other chemical or drug dispensed with the intent of causing an abortion"), and 18-622 ("Every person who performs or attempts to perform an abortion as defined in this chapter commits the crime of criminal abortion."). But the FDA's elimination of the in-person dispensing requirement will undermine Idaho's ability to enforce its laws. Specifically, without the in-person dispensing requirement, mifepristone will be able to travel across Idaho's

borders and be used to unlawfully induce abortions in Idaho. Mifepristone will no longer be subject to the controlled delivery system that the FDA had always required and deemed necessary. Under the FDA's new rule, for example, a health care provider in Washington could conduct a telehealth appointment with an Idaho resident and prescribe her mifepristone. Further, an Idaho resident could travel to Washington to have a mifepristone prescription filled by a pharmacy in Washington and return to Idaho with mifepristone. Each of these scenarios will result in an influx of mifepristone in Idaho, with no safeguards to prevent the drug from freely circulating and being administered unlawfully and improperly.

53. Under the FDA's new rule, women and unborn children in Idaho will also be put at increased risk. The elimination of the in-person dispensing requirement further removes women from medical care necessary to protect them from the dangerous potential of mifepristone. And the elimination of the in-person dispensing requirement will also endanger unborn children in Idaho by making it more likely that such children who are protected by Idaho law or who are too old to "safely" be aborted by the drug are nevertheless subjected to the drug's fatal effects.

54. The increased risk to Idaho women and unborn children will further harm Idaho by causing it to incur additional medical care expenses, including emergency care, some of which is borne by Idaho through Medicaid expenditures. As the FDA recognized, elimination of the in-person dispensing requirement has been shown to result in more emergency and urgent care visits.

55. The longstanding in-person dispensing requirement has also created reliance interests for Idaho. Effective enforcement of Idaho's law

and protection of Idaho women and unborn children has been built around and depends on mifepristone's REMS—including an in-person dispensing requirement.

56. Idaho thus has both quasi-sovereign and sovereign interests that are harmed by the FDA's decision to eliminate mifepristone's in-person dispensing requirement.

The FDA's Action Harms Iowa and its Residents

57. Iowa is principally responsible for ensuring the safety of its citizens.

58. Iowa also has "legitimate interests" in the "respect for and preservation of prenatal life at all stages of development." *Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228, 2284 (2022).

59. The FDA's decision to eliminate mifepristone's in-person dispensing requirement will harm Iowa women and prenatal life.

60. As the FDA readily acknowledges, mifepristone is a dangerous drug that can cause death or serious bodily harm.

61. The 23-year requirement that mifepristone be prescribed and administered in person in a clinical setting by a certified health care provider was a sensible, necessary requirement.

62. Taking mifepristone—even as prescribed—can cause serious bodily harm requiring immediate medical attention or death.

63. Without the in-person dispensing requirement, women in Iowa will be exposed to the dangerous complications mifepristone may cause and will be left without any professional medical oversight or prompt medical assistance.

64. Taking mifepristone when contraindicated increases the likelihood of death or serious bodily harm.

65. Without the in-person dispensing requirement, women in Iowa who do not meet the indications for use will be able to take mifepristone. In other words, the in-person dispensing requirement is a necessary feature to ensure that women with contraindications don't take mifepristone.

66. Taking mifepristone beyond the approved-for-use 70-day gestational period increases the likelihood of death or serious bodily harm.

67. Without the in-person dispensing requirement, important safeguards will no longer protect women in Iowa from being administered the drug outside of the 70-day gestational limitation.

68. The in-person dispensing requirement is the safest and surest way to protect women from being administered mifepristone beyond the 70-day gestational period.

69. Iowa has a sovereign interest in ensuring that its laws are enforced and not undermined. *See Alfred L. Snapp Son, Inc. v. Puerto Rico ex rel. Pedro Barez*, 458 U.S. 592, 601 (1982). But the FDA's elimination of the in-person dispensing requirement will undermine Iowa's ability to enforce its laws. Specifically, without the in-person dispensing requirement, mifepristone will be able to travel across Iowa's borders and potentially violate state or federal law to unlawfully induce abortions in Iowa. Mifepristone will no longer be subject to the controlled delivery system that the FDA had always required and deemed necessary.

70. Under the FDA's new rule, women and unborn children in Iowa will also be put at increased risk. The elimination of the in-person dispensing requirement further removes women from medical care necessary to protect them from the potentially dangerous mifepristone. And

the elimination of the in-person dispensing requirement will also endanger unborn children in Iowa by making it more likely that such children who may be too old to "safely" be aborted by the drug are nevertheless subjected to the drug's fatal effects.

71. The longstanding in-person dispensing requirement has also created reliance interests for Iowa. Effective enforcement of Iowa's law and protection of Iowa women and unborn children has been built around and depends on mifepristone's REMS—including an in-person dispensing requirement.

72. Iowa thus has both quasi-sovereign and sovereign interests that are harmed by the FDA's decision to eliminate mifepristone's in-person dispensing requirement.

The FDA's Action Harms Montana and its Residents

73. Montana has a sovereign interest in ensuring that its laws are enforced and not undermined. *See Alfred L. Snapp Son, Inc. v. Puerto Rico ex rel. Pedro Barez*, 458 U.S. 592, 601 (1982). Montana law protects women from abortion-inducing drugs like mifepristone. *See* Mont. Code Ann. § 50-20-702(1) (recognizing a compelling state interest in "protecting the health and welfare of a woman considering a chemical abortion"); *id.* § 50-20-703(2) (defining "[a]bortion-inducing drug" or "chemical abortion" as drugs with "abortion-inducing properties" that are "prescribed specifically with the intent of causing an abortion," including "mifepristone, misoprostol, and methotrexate"); *id.* §§ 50-20-704–05, 707 (detailing the in-person, distribution, and informed consent requirements for abortion-inducing drugs); *id.* § 50-20-711 ("A person who purposely or knowingly or negligently violates any provision of this part is guilty of a felony[.]"). Even though Montana's in-person dispensing requirement has

been preliminarily enjoined, *Planned Parenthood of Mont. v. State*, 515 P.3d 301, 314-15 (Mont. 2022), Montana intends to enforce that law if and when the preliminary injunction is dissolved. And the FDA's elimination of the in-person dispensing requirement will undermine Montana's ability to enforce its laws and to ensure that mifepristone is administered safely and lawfully.

74. Montana thus has both quasi-sovereign and sovereign interests that are harmed by the FDA's decision to eliminate mifepristone's in-person dispensing requirement.

The FDA's Action Harms Nebraska and its Residents

75. Nebraska has a sovereign interest in ensuring that its laws are enforced and not undermined. *See Alfred L. Snapp Son, Inc. v. Puerto Rico ex rel. Pedro Barez*, 458 U.S. 592, 601 (1982). Nebraska law protects women and prenatal life from abortion-inducing drugs like mifepristone. *See* Neb. Rev. Stat. § 28-335(2).

76. Nebraska thus has both quasi-sovereign and sovereign interests that are harmed by the FDA's decision to eliminate mifepristone's in-person dispensing requirement.

The FDA's Action Harms South Carolina and its Residents

77. South Carolina is principally responsible for ensuring the safety of its citizens.

78. As detailed above, the FDA's decision to eliminate mifepristone's in-person dispensing requirement will harm South Carolina women and prenatal life.

79. The increased risk to South Carolina women and unborn children will further harm South Carolina by causing it to incur additional

medical care expenses, including emergency care, some of which is borne by South Carolina through Medicaid expenditures.

80. The longstanding in-person dispensing requirement has also created reliance interests for South Carolina. Effective enforcement of South Carolina law and protection of South Carolina women and unborn children has been built around and depends on mifepristone's REMS—including an in-person dispensing requirement.

81. South Carolina thus has both quasi-sovereign and sovereign interests that are harmed by the FDA's decision to eliminate mifepristone's in-person dispensing requirement.

The FDA's Action Harms Texas and its Residents

82. Texas is principally responsible for ensuring the safety of its citizens.

83. As detailed above, the FDA's decision to eliminate mifepristone's in-person dispensing requirement will harm Texas women and prenatal life.

84. The increased risk to Texas women and unborn children will further harm Texas by causing it to incur additional medical care expenses, including emergency care, some of which is borne by Texas through Medicaid expenditures.

85. The longstanding in-person dispensing requirement has also created reliance interests for Texas. Effective enforcement Texas law and protection of Texas women and unborn children has been built around and depends on mifepristone's REMS—including an in-person dispensing requirement.

86. Texas thus has both quasi-sovereign and sovereign interests that are harmed by the FDA's decision to eliminate mifepristone's in-person dispensing requirement.

The FDA's Action Harms Utah and its Residents

87. Utah is principally responsible for ensuring the safety of its citizens.

88. As detailed above, the FDA's decision to eliminate mifepristone's in-person dispensing requirement will harm Utah women and prenatal life.

89. The increased risk to Utah women and unborn children will further harm Utah by causing it to incur additional medical care expenses, including emergency care, some of which is borne by Utah through Medicaid expenditures.

90. The longstanding in-person dispensing requirement has also created reliance interests for Utah. Effective enforcement Utah law and protection of Utah women and unborn children has been built around and depends on mifepristone's REMS—including an in-person dispensing requirement.

91. Utah thus has both quasi-sovereign and sovereign interests that are harmed by the FDA's decision to eliminate mifepristone's in-person dispensing requirement.

CLAIM I
(Violation of 5 U.S.C. § 553 – Notice and Comment Requirement)

92. Plaintiffs reallege and incorporate by reference the facts and allegations set forth in all preceding paragraphs as if set forth in full herein.

93. The FDA's promulgation of the mifepristone 2023 REMS was

a final agency action that is causing, and will continue to cause, Idaho irreparable harm.

94. When the FDA promulgated the mifepristone 2023 REMS, it engaged in rulemaking that was subject to the APA's notice and comment requirements. *See* 5 U.S.C. § 553. No exceptions to the notice and comment requirements applied. *See id.*

95. The FDA's promulgation of the mifepristone 2023 REMS was done unilaterally and without complying with the notice and comment requirements under the APA.

96. Accordingly, the FDA's decision to eliminate mifepristone's in-person dispensing requirement without abiding by the notice and comment requirements of the APA is procedurally invalid and must be vacated. *See Paulsen v. Daniels*, 413 F.3d 999, 1008 (9th Cir. 2005).

CLAIM II
(Violation of 5 U.S.C. § 706 – Arbitrary and Capricious Agency Action)

97. Plaintiffs reallege and incorporate by reference the facts and allegations set forth in all preceding paragraphs as if set forth in full herein.

98. The FDA's promulgation of the mifepristone 2023 REMS was a final agency action that is causing, and will continue to cause, Idaho irreparable harm.

99. Mifepristone's in-person dispensing requirement is necessary to assure safe use of the drug.

100. The FDA did not adequately explain or support its decision to eliminate mifepristone's in-person dispensing requirement and it failed

to consider relevant and necessary facts and data, including reliance interests. *See Dep't of Homeland Sec. v. Regents of the Univ. of California*, 140 S. Ct. 1891, 1913 (2020); *F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502, 513 (2009).

101. Moreover, the FDA stated need for eliminating mifepristone's dispensing requirement was pretextual. *See Dep't of Com. v. New York*, 139 S. Ct. 2551, 2576 (2019).

102. Accordingly, the FDA's decision to eliminate mifepristone's in-person dispensing requirement is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

CLAIM III
(Violation of 5 U.S.C. § 706 – Agency Action in Excess of Statutory Authority)

103. Plaintiffs reallege and incorporate by reference the facts and allegations set forth in all preceding paragraphs as if set forth in full herein.

104. Under the APA, a final agency action is unlawful and must be set aside if it is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(C).

105. The FDCA requires the FDA to impose REMS for dangerous drugs like mifepristone. 21 U.S.C. § 355-1(a)(1).

106. The FDCA specifically includes in-person dispensing as a mitigation requirement that the FDA may require. 21 U.S.C. § 355-1(f)(3)(C).

107. By eliminating mifepristone's in-person dispensing requirement, the FDA has violated the FDCA's requirement that a REMS must "ensure that the benefits of the drug outweigh the risks of the drug," 21 U.S.C. § 355-1(a)(1), and has thus exceeded its statutory authority. 5

U.S.C. § 706(2)(C); *Trout Unlimited v. Pirzadeh*, 1 F.4th 738, 751 (9th Cir. 2021).

PRAYER FOR RELIEF

WHEREFORE, Idaho, Iowa, Montana, Nebraska, South Carolina, Texas, and Utah respectfully request that the Court:

(1) Adjudge and declare, pursuant to 28 U.S.C. § 2201, that the FDA's final agency action on January 3, 2023 modifying the mifepristone REMS violated the notice-and-comment requirements under the Administrative Procedure Act and is therefore invalid;

(2) Adjudge and declare, pursuant to 28 U.S.C. § 2201, that the FDA's final agency action on January 3, 2023 modifying the mifepristone REMS is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law under the Administrative Procedure Act;

(3) Adjudge and declare, pursuant to 28 U.S.C. § 2201, that the FDA's final agency action on January 3, 2023 modifying the mifepristone REMS exceeds the statutory authority granted to the FDA under the FDCA;

(4) Enjoin Defendants, pursuant to 28 U.S.C. § 2202, from enforcing or applying the January 3, 2023 mifepristone REMS;

(5) Vacate the FDA's January 3, 2023 final agency action;

(6) Award Idaho, Iowa, Montana, Nebraska, South Carolina, Texas, and Utah such additional relief as the Court may deem just, proper, and necessary, including their attorneys' fees and costs associated with this litigation.

Dated: March 30, 2023

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Attorney General of Idaho

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COUNSEL FOR STATE OF UTAH

Exhibit 1

December 16, 2021

Graham Chelius, M.D.
The Society of Family Planning
The California Academy of Family Physicians

Dear Dr. Chelius:

This letter is to inform you that FDA has completed its review of the Mifepristone Risk Evaluation and Mitigation System (REMS) Program.[1] The agency has determined that the Mifepristone REMS Program continues to be necessary to ensure that the benefits of the drug outweigh the risks. However, we have determined that it must be modified to minimize the burden on the health care delivery system of complying with the REMS and to ensure that the benefits of the drug outweigh the risks. See 21 USC 355-1(g)(4)(B). The modifications to the REMS will consist of: (1) removing the requirement that mifepristone be dispensed only in certain healthcare settings, specifically clinics, medical offices, and hospitals (i.e., the "in-person dispensing requirement"); and (2) adding a requirement that pharmacies that dispense the drug be specially certified.

A REMS Modification Notification letter has been sent to both Applicants subject to the Mifepristone REMS Program. The letter describes the modifications and directs the Applicants to submit prior approval supplements within 120 days. We have also answered a related citizen petition from the American Association of Pro-Life Obstetricians and Gynecologists and the American College of Pediatricians. That response will be posted in the public docket (Docket No. FDA-2019-P-1534; available at www.regulations.gov).

Sincerely,

Patrizia A. Cavazzoni -S

Digitally signed by Patrizia A. Cavazzoni -S
Date: 2021.12.16 15:05:01 -05'00'

Patrizia Cavazzoni, M.D.
Director
Center for Drug Evaluation and Research

[1] We also note your letter of September 29, 2021 to us on this subject.

Exhibit 2

U.S. FOOD & DRUG ADMINISTRATION

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American Association of Pro-Life Obstetricians and Gynecologists
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President
American College of Pediatricians
P.O. Box 357190
Gainesville, FL 32635-7190

December 16, 2021

Re: Docket No. FDA-2019-P-1534

Dear Drs. Harrison and Van Meter:

This letter responds to your citizen petition submitted to the Food and Drug Administration (FDA or Agency) on March 29, 2019, on behalf of the American Association of Pro-Life Obstetricians and Gynecologists and the American College of Pediatricians (Petition). In the Petition, you request that FDA: (1) restore and strengthen elements of the Mifeprex regimen and prescriber requirements approved in 2000, and (2) retain the Mifeprex Risk Evaluation and Mitigation Strategy (REMS) and continue limiting the dispensing of Mifeprex to patients in clinics, medical offices, and hospitals, by or under the supervision of a certified prescriber.

Specifically, in your Petition you request that the Agency:

(1) Restore and strengthen elements of the Mifeprex regimen and prescriber requirements approved in 2000, to include the following:

- Indications and Usage - Mifeprex, in a regimen with misoprostol, for the termination of intrauterine pregnancy, should be limited to 49 days gestation.

- Dosage and Administration:
  - Mifeprex should be administered by or under the supervision of a physically present and certified physician who has ruled out ectopic pregnancy.

  - The use of Mifeprex and misoprostol for the termination of pregnancy should require three office visits by the patient.

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- Contraindications - Mifeprex use is contraindicated for patients who do not have convenient access to emergency medical care.

- Adverse Event Reporting - Certified prescribers, emergency medical personnel, physicians treating complications, and Danco Laboratories should report to FDA's MedWatch Reporting system any deaths, hospitalizations, blood transfusions, emergency room visits, failures requiring surgical completion, ongoing pregnancy, or other major complications following the use of Mifeprex and misoprostol.

- Additional studies - The Mifeprex REMS should require a formal study of outcomes for at-risk populations, including: patients under the age of 18; patients with repeat Mifeprex abortions; patients who have limited access to emergency room services; and patients who self-administer misoprostol.

(2) Retain the Mifeprex REMS and continue limiting the dispensing of Mifeprex to patients in clinics, medical offices, and hospitals, by or under the supervision of a certified prescriber.

We have carefully considered the information submitted in your Petition and other relevant data available to the Agency. Based on our review of this information, your Petition is granted in part and denied in part.

I. BACKGROUND

A. Mifeprex

On September 28, 2000, FDA approved Mifeprex for the medical termination of intrauterine pregnancy through 49 days' pregnancy (new drug application (NDA) 020687). The application was approved under part 314, subpart H (21 CFR part 314, subpart H), "Accelerated Approval of New Drugs for Serious or Life-Threatening Illnesses" (subpart H). Specifically, § 314.520 of subpart H provides for approval with restrictions that are needed to assure the safe use of the drug product. In accordance with § 314.520, FDA restricted the distribution of Mifeprex as specified in the September 2000 approval letter.[1]

Subsequently, Mifeprex was identified as one of the products that was deemed to have in effect an approved REMS under the Food and Drug Administration Amendments Act of 2007 (FDAAA) because on the effective date of Title IX, subtitle A of FDAAA (March 28, 2008), Mifeprex had in effect elements to assure safe use.[2] Accordingly, in June 2011, we approved a REMS for Mifeprex, consisting of a Medication Guide, elements to assure safe use (ETASU), an implementation system, and a timetable for submission of assessments of the REMS.

Elements to assure safe use included: (1) prescriber certification (ETASU A); (2) that Mifeprex is dispensed only in certain healthcare settings by or under the supervision of a certified prescriber

[1] See https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2000/20687appltr.pdf.
[2] 73 FR 16313 (Mar. 27, 2008).

(ETASU C); and (3) that Mifeprex is dispensed only with documentation of safe use conditions (ETASU D). Documentation of safe use conditions consists of a Patient Agreement Form between the prescriber and the patient indicating that the patient has received counseling from the prescriber regarding the risk of serious complications associated with Mifeprex.

On March 29, 2016, we approved an efficacy supplement (S-020) to NDA 020687 for Mifeprex submitted by the applicant Danco Laboratories, LLC (S-020 efficacy supplement). The approval included changes in the dose of Mifeprex and the dosing regimen for taking Mifeprex and misoprostol (including the dose of misoprostol and a change in the route of misoprostol administration from oral to buccal (in the cheek pouch); the interval between taking Mifeprex and misoprostol; and the location at which the patient may take misoprostol). The approval also modified the gestational age up to which Mifeprex has been shown to be safe and effective, as well as the process for follow-up after administration of the drug.

Specifically, the following changes, among others, were made as part of the 2016 approval:[3]

- Revised the dosing regimen to consist of 200 mg of Mifeprex taken by mouth, followed in 24-48 hours by 800 mcg of misoprostol taken buccally (in the cheek pouch). This differs from the originally approved dosing regimen of 600 mg of oral Mifeprex followed 48 hours later by 400 mcg of oral misoprostol.

- Revised the indication for use of Mifeprex, in a regimen with misoprostol, to extend the maximum gestational age for the medical termination of intrauterine pregnancy from 49 days to 70 days.

- Reduced the number of office visits by the patient under the approved regimen from three to one.

- Replaced the term "physician" with the term "healthcare provider."

In addition, after reviewing the data and information submitted by the applicant in the S-020 efficacy supplement, and after taking into consideration the safety data that had become available since the initial approval of Mifeprex in 2000, we determined the Mifeprex REMS continued to be necessary to ensure the benefits of the product outweigh the risks. However, we approved modifications to the Mifeprex REMS that reflected the changes approved in the efficacy supplement. These changes to the REMS included, among others:[4]

- Updating the Prescriber Agreement Form to reflect the revised indication and dosing regimen.

- Removing the Medication Guide as a REMS element (but retaining the Medication Guide as labeling).

[3] See https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/020687Orig1s020ltr.pdf and https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf.
[4] See https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020RemsR.pdf.

- Removing the requirement that certified prescribers report certain enumerated adverse events to the applicant (specifically, any hospitalization, transfusion or other serious adverse events), but retaining the requirement that certified prescribers report all deaths to the sponsor.

Under the March 2016 approval, the Mifeprex REMS also continued to require that Mifeprex be dispensed to patients only in certain healthcare settings, specifically, clinics, medical offices, and hospitals, by or under the supervision of a certified prescriber.[5]

B. Generic Version of Mifeprex

On April 11, 2019, we approved GenBioPro, Inc.'s generic version of Mifeprex, Mifepristone Tablets, 200 mg (abbreviated new drug application (ANDA) 091178). This action took place after this Petition was submitted to the Agency. As required by 21 CFR 314.94(a)(8), GenBioPro's approved generic version of Mifeprex, Mifepristone Tablets, 200 mg, has the same labeling (with certain permissible differences) as the brand product it references, Mifeprex. Accordingly, although we refer to the Mifeprex labeling in several sections of this response, our discussions in this response apply equally to both the NDA and the generic product labeling, unless otherwise specifically noted.[6]

GenBioPro's generic version of Mifeprex is subject to the same ETASU as its listed drug (21 U.S.C. -1(i)). At the time we approved GenBioPro's generic version of Mifeprex, that ANDA product was required to use a single, shared system for the ETASU with the brand drug product, Mifeprex, unless the requirement was waived by FDA (21 U.S.C. 355-1(i)). FDA did not waive this requirement. Accordingly, at the same time that FDA approved GenBioPro's generic version of Mifeprex in 2019, FDA approved a supplemental new drug application (sNDA) for Mifeprex, approving modifications to the existing, approved REMS for Mifeprex to establish a single, shared system REMS for mifepristone products for the medical termination of intrauterine pregnancy through 70 days gestation (referred to as the Mifepristone REMS Program). In establishing the single, shared system REMS in 2019, no substantive changes were made to the ETASU in the March 2016 Mifeprex REMS. References to the REMS in this response refer to the Mifepristone REMS Program established in 2019, unless otherwise noted.

C. In-Person Dispensing Requirement During the COVID-19 PHE

[5] See https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/020687Orig1s020ltr.pdf.

[6] We note that Korlym and the generic version of Korlym (Mifepristone Tablets, 300 mg) contain the same active ingredient – mifepristone - as Mifeprex and the generic version of Mifeprex (Mifepristone Tablets, 200 mg). Although these drug products contain the same active ingredient, their intended uses target different receptors, and the products have different strengths and use different dosing regimens. Korlym and the generic version of Korlym are approved for the control of hyperglycemia (high blood sugar levels) due to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes or glucose intolerance, and have failed surgery or are not candidates for surgery. References to mifepristone in this response refer to the use of mifepristone for the medical termination of intrauterine pregnancy through 70 days gestation, unless otherwise noted.

FDA has recognized that during the COVID-19[7] public health emergency (PHE),[8] certain REMS requirements for various products may be difficult to comply with because patients may need to avoid public places and patients suspected of having COVID-19 may be self-isolating and/or subject to quarantine. The Agency has also received queries concerning products with REMS that have ETASUs, including REMS with ETASUs that restrict distribution, and the impact of such ETASUs on patient access when patients self-isolate or are subject to quarantine.

In April 2021, FDA communicated its intent to exercise enforcement discretion during the COVID-19 PHE regarding the requirement in the Mifepristone REMS Program that mifepristone used for medical termination of intrauterine pregnancy through 70 days gestation be dispensed to patients by or under the supervision of a certified prescriber only in certain healthcare settings, specifically clinics, medical offices, and hospitals (referred to as the "in-person dispensing requirement").

Specifically, FDA communicated that provided all other requirements of the Mifepristone REMS Program are met, the Agency intends to exercise enforcement discretion with respect to the in-person dispensing requirement of the Mifepristone REMS Program, including any in-person requirements that may be related to the Patient Agreement Form, during the COVID-19 PHE. This determination, which FDA made on April 12, 2021, was effective immediately. We also note that from July 13, 2020 to January 12, 2021, per a court order, FDA was enjoined from enforcing the in-person dispensing requirement of the Mifepristone REMS Program.[9]

Further, and as we also communicated on April 12, 2021, to the extent all of the other requirements of the Mifepristone REMS Program are met, the Agency intends to exercise enforcement discretion during the COVID-19 PHE with respect to the dispensing of Mifeprex or the approved generic version of Mifeprex, Mifepristone Tablets, 200 mg, through the mail, either by or under the supervision of a certified prescriber, or through a mail-order pharmacy when such dispensing is done under the supervision of a certified prescriber.

FDA's intent to exercise enforcement discretion with respect to these requirements during the COVID-19 PHE was the result of a thorough scientific review by experts within FDA's Center for Drug Evaluation and Research (CDER), who evaluated relevant information, including available clinical outcomes data and adverse event reports.

D. Minor Modification

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[7] The virus has been named "SARS-CoV-2" and the disease it causes has been named "Coronavirus Disease 2019" (COVID-19).

[8] Secretary of Health and Human Services, Determination that a Public Health Emergency Exists (originally issued Jan. 31, 2020, and subsequently renewed), *available at* https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx.

[9] *Am. Coll. of Obstetricians & Gynecologists v. FDA*, 472 F. Supp. 3d 183, 233 (D. Md. July 13, 2020), order clarified, 2020 WL 8167535 (D. Md. Aug. 19, 2020) (preliminarily enjoining FDA from enforcing the in-person dispensing requirement and any other in-person requirements of the Mifepristone SSS REMS); *FDA v. Am. Coll. of Obstetricians & Gynecologists*, 141 S. Ct. 578 (Jan. 12, 2021) (staying the preliminary injunction imposed by the District Court).

In response to a request submitted by the applicants, FDA approved a minor modification to the Mifepristone REMS Program on May 14, 2021. This minor modification revised the Patient Agreement Form to use gender neutral language. Specifically, the pronouns "she" and "her" in the Patient Agreement Form were replaced with "the patient." The minor modification also included revisions to the REMS document to be consistent with the revisions to the Patient Agreement Form. These changes did not affect the substance of the Patient Agreement Form, the REMS document, or the Mifepristone REMS Program.

E. Review of the Mifepristone REMS Program

In 2021, FDA also undertook a full review of the Mifepristone REMS Program.[10] In conducting this review, FDA reviewed multiple different sources of information, including published literature, safety information submitted to the Agency during the COVID-19 PHE, FDA Adverse Event Reporting System (FAERS) reports, the first REMS assessment report for the Mifepristone REMS Program, and information provided by advocacy groups, individuals, and the Plaintiffs in ongoing litigation, as well as information submitted by the sponsors of the NDA and the ANDA (together, the Applicants). As discussed in more detail below, based on our review of this information, FDA has determined that certain elements of the Mifepristone REMS Program remain necessary to assure the safe use of mifepristone for medical termination of intrauterine pregnancy through 70 days gestation; and therefore, the Mifepristone REMS Program continues to be necessary to ensure the benefits outweigh the risk. Specifically, we find that the healthcare provider certification and dispensing of mifepristone to patients with evidence or other documentation of safe use conditions continue to be necessary components of the REMS to ensure the benefits of mifepristone outweigh the risks for this indication.

We also find that the in-person dispensing requirement is no longer necessary to assure the safe use of mifepristone for medical termination of intrauterine pregnancy through 70 days gestation. We have concluded that mifepristone will remain safe and effective for medical abortion if the in-person dispensing requirement is removed, provided all the other requirements of the REMS are met and pharmacy certification is added.[11] Removing the in-person dispensing requirement will render the REMS less burdensome to healthcare providers and patients, and provided all other requirements of the REMS are met, including the additional requirement for pharmacy certification, the REMS will continue to ensure that the benefits of mifepristone for medical abortion outweigh the risks. Accordingly, today we are sending a REMS Modification Notification letter to both Applicants in the Mifepristone REMS Program. As stated in that letter, FDA has concluded that a modification is necessary and must include the following changes:

- Removing the requirement that mifepristone be dispensed only in certain healthcare settings, specifically clinics, medical offices, and hospitals.

[10] We note that the Agency is in litigation regarding the Mifepristone REMS Program and committed to conducting a full review of the Mifepristone REMS Program, including reviewing any relevant data and evidence submitted to the Agency by the Plaintiffs in that litigation (*Chelius et al v. Becerra*, Joint Mot. to Stay Case Pending Agency Review, ECF No. 148, May 7, 2021, Civ. No. 1:17-00493 (D. Haw.)).

[11] Although we have determined that the Mifepristone REMS Program must be modified to add a requirement for pharmacy certification, this was not raised in your Petition and therefore is not discussed further in this response.

- Adding a requirement that pharmacies that dispense the drug be specially certified.

II. DISCUSSION OF ISSUES RAISED

A. Mifeprex Regimen

1. Indications and Usage

In the Petition, you ask FDA to restore and strengthen elements of the Mifeprex regimen and prescriber requirements approved in 2000, to limit Mifeprex, in a regimen with misoprostol, for the termination of intrauterine pregnancy, to 49 days gestation (Petition at 1 and 3). For the reasons explained below, we deny this request.

Citing to a 2011 study and a practice bulletin issued by the American College of Obstetricians and Gynecologists (ACOG), you state that medical abortion[12] regimens demonstrate an increase in complications and failures, including serious risks of hemorrhage, infection, and ongoing pregnancy, after 49 days gestation (Petition at 3-4).

Our review of the S-020 efficacy supplement in 2016 concluded that Mifeprex, in a regimen with misoprostol, is safe and effective for medical termination of intrauterine pregnancy through 70 days gestation.[13] Complete medical abortion rates from the pivotal clinical trials relied on for the initial approval of Mifeprex (with an indication for medical termination of intrauterine pregnancy through 49 days gestation) were 92.1 percent and 95.5 percent in the United States and French trials, respectively.[14] The studies reviewed in support of the 2016 approval for Mifeprex (with an indication for medical termination of intrauterine pregnancy through 70 days gestation) showed comparable efficacy. The 2016 Clinical Review of the S-020 efficacy supplement summarized clinical outcomes and adverse effects from 22 studies (7 in the United States and 15 from outside the United States) through 70 days gestation, using the currently approved regimen of 200 mg oral mifepristone with 800 mcg buccal misoprostol. The ranges of complete medical abortion rates calculated by the clinical reviewer were 93.2 percent to 98.7 percent in the United States studies, and 92 percent to 98 percent in the non-United States studies.[15]

Serious adverse events associated with the use of mifepristone through 70 days gestational age are rare. Per the current mifepristone labeling, the rates of serious adverse events are low: transfusions are 0-0.1 percent, sepsis is less than 0.01 percent, hospitalization related to medical abortion is 0-0.7 percent, and hemorrhage is 0.1 percent.[16] As discussed

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[12] In this response, the terms "medical abortion" and "medication abortion" both refer to the use of mifepristone, in a regimen with misoprostol, for the medical termination of intrauterine pregnancy.
[13] See 2016 Clinical Review available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf, at 32-38 and 47-47.
[14] See 1999 Medical Officer's Review, available at http://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/20687_Mifepristone_medr_P1.pdf, at 11 (Table 1) and 16.
[15] See 2016 Clinical Review, supra n. 13, at 28-31.
[16] See https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/020687s022lbl.pdf.

throughout this response, the benefit/risk assessment supported our 2016 conclusion that the product is safe and effective through 70 days gestation.

In support of your assertion that medical abortion demonstrates an increase in complications after 49 days gestation, you cite to Mentula, et al.,[17] a register-based, retrospective cohort study that included 18,248 women in Finland who underwent medical abortion between January 1, 2003, and December 31, 2006 (Petition at 3). As an initial matter, we note that the Mentula study was primarily designed to assess the immediate adverse events following medical abortion in the second trimester (13 to 24 gestational weeks as defined by the authors) and then compare those events to those identified with medical abortion in the first trimester (up to 12 gestational weeks as defined by the authors). The study was not designed to compare rates of complications across gestational weeks within the first trimester. It is true that the Mentula publication includes information on the percentages of women who had surgical evacuation following medical abortion and the percentages of women who had infection following medical abortion, based on weekly gestational age, from 5 weeks to 20 weeks gestation.[18] However, the data in the Mentula study are relatively old (2003-2006); in our 2016 review of the S-020 efficacy supplement, we conducted an extensive review of more recent data[19] and concluded that Mifeprex, in a regimen with misoprostol, is safe and effective for medical termination of intrauterine pregnancy through 70 days gestation.

You also cite to ACOG Practice Bulletin No. 143, which states: "the risk of clinically significant bleeding and transfusion may be lower in women who undergo medical abortion of gestations up to 49 days compared with those who undergo medical abortion of gestations of more than 49 days."[20] This statement is based on a 1998 publication which evaluated patients undergoing medical abortion with mifepristone 600 mg and then oral misoprostol 400 mcg two days later.[21] The regimen studied in this 1998 publication is not the currently approved regimen for mifepristone in the United States. Further, ACOG Practice Bulletin No. 143 has been withdrawn and replaced by Practice Bulletin No. 225, which was published in October 2020 and no longer contains this statement.[22]

You also state that the failure rate of the approved regimen (which you refer to as the "buccal misoprostol regimen") increases as the gestational age increases, especially at

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[17] Mentula MJ, Niinimake M, Suhonen S, et al. Immediate Adverse Events After Second Trimester Medical Termination of Pregnancy: Results of a nationwide registry study, Human Reproduction. 2011;26(4):927-932.
[18] Id. at Fig. 2 and Fig. 3. Surgical intervention after medical abortion and infection after medical abortion are two distinct adverse events. The calculation of abortion completion rates accounts for the need for surgical intervention. In clinical studies we reviewed, success of medical abortion was defined as the complete expulsion of the products of conception without the need for surgical intervention.
[19] See 2016 Cross-Discipline Team Leader Review, available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020CrossR.pdf, at 37 (Table 4).
[20] Petition at 3. See Medical Management of First-Trimester Abortion. ACOG Practice Bulletin Number 143. March 2014 (Reaffirmed 2016. Replaces Practice Bulletin Number 67, October 2005); Obstet Gynecol. 2014 Mar;123(3):676-692 at 680.
[21] Spitz I, Bardin CW, Benton L, Robbins A. Early pregnancy termination with mifepristone and misoprostol in the United Sates, NEJM. 1998;338 (18):1241-1247.
[22] See ACOG Practice Bulletin No. 225. Medication Abortion Up to 70 Days of Gestation. Obstetrics and Gynecology 2020; 136(4); e31 to e47.

gestational ages greater than 49 days, relying on a 2015 meta-analysis,[23] and that the gestational limit should not have been increased (Petition at 3-4). We agree that the failure rate of medical abortion regimens, including the currently approved regimen, generally increases with increasing gestational age. However, the increase in failure rate with each incremental week of gestation, as described in approved mifepristone labeling and in this 2015 meta-analysis, is small, and we believe that the benefit/risk profile for medical termination of intrauterine pregnancy between 49 and 70 days gestation remains acceptable.

For these reasons, we deny your request that FDA limit mifepristone, in a regimen with misoprostol for the termination of intrauterine pregnancy, to 49 days gestation.

2. Dosage and Administration

a. Prescriber Qualifications

You state that FDA should limit the "ability" to prescribe and dispense Mifeprex to qualified, licensed physicians, rather than permitting non-physicians to apply to be certified prescribers, because of the regimen's serious risks and because physicians are better trained to diagnose patients who have contraindications to Mifeprex and to verify gestational age (Petition at 4). We do not agree.

Healthcare providers who are licensed to prescribe can become certified in REMS programs if they are able to meet the applicable REMS requirements. To become certified to prescribe mifepristone under the Mifepristone REMS Program, the prescriber must review the prescribing information for mifepristone and complete a Prescriber Agreement Form. By signing the form, the prescriber agrees that they meet certain qualifications, including the ability to date pregnancies accurately and to diagnose ectopic pregnancies. These healthcare providers must also: (1) be able to provide any necessary surgical intervention or have made arrangements for others to provide for such care; or (2) be able to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary.[24]

In our review of the S-020 efficacy supplement in 2016, we determined that available data support that Mifeprex is safe and effective when prescribed by midlevel providers, such as physician assistants and nurse practitioners, as well as by physicians.[25] Our 2016 review included four studies that evaluated the safety and efficacy of medical abortion when performed by non-physician healthcare providers. Two trials evaluated the currently

[23] Petition at 4, fn. 6 (citing Chen MJ, Creinin MD, *Mifepristone with Buccal Misoprostol for Medical Abortion*, Obstet. Gynecol 126 (1) July 2015 12-21).
[24] See https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/020687s022lbl.pdf; see also https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=390.
[25] See 2016 Clinical Review, supra n. 13, at 79; see also 2016 Cross-Discipline Team Leader Review, supra n. 19, at 17-18. We also note that in most states, midlevel clinicians, such as physician assistants and nurse practitioners, are licensed to prescribe medications.

approved Mifeprex and buccal misoprostol regimen (Olavarrieta and Kopp Kallner);[26,27] one trial studied a regimen using vaginal misoprostol (Warringer);[28] a fourth study did not specify the route of misoprostol administered (Puri).[29] Olavarrieta reported a completion rate of 97.9 percent when medical abortion was provided by nurses as compared with 98.4 percent with physicians. Kopp Kallner reported a completion rate of 99 percent with certified nurse midwives versus 97.4 percent with physicians. Warriner reported an abortion completion rate of 97.4 percent with nurses as compared with 96.3 percent with physicians. Puri reported an abortion completion rate of 96.8 percent when the service was provided by nurse-midwives as compared with 97.4 percent in the "standard care" group.[30] Our 2016 review also included a systematic review of six controlled clinical studies by Renner;[31] the authors concluded that the evidence "indicates that trained mid-level providers may effectively and safely provide first trimester surgical and medical termination of pregnancy services." Additionally, Barnard et al., in a Cochrane systematic review, assessed the safety and effectiveness of abortion procedures administered by mid-level providers (nurse practitioners, midwives, other non-physician healthcare providers) compared to doctors.[32] The authors concluded, based in part on two of the studies that we had reviewed in 2016,[33] that there was no statistically significant difference in the risk of failure for medical abortions performed by mid-level providers compared with doctors.

We also believe that the identification of patients for whom the use of mifepristone is contraindicated can be done by mid-level healthcare providers, as well as physicians. Mifepristone in a regimen with misoprostol for medical termination of intrauterine pregnancy through 70 days gestation is contraindicated in patients with any of the following conditions:[34]

- Confirmed or suspected ectopic pregnancy or undiagnosed adnexal mass

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[26] Olavarrieta CD, Ganatra B, Sorhaindo A, et al. Nurse versus Physician-provision of Early Medical Abortion in Mexico: A Randomized Controlled Non-Inferiority Trial. Bull World Health Organ. 2015;93:249-258.

[27] Kopp Kallner H, Gomperts R, Salomonsson E, et al. The efficacy, safety and acceptability of medical termination of pregnancy provided by standard care by doctors or by nurse-midwives: a randomised controlled equivalence trial. BJOG. 2015; 122: 510-517.

[28] Warriner IK, Wang D, et al. Can midlevel health-care providers administer early medical abortion as safely and effectively as doctors? A randomized controlled equivalence trial in Nepal. Lancet. 2011; 377: 1155-61.

[29] Puri M, Tamang A, Shrestha P, et al. The role of auxiliary nurse-midwives and community health volunteers in expanding access to medical abortion in rural Nepal. Reproductive Health Matters. 2015; 22(44) 94-103.

[30] 2016 Clinical Review, supra n. 13, at 43.

[31] Renner RM, Brahmi D, Kapp N. Who can provide effective and safe termination of pregnancy care? A systematic review. BJOG 2013 Jan;120(1):23-31.

[32] Barnard S, Kim C, Park MN, Ngo TD. Doctors or mid-level providers for abortion (Review). Cochran Database of Systematic Reviews. 2015, Issue 7.

[33] Of the medical abortion studies reviewed by Barnard et al (Id.), two were reviewed by the Agency as part of the review of the S-020 supplement in 2016. See Warriner et al (supra n. 28) and Kopp Kallner et al (supra n. 27). The third used a different dose of misoprostol than the currently approved regimen. See Jejeebhoy SJ, Kalyanwalaa S, Zaviera AJF, Kumara R, Mundleb S, Tankc J, et al. Feasibility of expanding the medication abortion provider based in India to include avurvedic physicians and nurses. International Perspectives on Sexual and Reproductive Health 2012;38(3)133-42)

[34] See https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/020687s022lbl.pdf.

- An intrauterine device in place
- Chronic adrenal failure
- Concurrent long-term corticosteroid therapy
- History of allergy to mifepristone, misoprostol, or other prostaglandins
- Hemorrhagic disorder or concurrent anticoagulant therapy
- Inherited porphyrias

These contraindications can be assessed by trained healthcare providers who prescribe mifepristone by obtaining a medical history, from medical records, and/or from physical examination or ultrasound if appropriate. We continue to believe that available data support the conclusion that mid-level healthcare providers, as well as physicians, possess the clinical and counseling skills necessary to provide medical abortion. We note this is consistent with ACOG's statement in its current practice bulletin that "[i]n addition to physicians, advanced practice clinicians, such as nurse-midwives, physician assistants, and nurse practitioners, possess the clinical and counseling skills necessary to provide first-trimester medical abortion."[35] Further, if necessary, ultrasound training and certification is available to nurse practitioners and physician assistants, as well as physicians.[36] In sum, available information supports that mid-level healthcare providers as well as physicians can determine whether mifepristone is an appropriate treatment for a particular patient and dispense it.

You also assert that FDA should strengthen the requirement that providers accurately assess the duration of the pregnancy by mandating that gestational age be assessed by ultrasound (Petition at 5). We refer you to FDA's 2016 Response to the citizen petition submitted to Docket No. FDA-2002-P-0364 (the "2016 CP Response"), where FDA stated that the determination of gestational age does not always require an ultrasound. In the 2016 CP Response, FDA stated it had "determined that it was inappropriate for us to mandate how providers clinically assess women for duration of pregnancy and for ectopic pregnancy. These decisions should be left to the professional judgment of each provider, as no method (including TVS [transvaginal ultrasound]) provides complete accuracy. The approved labeling for Mifeprex recommended ultrasound evaluation as needed, leaving this decision to the judgment of the provider."[37]

In the Petition, you reference the Prescriber Agreement Form, in which the provider must attest they have the ability to: (1) accurately assess the duration of the pregnancy; (2) diagnose ectopic pregnancies; and (3) provide surgical intervention if needed (or have made plans to provide such care through others), and you state that a provider who does not physically meet with and examine a patient, but simply consults with the patient over the Internet, is not capable of fulfilling these requirements, or of ruling out additional

[35] ACOG Practice Bulletin No. 225, supra n. 22.
[36] American Institute of Ultrasound in Medicine. Accessed November 26, 2021. https://www.aium.org/officialStatements/70.
[37] FDA's citizen petition response dated March 29, 2016, to the citizen petition submitted by the American Association of Pro-Life Obstetricians and Gynecologists, the Christian Medical and Dental Association, and Concerned Women for America on August 20, 2002, Docket No. FDA-2002-P-0364 at 18. See https://www.regulations.gov/document/FDA-2002-P-0364-0002.

contraindications (Petition at 5-6). You state that FDA should require certified prescribers to be physically present when Mifeprex is dispensed so that they can appropriately examine patients and rule out contraindications to the use of Mifeprex (Petition at 4).

Certified prescribers do not have to be physically present with the patient as long as they have confirmed the patient's gestational age and intrauterine pregnancy. As noted above, in the 2016 CP response, FDA "determined that it was inappropriate for us to mandate how providers clinically assess women for duration of pregnancy and for ectopic pregnancy."[38] Moreover, the evaluation of patients for contraindications to medical abortion does not necessarily require direct physical contact with the certified prescriber and can be done in different types of healthcare settings. A certified prescriber can also review the Patient Agreement Form[39] with the patient, fully explain the risks of the mifepristone treatment regimen, and answer any questions, as in any consent process, without physical proximity. See also section II.B.1.c (ETASU C – In-person Dispensing).

With respect to providing surgical intervention in cases of incomplete abortion or severe bleeding and assuring patient access to medical facilities equipped to provide blood transfusions and resuscitation (if necessary), the Prescriber Agreement Form does not reflect a requirement that the certified prescriber must provide such care personally; rather, the prescriber must agree that they have the ability to provide such care or that they have made plans to provide such care through others, and that they have the ability to assure the patient has access to appropriate medical facilities. It is common practice for healthcare providers to provide emergency care coverage for other healthcare providers' patients, and in many places, hospitals employ "hospitalists" to provide care to all hospitalized patients. We also note ACOG's statement that "[i]n rare cases, a patient who undergoes a medication abortion may need to obtain an additional intervention, such as uterine aspiration. If the prescribing clinician does not perform the intervention, it is medically appropriate to provide a referral."[40]

For these reasons, we deny your request that FDA limit the "ability" to prescribe and dispense mifepristone to licensed physicians, and we deny your request that FDA require certified providers to physically meet with and examine the patient.

b. Office Visits and Administration of Mifepristone/Misoprostol

In the Petition, you state that the use of mifepristone and misoprostol should require three office visits by the patient (Petition at 7). In support of this position, you state the following:

- Drug-induced abortion is contraindicated for patients who are not available for follow-up contact or evaluation (Petition at 10).

[38] Id.
[39] See https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=390.
[40] ACOG Practice Bulletin Number 225 supra n. 22.

- Abortion complications are more frequent when women abort at home and more healthcare oversight is needed (Petition at 8).

- Home administration of misoprostol does not permit healthcare providers to control when their patients take misoprostol and without monitoring:

    - a patient may take buccal misoprostol before the minimum 24-hour period after taking Mifeprex, which leads to a significantly increased failure rate (Petition at 7).

    - a patient may swallow misoprostol rather than administer it buccally, and oral administration is not as effective as buccal administration in ending the pregnancy (Petition at 7).

- Because providers may now "confirm" that a patient's drug-induced abortion was successful without a clinic visit, this increases the threat that Rh-negative patients will not receive Rhogam, which is necessary to prevent serious risks in subsequent pregnancies (Petition at 7 and 9).

We address each of these points below.

i. Follow-up Care

The safe use of mifepristone when used in the approved regimen with misoprostol is not contingent on a specific number of office visits being made by the patient undergoing a medical termination of pregnancy. The 2016 labeling change for Mifeprex regarding post-treatment assessment, including the change to the approved regimen to reduce the number of offices visits from three to one, was based on evidence reviewed in the S-020 efficacy supplement. We concluded, upon reviewing the data, that three office visits were not necessary to assure the safe use of Mifeprex.[41]

In your Petition, you point to statements by ACOG that medical abortion is contraindicated for patients who are not available for follow-up contact or evaluation (Petition at 8, 10). The ACOG statements you point to are from ACOG Practice Bulletin No. 143, which has been withdrawn and replaced by Practice Bulletin No. 225.[42] Neither of the statements from the withdrawn Practice Bulletin nor Practice Bulletin No. 225 contraindicate medical abortion in women who are not available for an in-clinic follow-up visit. The current ACOG recommendations indicate that for medical abortion, "[f]ollow-up can be performed by telephone at 1 week, with subsequent at-home urine pregnancy testing at 4 weeks after treatment, which avoids the need for the patient to go to a facility."[43] The patient and their healthcare provider should determine the best option for follow-up as part of the consultation and consent process.[44] As reflected in ACOG's guidance, appropriate follow-

[41] See 2016 Clinical Review, supra n. 13, at 44 and 64-67.
[42] ACOG Practice Bulletin Number 225, supra n. 22.
[43] Id.
[44] Id.

up after medical termination of a pregnancy may be accomplished in multiple ways and not all require an in-clinic visit.

You also question findings in multiple studies that evaluated the effectiveness of semiquantitative urine pregnancy tests (multi-level pregnancy tests, or MLPT) and low sensitivity urine pregnancy tests (LSPT) to rule out on-going pregnancies and assessed the ability of patients to self-administer these tests and interpret the test results (Petition at 9-10). Overall, these studies concluded that in the majority of women, it is feasible to use a simplified test to determine if further follow-up is necessary. A recent systematic review and meta-analysis by Baiju assessed the effectiveness and safety of self-assessment of the outcome of medical abortion completed at home versus routine clinic follow-up after medical abortion, concluding self-assessment was not inferior to routine clinic follow-up.[45] We note that this is consistent with current ACOG recommendations, which state that "follow-up can be performed by telephone at 1 week, with subsequent at-home urine pregnancy testing at 4 weeks after treatment, which avoids the need for the patient to go to a facility."[46]

You also assert that it is important for a patient to be under observation after taking misoprostol to ensure that they are appropriately monitored and provided sufficient pain medication (Petition at 8). You cite the World Health Organization (WHO)'s statement in guidance that up to 90 percent of women will abort within 4-6 hours after taking misoprostol; you further state that the 2000 regimen permitted patients to be in the clinic during this time period (Petition at 8). Your reference to the WHO guidance document[47] appears to be out of context. The WHO guidance takes no position on whether women should return to and remain in the clinic during a follow-up visit for purposes of taking misoprostol; in fact, it explicitly recognizes that post-abortion care may not require a follow-up visit if the patient is adequately counseled.[48] In the United States, and as reflected in the approved labeling, medical termination of pregnancy usually involves patients terminating the pregnancy at home, with appropriate follow-up that may not include a return visit.

ii. At Home Medical Abortion and Healthcare Oversight

In addition, you cite a 2018 study to support your statement that abortion complications are more frequent when women abort at home (Petition at 8). The study evaluated complications following medical abortion (both less than 12 weeks and more than 12 weeks gestation) as well as following surgical abortion, at one hospital in Sweden between 2008 and 2015.[49] For the years 2008 to 2010, data were collected retrospectively; for the years

[45] Baiju, N, Acharya, G, D'Antonio, F, et al. 2019. Effectiveness, safety and acceptability of self-assessment of the outcome of first-trimester medical abortion: a systematic review and meta-analysis. BJOG; 126:1536-1544.
[46] ACOG Practice Bulletin Number 225, supra n. 22.
[47] World Health Organization, Safe Abortion: technical and policy guidance for health systems – 2nd edition. 2012. Page 45 and Section 2.2.2.1 Medication for pain.
[48] Id. at Section 2.3 Post-abortion care and follow-up, at 52.
[49] Carlsson I, Breding K, Larsson PG, 2018, Complications Related to Induced Abortion: A Combined Retrospective and Longitudinal Follow-up Study, BMC Women's Health 18:158.

2011 to 2015, data were collected prospectively. In this study, medical abortions after 12 gestational weeks all occurred at the hospital. The authors report that, among medical abortions less than 12 weeks, the complication frequency increased from 5.4 percent (2008 to 2010) to 8.2 percent (2015). However, the authors also compared the complications related to medical abortions that occurred at less than 12 gestational weeks between "at home" abortions (managed as an outpatient) and "at the hospital" abortions, in 2015 and found no statistically significant difference (8.2 percent "at home" versus 8.0 percent at the hospital). For pregnancies less than or equal to 9 gestational weeks, the rates are similar for the "at home" group (10.0 percent) and the "at the hospital" group (9.3 percent). Notably, as part of our review and approval of the S-020 efficacy supplement in 2016, we assessed serious adverse events by gestational age, including hospitalizations, serious infection requiring hospitalization or intravenous antibiotics, bleeding requiring transfusion, and ectopic pregnancy, as reported in the literature submitted by the Applicant. We concluded that these serious adverse events are rarely reported in the literature and that the regimen of mifepristone 200 mg followed by buccal misoprostol 800 mcg in 24-48 hours is safe to approve for use through 70 days gestation.[50]

You also state that medical abortion is a longer process than surgical abortion and that it requires more attention and care from healthcare providers (Petition at 10). We agree that medical abortion can be a longer process than surgical abortion,[51] but we disagree that medical abortion always requires in-person follow-up with a healthcare provider. Not all of the complications associated with medical abortion necessarily require more intensive management from healthcare providers during a follow-up visit. The question of whether to include an in-person follow-up visit should be discussed by the healthcare provider and the patient. We have concluded that medical abortions are safe and effective for patients who are appropriate candidates and reducing the number of clinic visits does not compromise patient safety.

The current approved labeling for mifepristone for medical termination of pregnancy states that complete pregnancy termination "can be confirmed by medical history, clinical examination, human Chorionic Gonadotropin (hCG) testing, or ultrasonographic scan." Not all these modalities require an in-clinic assessment during a follow-up visit. Our review of the S-020 efficacy supplement concluded that "available data support … that there are a variety of follow-up modalities that can adequately identify the need for additional intervention."[52] We note that these findings are also consistent with ACOG guidelines, which state that "[r]outine in-person follow-up is not necessary after uncomplicated medication abortion" and recommend several methods for post-treatment follow-up, as appropriate, including serial serum hCG testing alone or telephone follow-up at one week after treatment followed by urine pregnancy testing at four weeks after treatment.[53] Because there is more than one effective method to detect an on-going pregnancy, we conclude that the way in which post-treatment follow-up is performed may be determined by the healthcare provider and the patient.

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[50] 2016 Clinical Review, supra n. 13, at 51-57.
[51] See ACOG Practice Bulletin Number 225, supra note 22.
[52] 2016 Cross Discipline Team Leader Review, supra n. 19, at 17.
[53] ACOG Practice Bulletin Number 225, supra note 22.

iii. Misoprostol

In the Petition, you make a number of assertions regarding the use of misoprostol. We address each in turn.

First, you assert that a patient may take misoprostol before the prescribed minimum 24-hour period after taking Mifeprex, thereby rendering the regimen ineffective, and that home administration of misoprostol does not permit health providers to control when their patients take misoprostol (Petition at 7). You similarly assert that the use of buccal misoprostol sooner than 24 hours after administering mifepristone leads to significantly increased failure rates (Petition at 7).

As an initial matter, our review of the S-020 efficacy supplement in 2016 included data that evaluated the home use of misoprostol in over 30,000 women. The data showed that Mifeprex was safe and effective in a regimen with misoprostol when misoprostol was self-administered at home.[54] Therefore, any incorrect administration resulting in a failed abortion was infrequent and did not significantly affect the safety and efficacy of medical abortion. Furthermore, because the process of expelling the pregnancy may begin as soon as 2 hours after taking misoprostol, there is a benefit in allowing patients to choose when and where to start this process, to maximize the possibility of their being at a safe place at a convenient time to experience cramping and bleeding.[55]

In support of your assertion of significantly increased failure rates, you cite a pilot study by Lohr et al.[56] Lohr et al. assessed the complete abortion rate using simultaneous oral mifepristone and buccal misoprostol in three gestational age groupings (less than or equal to 49 days, 50-56 days, 57-63 days) and compared the rates with those published in previous pilot investigations[57] using simultaneous oral mifepristone and vaginal misoprostol in the same three gestational age groupings. The complete abortion rates reported by Lohr at 24 hours for oral mifepristone and buccal misoprostol were 72.5 percent, 69.2 percent, and 72.5 percent, respectively; the complete abortion rates at two weeks, however, were 97.5 percent, 100 percent, and 94.9 percent, respectively (and are consistent with the completion rates as described in the approved labeling).[58] The published complete abortion rates at 24 hours for simultaneous oral mifepristone and vaginal misoprostol administration were 90 percent, 88 percent, and 83 percent, respectively, for the gestational age groupings and the complete abortion rates at 2 weeks were 98 percent, 93 percent, 90 percent, respectively. Based on the data presented in Lohr,

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[54] See 2016 Clinical Review, supra n. 13, at 41 and 48.
[55] Id. at 38.
[56] Petition at 7 (referencing Lohr PA, Reeves MF, Hayes JL, et al., 2007, Oral Mifepristone and Buccal Misoprostol Administered Simultaneously for Abortion: A Pilot Study, Contraception, 76:215-220).
[57] Schreiber CA, Creinin MD, Harwood B, Murthy AS. A pilot study of mifepristone and misoprostol administered at the same time for abortion in women with gestation from 50 to 63 days. Contraception 2005;71:447–50; Murthy AS, Creinin MD, Harwood B, Schreiber C. A pilot study of mifepristone and misoprostol administered at the same time for abortion up to 49 days gestation. Contraception 2005;71:333–6.
[58] See https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/020687s022lbl.pdf.

the use of buccal misoprostol at the same time as oral mifepristone does not adversely affect efficacy, although expulsion may be delayed. As recommended in Section 2.3 of the approved labeling, follow-up at 7-14 days after administration of mifepristone is more appropriate to evaluate efficacy.[59] It is misleading to only reference the abortion completion rates observed at the 24-hour timepoint from Lohr. Therefore, we do not agree that data from Lohr indicate higher failure rate with misoprostol taken before the prescribed minimum 24-hour period after taking mifepristone.

Although we disagree that Lohr demonstrates a higher failure rate with misoprostol taken before 24-hours after taking mifepristone, we note that our 2016 review of the S-020 efficacy supplement referenced a 2013 systematic review by Raymond, which concluded that if the interval between mifepristone and misoprostol interval is less than or equal to 24 hours, the procedure is less effective compared to an interval of 24-48 hours.[60] As explained above, the data reviewed in 2016 showed that Mifeprex, in a regimen with misoprostol administered at home, was safe and effective. Therefore, incorrect administration, if it occurred, was infrequent and did not significantly affect the safety and efficacy of medical abortion. However, in light of the data reviewed, section 2.1 of the labeling approved in 2016 (as well as the currently approved labeling and Medication Guide) states that there should be a "minimum 24-hour interval between" mifepristone and misoprostol (emphasis included in the labeling).[61] The approved dosing regimen also states that misoprostol is taken within 24 to 48 hours after taking mifepristone and acknowledges that the effectiveness of the regimen may be lower if misoprostol is administered less than 24 hours after mifepristone administration.

In addition to your concerns that a woman may take misoprostol too soon after administering mifepristone, you also state that waiting until 24 hours after administering mifepristone does not guarantee success (Petition at 7-8). In support of this concern, you cite a 2015 review by Chen and Creinin. You state that this review found "women taking misoprostol earlier than 48 hours after Mifeprex are more likely to fail the regimen" (Petition at 8). Chen and Creinin included studies in which the intervals between mifepristone and buccal misoprostol were 24 hours or 24-48 hours and stated that "based on the available literature, the overall efficacy of regimens with a 24-hour interval between mifepristone and buccal misoprostol is significantly lower than those with a 24- to 48-hour interval (94.2 percent compared with 96.8 percent)."[62] The rate differences were statistically significant, but both regimens were more effective than the 92 percent efficacy rate of the original regimen approved in 2000 (administering misoprostol 48 hours after taking mifepristone).

Finally, you also express concern that if misoprostol is self-administered, a woman may swallow it rather than keep the pill between her cheek and gum, and oral administration of

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[59] See https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/020687s022lbl.pdf.
[60] 2016 Clinical Review, supra n. 13, at 31 (citing 8 Raymond EG, et al. First-trimester medical abortion with mifepristone 200 mg and misoprostol: a systematic review. Contraception 2013;87(1):26-37.)
[61] See https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/020687s022lbl.pdf.
[62] See Chen MJ and Creinin MD. Mifepristone with buccal misoprostol for medical abortion. Obstet Gynecol. 2015;126(1):12-21; see also 2016 Clinical Review, supra n. 13, at 21.

misoprostol (i.e., swallowing the pill) following the lower dose of mifepristone in the current regimen is not as effective in ending the pregnancy (Petition at 7). Winikoff et al. specifically studied the use of oral compared to buccal misoprostol 24-36 hours after mifepristone 200 mg with overall success rates of 91.3 percent and 96.2 percent, respectively.[63] Both regimens resulted in a greater than 91 percent successful medical abortion. Although the study showed decreased efficacy with oral versus buccal administration in 57-63 days gestational age, there were no statistical differences in other gestational age groupings. Even assuming there is a small proportion of women who are 57-63 days gestational age and use oral administration of misoprostol (rather than buccal as labeled), a small decrease in the reported efficacy in that population would not justify requiring a clinic visit for all women undergoing medical abortion.

Overall, studies support the efficacy of the mifepristone, in a regimen with misoprostol when taken by the patient at home, Therefore, we do not agree that an in-person visit is necessary to manage administration of misoprostol.

iii. Rh-Negative Patients

In the Petition, you state that a follow-up examination is particularly critical for Rh-negative patients and that without that follow-up examination, women will not receive Rhogam after the abortion, increasing their risk of subsequent Rh isoimmunization, which can endanger future pregnancies (Petition at 9). You suggest that a clinic visit after the administration of Mifeprex is important for Rh-negative women to receive Rhogam and that removing the required follow-up visit puts Rh-negative women at risk for isoimmunization. We do not agree.

Rh testing is standard of care in the United States and RhD immunoglobulin (such as Rhogam) should be administered if indicated. Further, administration of RhD immunoglobulin should be given within 72 hours of a sensitizing event (e.g., medical abortion).[64] However, the facility where the RhD immunoglobulin injection occurs (clinic, hospital or laboratory) is not critical. A shift from medical clinics to hospitals for administration of injections has occurred over the years due to shortages of RhD immunoglobulin and poor reimbursement for RhD immunoglobulin injection from third-party payers.[65] This has resulted in pregnant women frequently obtaining routine 28-week RhD immunoglobulin injections at hospitals/laboratories with a prescription provided by their healthcare providers. This same process of obtaining RhD immunoglobulin via prescription is available to patients after medical termination of pregnancy and does not require a follow-up clinic visit.

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[63] Winikoff B, Dzuba, IG, Creinin MD, et al, 2008, Two Distinct Oral Routes of Misoprostol in Mifepristone Medical Abortion, Obstet Gynecol 112(6):1303-1310.

[64] ACOG Practice Bulletin No. 181. Prevention of Rh D Alloimmunization. August 2017.

[65] See https://www.mdedge.com/obgyn/article/61083/practice-management/rhogam-injections-payment-levels-vary-among-insurers.

In summary, the totality of data on the efficacy and safety of medical abortion at less than 70 days gestation, derived from numerous studies, has characterized the complications and rates of complications for completing medical abortion at home, and the findings show medical abortion at home is both safe and effective without three office visits. We therefore deny your request that the use of mifepristone in a regimen with misoprostol require three office visits by the patient.

c. Contraindications

In the Petition, you assert that critical language contraindicating Mifeprex for patients without access to appropriate emergency medical care was excluded from the 2016 Mifeprex labeling. You cite to a study[66] and ACOG statements as evidence that medical abortions have greater risks and more need for emergency "operation" than a surgical abortion, particularly for patients in rural areas with limited access to emergency medical care (Petition at 11).

Although inadequate access to medical facilities for appropriate care was removed from the list of contraindications in section 4 of the approved labeling when we approved the S-020 efficacy supplement, the 2016 Mifeprex labeling and the currently approved mifepristone labeling, as well as the Mifepristone REMS Program, continue to include appropriate instructions for providers regarding patient access to appropriate medical care.[67] For example, the Boxed Warning includes language directing healthcare providers to ensure that the patient knows whom to call and what to do, including potentially going to an emergency room, if the patient experiences serious events associated with the use of mifepristone. The labeling also directs healthcare providers, as part of the dosing regimen, to give the patient the name and phone number of a healthcare provider who will be handling emergencies.[68] In addition, one of the required qualifications listed in the Prescriber Agreement Form is the "[a]bility to provide surgical intervention in cases of incomplete abortion or severe bleeding, or to have made plans to provide such care through others, and ability to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary."[69] Therefore, although certain language about access to medical facilities was removed from the approved labeling in 2016, we disagree that critical language about access to appropriate emergency medical care is lacking from the approved labeling.

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[66] See Petition Reference Document No. 17 (Harrison Affidavit: Donna Harrison, M.D., Aff. *Okla. Coalition for Reproductive Justice v. Cline*, Case No. CV-2014-1886 (Feb. 24, 2015), ¶115 (referencing M. Niinimaki et al., Immediate Complications after Medical compared with Surgical Termination of Pregnancy, Obstet. Gynecol. 114:795 (Oct. 2009)).

[67] See Mifeprex labeling, approved 2016. https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf. See also current labeling at https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/020687s022lbl.pdf.

[68] Id.

[69] Mifepristone REMS Program, https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=390. Emphasis added.

You also cite information in Box 1, Features of Medical and Surgical Abortion (page 3) in the ACOG Practice Bulletin No. 143.[70] As mentioned above, the ACOG Practice Bulletin No. 143 has been withdrawn and the language you cite is not included in the current Practice Bulletin No. 225.

d. Adverse Event Reporting

In the Petition, you assert that even under the regimen approved in 2000, it was difficult to collect accurate and complete adverse event information for Mifeprex, and that collecting such information is virtually impossible under the regimen approved in 2016 because prescribers only are required to report deaths associated with Mifeprex (Petition at 12). You also assert that FDA cannot adequately assess the safety of the current Mifeprex regimen without comprehensive information on adverse events (Petition at 12). You state that certified prescribers should at a minimum be required to report the following to FDA's MedWatch reporting system and to the sponsor: deaths, hospitalizations, blood transfusions, emergency room visits, failures requiring surgical completion, ongoing pregnancy, or other major complications, including detailed information on these events (Petition at 13).

We acknowledge that there is always a possibility with any drug that some adverse events are not being reported, because reporting to the Agency's MedWatch program by health care professionals and patients is voluntary. We do not agree, however, that the 2016 changes to the prescriber reporting requirements limit our ability to adequately monitor the safety of mifepristone for medical termination of pregnancy. Prior to the 2016 approval of the S-20 efficacy supplement, we assessed approximately 15 years of adverse event reports both from the Applicant and through the MedWatch program and determined that certain ongoing additional reporting requirements under the Mifeprex REMS, such as hospitalization and blood transfusions, were not warranted. This assessment was based on the well-characterized safety profile of Mifeprex, with known risks occurring rarely, along with the essentially unchanged safety profile of Mifeprex during this 15-year period of surveillance. Accordingly, the Prescriber Agreement Form was amended as part of our 2016 approval of the S-20 efficacy supplement to require, with respect to adverse event reporting, only that prescribers report any cases of death to the Applicant.

We also note that the reporting changes to the Prescriber Agreement Form as part of our 2016 approval do not change the adverse event reporting requirements for the Applicants. Like all other holders of approved NDAs and ANDAs, the Applicants are required to report all adverse events, including serious adverse events, to FDA in accordance with the requirements set forth in FDA's regulations (see 21 CFR 314.98, 21 CFR 314.80, and 21 CFR 314.81). FDA also routinely reviews the safety information provided by the Applicants in the Annual Reports. As with all drugs, FDA continues to closely monitor the postmarketing safety data on mifepristone for the medical termination of pregnancy.

[70] Petition at 11. Medical Management of First-Trimester Abortion. ACOG Practice Bulletin Number 143. March 2014 (Reaffirmed 2016. Replaces Practice Bulletin Number 67, October 2005); Obstet Gynecol. 2014 Mar;123(3):676-692 at 680.

You state that FDA should provide guidance to emergency healthcare providers and physicians so that they know how to distinguish complications following drug-induced abortion from complications following spontaneous miscarriage (Petition at 13). We disagree that specific guidance is needed at this time. In the past, when appropriate, FDA has worked with the NDA Applicant to issue communications to healthcare providers and emergency department providers concerning certain serious adverse events.[71] Furthermore, the approved Medication Guide advises patients to take the Medication Guide with them if they need to go to the emergency room or seek care from a healthcare provider other than the one who dispensed the medication to them, so the emergency room or healthcare provider understands the patient is having a medical abortion. We have not identified a change in the safety profile of mifepristone that would warrant additional communications to healthcare providers and emergency department providers concerning complications following medical abortion. If we become aware of safety information that merits further communications with emergency department providers or healthcare providers, or that warrants revisions to the approved labeling, we will act as appropriate.

You also assert that many Mifeprex prescribers "violate FDA protocol," instructing their patients to lie to emergency medical personnel, and that this prevents emergency healthcare providers from appropriately caring for their patients and further decreases the likelihood that adverse events will be reported (Petition at 12). Your only support for this claim is a reference to instructions from the organization Aid Access[72] to patients that they can tell emergency room staff that they had a miscarriage and do not need to tell medical staff that they had a medical abortion. The Petition does not provide any data or additional information establishing "many Mifeprex prescribers violate FDA protocol, instructing their patients to lie," or that these providers thereby prevented appropriate care and decreased the number of adverse events reported.

B. REMS

1. Request to Retain Mifeprex REMS

In your Petition, you request that FDA retain the Mifeprex REMS (Petition at 14). We agree that a REMS is necessary to ensure that the benefits of mifepristone in a regimen with misoprostol outweigh the risks. FDA's determination as to whether a REMS is necessary

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[71] See Historical Information on Mifepristone (Marketed as Mifeprex), available at http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111334.htm. For example, the NDA applicant and FDA agreed that there was a need to issue a Dear Health Care Provider letter in April 2002 and a Dear Emergency Room Director letter in September 2004. The fact that these letters were issued does not imply that the approved mifepristone regimen is unsafe; it is not uncommon for drug sponsors to issue "Dear Health Care Provider" letters, and, as noted in the Mifepristone Q&A document posted on our Web site in April 2002, "[w]hen FDA receives and reviews new information, the agency provides appropriate updates to doctors and their patients so that they have essential information on how to use a drug safely."

[72] We note that Aid Access facilitated the sale of unapproved mifepristone and misoprostol to U.S. consumers and that FDA sent Aid Access a warning letter asking it to promptly cease causing the sale of unapproved and misbranded drugs to U.S. consumers. US FDA Warning Letter to Aidaccess.org, dated March 8, 2019. https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/aidaccessorg-575658-03082019.

to ensure that the benefits of a drug outweigh its risks is a complex, drug-specific inquiry, reflecting an analysis of multiple, interrelated factors and of how those factors apply in a particular case.[73] In conducting this analysis, FDA considers whether (based on premarketing or postmarketing risk assessments) there is a particular risk or risks associated with the use of the drug that, on balance, outweigh its benefits and whether additional interventions beyond FDA-approved labeling are necessary to ensure that the drug's benefits outweigh its risks.[74]

As described in the background section of this response (see section I.A.), FDA determined that interventions in addition to the FDA-approved labeling were necessary to ensure that the benefits of Mifeprex outweighed its risks when the drug was initially approved in 2000, and periodic re-evaluations of the REMS since that time have reached the same conclusion. As further described in the background section of this response (see section I.E.), FDA recently undertook a review of the Mifepristone REMS Program. As explained below, the Mifepristone REMS Program continues to be necessary to ensure the benefits outweigh the risks.

After review of multiple different sources of information, including published literature, safety information submitted to the Agency during the COVID-19 PHE, FAERS reports, the first REMS assessment report for the Mifepristone REMS Program, and information provided by advocacy groups, individuals, and the Plaintiffs in ongoing litigation,[75] as well as information submitted by the Applicants, we have concluded that the REMS can be modified to reduce the burden on the health care delivery system without compromising patient safety. As explained below, we agree that the healthcare provider certification (ETASU A) and dispensing of mifepristone to patients with evidence or other documentation of safe use conditions (ETASU D) continue to be necessary components of the REMS to ensure the benefits outweigh the risks. However, we have concluded that the Mifepristone REMS Program must be modified to remove the requirement under ETASU C that mifepristone be dispensed only in certain healthcare settings, specifically clinics, medical offices, and hospitals.

Below, we discuss each of these elements of the Mifepristone REMS Program.

a. ETASU A – Prescriber Certification/Qualifications

ETASU A under the Mifepristone REMS Program requires healthcare providers who prescribe mifepristone to be certified. In order to become certified, prescribers must: 1) review the prescribing information for mifepristone and 2) complete the Prescriber Agreement Form. In signing the Prescriber Agreement Form, prescribers agree they meet the qualifications listed below:

[73] See FDA Guidance for Industry, *REMS: FDA's Application of Statutory Factors in Determining When a REMS Is Necessary* (Apr. 2019).
[74] Id.
[75] See supra n. 10.

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- Ability to assess the duration of pregnancy accurately
- Ability to diagnose ectopic pregnancies
- Ability to provide surgical intervention in cases of incomplete abortion or severe bleeding, or to have made plans to provide such care through others, and ability to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary.
- Has read and understood the Prescribing Information of mifepristone (which the provider can access by phone or online).

In addition to meeting these qualifications, as a condition of certification the healthcare provider also agrees to follow the guidelines for use below:

- Review the Patient Agreement Form with the patient and fully explain the risks of the mifepristone treatment regimen. Answer any questions the patient may have prior to receiving mifepristone.
- Sign and obtain the patient's signature on the Patient Agreement Form.
- Provide the patient with a copy of the Patient Agreement Form and the Medication Guide.
- Place the signed Patient Agreement Form in the patient's medical record.
- Record the serial number from each package of mifepristone in each patient's record.
- Report deaths to the Applicant, identifying the patient by a non-identifiable patient reference and the serial number from each package of mifepristone.

Our review of the published literature did not identify any studies comparing healthcare providers who met these qualifications with healthcare providers who did not. In the absence of such studies, there is no evidence to contradict our previous finding that prescribers' ability to accurately date pregnancies, diagnose ectopic pregnancies, and provide surgical intervention either personally or through others, is necessary to mitigate the serious risks associated with the use of mifepristone in a regimen with misoprostol. Therefore, our conclusion continues to be that a healthcare provider who prescribes mifepristone in a regimen with misoprostol should meet the above qualifications. Absent these provider qualifications, we are concerned that serious and potentially fatal complications associated with medical abortion, including missed ectopic pregnancy and heavy bleeding from incomplete abortion, may not be detected or appropriately managed.

Accordingly, we have determined that ETASU A must remain an element of the Mifepristone REMS Program to ensure the benefits outweigh the risks. Maintaining the requirement for prescriber certification ensures that providers meet the necessary qualifications and adhere to the guidelines for use listed above. The burden of prescriber certification has been minimized to the extent possible by requiring prescribers to certify only one-time for each applicant.

Although we agree with your request to retain the REMS for mifepristone (now the Mifepristone REMS Program) insofar as it pertains to ETASU A, as discussed in section II.A.2.a of this response, we do not agree with your request that the healthcare provider needs to be a licensed physician to meet this requirement.

b. ETASU D – Requirement For The Drug To Be Dispensed With Evidence Or Other Documentation Of Safe-Use Conditions

ETASU D under the Mifepristone REMS Program requires mifepristone to be dispensed with evidence or other documentation of safe-use conditions. To receive mifepristone for medical termination of intrauterine pregnancy through 70 days gestation, the patient must sign a Patient Agreement Form indicating that the patient has received, read, and been provided a copy of the Patient Agreement Form and received counseling from the prescriber regarding the risk of serious complications associated with mifepristone for this indication. The Patient Agreement Form ensures that patients are informed of the risks of serious complications associated with mifepristone for this indication. In a number of approved REMS, Patient Agreement Forms or Patient Enrollment Forms ensure that patients are counseled about the risks of the product and/or informed of appropriate safe use conditions.[76]

As a condition of certification under the Mifepristone REMS Program, healthcare providers must follow the guidelines for use of mifepristone, including reviewing the Patient Agreement Form with the patient, fully explaining the risks of the treatment regimen and answering any questions the patient may have before receiving the medication. With this form, the patient acknowledges that they have received and read the form, and that they have received the counseling regarding when to take mifepristone, the risk of serious complications associated with mifepristone and what to do if they experience adverse events (e.g., fever, heavy bleeding). Both the healthcare provider and patient must sign the document and the patient must receive a copy of the signed form. In addition to the counseling described in the Patient Agreement Form, patients also receive a copy of the Medication Guide for mifepristone. Ultimately, the Patient Agreement Form serves as an important counseling component, and documentation that the safe use conditions of the Mifepristone REMS Program have been satisfied, as the prescriber is required to place the signed Patient Agreement Form in the patient's medical record.

In addition, we conducted an updated review of published literature since 2016 to assess the utility of maintaining the Patient Agreement Form as part of the Mifepristone REMS Program, and these studies do not provide evidence that would support removing ETASU D. For these reasons, we have determined that ETASU D must remain an element of the Mifepristone REMS Program to ensure the benefits outweigh the risks.

[76] REMS@FDA, https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm, Accessed November 15, 2021.

c. ETASU C – In-Person Dispensing

ETASU C under the Mifepristone REMS Program currently requires mifepristone to be dispensed to patients only in certain healthcare settings, specifically clinics, medical offices, and hospitals, by or under the supervision of a certified prescriber. This creates what we refer to in this response as an in-person dispensing requirement under the REMS; i.e., the patient must be present in person in the clinic, medical office, or hospital when the drug is dispensed. The mifepristone REMS document currently states that mifepristone may not be distributed to or dispensed through retail pharmacies or settings other than a clinic, medical office, or hospital. As explained below, based on a recent review of the REMS, we believe that the Mifepristone REMS Program must be modified to remove the requirement that mifepristone be dispensed only in certain healthcare settings, specifically clinics, medical offices, and hospitals, because this requirement is no longer necessary to ensure that the benefits of the drug outweigh the risks. This conclusion is based on our review of information from the Mifepristone REMS Program one-year (1st) REMS[77] assessment data and postmarketing safety information, and supported by our review of the published literature.

i. Assessment Data

As part of our review of the REMS, we evaluated information included in the 1st REMS assessment report for the Mifepristone REMS Program, which included healthcare provider certification data, program utilization data, and non-compliance data. This 1st REMS assessment report covers a reporting period between April 11, 2019 through February 29, 2020. During this reporting period, a small number of non-compliance events were reported.

As described in section I.C. of this response, during the timeframe from January 27, 2020 through September 30, 2021, there were periods when the in-person dispensing requirement was not enforced. To better understand whether there was any impact on safety or non-compliance during the periods when the in-person dispensing requirement was not enforced, we requested additional information from the Applicants to provide for more comprehensive assessment of the REMS for the time period from January 27, 2020 (the effective date of the COVID-19 PHE) to September 30, 2021. We requested the Applicants provide a summary and analysis of any program deviation or non-compliance events from the REMS requirements and any adverse events that occurred during this time period that had not already been submitted to FDA. The NDA and the ANDA Applicants reported a total of eight cases reporting adverse events between January 27, 2020 and September 30, 2021. These eight cases were also identified in the FAERS database and are described below.

The number of adverse events reported to FDA during the COVID-19 PHE with mifepristone use for medical termination of pregnancy is small, and the data provide no

[77] This REMS assessment report was the first submitted following the approval of the single, shared system REMS for mifepristone.

indication that any program deviation or noncompliance with the Mifepristone REMS Program contributed to these reported adverse events.

ii. FAERS/Postmarketing Safety Data

FDA routinely monitors postmarketing safety data for approved drugs through adverse events reported to our FAERS database,[78] through our review of published medical literature, and when appropriate, by requesting applicants submit summarized postmarketing data. For our recent review of the REMS, we searched our FAERS database, reviewed the published medical literature for postmarketing adverse event reports for mifepristone for medical termination of pregnancy, and requested that the Applicants submit a summary and analysis of certain adverse events. Our review of this postmarketing data indicates there have not been any new safety concerns with the use of mifepristone for medical termination of pregnancy through 70 days gestation, including during the time when in-person dispensing was not enforced.

In order to evaluate the periods when in-person dispensing was and was not enforced, we conducted a search of the FAERS database and the published medical literature to identify U.S. postmarketing adverse events that reportedly occurred from January 27, 2020 through September 30, 2021 with mifepristone use for medical termination of pregnancy. The data for this time period were then further divided into the date ranges when in-person dispensing was enforced per the REMS (January 27, 2020 - July 12, 2020 and January 13, 2021 - April 12, 2021) versus when in-person dispensing was not enforced: July 13, 2020 - January 12, 2021 (in-person dispensing enforcement was temporarily enjoined) and April 13, 2021 - September 30, 2021 (enforcement discretion for in-person dispensing because of the COVID-19 PHE).

Based on the above search, a total of eight cases were identified in FAERS and no additional case reports were identified in the medical literature. Two of the eight cases reported adverse events that occurred when in-person dispensing was being enforced (i.e., January 27, 2020-July 12, 2020 and January 13, 2021-April 12, 2021). These two cases reported the occurrence of uterine/vaginal bleeding (case 1) and uterine/vaginal bleeding and sepsis (case 2). Of note, uterine/vaginal bleeding and sepsis are labeled adverse events. Five of the eight cases reported adverse events that occurred when in-person dispensing was not enforced (i.e., July 13, 2020-January 12, 2021 and April 13, 2021-September 30, 2021); however, the narratives provided in the FAERS reports for three of the five cases explicitly stated that mifepristone was dispensed in-person. These five cases reported the occurrence of ongoing pregnancy (case 3), drug intoxication and death approximately 5 months after ingestion of mifepristone (case 4), death [cause of death is currently unknown] (case 5), sepsis and death (case 6), and pulmonary embolism (case 7). Of note, ongoing pregnancy and sepsis, including the possibility of fatal septic shock, are labeled adverse events. The remaining case reported the occurrence of oral pain/soreness (case 8) in July

[78] FAERS is a database that contains adverse event reports, medication error reports and product quality complaints resulting in adverse events that were submitted to FDA. The database is designed to support FDA's post-marketing safety surveillance program for drug and therapeutic biologic products.

2021, but did not provide sufficient information to determine the exact date of the adverse event.

As discussed in section II.A.2.d., the Applicants report adverse events, including serious adverse events, to FDA in accordance with applicable regulations.[79] To enable additional review of adverse events, Applicants were requested to provide a summary and analysis for adverse events reported with incomplete medical abortion requiring surgical intervention to complete abortion, blood transfusion following heavy bleeding or hemorrhage, ectopic pregnancies, sepsis, infection without sepsis, hospitalization related to medical abortion, and emergency department/urgent care encounter related to medical abortion. The Applicant for Mifeprex provided the requested summary of postmarketing safety information from March 29, 2016, when S-020 was approved, through September 30, 2021. The Applicant for the generic provided the requested summary of postmarketing safety information from April 11, 2019 (date of initial approval) through September 30, 2021. The information provided by the Applicants included the same cases identified in FAERS, as discussed above.

We analyzed the FAERS data referenced above to determine if there was a difference in adverse events when in-person dispensing was and was not enforced. Based on FDA's review of this data, we concluded that there does not appear to be a difference in adverse events when in-person dispensing was and was not enforced and that mifepristone may be safely used without in-person dispensing. FDA's review of the summary and analysis data submitted by the Applicants (which, as noted above, included the same cases identified from FAERS) did not change this conclusion.

iii. Published Literature

As noted above, we also conducted an extensive review of the published literature since March 29, 2016 (the date the S-020 efficacy supplement for Mifeprex was approved) through September 30, 2021.[80] Published studies have described alternatives in location and method for dispensing mifepristone by a certified prescriber (or equivalent healthcare provider in countries other than the United States). Some studies have examined replacing in-person dispensing in certain healthcare settings with dispensing at retail pharmacies[81]

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[79] See 21 CFR 314.98, 21 CFR 314.80, and 21 CFR 314.81.

[80] In support of your request that we retain the REMS and continue limiting the dispensing of Mifeprex to patients in clinics, medical offices, and hospitals by or under the supervision of a certified prescriber, you reference two studies that you assert do not comply with the REMS (Petition at 19-22). Outcomes from both of the studies you reference have been reported in the published literature and are addressed in the discussion that follows. We note that as a general matter, a clinical investigation of an approved drug that is subject to a REMS can take place in healthcare settings outside those provided for in the REMS. When an approved drug that is subject to a REMS is studied in a clinical trial, the REMS does not apply to the use of the drug in that clinical trial. However, FDA reviews the protocol to ensure that it will be conducted in a manner that adequately addresses the risks that the REMS is intended to mitigate, such that the trial participants will not be exposed to an unreasonable and significant risk of illness or injury. See 21 CFR 312.42(b)(1)(i) and (b)(2)(i).

[81] Grossman D, Baba CF, Kaller S, et al. Medication Abortion With Pharmacist Dispensing of Mifepristone. Obstet Gynecol 2021;137:613–22; Rocca CH, Puri M, et al. Effectiveness and safety of early medication

and dispensing mifepristone from pharmacies by mail.[82] Other studies have evaluated two modes of dispensing by prescribers: (1) prescribers mailing the medications to patients,[83] and (2) prescribers using couriered delivery of medications.[84] Different studies have evaluated dispensing mifepristone by mail by an entity described as "a partner organization."[85]

We note that the ability to generalize the results of these studies to the United States population is hampered by differences between the studies with regard to pre-abortion care (e.g., telemedicine versus in-person). In addition, the usefulness of the studies is limited in some instances by small sample sizes and lack of follow-up information on outcomes with regard to both safety and efficacy. There are also factors which complicate the analysis of the dispensing element alone. Some of these factors are: (1) only a few studies have evaluated alternatives for in-person dispensing of mifepristone in isolation (for example, most studies on mail dispensing of mifepristone also include telemedicine consultation); and (2) because most serious adverse events with medical abortion are infrequent, further evaluation of changes in dispensing would require studies with larger numbers of participants. We did not find any large clinical studies that were designed to collect safety outcomes in healthcare systems similar to the United States. Despite the limitations of the studies we reviewed, we have concluded that overall the outcomes of these studies are not inconsistent with our conclusion that, based on the 1st year REMS assessment report and postmarketing safety data, mifepristone will remain safe and efficacy will be maintained if the in-person dispensing requirement is removed from the Mifepristone REMS Program.

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abortion provided in pharmacies by auxiliary nurse-midwives: A non-inferiority study in Nepal. PLoS ONE 13(1): e0191174. https://doi.org/10.1371/journal.pone.019117; Wiebe ER, Campbell M, et al. Comparing telemedicine to in-clinic medication abortions induced with mifepristone and misoprostol. Contracept X. 2020; 2: 100023.

[82] Grossman D, Raifman S, Morris N, et.al. Mail-order pharmacy dispensing of mifepristone for medication abortion after in-person clinical assessment. Contraception 2021, ISSN 0010-7824, https://doi.org/10.1016/j.contraception.2021.09.008, Available online 20 September 2021; Upadhyay UD, Koenig LR, Meckstroth KR. Safety and Efficacy of Telehealth Medication Abortion in the US During the COVID-19 Pandemic. JAMA Network Open. 2021;4(8):e2122320, doi:10.1001/jamanetworkopen.2021.22320; Hyland P, Raymond EG, Chong E. A direct-to-patient telemedicine abortion service in Australia: Retrospective analysis of the first 18 months. Aust N Z J Obstet Gynaecol 2018;58: 335-340.

[83] See Anger HA, Raymond EG, et al. Clinical and service delivery implications of omitting ultrasound before medication abortion provided via direct-to-patient telemedicine and mail. Contraception 2021 Jul 28;S0010-7824(21)00342-5. doi: 10.1016/j.contraception.2021.07.108. Published online. Raymond E, Chong E, et al. TelAbortion: evaluation of a direct to patient telemedicine abortion service in the United States. Contraception 2019; 100:173-177. See also Chong et al., infra n. 103 Kerestes et al., infra n. 105, and Aiken et al., infra n. 106.

[84] Reynolds-Wright JJ, et al. BMJ Sex Reprod Health 2021;0:1–6. doi:10.1136/bmjsrh-2020-200976.

[85] Endler M, Beets L, Gemzell Danielsson K, Gomperts R. Safety and acceptability of medical abortion through telemedicine after 9 weeks of gestation: a population-based cohort study. BJOG 2019;126;609-618. Norten H, Ilozumba O, Wilkinson J, Gemzell Danielsson K, Gomperts R. 10-year evaluation of the use of medical abortion through telemedicine: a retrospective cohort study. BJOG 2021; https://doi.org/10.1111/1471-0528.16765; Aiken ARA, Digol I, Trussell J, Gomperts R. Self-reported outcomes and adverse events after medical abortion through online telemedicine: population based study in the Republic of Ireland and Northern Ireland. BMJ 2017;357:j2011 http://dx.doi.org/10.1136/bmj.j2011.

Below is a summary of our review of the literature, organized by the methods of dispensing mifepristone that were studied.

(a) Retail pharmacy dispensing

Three studies reported medical abortion outcomes for retail pharmacy dispensing of mifepristone after clinical evaluation (Grossman,[86] Rocca,[87] Wiebe[88]). Grossman conducted a US-based study in which mifepristone and misoprostol were dispensed from a pharmacy partnered with the clinic. Complete abortion without additional procedures occurred in 93.5 percent of participants with known outcomes. The reported proportion of complete abortion is within the range described in the approved mifepristone labeling. No participants experienced a serious adverse event, were hospitalized or required transfusion. Three participants had emergency department (ED) visits with treatment (intravenous hydration, pain medication, pelvic infection after uterine aspiration for incomplete abortion). The study safety and efficacy outcomes are consistent with labeled outcome frequencies. The study has limited generalizability because it was conducted in two US states and involved partnered pharmacies, some of which were in the same building as the clinic. Additionally, all participating pharmacies in this study were required to have a pharmacist on duty during clinic hours who had been trained in the study protocol and was willing to dispense mifepristone. The study conditions may not be generalizable to United States retail pharmacies; there is insufficient information to assess this.

Rocca[89] conducted an observational study evaluating participants who obtained medical abortions in Nepal by comparing the provision of medical abortion service by newly trained nurse midwives in pharmacies to medical abortion provided in government-certified clinics. The authors reported that, with respect to complete abortion (greater than 97 percent) and complications (no hospitalizations or transfusions), evaluation and dispensing in pharmacy was non-inferior to in-clinic evaluation and dispensing.

Wiebe,[90] in a retrospective, chart review study conducted in Canada, compared abortion outcomes of women who underwent medical abortion with telemedicine consult, and either received medications by courier or picked them up at a local pharmacy, with outcomes of a matched control cohort of women who received the medications at a pharmacy after an in-clinic visit. The groups had similar documented complete medical abortion outcomes (equal to or greater than 95 percent participants with known outcomes). The telemedicine group had one case of hemorrhage (0.5 percent) and one case of infection requiring antibiotics (0.5 percent) compared with no cases of hemorrhage or infection requiring antibiotics in the in-clinic cohort. The telemedicine group had more ED visits (3.3 percent compared to 1.5 percent in-clinic cohort). Both models of dispensing mifepristone resulted in efficacy and safety outcomes within labeled frequency.

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[86] Grossman et al., supra n. 81.
[87] Rocca et al., supra n. 81.
[88] Wiebe et al., supra n. 81.
[89] Rocca et al., supra n. 81.
[90] Wiebe et al., supra n. 81.

None of the three studies allow a determination regarding differences in safety between in-person dispensing by a certified prescriber in a health care setting and dispensing through a retail pharmacy, due to limitations on the generalizability of the results of the studies to the current retail pharmacy environment in the United States. The outcome findings from the one United States study (Grossman)[91], in which the pharmacies were partnered with prescribers, are unlikely to be broadly generalizable to the current retail pharmacy environment and do not reflect typical prescription medication availability with use of retail pharmacy dispensing. For the retail pharmacy dispensing study in Canada (Wiebe),[92] timely provision of medication from the retail pharmacy was accomplished by either courier to the woman or faxed prescription to the woman's pharmacy. It is unknown whether conditions that would allow timely access to medications for medical abortion would occur in retail pharmacies throughout the United States, suggesting the findings from that study may not be broadly generalizable. The third study (Rocca)[93] evaluated medical abortion provided in Nepali pharmacies and essentially moved the abortion provider and clinical examination into the pharmacy, a scenario that is not, at this time, applicable to the United States retail setting.

(b) Mail order pharmacy

Three studies evaluated mail order pharmacy dispensing (Grossman,[94] Upadhyay,[95] Hyland[96]). Grossman published an interim analysis of an ongoing prospective cohort study evaluating medical abortion with mifepristone and misoprostol dispensed by mail-order pharmacy after in-person clinical assessment. Complete abortion without additional procedures occurred in 96.9 percent of participants with known outcomes. Two (0.9 percent) participants experienced serious adverse events; one received a blood transfusion and one was hospitalized overnight. Nine (4 percent) participants attended 10 ED visits. In this interim analysis, the outcomes are consistent with labeled frequencies.

Upadhyay[97] reports findings from a retrospective cohort study of women undergoing medical abortion in the United States without a consultation or visit. Eligibility was assessed based on a participant-completed online form collecting pregnancy and medical history. Participants who were considered eligible received medication delivered by a mail-order pharmacy. Abortion outcome was determined by either an assessment on day 3 or a 4-week pregnancy test. The investigators reported a complete abortion rate without additional procedures of 95 percent for participants with known outcomes and stated that no participants had any major adverse events. The proportion of abortion outcomes assessed at 3 days versus 4 weeks is not reported. Regardless, determining outcomes at 3 days is insufficient to determine outcome rates or safety findings because a 3-day follow-up period is too short. As recommended in Section 2.3 of the approved labeling, follow-up at

[91] Grossman et al., supra n. 81.
[92] Wiebe et al., supra n. 81.
[93] Rocca et al., supra n. 81.
[94] Grossman et al, supra n. 82.
[95] Upadhyay et al., supra n. 82.
[96] Hyland et al., supra n. 82.
[97] Upadhyay et al., supra n. 82.

7-14 days after administration of mifepristone is more appropriate to evaluate safety and efficacy. This study used a model with numerous deviations from standard provision of medical abortion in the United States, such as no synchronous interaction with the prescriber during informed consent or prior to prescribing medication and no confirmation of self-reported medical, surgical, and menstrual history. These deviations, limited follow-up information, and small sample size limit the usefulness of this study.

Hyland[98] describes findings from a cohort study in Australia evaluating medical abortion outcomes utilizing telemedicine and a central mail order pharmacy. Complete abortions without additional procedures occurred in 96 percent of participants with documented outcomes and is consistent with labeled efficacy. Of the participants included in the analysis, 95 percent had no face-to-face clinical encounters after medications were mailed while 3 percent were admitted to the hospital and 2 percent had an outpatient encounter. One participant who was hospitalized and underwent a surgical uterine evacuation received a transfusion. Not included in the findings are 7 hospitalizations occurring in 7 participants who did not have "full follow up." The authors do not report any other adverse events and conclude use of the telemedicine medical abortion service is safe. However, the reasons for hospitalization are not discussed by the authors; therefore, it is unknown why the patients were hospitalized. Although the reported frequency of hospitalizations (3 percent) is higher than the less than 1 percent in the FDA-approved mifepristone labeling, conclusions on the safety findings cannot be made in the absence of information about the reasons for hospitalization. Other limitations of this study include incomplete information about outcomes with face-to-face encounters.

Overall, the three studies evaluating mail order pharmacy dispensing suggest that efficacy of medical abortion is maintained with mail order pharmacy dispensing. With respect to safety, in the Grossman study[99] the interim analysis, although small, does not raise serious safety concerns. Safety findings from the Hyland[100] study are difficult to interpret. Although only one transfusion is reported and the authors state the findings demonstrate safety, a higher hospitalization rate and lack of information on the reasons for hospitalization preclude reaching any conclusions about the safety findings. Lastly, the Upadhyay[101] study had no reported adverse events, but the findings are less useful because of the limited follow-up, and because medical abortions were provided using a model with numerous deviations from standard provision of medical abortion in the United States.

(c) Clinic dispensing by mail

A total of five studies evaluated clinic dispensing by mail. Gynuity Health Projects conducted a prospective cohort study (the "TelAbortion" study) evaluating use of telemedicine for remote visits and mifepristone being dispensed from clinics via overnight or regular tracked mail. Three publications reviewed have reported outcomes for the Gynuity population exclusively: Raymond (outcomes from May 2016 to December

[98] Hyland et al., supra n. 82.
[99] Grossman et al., supra n. 82.
[100] Upadhyay et al., supra n. 82.
[101] Hyland et al., supra n. 82.

2018),[102] Chong (outcomes from May 2016 to September 2020)[103] and Anger (outcomes from March 2020 to September 2020).[104] A fourth study, Kerestes,[105] reports outcomes of medical abortion at the University of Hawai'i from April 2020 to November 2020 and a fifth study, Aiken (2021)[106] reports outcomes of medical abortion up to 70 days gestational age in the United Kingdom before and during the COVID-19 PHE in a retrospective cohort study.

In Raymond,[107] complete abortion without additional procedures occurred in 93 percent of participants with known outcomes. There were two hospitalizations (one participant received a transfusion for severe anemia despite having had a complete abortion) and 7 percent of participants had clinical encounters in ED/urgent care centers. The reported outcomes are similar to outcomes described in approved labeling except the combined ED/urgent care center encounters (7 percent) exceeded the ED visits in approved labeling (2.9-4.6 percent).[108] Of note, the authors state that half of the ED/urgent care visits did not entail any medical treatment. In Chong,[109] approximately 50 percent of the medical abortions occurred during the period of the COVID-19 PHE. Complete abortion without an additional procedure occurred in 95 percent of those with known outcomes. Transfusions were 0.4 percent and hospitalizations were 0.7 percent; 6 percent of participants had unplanned clinical encounters in ED/urgent care. Surgical interventions were required in 4.1 percent to complete abortion. The reported outcomes in Chong (which updated the findings described in Raymond) are similar to outcomes described in approved labeling except that (as with the Raymond study it updated) the combined ED/urgent care center encounters (6 percent) exceeded the ED visits in approved labeling (2.9-4.6 percent).

Anger,[110] which compared outcomes among participants enrolled in the Gynuity study who did ("test medical abortion cohort") versus did not ("no-test medical abortion cohort")[111]

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[102] Raymond et al., supra n. 83.
[103] Chong E, Shochet T, et al. Expansion of a direct-to-patient telemedicine abortion service in the United States and experience during the COVID-19 pandemic. Contraception 2021;104:43-48.
[104] Anger et al., supra n. 83.
[105] Kerestes C, Murayama S, et al. Provision of medication abortion in Hawai'i during COVID-19: Practical experience with multiple care delivery models. Contraception 2021 Jul;104(1):49-53. doi:10.1016/j.contraception.2021.03.025. Epub 2021 Mar 28.
[106] Aiken ARA, Lohr PA, et al. Effectiveness, safety and acceptability of no-test medical abortion (termination of pregnancy) provided via telemedicine: a national cohort study. BJOG 2021;128:1464–1474.
[107] Raymond, supra n. 83.
[108] The authors reported the combined frequency of emergency department/urgent care visits, whereas the approved labeling includes the frequency for emergency department (emergency room) visits. Therefore it is unknown whether the frequency of emergency department visits in the trial, as distinct from the combined frequency of emergency department/urgent care visits, is comparable to the frequency of emergency department visits reflected in approved labeling.
[109] Chong et al., supra n. 103.
[110] Anger et al., supra n. 83.
[111] "No-test medication abortion" refers to medical abortion provided without a pretreatment ultrasound, pelvic examination or laboratory tests when, in the judgment of the provider, doing so is medically appropriate (appropriateness based on history and symptoms); "no-test medication abortion" does include post-abortion follow up. A sample protocol is described by Raymond et al." (Raymond EG, Grossman D, Mark A, et.al. Commentary: No-test medication abortion: A sample protocol for increasing access during a pandemic and beyond. Contraception 2020;101:361-366)

have confirmation of gestational age/intrauterine location with an examination or ultrasound, found that those without an examination or ultrasound prior to medical abortion were more likely to require procedural interventions and had more unplanned clinical encounters.[112] There were no reported ectopic pregnancies in either group. The number of ED/urgent care visits and the proportion of unplanned clinical encounters that led to medical treatment were not reported. In the "test" group, complete medical abortion was confirmed in 98 percent of participants with known outcomes; one participant was "hospitalized and/or blood transfusion" and 8 percent had an unplanned clinic encounter (participant sought in-person medical care related to abortion and the visit was not planned prior to abortion). In the "no-test" group, complete medical abortion was confirmed in 94 percent of participants with known outcomes; two participants were "hospitalized and/or blood transfusion" and 12.5 percent had an unplanned clinical encounter.

Kerestes[113] included three different delivery models: traditional in-person visits, telemedicine consultation with in-person pick-up of medications, and telemedicine consultation with delivery of medications by mail (most of the latter were enrolled through Gynuity's TelAbortion study). Among participants with follow-up data, the rates of successful medical abortion without surgery were consistent with outcomes in approved labeling. Blood transfusion was given to two participants (both in the telemedicine plus in-person pickup group). Although ED visits occurred the most frequently in the telemedicine plus mail group (four participants or 5.8 percent) and the least in the in-person group (two participants or 2.1 percent), the study reported no increases in other serious adverse events. Aiken (2021)[114] reported outcomes before and during the pandemic in a retrospective cohort study in the United Kingdom. The study compared the two cohorts: one before the pandemic with in-person visits and dispensing (traditional model) and one during the pandemic with either an in-person visit and in-person dispensing or a telemedicine visit and dispensing by mail or picked up from the clinic (hybrid model). Complete abortion occurred in greater than 98 percent in both cohorts; the rate was slightly higher in the telemedicine group than in the in-person group. There were no significant differences in the rates of reported serious adverse events. The investigators' analysis determined that the efficacy and safety were comparable between both cohorts and concluded the hybrid model for medical abortion is effective and safe.

Taken together, data from the three Gynuity study reports (Raymond, Chong, and Anger), Kerestes, and Aiken (2021) support that efficacy of medical abortion was maintained when mifepristone was dispensed by mail from the clinic. Study reports of Raymond, Chong, and Kerestes all suggest there may be an increase in ED/urgent care visits with telemedicine visits and dispensing by mail from the clinic, but without increases in other serious adverse events. Anger's comparative analysis suggests a pre-abortion examination may decrease the occurrence of procedural intervention and decrease the number of unplanned visits for postabortion care. The Aiken (2021) study appears to be of sufficient

[112] We note that the two cohorts were not randomized in the Anger study; they had different baseline characteristics. Consequently, findings based on the comparisons between the two cohorts should be interpreted carefully.
[113] Kerestes et al., supra n. 105.
[114] Aiken et al., supra n. 106.

sample size to determine whether safety outcomes with mail dispensing differ from in-person dispensing; however, significant limitations include that the analysis was based on deidentified information and the investigators were unable to verify the outcomes extracted. Further, the study's design did not capture all serious safety outcomes, thus limiting the certainty of the findings.

Notwithstanding the limitations discussed above, these studies overall support that dispensing by mail from the clinic is safe and effective. Although the literature suggests there may be more frequent ED/urgent care visits related to the use of mifepristone when dispensed by mail from the clinic, there are no apparent increases in other serious adverse events related to mifepristone use.

(d) Clinic dispensing by courier

Reynolds-Wright[115] reported findings from a prospective cohort study of participants at less than 12 weeks gestational age in Scotland undergoing medical abortion at home that provided mifepristone for pick up at the service or by couriered delivery to woman's home. The outcomes from this study in Scotland are consistent with the outcomes in the approved mifepristone labeling. However, the number of couriered deliveries was not reported. Thus this study does not provide abortion outcomes separately for couriered delivery of mifepristone and misoprostol. The study shares the same limitations as the Aiken (2021) study; the study's design did not capture all serious safety outcomes, thus limiting the certainty of the findings.

(e) Partner organization dispensing by mail

Women on Web (WoW), an internet group, connects patients and providers outside of the US and provides medical abortion globally, dispensing mifepristone through "a partner organization" by mail. WoW uses a model with numerous deviations from the standard provision of medical abortion in the United States. For example, this model has no synchronous interaction with the prescriber during informed consent or prior to prescribing medication and no confirmation of self-reported medical, surgical, and menstrual history or confirmed pregnancy testing. Three studies (Endler, Norten, and Aiken (2017))[116] reported outcomes based on dispensing through this model. Endler and Norten reported outcomes from WoW cohorts but do not provide relevant information on mifepristone dispensing by mail because neither provide meaningful outcomes data for consideration. Although Aiken (2017) is a large cohort study, the outcomes are self-reported and an unusually high rate of outcomes are unaccounted for; these limitations result in the data being insufficient to determine the safety of dispensing mifepristone by mail though a partner organization.

In sum, there are insufficient data from the literature we have reviewed to determine the safety and efficacy of dispensing from a retail pharmacy, by courier, or by a partner organization. With respect to dispensing mifepristone by mail, our review of the literature indicates that dispensing mifepristone by mail from the clinic or from a mail order

[115] Reynolds-Wright JJ, et al. BMJ Sex Reprod Health 2021;0:1–6. doi:10.1136/bmjsrh-2020-200976.
[116] Endler et al., Norten et al., and Aiken et al., supra n. 85.

pharmacy does not appear to jeopardize the efficacy of mifepristone for medical abortion. While the studies we reviewed are not adequate on their own to establish the safety of the model of dispensing mifepristone by mail, the safety and efficacy outcomes reported in these studies remain within the ranges labeled for the approved mifepristone products. Although the literature suggests there may be more frequent ED/urgent care visits related to the use of mifepristone when dispensed by mail from the clinic, there are no apparent increases in other significant adverse events related to mifepristone use.

Based on the REMS assessment data, FAERS data from the time period when the in-person dispensing requirement was not being enforced, and our review of the literature, we conclude that mifepristone will remain safe and effective if the in-person dispensing requirement is removed, provided all the other requirements of the REMS are met and pharmacy certification is added. Removing the in-person dispensing requirement will render the REMS less burdensome to healthcare providers and patients, and provided all other requirements of the REMS are met, including the additional requirement for pharmacy certification, the REMS will continue to ensure that the benefits of mifepristone for medical abortion outweigh the risks. Therefore, to reduce the burden imposed by the Mifepristone REMS Program, the REMS must be modified to remove the in-person dispensing requirement, which would allow, for example, dispensing of mifepristone by mail via certified prescribers or pharmacies, in addition to in-person dispensing in clinics, medical offices and hospitals as currently outlined in ETASU C.

In your Petition, you state that "[e]liminating or relaxing the REMS to facilitate Internet or telephone prescriptions would be dangerous to women and adolescent girls" and that "health care providers prescribing abortion-inducing drugs over the Internet or phone or before a patient is even pregnant cannot adequately evaluate patients for contraindications to the drugs" (Petition at 18-19).

We do not agree that eliminating the REMS requirement for the dispensing of Mifeprex in certain healthcare settings will be dangerous to patients, nor do we agree that doing so will affect the ability of healthcare providers to evaluate women for contraindications to mifepristone in a regimen with misoprostol for medical termination of intrauterine pregnancy through 70 days gestation. There are many factors that contribute to patient safety, including evaluation of a patient, informed consent, development of a follow-up plan, and provision of a contact for emergency care. All of these can occur in many types of healthcare settings. The evaluation of patients for contraindications to medical abortion does not necessarily require direct physical contact with the certified prescriber.

You also assert that telemedicine abortion absolves abortion providers of responsibility for the well-being of their patients (Petition at 19). We do not agree. Healthcare providers who prescribe mifepristone are responsible for the well-being of their patients regardless of mode of evaluation or dispensing of medication. The Agency agrees with the American Medical Association that a healthcare provider-patient relationship is entered when the "physician serves a patient's medical needs;"[117] in the context of medical abortion, this

[117] See www.ama-assn.org/delivering-care/ethics/patient-physician-relationships.

healthcare provider-patient relationship continues until resolution of the pregnancy or transfer of care to another healthcare provider.[118]

We also note that patients who are not pregnant at the time of evaluation would not be appropriate candidates for being prescribed mifepristone for medical termination of pregnancy because they do not fulfill the approved indication of having an intrauterine pregnancy of up to 70 days gestation.

2. Other Safety Issues and Additional Studies

In support of your request that we retain the Mifeprex REMS, you cite the Council for International Organizations of Medical Sciences' (CIOMS) definition of "rare" to assert that because "about 1 out of 100 women" using Mifeprex and misoprostol require surgery, serious complications are common, not rare (Petition at 15-16).[119] Although we agree that certain elements of the Mifepristone REMS Program are necessary to assure the safe use of mifepristone, we do not agree with your assertion.

In the Petition, you state that the Medication Guide improperly downplays the risks of the use of Mifeprex in a regimen with misoprostol and you cite the Medication Guide as stating "'*rarely*, serious and potentially life-threatening bleeding, infections, and other problems can occur following . . . medical abortion.' Specifically, 'in about 1 out of 100 women [administered Mifeprex and misoprostol] bleeding can be so heavy that it requires a surgical procedure." (Petition at 15). Using these two separate statements in the Medication Guide, you argue that the CIOMS's definition of rare ("1 out of 1000") means that if 1 out of 100 women using Mifeprex in a regimen with misoprostol require surgery, serious complications are common, not rare. (Petition at 16). However, your reference to the two sentences in the Medication Guide conflates two different clinical scenarios: (1) the adverse event of serious and potentially life-threatening bleeding, and (2) treatment failure.

The first sentence you reference states: "Although cramping and bleeding are an expected part of ending a pregnancy, rarely, serious and potentially life-threatening bleeding, infections, or other problems can occur following a miscarriage, surgical abortion, medical abortion, or childbirth." This statement refers to life-threatening adverse events that can occur during termination regardless of gestational age or during miscarriage or childbirth regardless of the mode of delivery (e.g., vaginal delivery or cesarean section). At the time of our review of the clinical studies submitted to support the S-020 efficacy supplement, the reported rate of death in the studies reviewed, based on one death, was 0.007 percent (very rare under the CIOMS definition).[120] The rate of infections requiring hospitalization or

[118] See https://www.ama-assn.org/delivering-care/ethics/ethical-practice-telemedicine.
[119] Council for International Organizations of Medical Sciences. Guidelines for Preparing Core Clinical Safety Information on Drugs Second Edition. 1999. https://cioms.ch/wp-content/uploads/2018/03/Guidelines-for-Preparing-Core-Clinical-Safety-Info-Drugs-Report-of-CIOMS-Working-Group-III-and-V.pdf. Accessed December 13, 2021 (CIOMS).
[120] Id. at 36 (defining the "very rare" standard category of frequency as less than 0.01 percent).

intravenous antibiotics was less than 0.1 percent (rare under the CIOMS definition),[121] and rates of transfusion were 0.03-0.7 percent (rare to uncommon under the CIOMS definition).[122] Therefore, "rarely" accurately refers to the frequency of the adverse events referenced in this statement.

The second sentence you reference from the Medication Guide states: "In about 1 out of 100 women, bleeding can be so heavy that it requires a surgical procedure (surgical aspiration or D&C)." This statement refers to the rate of surgical procedures for bleeding following treatment with mifepristone. Heavy bleeding or hemorrhage after medical abortion is a small subset of bleeding and can require a surgical procedure due to ongoing pregnancy or incomplete expulsion; these are considered failed treatment rather than adverse events and are not characterized using the CIOMS definitions. Even if heavy, bleeding after medical abortion may not be considered a serious adverse event unless clinically diagnosed as hemorrhage or requiring a transfusion. Furthermore, in the vast majority of medical abortions, surgical intervention is not necessary.

You also cite a 2009 study and a 2018 study to assert that medical abortions carry greater risks than surgical abortions (Petition at 16). The 2009 Niinimaki, et al.[123] study reported overall incidences of immediate adverse events (up to 42 days) in medical and surgical abortions performed in women undergoing induced abortion from 2000-2006 based on data from the Finnish national registries. We agree that the overall incidence of adverse events for medical abortion was fourfold higher when compared with surgical abortion (20.0 percent versus 5.6 percent). Specifically, the incidence of hemorrhage, incomplete abortion, and surgical (re)evacuation were higher for medical abortion. However, the authors specifically noted that because medical abortion is associated with longer uterine bleeding, the high rate of events, which were pulled from a national registry reflecting both inpatient and outpatient visits, is not surprising. They opined that uterine bleeding requiring surgical evacuation probably better reflects the severity of bleeding after termination of pregnancy; the incidence of such bleeding was relatively low, although it was more common with medical abortion. In addition, the authors acknowledged there are inherent weaknesses in registry-based studies; there is variable reliability both of diagnoses and of severity of diagnoses. Nevertheless, the authors concluded that both methods are generally safe and recommended discussing the adverse event profiles of different methods when counseling women seeking pregnancy termination.

We note that Ireland, et al.[124] reported findings from a more recent retrospective cohort study of 30,146 United States women undergoing pregnancy termination before 64 days of gestation from November 2010 to August 2013. Efficacy of pregnancy termination was 99.6 percent and 99.8 percent for medical and surgical abortion, respectively.

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[121] Id. at 36 (defining the "rare" standard category of frequency as greater than or equal to 0.01 percent and less than 0.1 percent).
[122] Id. at 36 (defining the "uncommon" standard category of frequency as greater than or equal to 0.1 percent and less than 1 percent); see also 2016 Clinical Review, supra n. 13, at 47 and 51.
[123] Niinimaki M, Pouta A, Bloigu A, et al. Immediate complications after medical compared with surgical termination of pregnancy. Obstet Gynecol. 2009;114(4):795-804.
[124] Ireland LD, Gatter, M, Chen, A. 2015. Medical Compared with Surgical Abortion for Effective Pregnancy Termination in the Frist Trimester. Obstetrics & Gynecology 126;22-28.

Unanticipated aspiration for persistent pain, bleeding or both were 1.8 percent and 0.4 percent for medical and surgical abortion respectively. These findings are compatible with the Niinimaki study findings. There was no difference in major adverse events as defined by the authors (emergency department visit, hospitalization, uterine perforation, infection, hemorrhage requiring transfusion) between the groups. The authors conclude medical and surgical abortion before 64 days of gestation are both highly effective with low complication rates.

The 2018 Carlsson study is addressed above in section II.A.2.b.ii. of this response; as discussed above, that study showed no statistically significant difference between the overall complication rates between an "at home" and "at the hospital" abortion.[125]

We acknowledge that medical abortion is known to have more days of bleeding and increased rates of incomplete abortion compared to surgical abortion. However, as noted above, in the vast majority of medical abortions, surgical intervention is not necessary. Thus, medical abortion and surgical abortion are two options; both have benefits, side effects, and potential complications. Patients and their healthcare providers should discuss which method is preferable and safer according to each woman's unique situation.

You state that the Mifeprex REMS should require a formal study for at-risk populations, including: patients under the age of 18; patients with repeat Mifeprex abortions; patients with limited access to emergency room services; and patients who self-administer misoprostol (Petition at 13-14). As we explain below, additional studies are not needed at this time.

In justifying your assertion that a formal study is required in patients under the age of 18, you state that Mifeprex was approved for use in the pediatric population in 2000 after the requirement for studies in the pediatric population was waived (Petition at 13-14). The approved indication for mifepristone does not limit its use by age. Although patients age 17 and under were not included in the clinical trials supporting the initial approval of Mifeprex in 2000, we stated at the time that the safety and efficacy were expected to be the same for postpubertal (i.e., post-menarchal) adolescents. Our conclusion in 2000 that pediatric studies of Mifeprex were not needed for approval was consistent with FDA's implementation of the regulations in effect at that time. Because we determined that there were sufficient data from studies of mifepristone, the original Mifeprex approval should have reflected the Agency's conclusion that the pediatric study requirements were waived for pre-menarchal females and that the pediatric study requirements were met for post-menarchal adolescents, rather than stating that the Agency was waiving the requirements for all pediatric age groups.

As currently required by the Pediatric Research Equity Act (PREA),[126] certain applications or supplemental applications must include pediatric assessments of the safety and effectiveness of the drug for the claimed indication(s) in all relevant pediatric

[125] Carlsson et al., supra n. 49.
[126] Section 505B of the FD&C Act (21 U.S.C. 355c).

subpopulations, unless that requirement is waived or deferred.[127] In accordance with PREA, when FDA reviewed the S-020 efficacy supplement, a partial waiver was granted for pediatric studies in pre-menarchal females because pregnancy does not occur in premenarchal females. We also determined that the applicant had fulfilled the pediatric study requirement in post-menarchal adolescents. This determination was based on data extrapolated from adults and information in literature. Review of these findings found the safety and efficacy in this population to be similar to the safety and efficacy in the adult population.[128] Therefore, we do not agree that a formal study is required in patients under 18.

With regard to your concerns about repeat abortions and your assertion that a study is necessary in this population, we acknowledge that published data concerning adverse reproductive health outcomes in U.S. women who undergo repeat medical abortions are limited. We concluded in our 2016 review of the S-020 efficacy supplement that there is no evidence that repeated medical or surgical abortion is unsafe or that there is a tolerance effect. We also noted that return to fertility after the use of mifepristone is well documented. [129] This is reflected both in Section 17 of the approved labeling, Patient Counseling Information, which states that the provider should "inform the patient that another pregnancy can occur following medical abortion and before resumption of normal menses," and in the Medication Guide, which states "You can become pregnant again right after your pregnancy ends." Although you state that more than one out of every three abortions in the United Sates is a repeat abortion (Petition at 14),[130] we are not aware of reports suggesting greater safety concerns in repeat abortions than a first-time abortion. Therefore, we do not agree that a study is necessary in this population. You also cite a published study, using a mouse model, of repeated medical termination of pregnancy that showed repeat medical abortion impaired the reproductive function of female mice (Petition at 14).[131] Per our 2016 review, there is no evidence in available clinical data that repeated medical or surgical abortion is unsafe, or that fertility is impaired by the use of mifepristone; therefore, data from a single non-clinical study in mice are not persuasive.[132]

With respect to your request for a formal study of mifepristone for medical abortion in women without access to emergency care, we disagree that such a study is necessary. In order to become a certified prescriber, a healthcare provider must agree that they have the ability to provide surgical intervention in cases of incomplete abortion or severe bleeding or have made plans to provide such care through others, and that they have the ability to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary. These prescriber qualifications ensure that mifepristone is prescribed to women for whom emergency care is available.

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[127] Section 505B(a)(2) of the FD&C Act (21 U.S.C. 355c(a)(2)).
[128] 2016 Clinical Review, supra n. 13, at 74-76.
[129] Id. at 47.
[130] In support of this assertion, you cite Jones R, Jerman J, Ingerick M. Which abortion patients have had a prior abortion? Findings from the 2014 U.S. Abortion Patient Survey. J Womens Health.
[131] Lv F, Xu X, Zhang S, et al. Repeated abortion affects subsequent pregnancy outcomes in BALB/c mice. PLoS One. 2012;7(10):e48384. doi:10.1371/journal.pone.0048384.
[132] 2016 Clinical Review, supra n. 13, at 47.

Finally, you assert that FDA should require a formal study in patients who self-administer misoprostol. As explained in section II.A.2.b.ii of this response, FDA conducted a literature review of self-administration of misoprostol at home as part of its review of the S-020 efficacy supplement and found no safety or efficacy concerns with home self-administration of misoprostol. Therefore, we disagree that a formal study is required in this population.

With regard to safety generally, in addition to the FAERS data provided above (see section II.B.1.c.ii. in this response), FDA routinely monitors adverse events reported to FAERS and published in the medical literature for mifepristone for medical termination of pregnancy through 70 days gestation. We have not identified any new safety concerns with the use of mifepristone for this indication.

3. Other Articles

In your Petition, you reference several documents that discuss alternative models of providing abortion medications and advocate for the lifting of the REMS on mifepristone (Petition at 23-24). You assert that these recent publications demonstrate how abortion advocates will continue to pressure FDA to eliminate the REMS and move towards over-the-counter access for Mifeprex.[133]
We agree that the overarching message in the publications you reference appears to be advocating self-management of medical abortion. Nonetheless, as discussed in this response, we have determined that the Mifepristone REMS Program continues to be necessary for the safe use of this drug product, with some modifications.

III. CONCLUSION

For the reasons set forth above, we deny your request that FDA restore and strengthen elements of the Mifeprex regimen and prescriber requirements approved in 2000; and we grant in part and deny in part your request to retain the Mifepristone REMS Program. As with all approved drug products, we will continue to monitor the safety of mifepristone for the approved indication and take any appropriate actions.

Sincerely,

Patrizia A. Cavazzoni -S

Digitally signed by Patrizia A. Cavazzoni -S
Date: 2021.12.16 15:05:41 -05'00'

Patrizia Cavazzoni, M.D.
Director
Center for Drug Evaluation and Research

[133] You also reference clinical trials relating to the use of mifepristone for spontaneous miscarriage management and question the results of studies related to this use (Petition at 16-18). The use of mifepristone for the management of early miscarriage is not an approved indication for this drug product and is outside the scope of the Mifepristone REMS Program. Therefore, we do not address it in this response.

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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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I. INTRODUCTION

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

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

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

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

The same issues were also raised repeatedly prior to 2022. FDA performed a "full review" of the REMS in 2021 after being sued in federal court in Hawaii. ECF No. 51-4 at 6. The 2021 review, prompted by litigation where FDA did not even raise exhaustion, covered all the same points: the REMS, while medically useless, trigger unnecessary costs and erect significant obstacles to patient care. *See* Hughes Decl. Exs. B, C. Similarly, as FDA acknowledges (Resp. at 15–16), fifteen Plaintiff States asked the FDA in 2020 to eliminate the REMS, identifying the patient agreement and certification requirements as "onerous and medically unnecessary"—but received only a form response. Hughes Decl. Ex. D at 2–3; ECF No. 51-11. The States' letter there was part of a chorus of contemporaneous letters and litigation urging FDA to abandon the REMS, just as the States urge here. *See, e.g.*, ECF Nos. 1-9, 1-10, 1-12; Hughes Decl. Exs. B–M; *Am. Coll. of Obstetricians & Gynecologists v. FDA*, 472 F. Supp. 3d 183 (D. Md. 2020).

These recent appeals to FDA occurred against the backdrop of the agency's 2016, full-scope review of the REMS (ECF No. 1-3), in which FDA ignored or minimized the absence of evidence supporting the REMS, failed to consider evidence of the burdens they impose in practice, and departed from its own internal experts' recommendation (as the 2022 citizen petition pointed out). Hughes Decl. Ex. A; ECF No. 35 ¶¶ 93–102; ECF No. 1-11 at 25 (unanimous

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

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conclusion of CDER clinical team). The 2016 review squarely considered the same issues the States raise here, which were also presented earlier in 2016 and twice in 2015. Schreiber Decl. ¶ 43; ECF No. 1-9; Hughes Decl. Exs. E, F; ECF 1-10 at 27. Simply put, if this record does not satisfy exhaustion, nothing does.

This record also demonstrates why raising the same issues yet again would be futile, distinguishing this case from those on which FDA relies. Resp. at 15; *see El Rescate Legal Servs., Inc. v. EOIR*, 959 F.2d 742, 747 (9th Cir. 1991) ("[T]here is no requirement of exhaustion where resort to the agency would be futile."); *McCarthy v. Madigan*, 503 U.S. 140, 146, 148–49 (1992) (futility "weigh[s] heavily against requiring administrative exhaustion"). Here, it is clear that FDA's position is "already set[.]" *El Rescate*, 959 F.2d at 747. On this point, FDA asserts only that its form response to the States' 2020 letter did not, standing alone, demonstrate futility. Resp. at 16 n.3. But this ignores FDA's rejection of successive requests to eliminate the REMS—even from its own internal experts.

FDA claims this case involves "technical and factual assertions" that it has had no opportunity to consider. Resp. at 14. This is wrong, as all three of FDA's examples demonstrate. *First*, FDA complains about "studies that were not before the agency at the time of" its December 2021 review. *Id.* at 14, 25. But as noted above, FDA was able to consider these studies for purposes of the 2023 REMS, because ACOG cited them in its 2022 petition. FDA "cannot credibly argue" that *another* "formal application" from the States with identical information would make any difference. *Chinook Indian Nation v. Zinke*, 326 F. Supp. 3d 1128, 1144

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

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

2. The States have established standing

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

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

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

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

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

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

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

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

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

4. The 2023 REMS is blatantly arbitrary and capricious

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

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

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

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

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

> Mifepristone's chemical structure itself supports the conclusion that 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. Because it is so similar in structure to a widely used progestin,

mifepristone is unlikely to be toxic to patients.

Schreiber Decl. ¶ 22. FDA knows mifepristone is fundamentally safe without a REMS: it approved Korlym without one. But when it came to mifepristone for abortion, FDA not only failed to consider evidence of its inherent safety, it expressly "excluded" such evidence from its review. ECF No. 51-4 at 12–13 (FDA's analysis "excluded . . . [i]nformation pertinent to molecular or other basic science aspects of mifepristone").

Lastly, FDA wholly failed to consider the patient harms caused by the REMS. *See Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (agency action is "arbitrary and capricious if the agency . . . entirely failed to consider an important aspect of the problem"). There is, for example, no discussion whatsoever in FDA's 2021 memo about the REMS reducing medication abortion's availability or deterring providers. Rather, the memo makes clear that FDA *decided to disregard* studies showing the REMS acts as a barrier to patient care. ECF No. 51-4 at 12 (noting that FDA's analysis "excluded" . . . "[i]nformation from survey studies or qualitative studies that evaluated perspectives on and/or satisfaction with medical abortion procedures from patients, pharmacists, clinic staff, or providers, even if the study assessed REMS ETASUs"). Indeed, FDA explicitly excluded one of the studies it now faults the States for not bringing to its attention via a citizen petition. *Id.* at 49 (noting that FDA disregarded Calloway D et al. Contraception 2021; 104(1): 24–28 because it "[p]rimarily addresses provider stigma around abortion care").

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

B. The Plaintiff States Are Irreparably Harmed

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

This argument completely ignores the unprecedented crisis in abortion access following *Dobbs*. The harms caused by the 2023 REMS must be analyzed in this context, which Defendant Becerra himself described as "a moment of crisis in health care." Hughes Decl. Ex. G. Since *Dobbs*, the States have experienced a tidal wave of out-of-state patients seeking abortions. ECF No. 4-1: Cantrell Decl. ¶¶ 5, 7; Dillon Decl. ¶¶ 8–13; *see also* Nelson Decl. ¶ 10. For example, in January 2023, Planned Parenthood of Greater Washington and Northern Idaho saw a ***75% increase*** in Idaho patients, compared with January 2022, including a "***90% increase*** for medication abortion visits from Idaho." Dillon Decl. ¶ 10 (emphasis added). This increased patient volume has led to delays in abortion care and other consequences, including higher risks of complications, increased costs, and unnecessary trauma and stress for patients, as well as increasing burdens on an already overtaxed healthcare system. *Id.* ¶¶ 14–22; 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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under unprecedented attack. Tellingly, Defendants are silent on the effect of an injunction on patients. Rather, they rely entirely on self-preservation concerns about the need to "defer[] to FDA's judgments." Resp. at 30. But that rationale for deference evaporates here, where FDA has acted contrary to law and abused its discretion by re-imposing arbitrary and unfounded restrictions on medication abortion. The public interest and equities weigh strongly in the States' favor.

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

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

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).

DATED this 24th day of March, 2023.

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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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UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF WASHINGTON

STATE OF WASHINGTON, *et al.*, Plaintiffs, v. U.S. FOOD AND DRUG ADMINISTRATION, *et al.*, Defendants.	No. 1:23-cv-03026 DEFENDANTS' RESPONSE IN OPPOSITION TO PLAINTIFF STATES' MOTION FOR PRELIMINARY INJUNCTION

DEFENDANTS' RESPONSE IN OPPOSITION TO PLAINTIFF STATES' MOTION FOR PRELIMINARY INJUNCTION

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INTRODUCTION

More than 22 years ago, the U.S. Food and Drug Administration (FDA) approved mifepristone as safe and effective for termination of early pregnancy subject to certain restrictions on distribution.[1] While FDA has approved modifications to that set of restrictions (known since 2007 as a Risk Evaluation and Mitigation Strategy (REMS)) on several occasions, the restrictions have always required that patients sign a Patient Agreement Form and that health-care providers become certified and agree, among other things, that they have the ability to accurately date pregnancies, diagnose ectopic pregnancies, and provide or arrange for surgical intervention if necessary. And until January 3, 2023, the REMS required mifepristone to be dispensed in clinics, medical offices, and hospitals, by or under the supervision of a certified provider (the in-person dispensing requirement). Prior to that time, the REMS did not permit pharmacies to dispense the drug.

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

During this more-than-two-decade period (spanning from September 2000 to January 2023), Plaintiffs did not object to *any* of these requirements by filing a citizen petition (*see* 21 C.F.R. §§ 10.25, 10.30, 10.45) or by seeking judicial relief. Then, on January 3, 2023, FDA approved supplemental applications that modified the REMS to remove the in-person dispensing requirement and permit certified pharmacies to dispense the drug. Plaintiffs now rely on FDA's January 2023 REMS modification—which *reduced* the restrictions on the distribution of mifepristone—as a springboard to ask this Court to preliminarily enjoin FDA from applying restrictions that it first imposed when mifepristone was approved in 2000. Plaintiffs also ask this Court to preliminarily enjoin FDA "from taking any action to remove mifepristone from the market or cause the drug to become less available," despite bringing no claim supporting that relief.

The Court should deny Plaintiffs' Motion for Preliminary Injunction. Plaintiffs are unlikely to succeed on the merits. First, they failed to administratively exhaust their claims by filing a citizen petition with the agency (as agency regulations require), so as to give the agency an opportunity to apply its expertise in the first instance. Had Plaintiffs done so, FDA would have carefully evaluated their claims that the REMS is unnecessary to assure safe use of mifepristone and unduly impedes access to the drug. These matters lie at the heart of the agency's core statutory mandate, and FDA is entitled to evaluate these issues

in the first instance. Second, Plaintiffs lack standing to challenge an agency action the sole effect of which was to make the REMS *less* restrictive and permit dispensing of the drug by certified pharmacies. Third, on the merits, Plaintiffs disregard FDA's reasoned explanation for its 2023 REMS modification and fail to show that FDA acted unreasonably or contrary to law.

Nor have Plaintiffs met their burden on any of the other preliminary injunction factors. They cannot credibly claim to be irreparably harmed by FDA's decision to retain two 22-year-old requirements, remove the in-person dispensing requirement, and permit certified pharmacies to dispense mifepristone. Tellingly, for over two decades, Plaintiffs did not challenge requirements that, on net, were *more* restrictive than the modified REMS FDA approved on January 3, 2023. At the very least, their delay shows that any harm is not so significant as to justify a preliminary injunction that would upset the status quo and enjoin FDA from "enforcing or applying" (Mot. 34) requirements that in its expert judgment are necessary to assure the drug's safe use. Finally, even if Plaintiffs were entitled to some relief (they are not), the preliminary injunction that they request is not tailored to their claims, violates the well-established principle that the proper remedy in an Administrative Procedure Act (APA) case is limited to the challenged agency action, and is inconsistent with Federal Rule of Civil Procedure 65(d).

BACKGROUND

I. Statutory and Regulatory Background

The Federal Food, Drug, and Cosmetic Act (FDCA) generally prohibits the interstate distribution of new drugs that have not received FDA approval. 21 U.S.C. § 355(a). In deciding whether to approve a new drug, FDA evaluates whether a new drug application contains scientific evidence demonstrating that the drug is safe and effective for its intended uses. *Id.* § 355(d); *see also* 21 C.F.R. §§ 314.50, 314.105(c). Similarly, when a sponsor submits a supplemental new drug application proposing changes to the conditions of approval for a drug (such as changes to a drug's labeling or FDA-imposed restrictions), FDA reviews the scientific evidence submitted in support of the changes. *See* 21 C.F.R. § 314.70.

Since 1992, FDA's regulations (the Subpart H regulations) have authorized FDA to require conditions "needed to assure safe use" of certain new drugs. Final Rule, 57 Fed. Reg. 58,942, 58,958 (Dec. 11, 1992) (codified at 21 C.F.R. § 314.520). In the Food and Drug Administration Amendments Act of 2007 (FDAAA), Congress codified and expanded the Subpart H regulations by giving FDA authority to require a REMS when it determines that such restrictions are necessary to ensure that the benefits of a drug outweigh the risks. *See* Pub. L. No. 110-85, tit. IX, § 901 (codified at, *inter alia*, 21 U.S.C. § 355-1). FDA may require that a REMS include "elements to assure safe use" if necessary to mitigate a

serious health risk and if certain statutory criteria relating to ensuring safety and minimizing the burden of restrictions are satisfied. *See* 21 U.S.C. § 355-1(f)(1)-(2).

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

FDAAA also provides standards for modifying an existing REMS. *See* 21 U.S.C. § 355-1(g)(4). As relevant here, FDA may require an applicant to "submit a proposed modification" to the REMS if the agency "determines that 1 or more goals or elements should be added, modified, or removed" from the approved REMS to "ensure the benefits of the drug outweigh the risks of the drug" or "minimize the burden on the health care delivery system of complying with the strategy." *Id.* § 355-1(g)(4)(B); *see also id.* § 355-1(f)(5)(B)-(C). If FDA requires a modification to a REMS, the applicant must propose that modification within 120 days. *Id.* § 355-1(g)(4)(B).

II. Factual and Procedural Background

In 2000, FDA approved the marketing of mifepristone (under the brand name Mifeprex) for medical termination of early intrauterine pregnancy when used in a regimen with an already-approved drug, misoprostol. At the same time, to assure its safe use, FDA placed certain Subpart H "restrictions to assure safe use" on the distribution and use of the drug product, including requirements that (1) patients sign a Patient Agreement Form, (2) healthcare providers certify (among other things) that they have the ability to accurately date pregnancies, diagnose ectopic pregnancies, and either perform surgical intervention or arrange for others to perform it if necessary, and (3) the drug be dispensed in person at a certified provider's office. *See* Compl. Ex. D, at 4.

Because these restrictions were in place on the effective date of FDAAA, mifepristone was "deemed to have in effect an approved [REMS]" that continued these "elements to assure safe use." Pub. L. No. 110-85, § 909(b)(1); *see also* 73 Fed. Reg. 16,313 (Mar. 27, 2008). In 2011, FDA approved the post-FDAAA mifepristone REMS after determining that it remained "necessary … to ensure the benefits of [mifepristone] outweigh the risks of serious complications." Katzen Decl. Ex. A. After FDA approved a generic version of the drug in 2019, it approved a single, shared system REMS for both Mifeprex and the generic version, known as the Mifepristone REMS Program. Katzen Decl. Ex. B.

FDA has since reviewed and modified the Mifepristone REMS Program.[2] On May 7, 2021, FDA announced that it would review elements of the Mifepristone REMS Program to determine whether those elements should be modified. Katzen Decl. Ex. C (REMS Modification Rationale Review) at 8. FDA's review encompassed "multiple different sources of information," including "published literature," "safety information," adverse event reports, a "REMS assessment report" submitted by the applicants, and "information provided by advocacy groups, individuals, and the [a]pplica[tion holders]." *Id.* at 10. The agency's literature review covered material published between March 29, 2016 (the date of the last REMS modification) and July 26, 2021, and included publications found on PubMed and Embase or provided by "advocacy groups, individuals, plaintiffs in [*Chelius v. Becerra*, 1:17-493-JAO-RT (D. Haw.)], and the [a]pplicat[ion holders]," as well as "healthcare providers and researchers." *Id.* at 10-11.

On December 16, 2021, FDA announced its conclusion that "certain elements of the Mifepristone REMS Program remain necessary to assure the safe use of mifepristone" and that "the Mifepristone REMS Program continues to be

[2] https://perma.cc/7BQC-AJP9 (see Approval Date(s) and History, Letters, Labels, Reviews for NDA 020687).

necessary to ensure the benefits outweigh the risk." Katzen Decl. Ex. D at 6. Specifically, FDA found that prescriber certification and the Patient Agreement Form continue to be necessary components of the REMS. *Id.* at 22. At the same time, FDA found that the REMS "must be modified to remove" the in-person dispensing requirement, which would "allow, for example, dispensing of mifepristone by mail via certified prescribers or pharmacies." *Id.* at 35. Thus, FDA concluded based on its review that "mifepristone will remain safe and effective if the in-person dispensing requirement is removed, provided all the other requirements of the REMS are met and pharmacy certification is added." *Id.*

FDA explained its conclusions in a review memorandum. Katzen Decl. Ex. C. *First*, FDA explained its rationale for retaining the prescriber certification requirement, which allows mifepristone to be prescribed only by providers who are certified under the REMS and agree, among other things, that they can accurately date pregnancies, diagnose ectopic pregnancies, and perform or arrange for surgical intervention for patients who experience complications. *Id.* at 12-14. FDA explained that the prescriber certification requirement protected against the risk that providers would not detect and appropriately manage complications, such as missed ectopic pregnancy and heavy bleeding from incomplete abortion. *Id.* Because FDA's review of the relevant literature "did not identify any studies comparing providers who met" the qualifications required by the prescriber

certification "with providers who did not," there was "no evidence to contradict [FDA's] previous finding that" the requirement is "necessary to mitigate the serious risks associated with the use of mifepristone in a regimen with misoprostol." *Id.* Thus, the agency concluded that prescriber certification "continues to be a necessary component of the REMS to ensure the benefits of mifepristone for medical abortion outweigh the risks," and that "[t]he burden of prescriber certification has been minimized to the extent possible" because each provider need only provide one certification to each of the two drug application holders for mifepristone. *Id.*

Second, FDA explained that the Patient Agreement Form "ensures that patients are informed of the risks of serious complications associated with mifepristone," "serves as an important counseling component," and "document[s] that the safe use conditions of the Mifepristone REMS Program have been satisfied." *Id.* at 14-15. Although the agency considered removing this requirement in 2016, it ultimately decided to retain this requirement. *Id.* at 16. In 2021, FDA concluded that "literature that focused on the informed consent process" "d[id] not provide evidence that would support removing" the Patient Agreement Form requirement. *Id.* at 16-17. Among other things, the agency found that the Patient Agreement Form "is an important part of standardizing the medication information on the use of mifepristone that prescribers communicate to their patients," "does

not impose an unreasonable burden on providers or patients," and thus "remains necessary to assure the safe use of Mifepristone." *Id.* at 18.

Third, based on an extensive review of assessment reports submitted by the application holders, adverse event data, and the literature, FDA concluded that the in-person dispensing requirement was no longer necessary because, among other things, "there does not appear to be a difference in adverse events between periods during the COVID-19 [public health emergency] when the in-person dispensing requirement was being enforced and periods when the in-person dispensing requirement was not being enforced." *Id.* at 38. The agency therefore concluded that "mifepristone will remain safe and effective for medical abortion if the in-person dispensing requirement is removed, provided all the other requirements of the REMS are met, and pharmacy certification is added." *Id.* at 39.

FDA expressly tied the addition of the pharmacy certification requirement to the removal of the in-person dispensing requirement. *See id.* at 40 ("Given this modification to the dispensing requirements in the REMS, it is necessary to add a requirement for certification of pharmacies …."). Adding this requirement would "incorporate[] pharmacies into the REMS, ensur[ing] that [they] are aware of and agree to follow applicable REMS requirements, and … that mifepristone is only dispensed pursuant to prescriptions that are written by certified prescribers." *Id.* "Without pharmacy certification, a pharmacy might dispense product that was not

prescribed by a certified prescriber." *Id.* Consequently, to "ensure the benefits of mifepristone for medical abortion outweigh the risks while minimizing the burden imposed by the REMS on healthcare providers and patients," FDA approved "the removal of the in-person dispensing requirement" and added the "requirement for pharmacy certification." *Id.* at 41.

Accordingly, FDA directed the drugs' application holders to submit supplemental applications proposing conforming modifications to the REMS. Katzen Decl. Exs. E & F. The application holders submitted their supplemental applications in 2022, and FDA approved them on January 3, 2023, confirming its December 16, 2021, determination that mifepristone will remain safe and effective if the in-person dispensing requirement is removed, provided all the other REMS requirements are met and pharmacy certification is added. Katzen Decl. Exs. G at 9-15 & J.

STANDARD OF REVIEW

Preliminary injunctive relief is an "extraordinary and drastic" remedy that "may only be awarded upon a clear showing that the plaintiff is entitled to such relief." *Winter v. NRDC, Inc.*, 555 U.S. 7, 20-23 (2008); *Munaf v. Geren*, 553 U.S. 674, 689-90 (2008). "A plaintiff seeking a preliminary injunction must establish that [it] is [1] likely to succeed on the merits, [2] that [it] is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of

equities tips in [its] favor, and [4] that an injunction is in the public interest." *Recycle for Change v. City of Oakland*, 856 F.3d 666, 669 (9th Cir. 2017) (internal quotation marks omitted; alterations in original). The third and fourth factors merge when the federal government is the non-movant. *Drakes Bay Oyster Co. v. Jewell*, 747 F.3d 1073, 1092 (9th Cir. 2014) (citing *Nken v. Holder*, 556 U.S. 418, 435 (2009)). A preliminary injunction that "would alter, rather than preserve, the status quo" is "disfavored unless there is a very strong showing in favor of the moving party." *Miracle v. Hobbs*, 808 F. App'x 470, 473 (9th Cir. 2020).

ARGUMENT

I. Plaintiffs' Claims Are Unlikely To Succeed On The Merits

A. Plaintiffs Failed To Administratively Exhaust Their Claims

Plaintiffs challenge FDA's approval of supplemental applications proposing modifications to the Mifepristone REMS Program. That challenge is unlikely to succeed because Plaintiffs failed to exhaust their administrative remedies. As FDA has repeatedly demonstrated in approving modifications to the REMS over the past 22 years, the agency is committed to carefully evaluating new evidence and determining whether particular restrictions remain necessary to assure safe use of mifepristone. There is no reason to think the agency would take a different approach to Plaintiffs' evidence if Plaintiffs were to submit it to the agency.

The APA requires a party to exhaust any administrative remedy mandated by statute or agency rule. *See Darby v. Cisneros*, 509 U.S. 137, 153 (1993). FDA regulations set forth a detailed (and mandatory) administrative process for challenging agency action. As relevant here, "[a] request that [FDA] take or refrain from taking any form of administrative action must first be the subject of a final administrative decision based on [a citizen petition.]" 21 C.F.R. § 10.45(b); *id.* §§ 10.25(a), 10.30; *see also id.* § 10.1 (defining "administrative action" as "every act, including the refusal or failure to act, involved in the administration of any law by the Commissioner"). Moreover, when challenging an agency action, a party "who wishes to rely upon information or views not included in the administrative record shall submit them to the Commissioner with a new petition to modify the action under § 10.25(a)." *Id.* § 10.45(f).

Exhaustion requirements "avoid premature claims and [] ensure that the agency possessed of the most expertise in an area be given first shot at resolving a claimant's difficulties." *Idaho Sporting Cong., Inc. v. Rittenhouse*, 305 F.3d 957, 965 (9th Cir. 2002). Congress empowered FDA to weigh the scientific evidence and determine whether a drug's distribution restrictions are necessary to assure safe use. As the Ninth Circuit has explained, requiring a plaintiff challenging FDA approval of a drug application to first file a citizen petition is necessary to "prevent[] premature interference with agency processes so that the agency may

function efficiently and so that it many have an opportunity to correct is own errors, to afford the parties and courts the benefit of its experience and expertise, and to compile a record which is adequate for judicial review." *Center for Food Safety v. Hamburg*, 696 F. App'x 302, 303 (9th Cir. 2017).

Plaintiffs' claims turn on issues within the agency's scientific expertise. They involve technical and factual assertions about, for example, safety comparisons of mifepristone to other drugs and alleged unique burdens of REMS requirements on States—including burdens that Plaintiffs allege have arisen only after FDA's determination on December 16, 2021, that the REMS must be modified. *See, e.g.*, Am. Compl. ¶¶ 3, 25, 147, 176, 178-88, 212, 219; Mot. 1, 6, 16, 23. Their claims also rely on studies that were not before the agency at the time of that determination. *See, e.g.*, Am. Compl. ¶¶ 141 n.62, 143 n.66, 149 n.79, 150 n.80; Godfrey Decl. ¶ 22 n.21; Janiak Decl. ¶ 15 n.7. Requiring exhaustion will ensure that these "technical and policy questions" will be "addressed in the first instance by the agency with regulatory authority over the relevant industry rather than by the judicial branch." *See Astiana v. Hain Celestial Grp., Inc.*, 783 F.3d 753, 760 (9th Cir. 2015). This will "afford the parties and courts the benefit of [FDA's] experience and expertise, and [allow it] to compile a record which is adequate for judicial review." *Center for Food Safety*, 696 F. App'x at 303.

In similar cases, courts (including this one) have required a party challenging FDA's approval of a drug application or other marketing authorization to first file a citizen petition presenting the challenge to the agency. *See, e.g.*, *Jensen v. Biden*, No. 4:21-cv-5119, 2021 WL 10280395 (E.D. Wash. Nov. 19, 2021) (Rice, J.) (holding that plaintiff who failed to file a citizen petition did not exhaust administrative remedies in challenge to FDA emergency use authorizations); *Ass'n of Am. Physician & Surgeons, Inc. v. FDA (AAPS)*, 539 F. Supp. 2d 4, 21-24 (D.D.C. 2008) (holding that physicians and pharmacists who failed to file a citizen petition did not exhaust administrative remedies in challenge to FDA approval of a supplemental new drug application), *aff'd*, 358 F. App'x 179 (D.C. Cir. 2009); *see also Doe #1-#14 v. Austin*, 572 F. Supp. 3d 1224, 1234 (N.D. Fla. 2021) (refusing to consider extra-record material in challenge to FDA approval of a vaccine where "plaintiffs have not pursued an available administrative route … to force the FDA to consider the materials they submit here") (citing 21 C.F.R. § 10.45(f)).

Likewise, Plaintiffs here seek judicial review of FDA's approval of supplemental applications without first raising their challenge with the agency. Indeed, Plaintiffs never filed a citizen petition challenging *any* FDA action regarding *any* restriction on mifepristone in the 22 years that the drug has been marketed. While Plaintiffs objected to the REMS in a March 2020 letter

referencing a public docket regarding unrelated FDA guidance documents, *see* FDA-2020-D-1106-0061 at regulations.gov, that letter did not include all of their present contentions or reference the studies they now rely upon. In any event, Plaintiffs have never sought relief through a citizen petition, the agency's prescribed administrative remedy. *See* 21 C.F.R. § 10.30 (setting forth detailed requirements for citizen petitions); *Agua Caliente Tribe of Cuperño Indians of Pala Reservation v. Sweeney*, 932 F.3d 1207, 1219 (9th Cir. 2019) (holding that letter did not exhaust administrative remedies where statute prescribed a different process); *Reddic v. Evans*, 2011 WL 2181311, at *3 (N.D. Cal. Jun. 3, 2011) (same).[3]

Finally, Plaintiffs cannot satisfy the exhaustion requirements by pointing to the citizen petition submitted by the American College of Obstetricians and

[3] Nor is there anything in FDA's response to that letter (*see* Katzen Decl. Ex. J) that suggests submitting a citizen petition would have been futile. *See Biotics Research Corp. v. Heckler*, 710 F.2d 1375, 1378 (9th Cir. 1983) (finding "nothing in the record to indicate that a citizen's petition to the Commissioner" challenging agency conclusions set forth in a letter "would have been ineffective or futile"); *Agua Caliente*, 932 F.3d at 1219 (finding that agency's response to a letter "does not suggest futility").

Gynecologists (ACOG) in 2022. *See* Am. Compl. ¶¶ 139-43; Mot. 21, 25. ACOG and the other petitioners are not plaintiffs in this case. Moreover, that petition requested different relief. ACOG requested that FDA ask the holder of the new drug application for Mifeprex to submit an application to add miscarriage management as a new indication for mifepristone. FDA denied that request because it is up to the new drug application holder to decide whether to seek approval for a new indication. Compl. Ex. S. That conclusion led FDA to reject the petition's related request to eliminate or modify the REMS for mifepristone "so that it is not unduly burdensome for a miscarriage management indication." *Id.* The related request, FDA explained, was "premature" because miscarriage management "is not a currently approved indication for mifepristone." *Id*. ACOG's citizen petition did not ask FDA to consider the new reasons now offered by Plaintiffs for eliminating the REMS.

B. Plaintiffs Lack Standing

Plaintiffs also lack standing. To meet the "irreducible constitutional minimum of standing," *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992), Plaintiffs "must show (i) that [they] suffered an injury in fact that is concrete, particularized, and actual or imminent; (ii) that the injury was likely caused by the defendant[s]; and (iii) that the injury would likely be redressed by judicial relief,"

TransUnion LLC v. Ramirez, 141 S. Ct. 2190, 2203 (2021). Plaintiffs offer three theories of standing, but each of them fails.

First, Plaintiffs lack standing to sue the federal government as *parens patriae* on behalf of their residents. *See* Mot. 15. In general, a "State does not have standing as *parens patriae* to bring an action against the Federal Government." *Alfred L. Snapp & Son, Inc. v. Puerto Rico ex rel. Barez*, 458 U.S. 592, 610 n.16 (1982) (citing *Massachusetts v. Mellon*, 262 U.S. 447, 485–486 (1923)). Plaintiffs suggest that they have a "quasi-sovereign interest in the health and well-being" of their residents, but the federal government is "the ultimate parens patriae of every American citizen." *S. Carolina v. Katzenbach*, 383 U.S. 301, 324 (1966); *see also Gov't of Manitoba v. Bernhardt*, 923 F.3d 173, 180-83 (D.C. Cir. 2019) (applying this rule to APA claims); *cf. Challenge v. Moniz*, 218 F. Supp. 3d 1171, 1177-78 (E.D. Wash. 2016) (Rice, J.) (holding that Congress had "overridden" *Mellon's* limitation in a statute that "explicitly" defines the "person" who may sue "to include a state").

Second, Plaintiffs' argument that they suffer direct "pecuniary harms," Mot. 14, fails because they have not established that the challenged agency action—*i.e.*, FDA's January 3, 2023, approval of the supplemental applications modifying the Mifepristone REMS Program—caused those harms. Plaintiffs aver that their Medicaid programs incur greater costs when patients choose surgical abortion over

medication abortion, but apart from conclusory assertions, *see, e.g.*, Birch Decl. ¶ 10, they offer no support for their assertion that "the [January 2023] REMS *causes*" patients to obtain surgical abortions, *see* Mot. 15 (citing no evidence for this proposition). For example, they provide no evidence that, by requiring patients who wish to take mifepristone to sign a Patient Agreement Form and obtain the drug from or under the supervision of a certified prescriber or from a certified pharmacy, the REMS causes a substantial number of patients to obtain surgical abortion instead. Thus, Plaintiffs' assertion that the REMS "encourage[s]" patients to seek surgical abortion "is purely speculative" and therefore cannot support their standing. *See Simon v. E. Kentucky Welfare Rights Org.*, 426 U.S. 26, 42-43 (1976) (rejecting as speculative plaintiffs' unsupported contention that a tax policy would necessarily encourage hospitals to deny services to indigent patients).

Plaintiffs likewise fail to establish that FDA's January 2023 action caused the various "administrative burdens" on pharmacies of which Plaintiffs complain. Mot. 14. Many of the specific administrative tasks about which Plaintiffs complain reflect their independent choice to establish new systems that may facilitate their pharmacies' efforts to dispense mifepristone, but they do not reflect burdens imposed by the REMS itself. For example, while the REMS requires patients to sign a Patient Agreement Form before obtaining mifepristone, it does not require providers to "change[]" and "test" their information technology systems to "ensure

that patients who seek telehealth medication abortion can readily sign the Patient Agreement Form," Godfrey Decl. ¶ 35. And while the REMS requires pharmacies that wish to dispense mifepristone to first satisfy certain conditions, *see* Compl. Ex. P ("Pharmacy Agreement Form"), it does not require pharmacies to "develop[] new IT systems" to facilitate those efforts, or "creat[e] billing workflows specifically for insurance carriers that do not cover mifepristone," DasGupta Decl. ¶ 15.

Third, Plaintiffs' generalized "interest[] in delivering high-quality patient care," Mot. 14, also does not confer standing. This vague theory fails to identify a concrete injury to their providers' interest in practicing medicine. *See Spokeo, Inc. v. Robins*, 578 U.S. 330, 340-41 (2016) (to be concrete, an injury must be "real, not abstract" (citation and quotation marks omitted)). To the extent that Plaintiffs base this theory on their allegations that the REMS requirements they challenge harm patient care, that theory is speculative for the reasons explained above. *See supra* pp. 18-19. This theory of standing also lacks a limiting principle: it would give medical providers standing to challenge virtually any FDA action relating to drugs, since nearly every such action has some effect on the availability of drugs that providers may prescribe or recommend. Plaintiffs' vague assertion of an injury to their providers' interest in providing patient care therefore fails.

Finally, Plaintiffs' theories of standing fail for yet another reason: Plaintiffs do not meet their burden to show that success on their claims would redress their

injuries. Plaintiffs stress that they are challenging the specific action FDA took on January 3, 2023. *See* Am. Compl. ¶¶ 258, 262, 265, 269 (identifying the "2023 REMS" as the object of Plaintiffs' claims); Pls.' Resp. to Defs.' Mot. for Extension (Dkt. 19), 3 ("The REMS at the heart of this dispute did not take effect until January 3, 2023" such that Plaintiffs' claims were "not ripe until that date."). Yet it is unclear how enjoining or vacating that action[4] would redress Plaintiffs' injuries. After all, FDA's January 2023 decision *eased* the approved restrictions on mifepristone's distribution and made them less burdensome than they have ever been in the 22 years since the drug's approval.[5]

[4] For the reasons explained *infra* Part IV, Plaintiffs could not be entitled to any broader relief.

[5] Plaintiffs' claims should also fail for the additional reason that venue is improper. Plaintiffs assert venue is proper in this district based on the residence of the State of Washington. But a plaintiff entity "resides" only in the district where it has its "principal place of business," 21 U.S.C. § 1391(c)(2), which here is the state capital in the Western District of Washington. Defendants recognize, however, that the Ninth Circuit has held otherwise. *See California v. Azar*, 911 F.3d 558, 570 (9th Cir. 2018).

C. FDA's Actions Were Lawful And Reasonable

Plaintiffs' claims are unlikely to succeed even if the Court reaches the merits. Under the APA, the Court reviews agency action to determine whether it is arbitrary and capricious or contrary to law. 5 U.S.C. § 706. Applying the "forgiving" arbitrary-and-capricious standard, *Env'tl Def. Ctr., Inc. v. EPA*, 344 F.3d 832, 359 (9th Cir. 2003), the Court must uphold agency action unless "the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or if the agency's decision is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Turtle Island Restoration Network v. U.S. Dep't of Commerce*, 878 F.3d 725, 733 (9th Cir. 2017). Review is "at its most deferential" with respect to an agency's scientific determinations within its area of expertise. *Baltimore Gas & Elec., Co. v. Nat. Res. Def. Council, Inc.*, 462 U.S. 87, 103 (1982). In particular, "[FDA's] judgments as to what is required to ascertain the safety and efficacy of drugs fall squarely within the ambit of the FDA's expertise and merit deference from [courts]." *A.L Pharma, Inc. v. Shalala*, 62 F.3d 1484, 1490 (D.C. Cir. 1995) (quoting *Schering Corp. v. FDA*, 51 F.3d 390, 399 (3d. Cir. 1995)); *see also FDA v. Am. Coll. of Obstetricians & Gynecologists*, 141 S. Ct. 578, 579 (2021) (Roberts, C.J., concurring) (explaining

that the "significant deference" owed to FDA's judgments weighed against "compel[ling] the FDA to alter the regimen for medical abortion").

Under these principles, FDA's January 2023 decision should be upheld. When determining whether to modify elements to assure safe use in an approved REMS, FDA considers both the need for restrictions to ensure that the benefits of the drug outweigh the risks and the burdens restrictions impose on patients and the healthcare system more generally. *See* 21 U.S.C. § 355-1(g)(4)(B); *see also id.* § 355-1(f)(1), (2), (5)(B). Here, in deciding whether and how the Mifepristone REMS Program should be modified, FDA asked whether evidence since the agency's review of the REMS in 2016 established that a particular existing restriction either was no longer necessary to ensure that the benefits of the drug outweigh the risks or was unduly burdensome on patients or the healthcare system. After weighing the evidence before it, the agency concluded that the Patient Agreement Form and prescriber certification requirements must be retained; that the in-person dispensing requirement must be removed; and that a pharmacy certification requirement must be added to permit certified pharmacies to dispense mifepristone. The agency's explanation of these conclusions exemplified reasoned decisionmaking. *See supra* pp. 8-11. The APA requires no more.

Plaintiffs ignore (indeed, do not even mention) FDA's reasoned explanation for its approval of the January 2023 modification to the Mifepristone REMS

Program. Instead, they argue that FDA's approval is "contrary to law" because mifepristone is safe and the REMS restrictions are "unrelated" to any medical risk and unduly burdensome on rural patients. *See* Mot. 16-19. But Plaintiffs' argument misses the point—FDA has found mifepristone to be safe *with* the REMS requirements Plaintiffs seek to have removed. Katzen Decl. Ex. C at 39 ("[M]ifepristone will remain safe and effective for medical abortion if the in-person dispensing requirement is removed, *provided all the other requirements of the REMS are met, and pharmacy certification is added* ….") (emphasis added). In 2023, FDA considered the burdens of the REMS restrictions and explained that they could be reduced but that certain restrictions nonetheless remained necessary to assure the safe use of the product. Were Plaintiffs to submit new evidence in a citizen petition to FDA showing that the REMS is unnecessary to assure safe use of mifepristone and unduly burdens access to the drug (which they have not done, *see supra* pp. 12-17), FDA would carefully weigh that evidence, just as it has always done when evaluating the necessity of particular restrictions.

Contrary to Plaintiffs' suggestion (Mot. 21), the lack of a REMS for Korlym (a different drug with mifepristone as its active ingredient, *see supra* n.1) does not support a different conclusion. In deciding whether to require a REMS for a particular drug, FDA makes a case-by-case determination that involves weighing the drug's risks and benefits in light of its particular conditions of use and other

factors. *See* 21 U.S.C. § 355-1(a)(1). Thus, the fact that there is no REMS for Korlym does not compel FDA to reach the same result for Mifeprex and its generic, which have conditions of use very different from Korlym's. Indeed, FDA conducted this case-by-case inquiry for Korlym, explicitly considering the REMS for Mifeprex, and explained why Korlym does not require a REMS to assure safe use of the drug to treat Cushing's syndrome. *See* Katzen Decl. Ex. H.

Plaintiffs' remaining arguments simply underscore their failure to exhaust. They point to a single Canadian study which, according to Plaintiffs, shows that mifepristone is safe without restrictions. Mot. 21; Am. Compl. ¶ 143. But that study was conducted in 2022, after FDA had completed its literature review for the January 2023 REMS modification. Had Plaintiffs submitted a citizen petition asking FDA to consider this study, the agency would have done so. *See* 21 C.F.R. § 10.45(f) (providing that an interested party that wishes to rely on information not before FDA must first file a citizen petition). Similarly, if Plaintiffs believe they can identify burdens that FDA did not consider, they must raise those issues in a citizen petition to afford FDA an opportunity to consider them in the first instance.

Plaintiffs' arguments that FDA's approval of the January 2023 REMS modification was arbitrary and capricious, Mot. 19-26, likewise fail. Despite having joined a recent amicus brief recognizing that "there can be no doubt that the FDA's overall conclusions regarding medication abortion's safety and efficacy are

based on substantial evidence," *see* Katzen Decl. Ex. I at 2, Plaintiffs emphasize that the REMS is opposed by certain private medical organizations. Mot. 20-21. But the APA requires deference *to FDA*. *See, e.g.*, *Am. Coll. of Obstetricians & Gynecologists*, 141 S. Ct. at 579 (Roberts, C.J., concurring). Here, FDA met its burden to provide a reasoned explanation for its conclusion that the requirements of the REMS are scientifically justified, necessary to ensure the benefits of the drug outweigh the risks, and not unduly burdensome. Plaintiffs' arguments to the contrary either raise issues never put before the agency or rest on disagreement with how FDA weighed the relevant factors.[6] None of these arguments overcomes FDA's reasoned decisionmaking.

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[6] In a footnote, Plaintiffs contend that the January 2023 REMS modification violates the equal protection component of the Fifth Amendment. *See* Mot. 18-19 n.3. A conclusory argument presented in a footnote cannot provide the basis for a preliminary injunction. *See First Advantage Background Servs. Corp. v. Priv. Eyes, Inc.*, 569 F. Supp. 2d 929, 935 (N.D. Cal. 2008). Regardless, because Plaintiffs do not allege discrimination on the basis of any protected category, their claim is subject to rational basis review. *See, e.g.*, *Vargas v. Chelan Cnty. Regional Justice Ctr.*, No. CV-09-39, 2010 WL 685002, at *4 (E.D. Wash. Feb. 22, 2010).

II. Plaintiffs Fail To Show Irreparable Harm

Plaintiffs also have not met their burden to establish that they will suffer irreparable harm absent a preliminary injunction. To meet that burden, "[a] plaintiff must do more than merely allege imminent harm sufficient to establish standing; a plaintiff must *demonstrate* immediate threatened injury as a prerequisite to preliminary injunctive relief." *Boardman v. Pac. Seafood Grp.*, 822 F.3d 1011, 1022 (9th Cir. 2016) (quoting *Caribbean Marine Servs. Co., Inc. v. Baldrige*, 844 F.2d 668, 674 (9th Cir. 1988)). Because Plaintiffs fail to establish standing, they likewise cannot meet the higher burden to establish that they would likely face irreparable harm absent the requested relief.

Plaintiffs' two-decade delay in raising their claims to either FDA or any court further weighs against a finding of irreparable harm. Since 2000, restrictions on the distribution of mifepristone have been at least as restrictive as the 2023 REMS modification. As explained above, the Patient Agreement Form and prescriber certification have been required that entire time. And until January 2023, the REMS did not permit *any* pharmacy to dispense mifepristone, either with or without a pharmacy certification. Thus, the restrictions allegedly causing Plaintiffs'

For all the reasons described above, FDA's decision was rationally related to the legitimate governmental interest in ensuring drug safety.

injuries date back to 2000, and their delay in seeking relief "implies a lack of urgency and irreparable harm." *Oakland Tribune, Inc. v. Chronicle Publ'g Co.*, 762 F.2d 1374, 1377 (9th Cir. 1985). In short, Plaintiffs have "sle[pt] on [their] rights," which "demonstrate[es] that there is not an urgent need for 'speedy action.'" *ADM Milling Co v. Columbia Plateau Producers, L.L.C.*, 2:20-cv-0343, 2020 WL 5802344, at *6 (E.D. Wash. Sept. 28, 2020) (Rice, J.).

Plaintiffs attempt to show irreparable harm from the pharmacy certification requirement in isolation, divorced from the 2023 REMS modification as a whole. But the net effect of the 2023 REMS modification was to *reduce* the burden associated with accessing mifepristone: by removing the in-person dispensing requirement and adding a pharmacy certification requirement, FDA *permitted* the dispensing of mifepristone in a manner that was previously *prohibited*. Plaintiffs cannot show irreparable harm from FDA allowing pharmacies to dispense mifepristone on the condition that they satisfy the pharmacy certification requirement when, prior to January 2023, the REMS did not permit pharmacies to dispense mifepristone under any circumstances.

Moreover, even considering only the pharmacy certification requirement, Plaintiffs still waited nearly two months to file suit after the 2023 REMS modification was approved. *See Jensen*, 2021 WL 10280395, at *9 (Rice, J.) (holding that a delay of "nearly two months" weighed against finding irreparable

harm); *Wise v. Inslee*, No. 2:21-cv-0288, 2021 WL 4951571, at *6 (E.D. Wash. Oct. 25, 2021) (Rice, J.) (same). That delay is significant considering that Plaintiffs have known since December 16, 2021, about the forthcoming modification to the REMS and have been preparing for it since well before January 2023. *See, e.g.*, Reed Decl. ¶ 3 ("For the past four months, I have been participating in a work group at UW that is implementing the amended requirements for the FDA's mifepristone [REMS]."); Singh Decl. ¶ 3 ("[F]or the past 6 months, I have participated [in] operationalizing … FDA's updated [REMS] for mifepristone."); Prager Decl. ¶ 35 (averring that a workgroup to implement the modified REMS "has been meeting for 4 or 5 months"). Given this lead time in which Plaintiffs could have prepared to challenge the 2023 REMS modification, waiting almost two months after approval of that REMS evinces a lack of urgency.

In sum, Plaintiffs have not shown that they will face irreparable harm absent an injunction.

III. The Equities And Public Interest Weigh Against An Injunction

Plaintiffs have not shown that they are likely to succeed on the merits or that they are likely to suffer irreparable harm, so the Court need not address the balancing of equities or public interest. *Herb Reed Enters., LLC v. Fla. Ent. Mgmt., Inc.*, 736 F.3d 1239, 1251 (9th Cir. 2013). Nevertheless, those factors also weigh heavily against granting the requested relief.

As noted, a preliminary injunction that "would alter, rather than preserve, the status quo" is "disfavored unless there is a very strong showing in favor of the moving party." *Miracle*, 808 F. App'x at 473. "Where no new harm is imminent, and where no compelling reason is apparent, the district court [is] not required to issue a preliminary injunction against a practice which has continued unchallenged for several years." *Oakland Tribune, Inc.*, 762 F.2d at 1377. Considering that the Patient Agreement Form and prescriber certification requirements have existed for 22 years and the net effect of the 2023 REMS modification was to *reduce* restrictions on mifepristone's distribution, Plaintiffs have shown "no new harm" or "compelling reason" justifying a preliminary injunction. *Supra* pp. 27-29.

Plaintiffs' request is especially unjustified because it would undermine Congress's decision to delegate to FDA the responsibility for making scientific judgments about drug safety. *See* 21 U.S.C. § 393(b). The public interest is best served by deferring to FDA's judgments about what restrictions are necessary to ensure drugs are safe. That is particularly true here, where the agency's decisions regarding the conditions on the distribution of mifepristone reflect careful, deliberative decisionmaking informed by years of data. Had Plaintiffs contested those decisions by filing a citizen petition with FDA, the agency would have reached a considered expert judgment on Plaintiffs' claims and created an administrative record fit for judicial review. Instead, through this lawsuit, Plaintiffs

seek to deprive FDA of that opportunity, asking the Court to declare that mifepristone is safe under conditions that FDA has never approved. As Congress recognized, there is a strong public interest in having an expert scientific agency make scientific judgments about drug safety, and the requested injunction is an impermissible attempt to flout that institutional design.

IV. Plaintiffs' Requested Relief Exceeds Any Permissible Scope

Even if it were appropriate to enjoin enforcement or application of the 2023 REMS modification (it is not), relief beyond that would not be warranted. This includes Plaintiffs' unprecedented request—untethered to any actual claim for relief or specific harm they assert—to "preliminary enjoin[] FDA from … taking any action to remove mifepristone from the market or otherwise cause the drug to become less available." Mot. 34. That request should be rejected for at least three reasons.

First, Plaintiffs' proposed remedy fails a fundamental precept of preliminary injunctive relief: "[a]n injunction must be narrowly tailored to remedy the specific harm shown." *E. Bay Sanctuary Covenant v. Barr*, 934 F. 3d 1026, 1029 (9th Cir. 2019) (internal quotation marks omitted). Under that rule, an injunction is overbroad—and therefore impermissible—when it "reaches beyond the scope of the complaint and enjoins government regulations that were explicitly never challenged or litigated." *Church of Holy Light of Queen v. Holder*, 443 F. App'x

302, 303 (9th Cir. 2011); *see also Skydive Arizona, Inc. v. Quattrocchi*, 673 F.3d 1105, 1116 (9th Cir. 2012) ("Courts should not enjoin conduct that has not been found to violate any law."). Plaintiffs make no effort to connect their request that the Court enjoin "any action to remove mifepristone from the market or otherwise cause the drug to become less available" to any of their claims. Rather, after devoting the entirety of their Amended Complaint and Motion to attacking the January 2023 REMS modification, Plaintiffs simply announce that in addition to enjoining enforcement and application of that modification, they want this Court to prohibit FDA from doing anything that would make the drug less available.

Second, and relatedly, Plaintiffs' request for relief against hypothetical and unchallenged future agency action violates basic principles of administrative law. The APA allows parties to seek review only of discrete "agency actions." *See Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 891 (1990) ("Under the terms of the APA, respondent must direct its attack against some particular 'agency action' that causes it harm."); *Arrow Reliance, Inc. v. Califf*, No. 2:22-cv-1057, 2022 WL 18027595, at *2 (W.D. Wash. Dec. 30, 2022) (holding that the APA permits challenges to "circumscribed, discrete agency actions"). And when a party prevails on its APA challenge, the proper remedy—even in the context of a preliminary injunction—is "limited only to vacating the unlawful action, not precluding future agency decisionmaking." *Hill Dermaceuticals, Inc. v. FDA*, 709 F.3d 44, 46 n.1

(D.C. Cir. 2013); *see also, e.g.*, *Norton v. S. Utah Wilderness Alliance*, 542 U.S. 55, 65 (2004) ("The [APA's] limitation to *required* agency action rules out judicial direction of even discrete agency action that is not demanded by law."); *Lujan*, 497 U.S. at 893 ("[T]he flaws in the entire 'program'—consisting principally of the many individual actions referenced in the complaint, and presumably actions yet to be taken as well—cannot be laid before the courts for wholesale correction under the APA, simply because one of them that is ripe for review adversely affects one of respondent's members."). Here, even if Plaintiffs had valid challenges to the 2023 REMS modification (or to the imposition of the REMS generally), that would hardly justify injunctive relief against hypothetical future actions pertaining to mifepristone's general availability on the market.

Third, Plaintiffs' broad, amorphous remedy also would violate Rule 65(d), which requires that every injunction "state its terms specifically" and "describe in reasonable detail … the act or acts restrained or required." Fed. R. Civ. P. 65(d); *see, e.g.*, *Del Webb Communities, Inc. v. Partington*, 652 F.3d 1145, 1150 (9th Cir. 2011) (holding that an injunction's "general prohibition against using 'illegal, unlicensed and false practices' is too vague to be enforceable" because "[t]he examples of prohibited past conduct do not sufficiently define what additional future conduct will be covered"). Suppose, for example, FDA learns that a batch of mifepristone is contaminated. The FDCA authorizes FDA to recommend that the

Department of Justice institute proceedings to seize the violative product. *See* 21 U.S.C. § 334. Would Plaintiffs' proposed remedy prohibit that seizure action because it would reduce the availability of mifepristone? There is no limit in Plaintiffs' requested relief that would account for that situation, or any other exercise of FDA's statutorily conferred authority to execute the provisions of the FDCA as they pertain to mifepristone. Such broad relief is not permitted by Rule 65(d).

CONCLUSION

For the foregoing reasons, the Court should deny Plaintiffs' Motion for Preliminary Injunction.

March 17, 2023

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CERTIFICATE OF SERVICE

I hereby certify that, on March 17, 2023, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON

STATE OF WASHINGTON; STATE OF OREGON; STATE OF ARIZONA; STATE OF COLORADO; STATE OF CONNECTICUT; STATE OF DELAWARE; STATE OF ILLINOIS; ATTORNEY GENERAL OF MICHIGAN; STATE OF NEVADA; STATE OF NEW MEXICO; STATE OF RHODE ISLAND; STATE OF VERMONT; DISTRICT OF COLUMBIA; STATE OF HAWAII; STATE OF MAINE; STATE OF MARYLAND; STATE OF MINNESOTA; and COMMONWEALTH OF PENNSYLVANIA,

Plaintiffs,

v.

NO. 1:23-cv-3026-TOR

AMENDED COMPLAINT

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UNITED STATES FOOD AND DRUG ADMINISTRATION; ROBERT M. CALIFF, in his official capacity as Commissioner of Food and Drugs; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; and XAVIER BECERRA, in his official capacity as Secretary of the Department of Health and Human Services,

Defendants.

I. INTRODUCTION

1. The availability of medication abortion has never been more important. As states across the country have moved to criminalize and civilly penalize abortion, the Plaintiff States have preserved the right to access abortion care, and have welcomed people from other states who need abortion care. The extremely limited availability of abortion in other states, and the growing threat to abortion access nationwide, makes patients' access to medication abortion paramount. Medication abortion through a combination of mifepristone and misoprostol is the "gold standard" for early termination of pregnancy, used by the majority of people in the U.S. who choose to have an abortion.

2. More than 22 years ago, the United States Food and Drug Administration (FDA) approved mifepristone (under the brand name Mifeprex) to be used with the drug misoprostol, in a two-drug medication regimen to end an early pregnancy. Approval was based on a thorough and comprehensive

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review of the scientific evidence, which established that mifepristone is safe and effective.

3. Since this regimen was approved in 2000, mifepristone has been used approximately 5.6 million times in the United States.[1] As FDA acknowledged in 2016, mifepristone "has been increasingly used as its efficacy and safety have become well-established by both research and experience, and serious complications have proven to be extremely rare."[2] Mifepristone is safer than many other common drugs FDA regulates, such as Viagra and Tylenol.

4. Medication abortion is now the most common method of abortion in the United States. For example, almost 60% of abortions in Washington State are medication abortions.

5. But FDA has continued to hamper access by singling out mifepristone—and the people in the Plaintiff States who rely on it for their reproductive health care—for a unique set of restrictions known as a

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[1]FDA, Mifepristone U.S. Post-Marketing Adverse Events Summary through 06/30/2022, https://www.fda.gov/media/164331/download ("Mifepristone U.S. Post-Marketing Adverse Events"), ECF No. 1-2.

[2]FDA, Ctr. for Drug Evaluation & Research, No. 020687Orig1s020, Mifeprex Medical Review(s) at 12 (Mar. 29, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf ("FDA 2016 Medical Review"), ECF No. 1-3.

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Risk Evaluation and Mitigation Strategy (REMS). The restrictions on mifepristone are a particularly burdensome type of REMS known as Elements to Assure Safe Use (ETASU), which strictly limit who can prescribe and dispense the drug. FDA's decision to continue these burdensome restrictions in January 2023 on a drug that has been on the market for more than two decades with only "exceedingly rare" adverse events has no basis in science. It only serves to make mifepristone harder for doctors to prescribe, harder for pharmacies to fill, harder for patients to access, and more burdensome for the Plaintiff States and their health care providers to dispense.[3] Not only that, but the REMS require burdensome documentation of the patient's use of mifepristone for the purpose of abortion, making telehealth less accessible and creating a paper trail that puts both patients and providers in danger of violence, harassment, and threats of liability amid the growing criminalization and outlawing of abortion in other states.

6. FDA has imposed REMS for only 60 of the more than 20,000[4] FDA-approved prescription drug products marketed in the U.S. These cover dangerous

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[3]ECF No. 1-3 (FDA 2016 Medical Review) at 47.

[4]Office of the Commissioner, *FDA at a Glance: FDA Regulated Products and Facilities*, FDA (Nov. 2021), https://www.fda.gov/media/154548/download.

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drugs such as fentanyl and other opioids, certain risky cancer drugs, and high-dose sedatives used for patients with psychosis.[5]

7. This case is about whether it is improper and discriminatory for FDA to relegate mifepristone—a medication that has been used over 5 million times with very low rates of complications, very high rates of efficacy, and which is critical to the reproductive rights of the Plaintiff States' residents, as well as visitors who travel to the Plaintiff States to seek abortion care—to the very limited class of dangerous drugs that are subject to a REMS.

8. The Plaintiff States seek an order directing FDA to follow the science and the law. The Court should order FDA to remove the unnecessary January 2023 REMS restrictions that impede and burden patients' access to a safe, proven drug that is a core element of reproductive health care in the Plaintiff States.

II. JURISDICTION AND VENUE

9. The Court has subject matter jurisdiction under 28 U.S.C. § 1331, as this is a civil action arising under federal law, and under 5 U.S.C. § 702, as this is a civil action seeking judicial review of a final agency action.

10. This action for declaratory and injunctive relief is authorized by 28 U.S.C. §§ 2201 and 2202, by Federal Rules of Civil Procedure 57 and 65, and by the inherent equitable powers of this Court.

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[5] *Id.*

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11. The Court has personal jurisdiction over Defendants pursuant to 28 U.S.C. § 1391(e) because Defendants are agencies and officers of the United States.

12. Venue is proper in this district pursuant to 28 U.S.C. § 1391(a) because this is a judicial district in which Plaintiff State of Washington resides. Defendants' policies adversely affect the health and welfare of residents in the Plaintiff States, including in this district, and harm the financial interests of the Plaintiff States, including Washington. Abortion access is far more limited in Eastern Washington than in Western Washington, with the State's clinics concentrated in urban areas and the I-5 corridor.

III. PARTIES

Washington

13. The Attorney General is the chief legal adviser to the State. The Attorney General's powers and duties include acting in federal court on behalf of the State on matters of public concern.

14. As an operator of medical facilities that provide reproductive health care services and pharmacies that dispense mifepristone, Washington is directly subject to the January 2023 REMS and has standing to vindicate its proprietary interests in delivering high-quality patient care.

15. Washington also has standing because the 2023 REMS creates and maintains substantial and costly administrative burdens for State-operated hospitals, clinics, and pharmacies.

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16. Washington additionally brings this suit in its capacity as parens patriae to protect its quasi-sovereign interest in the health and well-being of Washington residents.

Oregon

17. Plaintiff State of Oregon is represented by its Attorney General, who is the chief law officer for the State. Oregon has a strong interest in the proper provision of health care within the state, particularly at public hospitals, and joins in its capacity as parens patriae to protect its quasi-sovereign interest in the health and well-being of Oregon residents.

Arizona

18. The Attorney General is the chief legal adviser to the State. The Attorney General's powers and duties include acting in federal court on behalf of the State on matters of public concern.

19. As the operator of facilities that provide reproductive health care and pharmaceutical services, Arizona is directly subject to the January 2023 REMS and has standing to vindicate it proprietary interests in delivering high-quality patient care.

20. Arizona also has standing because the 2023 REMS create and maintain substantial and costly administrative burdens for health care and pharmaceutical services provided in state owned or operated facilities.

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21. Arizona additionally brings this suit in it capacity as parens patriae to protect its quasi-sovereign interest in the health and well-being of Arizona residents.

Colorado

22. Plaintiff the State of Colorado is a sovereign state of the United States of America. This action is brought on behalf of the State of Colorado by Attorney General Phillip J. Weiser, who is the chief legal representative of the State of Colorado, empowered to prosecute and defend all actions in which the state is a party. Colo. Rev. Stat. § 24-31-101(1)(a).

Connecticut

23. The State of Connecticut is a sovereign state. The Attorney General is Connecticut's chief civil legal officer, responsible for supervising and litigating all civil legal matters in which Connecticut is an interested party, including federal court matters.

24. Medication abortion is indispensable to reproductive health care in Connecticut. According to the Centers for Disease Control, more than 65% of Connecticut abortions are medication abortions using mifepristone.

25. Access to mifepristone for medicated abortions is increasingly critical in Connecticut. An ongoing wave of hospital closures and consolidations threaten to leave swaths of the state without access to on-site reproductive healthcare, even as demand for abortion care has increased in the aftermath of *Dobbs*.

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26. Connecticut is directly subject to the January 2023 REMS and has standing to vindicate its proprietary interests in delivering high-quality patient care. Connecticut funds and operates the John Dempsey Hospital of the University of Connecticut Health Center (UConn Health) and its associated pharmacy. The Hospital provides reproductive health services, including prescribing mifepristone for medication abortions. The pharmacy dispenses mifepristone to patients.

27. Connecticut also has standing because the 2023 REMS create and maintain substantial and costly administrative burdens, including burdens to UConn Health and its associated pharmacy.

28. Connecticut additionally brings this suit in its capacity as parens patriae to protect is quasi-sovereign interest in the health and well-being of Connecticut residents.

Delaware

29. Plaintiff the State of Delaware is a sovereign state of the United States of America. This action is brought on behalf of the State of Delaware by Attorney General Kathleen Jennings, the "chief law officer of the State." *Darling Apartment Co. v. Springer*, 22 A.2d 397, 403 (Del. 1941). Attorney General Jennings also brings this action on behalf of the State of Delaware pursuant to her statutory authority. Del. Code Ann. tit. 29, § 2504.

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30. Delaware additionally brings this suit in its capacity as parens patriae to protect its quasi-sovereign interest in the health and well-being of Delaware residents.

Illinois

31. Plaintiff the State of Illinois is a sovereign state of the United States of America. This action is brought on behalf of the State of Illinois by Attorney General Kwame Raoul, the State's chief legal officer. *See* Ill. Const. art. V, § 15; 15 ILCS 205/4.

32. Illinois has standing because the 2023 REMS create barriers to accessing medically necessary abortion and miscarriage care, leading to subsequent health care costs, including emergency care, some of which is borne by the state through Medicaid expenditures.

33. Illinois additionally brings this suit in its capacity as parens patriae to protect its quasi-sovereign interest in the health and well-being of Illinois residents.

Attorney General of Michigan

34. Attorney General Dana Nessel is the chief legal adviser to the State of Michigan. The Attorney General's powers and duties include acting in federal court on behalf of the State on matters of public concern.

35. The Attorney General brings this suit in her capacity as parens patriae to protect Michigan's quasi-sovereign interest in the health and well-being of Michigan residents.

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Nevada

36. Plaintiff State of Nevada is represented by its Attorney General. The Attorney General is the chief legal officer of the State.

37. The Nevada Attorney General may commence or defend a suit in state or federal court when in his opinion a suit is necessary to protect and secure the interest of the State.

38. Nevada provides reproductive healthcare services including medication abortions using mifepristone.

39. As a provider of reproductive healthcare services, Nevada is subject to the January 2023 REMS program.

40. Nevada has standing to challenge the REMS because it imposes financial and administrative burdens on Nevada reproductive healthcare service providers seeking to prescribe and distribute mifepristone for medication abortions.

41. Nevada also has standing to challenge the program because the program interferes with its inherent authority to provide for the health and welfare of its residents. It imposes medically unnecessary barriers to Nevada's provision of reproductive healthcare using the least intrusive and most cost-effective means.

New Mexico

42. Plaintiff State of New Mexico, represented by and through its Attorney General, is a sovereign state of the United States of America.

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Attorney General Raúl Torrez is the chief legal officer of the State of New Mexico. He is authorized to prosecute all actions and proceedings on behalf of New Mexico when, in his judgment, the interest of the State requires such action. N.M. Stat. Ann. § 8-5-2(B). Likewise, he shall appear before federal courts to represent New Mexico when, in his judgment, the public interest of the state requires such action. N.M. Stat. Ann. § 8-5-2(J). This challenge is brought pursuant to Attorney General Torrez's statutory authority.

43. As an operator of medical facilities that provide reproductive health care services and pharmacies that dispense mifepristone, New Mexico is directly subject to the 2023 REMS and has standing to vindicate its proprietary interests in delivering high-quality patient care.

44. New Mexico also has standing because the 2023 REMS will impose substantial and costly administrative burdens for State-operated hospitals, clinics, and pharmacies.

45. New Mexico additionally brings this suit in its capacity as parens patriae to protect its quasi-sovereign interest in the health and well-being of New Mexico residents.

Rhode Island

46. The Rhode Island Attorney General is the chief legal officer for the State of Rhode Island. The Rhode Island Attorney General's powers and duties include acting in federal court on behalf of the State on matters of public concern.

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47. Rhode Island has standing because the 2023 REMS create barriers to accessing medically necessary abortion and miscarriage care, leading to subsequent health care utilization, including emergency care, some cost of which is borne by the state through Medicaid expenditures.

48. Rhode Island additionally brings this suit in its capacity as parens patriae to protect its quasi-sovereign interest in the health and well-being of Rhode Island residents.

Vermont

49. The Attorney General is the chief legal adviser to the State. The Attorney General's powers and duties include representing the State in civil causes when, in her judgment, the interests of the State so require.

50. Vermont brings this suit in its capacity as parens patriae to protect its quasi-sovereign interest in the health and well-being of Vermont residents.

District of Columbia

51. Plaintiff the District of Columbia is a sovereign municipal corporation organized under the Constitution of the United States. It is empowered to sue and be sued, and it is the local government for the territory constituting the permanent seat of the federal government. The District is represented by and through its chief legal officer, the Attorney General for the District of Columbia, Brian L. Schwalb. The Attorney General has general charge and conduct of all legal business of the District and all suits initiated by and

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against the District and is responsible for upholding the public interest. D.C. Code § 1-301.81 (2023).

Hawaii

52. The State of Hawaii, represented by and through its Attorney General, is a sovereign state of the United States of America.

53. Attorney General Anne E. Lopez is the chief legal officer of the State of Hawaii, and has the authority to appear, personally or by deputy, for the State of Hawaii in all courts, criminal or civil, in which the State may be a party or be interested. Haw. Rev. Stat. § 28-1 (2023). The Department of the Attorney General has the authority to represent the State in all civil actions in which the State is a party. Haw. Rev. Stat. § 26-7 (2023). This challenge is brought pursuant to the Attorney General's constitutional, statutory, and common law authority. *See* Haw. Const. art. V, § 6; Haw. Rev. Stat. § 26-7 (2023).

54. Hawaii has standing because the 2023 REMS creates barriers and imposes substantial administrative burdens on Hawaii reproductive healthcare providers, including pharmacies and State-operated healthcare facilities, seeking to prescribe mifepristone for medication abortion within the timeframes of its intended use.

55. Hawaii additionally brings this suit in its capacity as parens patriae to protect its quasi-sovereign interest in the health and well-being of Hawaii residents seeking timely access to medical care.

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Maine

56. Plaintiff the State of Maine is a sovereign state. This action is brought on behalf of the State of Maine by its Attorney General, who is a constitutional officer endowed with statutory and common law powers. As the chief legal officer for the State, the Attorney General may exercise all such power and authority as the public interest requires. The Attorney General has wide discretion in determining the public interest. The Attorney General's powers and duties include appearing for the State in all civil actions and proceedings in which the State is a party or has an interest. Me .Rev. Stat. tit. 5, § 191 (2023); *Superintendent of Ins. v. Att'y Gen.*, 558 A.2d 1197 (Me. 1989)

57. Maine has a strong interest in the proper provision and broad access to health care services within the State.

58. Maine has standing because the 2023 REMS creates barriers to accessing medically necessary abortion and miscarriage care, leading to subsequent health care costs, including emergency care, some of which is borne by the State through Medicaid expenditures.

59. Maine further has standing because Maine provides state-funded abortion services to Medicaid-eligible pregnant people, per Me. Rev. Stat. tit. 22, § 3196 (2023) (Coverage for Non-Medicaid Services for MaineCare Members) and 10-144 Me. Code R. Ch. 104 (Maine State Services Manual), Section 7 (Abortion Services for MaineCare Members).

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60. Because the 2023 REMS requirements improperly limit the number of providers who can prescribe mifepristone and the pharmacies that can fill prescriptions, fewer people have access to mifepristone abortions. This restriction may result in more higher-cost surgical abortions, resulting in additional State expenditures. Broad access to mifepristone is a critical tool for reducing the financial impact to the State.

61. Maine additionally brings this suit in its capacity as parens patriae to protect its quasi-sovereign interest in the health and well-being of Maine residents.

Maryland

62. Plaintiff, the State of Maryland, by and through its Attorney General Anthony G. Brown, brings this action. The Attorney General is Maryland's chief legal officer with general charge, supervision, and direction of the State's legal business. The Attorney General's powers and duties include acting on behalf of the State and the people of Maryland in the federal courts on matters of public concern. Under the Constitution of Maryland, and as directed by the Maryland General Assembly, the Attorney General has the authority to file suit to challenge action by the federal government that threatens the public interest and welfare of Maryland residents. Md. Const. art. V, § 3(a)(2); 2017 Md. Laws, Joint Resolution 1.

63. Maryland has standing because the 2023 REMS creates barriers to accessing abortion care, leading to subsequent health care utilization, including

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emergency and other hospital care, some cost of which is borne by the State through Medicaid expenditures.

64. Maryland additionally brings this suit in its capacity as parens patriae to protect its quasi-sovereign interest in the health and well-being of Maryland residents.

Minnesota

65. Plaintiff State of Minnesota is represented by its Attorney General, who is the chief legal officer for the State. The Attorney General's responsibilities include appearing in federal court on behalf of the State when the interests of the State require it.

66. Minnesota has a strong interest in the proper provision of health care within the State, particularly at public hospitals. Because hospitals and clinics funded or operated by the State and its units of government provide reproductive health care and pharmaceutical services, Minnesota is directly subject to the January 2023 REMS and has standing to vindicate its proprietary interests in delivering high-quality patient care.

67. Minnesota also has standing because the 2023 REMS creates and maintains substantial and costly administrative burdens for health care and pharmaceutical services provided in facilities owned or operated by the State and its units of government. The 2023 REMS creates barriers to accessing medically necessary abortion and miscarriage care, leading to subsequent increased health

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care costs, including emergency care. In many instances, this increased cost is paid for by the State.

68. Additionally, Minnesota brings this suit in its capacity as parens patriae to protect its quasi-sovereign interest in the health and well-being of Minnesota residents.

Pennsylvania

69. Plaintiff the Commonwealth of Pennsylvania is a sovereign state of the United States of America. This action is brought on behalf of the Commonwealth of Pennsylvania by the Attorney General, who is the chief law officer of the Commonwealth with statutory authority to bring actions on behalf of the Commonwealth. Pa. Const. art. IV, § 4.1; 71 Pa. Stat. and Cons. Stat. § 732-204 (West 2023).

Plaintiff States

70. The Plaintiff States collectively represent more than 87 million Americans with protected rights to abortion care.

Defendants

71. Defendant United States Food and Drug Administration (FDA) is an agency of the federal government within the United States Department of Health and Human Services (HHS). FDA is responsible for administering the provisions of the federal Food, Drug, and Cosmetic Act that are relevant to this Complaint.

72. Robert M. Califf is the Commissioner of the United States Food and Drug Administration and is sued in his official capacity. He is responsible for

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administering FDA and its duties under the federal Food, Drug, and Cosmetic Act.

73. Defendant HHS is a federal agency within the executive branch of the federal government.

74. Defendant Xavier Becerra is the Secretary of HHS and is sued in his official capacity. He is responsible for the overall operations of HHS, including FDA.

IV. ALLEGATIONS

A. Statutory Background

75. Under the Food, Drug and Cosmetic Act (FDCA), a new drug cannot be marketed and prescribed until it undergoes a rigorous approval process to determine that it is safe and effective. *See generally* 21 U.S.C. § 355. An approved prescription medication is subject to robust safeguards to ensure that it is 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 disciplinary laws regulating the practice of medicine and pharmacy, as well as additional warnings, indications, and instructions that FDA may impose specific to the medication.

76. FDA relies on this set of safeguards to ensure the safe and effective use of the *vast* majority of prescription drugs.

77. A "Risk Evaluation and Mitigation Strategy" (REMS) is an additional set of requirements, beyond the usual network of safeguards, that FDA

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may impose in the rare case when—and only when—"necessary to ensure that the benefits of the drug outweigh the risks of the drug[.]" 21 U.S.C. § 355-1(a)(1).

78. The most burdensome type of 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).

79. By statute, FDA may impose ETASU only for medications that demonstrate risks of serious side effects such as death, incapacity, or birth defects, and only where the risk of side effects is sufficiently severe that FDA could not approve, or would have to withdraw approval of, the medication, absent the ETASU. *Id.* §§ 355-1(b)(5), (f)(1)(A).

80. ETASU must not be "unduly burdensome on patient access to the drug, considering in particular . . . patients in rural or medically underserved areas," and must "minimize the burden on the health care delivery system[.]" *Id.* §§ 355-1(f)(2)(C)–(D).

81. In light of these stringent statutory limitations, REMS, and in particular an ETASU, are exceptionally rare: of the more than 20,000 prescription drug products approved by FDA and marketed in the U.S.,[6] there are only

[6] *Supra* n.5.

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60 REMS in place, 56 of which include an ETASU, covering dangerous drugs like fentanyl and other opioids.[7]

B. FDA's Approval of Mifepristone and the History of the Mifepristone REMS Program

82. The current FDA-approved regimen for the medical termination of early pregnancy involves two drugs: (1) *mifepristone*, which interrupts early pregnancy by blocking the effect of progesterone, a hormone necessary to maintain a pregnancy, and (2) *misoprostol*, which causes uterine contractions that expel the pregnancy from the uterus. Shortly after taking mifepristone and then misoprostol, a patient will experience a miscarriage.[8]

83. Mifepristone was first approved for medical termination of early pregnancy in France in 1988 and its approval expanded to the United Kingdom and European countries throughout the 1990s.

84. In 1996, the Population Council, a non-profit organization based in the United States, sponsored a New Drug Application (NDA) for Mifeprex for use in combination with misoprostol for the medical termination of early

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[7]ECF No. 1-4 (FDA Approved REMS).

[8]Taken alone, misoprostol also acts as an abortifacient—but it is less effective and causes more negative side effects than the mifepristone/misoprostol regimen. Misoprostol, however, it is not subject to a REMS; patients may obtain it from any provider and have it filled at retail or mail-order pharmacies.

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pregnancy. In 1999, the Population Council contracted with Danco Laboratories, L.L.C. (Danco) to manufacture and market the medication.

85. FDA approved the marketing of mifepristone under the brand name Mifeprex in September 2000,[9] concluding that mifepristone is safe and effective for medical termination of intrauterine pregnancy through 49 days' gestation when used in a regimen with the already-approved drug, misoprostol. In granting its approval, FDA extensively reviewed the scientific evidence and determined that mifepristone's benefits outweigh any risks.[10]

86. FDA's review included three clinical trials that together involved 4,000 women: two French trials that were complete at the time of the application, and one then-ongoing trial in the United States for which summary data on serious adverse events were available.[11] FDA has explained that "[t]he data from these three clinical trials . . . constitute substantial evidence that Mifeprex is safe and effective for its approved indication in accordance with the [FDCA]."[12] FDA

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[9]FDA NDA 20-687 Approval Memo, Sept. 28, 2000, ECF No. 1-5.

[10]Food and Drug Administration Approval and Oversight of the Drug Mifeprex, https://www.gao.gov/assets/gao-08-751.pdf, ECF No. 1-6.

[11]*Id.* at 5.

[12]2016 FDA Letter to Am. Ass'n of Pro-Life Obstetricians & Gynecologists, Christian Medical & Dental Ass'ns, and Concerned Women for

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also considered: (1) results from other European trials from the 1980s and 1990s in which mifepristone was studied alone or in combination with misoprostol or similar drugs; (2) a European postmarket safety database of over 620,000 women who used medication to terminate a pregnancy, approximately 415,000 of whom had received a mifepristone/misoprostol regimen[13]; and (3) data on the drug's chemistry and manufacturing.[14]

87. Despite the strong findings on the safety and efficacy of Mifeprex from clinical trials and European post-market experience, FDA originally approved Mifeprex under Subpart H of the FDCA regulations (the predecessor to the REMS statute) and imposed "restrictions to assure safe use"—a restricted distribution system—as a condition of approval.[15] For example, FDA imposed an in-person dispensing requirement (later "ETASU C," pursuant to 21 U.S.C. § 355-1(f)(3)(C)) and permitted the drug to be dispensed only in a

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Am. denying 2002 Citizen Petition, Docket No. FDA-2002-P0364 (Mar. 29, 2016) (Citizen Petition Denial) at 8, Mar. 29, 2016, ECF No. 1-7.

[13]*Id.* at 8.

[14]ECF No. 1-6, supra n.10.

[15]Although the Subpart H regulations are sometimes referred to as FDA's "accelerated approval" regulations, FDA has explained elsewhere that its 2000 approval of Mifeprex, which occurred more than four years after the new drug application was submitted to FDA, did not involve an accelerated review.

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hospital, clinic, or medical office, by or under the supervision of a "certified provider" (discussed more below), who at that time could only be a physician. FDA also imposed a prescriber-certification ETASU (later "ETASU A," pursuant to 21 U.S.C. § 355-1(f)(3)(A)), which prohibited health care providers from prescribing the drug unless they first attested to their clinical abilities in a signed form kept on file by the manufacturer, and agreed to comply with reporting and other REMS requirements. FDA also imposed a Patient Form ETASU (later "ETASU D," pursuant to 21 U.S.C. § 355-1(f)(3)(D)), requiring the prescriber and patient to review and sign a special form with information about the mifepristone regimen and risks, and required the prescriber to provide the patient with a copy and place a copy in the patient's medical record. The same information contained in the patient form is also included in the "Medication Guide" that is part of the FDA-approved labeling provided to patients with mifepristone.

88. FDA's decision to subject Mifeprex to an ETASU under Subpart H was highly unusual. In the fifteen years from 1992 (the year the Subpart H regulations were promulgated) to February 2007 (just before the creation of the REMS statute), only seven NDAs, including Mifeprex, were approved subject to ETASU under Subpart H.[16] By comparison, FDA approved 961 NDAs with no

[16] *Id.* at 27.

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additional restrictions in the roughly thirteen years from January 1993 to September 2005.[17]

89. The Food and Drug Administration Amendments Act of 2007 effectively replaced Subpart H of the FDCA regulations with the REMS statute. All drugs previously approved under Subpart H—including Mifeprex—were deemed by the Amendments Act to have a REMS in place. Following passage of the 2007 FDCA, Mifeprex continued to be subject to the same ETASU as before.

90. In 2011, FDA issued a new REMS for Mifeprex incorporating the same restrictions under which the drug was approved eleven years earlier.

91. In 2013, FDA reviewed the existing REMS and reaffirmed the restrictions already in place.[18]

92. In May 2015, Mifeprex's manufacturer (Danco) submitted a supplemental NDA proposing to update the label to reflect evidence-based practice across the country—mainly, the use of 200 mg of mifepristone instead of 600 mg. In July 2015, Danco also submitted its statutorily required REMS assessment, proposing minor modifications.

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[17]U.S. Gov't Accountability Off., *New Drug Development: Science, Business, Regulatory, and Intellectual Property Issues Cited as Hampering Drug Development Efforts*, GAO-07-49, 20 (Nov. 2006).

[18]FDA Final Risk Evaluation and Mitigation Strategy (REMS) Review (Oct. 10, 2013), ECF No. 1-8.

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93. This submission prompted a review of the Mifeprex label and REMS by FDA in 2015-2016. As part of that review, FDA received letters from more than 40 medical experts, researchers, advocacy groups, and professional associations who asked, *inter alia*, that the REMS be eliminated in their entirety.

94. Signatories requesting that FDA eliminate the Mifeprex REMS included the American College of Obstetricians and Gynecologists (ACOG), the leading professional association of physicians specializing in the health care of women, which represents 58,000 physicians and partners in women's health; the American Public Health Association (APHA), the nation's leading public health organization; the Director of Stanford University School of Medicine's Division of Family Planning Services and Research; the Chair of the Department of Obstetrics and Gynecology at the University of New Mexico School of Medicine; and the Senior Research Demographer in the Office of Population Research at Princeton University.

95. As one letter explained: "Although the FDA may have decided 15 years ago that the balance of risk and burden came out in favor of restricting mifepristone's indicated use and distribution, today both science and the current conditions surrounding patient access to abortion care call strongly for a reevaluation of the mifepristone label and REMS restrictions, especially its

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Elements to Assure Safe Use (ETASU)."[19] In asking FDA to "[e]liminate the REMS and ETASU for mifepristone," the letter specifically asked FDA to, among other things, (i) "[e]liminate the Prescriber Agreement certification requirement" and (ii) "remove the confusing and unnecessary Patient Agreement."[20]

96. The signatory organizations explained that the Prescriber Agreement certification requirement should be eliminated, because, among other things[21]:

a. "*The Prescriber's Agreement is unnecessary for the safe dispensation of mifepristone*. . . . [H]ealth care professionals are already subject to many laws, policies, and ordinary standards of practice that ensure they can accurately and safely understand and prescribe medications. Provider certification is not required for health care professionals to dispense other drugs, including drugs that carry black box, or boxed, warnings about their medical risks. Accutane, for example, has a boxed warning that describes the potential risks of the drug, but Accutane prescribers are not required to submit a certification form in order to prescribe it. Mifeprex also has a boxed warning and there is no medical reason for a Prescriber's Agreement to be required in addition."

b. "*The Prescriber's Agreement forces providers to identify themselves as abortion providers to a centralized entity (Danco Laboratories) inspected and regulated by the FDA, which could discourage some from offering medication abortion care to their patients*. In 2014, more than half of U.S. health care facilities that provide abortions

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[19]Letter from SFP, *et al.*, to Stephen Ostroff, M.D., Robert M. Califf, M.D., & Janet Woodcock, M.D., 1 (Feb. 4, 2016) (SFP Letter to FDA), ECF No. 1-9.

[20]*Id.* at 2–4.

[21]*Id.* at 3.

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(52%) experienced threats and other types of targeted intimidation, and one in five experienced severe violence, such as blockades, invasions, bombings, arsons, chemical attacks, physical violence, stalking, gunfire, bomb threats, arson threats, or death threats. Robert Dear's November 27, 2015, standoff at a Planned Parenthood health center in Colorado, which resulted in three deaths, provides one recent and chilling example of anti-abortion violence. Given such escalating harassment and violence against known abortion providers, clinicians may be understandably reluctant to add their names to a centralized database of mifepristone providers."

c. "*The Prescriber's Agreement would be incompatible and unnecessary if there were an expanded distribution system*. If dispensing venues are expanded as proposed . . . ordinary standards of practice and state regulations would govern pharmacists' and providers' distribution of mifepristone, and a specific certification process would be unnecessary. Furthermore, a distribution system that incorporates the Prescriber's Agreement would be extremely difficult to maintain as a practical matter. Pharmacists would need to check the certification status of each prescriber before filling a prescription, which they do not normally have to do when filling other prescriptions."

97. The organizations also argued that the Patient Agreement was unnecessary, explaining: "This requirement is medically unnecessary and interferes with the clinician-patient relationship. It should be eliminated entirely."[22]

98. The letter also urged FDA to "[c]onsider the current legal and social climate," explaining that "[t]he overall legal and social climate around abortion care intensifies all of the burdens that the mifepristone REMS places on patients

[22] *Id.* at 4.

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and makes it even more critical that the FDA lift medically unnecessary restrictions on the drug."[23] The letter concludes:

> Mifepristone continues to hold immense promise for patient access to a safe and effective early abortion option, but medically unnecessary regulations are impeding its full potential. Extensive scientific and clinical evidence of mifepristone's safety and efficacy, and the ever-increasing burden on patient access to abortion care, clearly demonstrate that mifepristone's REMS program is not needed to protect patients. In light of the FDA's statutory mandate from Congress to consider the burden caused to patients by REMS, and the agency's own stated commitment to ensuring that the drug restrictions do not unduly burden patient access, we ask that the FDA lift mifepristone's REMS . . . .[24]

99. FDA summarized these "Advocacy Group Communications" as follows:

> The Agency received three letters from representatives from academia and various professional organizations . . . . In general, these advocates requested FDA to revise labeling in a manner that would reflect current clinical practice, including the new dose regimen submitted by the Sponsor, and proposing to extend the gestational age through 70 days. Other requests were that the labeling not require that the drug-taking location for both Mifeprex and misoprostol be restricted to the clinic, and that labeling not specify that an in-person follow-up visit is required. The advocates also requested that any licensed healthcare provider should be able to prescribe Mifeprex and that the REMS be modified or eliminated, to remove the Patient Agreement and eliminate the prescriber certification, while allowing Mifeprex to be dispensed through retail pharmacies.[25]

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[23] *Id.* at 5.

[24] *Id.* at 6.

[25] FDA, Ctr. for Drug Evaluation & Research, 020687Orig1s020, Cross Discipline Team Leader Review 25 (Mar. 29, 2016), ECF No. 1-10.

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100. A multidisciplinary FDA review team considered the requested changes. This review concluded that "no new safety concerns have arisen in recent years, and that the known serious risks occur rarely," and that "[g]iven that the numbers of . . . adverse events appear to be stable or decreased over time, it is likely that . . . serious adverse events will remain acceptably low."[26]

101. Following the multidisciplinary review team's analysis, FDA made several changes to Mifeprex's indication, labeling, and REMS. Relying on safety and efficacy data from multiple studies, FDA increased the gestational age limit from 49 to 70 days.[27] FDA also reduced the number of required in-person clinic visits to one (whereas patients had previously been required to visit a clinic setting twice in order to receive the medication). FDA determined that at-home administration of misoprostol is safe because multiple studies showed that administration of the drug was "associated with exceedingly low rates of serious adverse events" and because administering misoprostol at home would more likely result in patients being in an "appropriate and safe location" when

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[26]ECF No. 1-3 (FDA 2016 Medical Review) at 9, 39, 47, 49.

[27]The overwhelming majority (80%) of abortions occur within the first 70 days (10 weeks) of pregnancy. Katherine Kortsmit, et al., *Abortion Surveillance – United States, 2020*, 71 CDC Morbidity & Mortality Weekly Report 10 at 12 (Nov. 25, 2022), https://www.cdc.gov/mmwr/volumes/71/ss/pdfs/ss7110a1-H.pdf.

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cramping and bleeding caused by the drug would begin.[28] FDA also found no significant difference in outcomes based on whether patients had follow-up appointments via phone call or in-person or based on the timing of those appointments. Additionally, FDA allowed a broader set of healthcare providers, rather than only physicians, to prescribe mifepristone, finding no serious risk to patients from expanding the types of healthcare providers who could become certified under the 2016 REMS.[29] But FDA still required that mifepristone, the first drug in the regimen, be administered in a clinic setting.

102. In addition, FDA expert review team and the Director of FDA's Center for Drug Evaluation and Research recommended eliminating the Patient Agreement Form because it contains "duplicative information already provided by each healthcare provider or clinic," "does not add to safe use conditions," and "is a burden for patients."[30] But they were overruled by the FDA

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[28]U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Research, 020687Orig1s020, Mifeprex Summary Review at 15 (Mar. 29, 2016) (2016 Summary Review), ECF No. 1-11.

[29]U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Research, 020687Orig1s020, Mifeprex REMS (Mar. 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020RemsR.pdf (hereinafter 2016 REMS).

[30]ECF No. 1-11 (2016 Summary Review) at 25.

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Commissioner, who directed the Form be retained.[31] FDA retained the in-person dispensing requirement and provider certification as well.

103. In 2019, FDA approved a different manufacturer's abbreviated new drug application for a generic version of mifepristone. When it approved the abbreviated NDA, FDA also established the Mifepristone REMS Program, which covers both Mifeprex and the generic.

104. In May 2020, the American College of Obstetricians and Gynecologists sued FDA, challenging the Mifepristone REMS Program's in-person dispensing requirement in light of the COVID-19 pandemic. *See Am. Coll. of Obstetricians & Gynecologists v. FDA*, 472 F. Supp. 3d 183 (D. Md. 2020), *stayed by FDA v. Am. Coll. of Obstetricians & Gynecologists*, 141 S. Ct. 578, 578 (2021) (mem.). Over FDA's objection that "based on FDA's scientific judgment, the In-Person Requirements are necessary to assure safe use of mifepristone and thus to protect patients' safety," *id.* at 228, the U.S. District Court for the District of Maryland preliminarily enjoined the in-person dispensing requirements, allowing healthcare providers to forgo it based on their

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[31]U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Research, 020687Orig1s020, Mifeprex Risk Assessment and Risk Mitigation Review(s): Letter from Janet Woodcock, M.D., Ctr. for Drug Evaluation & Research, Regarding NDA 020687, Supp 20, 1 (Mar. 28, 2016) (hereinafter "Woodcock Patient Agreement Memo"), ECF No. 1-12.

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medical judgment for the duration of the declared COVID-19 public health emergency. *Id.* at 233.

105. In April 2021, FDA suspended the in-person dispensing requirement during the COVID-19 public health emergency because, during the six-month period in which the in-person dispensing requirement had been enjoined, the availability of mifepristone by mail showed no increases in serious patient safety concerns. Thereafter, FDA commenced a formal REMS review.

106. Finally, on January 3, 2023, FDA modified the REMS by, *inter alia*, removing the in-person dispensing requirement entirely. However, as discussed further below, the Mifepristone REMS continue to impose both the Prescriber Agreement Form and the Patient Agreement Form. The 2023 REMS also added a new pharmacy-certification requirement.[32]

C. The Safety of Mifepristone

107. Mifepristone is extremely safe and effective for terminating early pregnancies.

108. As discussed above, FDA's approval of mifepristone in 2000 rested on a comprehensive evaluation of the scientific data, and FDA reasonably

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[32]FDA Risk Evaluation and Mitigation Strategy (REMS) Single Shared System for Mifepristone 200 MG (2023 REMS), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2023_01_03_REMS_Full.pdf, ECF No. 1-13.

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determined, in its expert judgment, that the evidence showed mifepristone is safe and effective for abortion of early pregnancy.

109. When FDA conducted another medical review of mifepristone in 2016 (based on the then 2.5 million uses of Mifeprex for medication abortion in the U.S. since the drug's 2000 approval) it found: "[Mifeprex] has been increasingly used as its efficacy and safety have become well established by both research and experience, and serious complications have proven to be extremely rare."[33] FDA observed at that time that "[m]ajor adverse events . . . are reported rarely in the literature on over 30,000 patients. The rates, when noted, are exceedingly rare, *generally far below 0.1%* for any individual adverse event."[34]

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[33]ECF No. 1-3 (FDA 2016 Medical Review) at 12; *see also* U.S. Food & Drug Admin., Full Prescribing Information for Mifeprex 7–8, Tables 1 & 2 (approved Mar. 2016), https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf ("Mifeprex Labeling"), ECF No. 1-14.

[34]ECF No. 1-3 (FDA 2016 Medical Review) at 47 (emphasis added); *see also* ECF No. 1-14 (Mifeprex Labeling) at 8, Table 2; *see also* Kelly Cleland et al., Significant Adverse Events and Outcomes After Medical Abortion, 121 OBSTETRICS & GYNECOLOGY 166, 166 (2013) ("Medical research has consistently demonstrated that mifepristone is safe and effective and that adverse

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The Agency further stated that "[t]he safety profile of Mifeprex is well-characterized and its risks well-understood after more than 15 years of marketing. Serious adverse events are rare and the safety profile of Mifeprex has not substantially changed."[35] Since that 2016 medical review, mifepristone has been used an additional 3 million times in the United States for medication abortion.

110. From the time mifepristone was approved in 2000, there have only been 28 reported associated deaths out of 5.6 million uses—an associated fatality rate of .00005%.[36] Further, FDA acknowledges that *none* of these deaths can be causally attributed to mifepristone. The 28 reported deaths were included in the adverse events summary "regardless of causal attribution to mifepristone" and included cases of homicide, drug overdose, ruptured ectopic pregnancy, and

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events and outcomes are exceedingly rare, occurring in less than a fraction of 1% of cases.").

[35]U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Research, 020687Orig1s020, Mifeprex Risk Assessment and Risk Mitigation Review(s): REMS Modification Memorandum at 3 (Mar. 29, 2016) (hereinafter 2016 REMS Modification Memorandum), ECF No. 1-15.

[36]ECF No. 1-2 (Mifepristone U.S. Post-Marketing Adverse Events Summary).

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sepsis (a life-threatening immune response to an infection).[37] And in its 2016 review, FDA noted that, while roughly half the deaths to that point were associated with Clostridial septic infections, "[t]here have been no Clostridial septic deaths reported in the US since 2009."[38]

111. In other cases of fatal infections associated with mifepristone, FDA has acknowledged that "the critical risk factor" is not mifepristone but "pregnancy itself," as similar infections "have been identified both in pregnant women who have undergone medical abortion and those who have not[.]"[39]

112. The specific serious complications identified in the FDA-approved labeling for Mifeprex are "Serious and Sometimes Fatal Infections or Bleeding." But the labeling specifies that such "serious and potentially life-threatening bleeding, infections, or other problems can occur following a miscarriage, surgical abortion, medical abortion or childbirth"—in other words, any time after the pregnant uterus is emptied—and that "[n]o causal relationship between the use of MIFEPREX and misoprostol and [infections and bleeding] has been established."[40]

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[37] *Id.*

[38] *Id.*

[39] ECF No. 1-7 at 26 n.69.

[40] ECF No. 1-14 (Mifeprex Labeling) at 2, 16.

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D. The January 2023 Mifepristone REMS

113. Despite this undisputed evidence of safety and effectiveness, FDA continues to impose a 2023 REMS with ETASU for mifepristone.

114. The current REMS was approved in January 2023 (the 2023 REMS).[41]

115. The 2023 REMS imposes three primary hurdles to accessing mifepristone. Two of these are continuing restrictions and the third is a new restriction. Each hurdle unduly restricts mifepristone access without any corresponding medical benefit.

116. ***First***, the REMS continues to provide that mifepristone can only be prescribed by a health care provider who has undergone a "special[] certif[ication]" process in which they attest that they can accurately date a pregnancy, diagnose an ectopic pregnancy, and provide surgical intervention or referral in the event of any complications.[42] This "special certification" must be submitted to each certified pharmacy to which a provider intends to submit Mifreprex prescriptions, and must also be submitted to the distributor if a prescriber intends to dispense in-office.

117. For many healthcare providers, becoming specially certified is unduly burdensome and raises safety concerns. Some providers are deterred by

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[41]ECF No. 1-13 (2023 REMS).

[42]Mifepristone Prescriber Agreement Forms, ECF No. 1-16.

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the unusual step of having to become certified to prescribe the medication; others, misled by mifepristone's REMS designation, misperceive it is a dangerous medication or out of the prescriber's scope of practice; and still others are not comfortable having their names compiled in a list of medication abortion prescribers for fear that they or their families may be targeted by anti-abortion activists. This fear is particularly acute for doctors who hold medical licenses in multiple states (with abortion laws different from the Plaintiff States'), and for medical residents in the Plaintiff States who intend to eventually practice in a state that heavily restricts abortion. These concerns, which FDA was made aware of as far back as 2016, are heightened now due to the growing criminalization and penalization of abortion, including laws that subject health care providers to criminal penalties and significant monetary liability.

118. ***Second***, although the 2023 REMS allows mifepristone to be dispensed directly by pharmacies (as opposed to being dispensed by a provider in a healthcare clinic, as prior REMS required), the REMS unnecessarily requires dispensing pharmacies to be "specially certified" by the drug's sponsor.[43]

119. Special certification requires pharmacies to verify that mifepristone prescriptions are written only by "certified" providers and to adhere to additional burdensome communication, recordkeeping, and training requirements beyond what is required for the vast majority of prescription drugs. Under the REMS, a

[43]Mifepristone Pharmacy Agreement Forms, ECF No. 1-17.

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pharmacy cannot dispense mifepristone to a patient until it confirms that the provider who wrote the prescription is specially certified.[44] This hurdle creates new costs and administrative burdens for pharmacies—and worse, threatens unnecessary delay patients seeking time-sensitive medication.

120. Further, by limiting mifepristone dispensing to "certified" pharmacies, the REMS requires healthcare providers to track which pharmacies are certified to dispense mifepristone, rather than allowing patients to select their pharmacy of choice. And the reverse is true as well—pharmacies that wish to dispense mifepristone must go through the added step of confirming that each mifepristone prescription comes from a "specially certified" provider.

121. ***Third*,** the 2023 REMS retains the requirement that each patient sign a Patient Agreement Form in order to receive a mifepristone prescription.[45] This form, among other things, requires a patient to certify: "I have decided to take mifepristone and misoprostol to end my pregnancy."[46] This Patient Agreement Form must be signed by both the patient and provider, a copy must be placed into the patient's medical record, and a copy must be given to the patient along with the Medication Guide.

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[44] *Id.*

[45] Mifepristone Patient Agreement Form, ECF No. 1-18.

[46] *Id.*

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122. This Patient Agreement Form creates significant privacy and safety issues for both patients and providers. It specifically identifies the patient as taking the medication for the purpose of ending their pregnancy—as opposed to, for instance, miscarriage management, for which the medication is also frequently prescribed. Anyone who obtains access to the patient's medical record will thus have evidence that the patient received the medication for abortion, which is a particular concern for patients who receive care from a provider in a state where abortion is legal but reside in a state where abortion is illegal. Making matters worse, for patients who receive mifepristone for miscarriage management, the evidence will be false. The form also identifies the provider to anyone who obtains access to the patient's medical record or sees the copy of the form that must be provided to the patient—potentially including, for example, a patient's spouse, partner, or parent. This exposes providers and patients to threats of potential violence, threats of legal liability (even when the care provided is lawful in the relevant Plaintiff State), or other life-altering consequences. On top of that, because patients who take the medication for miscarriage management are also required to sign the Patient Agreement Form, it may be traumatizing for individuals experiencing a miscarriage to nonetheless have to attest that they are "decid[ing]" to "end [their] pregnancy."

123. None of the harms caused by the Patient Agreement Form is necessary, as the information contained on the form is duplicative of the information already provided to patients in the five-page Medication Guide that

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accompanies mifepristone. The comprehensive Medication Guide answers questions such as: "What symptoms should I be concerned with?"; "Who should not take Mifepristone tablets?"; "What should I tell my healthcare provider before taking Mifepristone tablets?"; "How should I take Mifepristone tablets?"; and "What are the possible side effects of Mifepristone tablets?"[47] The Patient Agreement Form is also duplicative of provider counseling, as medical ethics require providers to counsel patients on the risks and benefits of all medications.

124. ***In sum***, although the 2023 REMS improved on the prior REMS by dropping the requirement to dispense mifepristone in person, the REMS nonetheless retains unduly burdensome, harmful, and unnecessary dispensing and prescribing requirements, continues to expose providers and patients to unnecessary privacy and safety risks, and creates new hurdles that further burden an already overstretched health care system.

E. The 2023 REMS Violate the FDCA

125. FDA's imposition of the burdensome 2023 REMS requirements is contrary to the FDCA.

126. As noted above, FDA may impose an ETASU on a medication only if the medication is "associated with a serious adverse drug experience," which the statute defines as one that "results in" death or "immediate risk of death,"

[47]Mifepristone Medication Guide, ECF No. 1-19.

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"inpatient hospitalization or prolongation of existing hospitalization," "persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions," or "a congenital anomaly or birth defect," or that "may jeopardize the patient and may require a medical or surgical intervention to prevent [such] an outcome . . . ." 21 U.S.C. §§ 355-1(f)(1)(A), (b)(4)(A)–(B). And an ETASU may be imposed only where "required . . . to mitigate a specific serious risk" of a serious adverse drug experience, and only where such risk is sufficiently severe that absent the ETASU, FDA would not approve or would withdraw approval of the medication. *Id.* §§ 355-1(b)(5), (f)(1)(A).

127. Mifepristone does not meet these stringent standards because it is not "associated with a serious adverse drug experience." To the contrary, FDA itself has concluded that serious adverse events following mifepristone use are "exceedingly rare."[48]

128. Since mifepristone was approved in 2000, there have been only 28 reported associated deaths out of 5.6 million uses—an associated fatality rate of .00005%. And not a single one of these deaths can be causally attributed to mifepristone.[49] By contrast, thousands of deaths have been associated with phosphodiesterase type-5 inhibitors for the treatment of erectile dysfunction

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[48]ECF No. 1-3 (FDA 2016 Medical Review) at 47; *see also* ECF No. 1-2 (Mifepristone U.S. Post-Marketing Adverse Events Summary).

[49]*Id.*

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(e.g., Viagra)—which are not subject to a REMS.[50] And "other drugs with higher complication rates, such as acetaminophen, aspirin, loratadine, and sildenafil, do not have REMS restrictions[.]"[51]

129. Moreover, the ETASU violates the FDCA's requirement that such restrictions not be "*unduly burdensome* on patient access to the drug, considering in particular . . . patients in rural or medically underserved areas," and must "minimize the burden on the health care delivery system[.]" 21 U.S.C. §§ 355-1(f)(2)(C)–(D) (emphasis added).

130. As explained in more detail below, the 2023 REMS significantly burdens patient access to mifepristone without *any* appreciable safety benefits.

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[50]Advancing New Standards in Reproductive Health , *Analysis of Medication Abortion Risk and the FDA report "Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2018"*, Mifepristone safety: Issue Brief (Apr. 2019), https://www.ansirh.org/sites/default/files/publications/files/mifepristone_safety_4-23-2019.pdf.

[51]2018 Congress of Delegates, *Resolution No. 506 (Co-Sponsored C) – Removing Risk Evaluation and Mitigation Strategy (REMS) Categorization on Mifepristone*, Am. Acad. Of Fam. Physicians (2019), https://www.reproductiveaccess.org/wp-content/uploads/2019/02/Resolution-No.-506-REMS.pdf.

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These burdens fall particularly heavily on rural patients in the Plaintiff States because the vast majority of "specially certified" providers practice in cities. Plus, with a number of states imposing severe restrictions on access to abortion care that used to be constitutionally protected, many patients in these medically underserved areas of the country are turning to Plaintiff State providers for this care. This is particularly pronounced in Plaintiff States sharing borders with states that allow little to no access—for example, in Washington, Oregon, and Nevada, which border Idaho, in Illinois, which borders Missouri and Indiana, and in New Mexico, which borders Texas. Against this backdrop, the 2023 REMS significantly and unduly burdens health care delivery in the Plaintiff States by imposing substantial, unjustified burdens on health care providers, clinics, pharmacies, and hospitals.

F. The 2023 REMS Are Unsupported by Science

131. The 2023 REMS requirements are not supported by scientific evidence.

132. First, the Patient Agreement Form remains in place even though the team of expert reviewers at FDA's Center for Drug Evaluation and Research (CDER) unanimously recommended eliminating it in 2016 because it is duplicative of informed consent laws and standards, "does not add to safe use

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conditions[,] . . . and is a burden for patients."[52] But this team of experts was overruled by the agency head.[53]

133. Similarly, the requirement that clinicians certify that they are competent to prescribe mifepristone provides no additional safety benefit beyond the numerous existing laws and safety standards already in place to ensure health care providers practice only within their competency. The certification requirement is also out of step with how FDA regulates other, less safe medications. Physicians are allowed to prescribe countless higher-risk drugs without first attesting to their competency to make an accurate diagnosis or provide follow-up care in the event of a complication.

134. The REMS requirement that pharmacies, too, must be "specially certified" in order to dispense mifepristone is similarly baseless. It requires pharmacies to confirm they have met the unnecessary provider-certification requirement before filling prescriptions, affords no patient safety benefits on top of the laws and standards governing the practice of pharmacy, and, instead, acts as a significant barrier to patient access to a time-sensitive medication.

135. Accordingly, the mifepristone REMS is opposed by leading medical organizations, including the American College of Obstetricians and

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[52]ECF No. 1-9 (2016 Summary Review) at 25.

[53]ECF No. 1-10 (Woodcock Patient Agreement Memo) at 1.

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Gynecologists (ACOG), the American Academy of Family Physicians (AAFP), and the American Medical Association (AMA).

136. Since at least 2016, ACOG's position has been "that a Risk Evaluation and Mitigation Strategy (REMS) is no longer necessary for mifepristone, given its history of safe use. The REMS requirement is inconsistent with requirements for other drugs with similar or greater risks, especially in light of the significant benefit that mifepristone provides to patients."[54]

137. And since at least 2018, AAFP's position has been that the REMS restrictions "are not based on scientific evidence"; are overly burdensome on practitioners and impede patient access to care, particularly "for patients who might prefer to go to their own physician and for rural patients who have no other access points beyond their local physician"; cause "delays in care, thereby increasing second-trimester and surgical abortions, both of which have increased complication rates"; and create "a barrier to safe and effective off-label uses of mifepristone, such as for anti-corticoid treatment of Cushing's disease, term labor induction, and miscarriage management[.]"[55]

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[54]Advocacy and Health Policy, *ACOG Statement on Medication Abortion*, ACOG (Mar. 30, 2016) https://www.acog.org/news/news-releases/2016/03/acog-statement-on-medication-abortion.

[55]*Supra* n.51.

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138. In a June 21, 2022, letter to FDA Commissioner Califf, ACOG and AMA urged the Agency to "eliminate the requirement for patients to sign a form to get the drug" and "lift the requirement that prescribers acquire a certification from the manufacturer," noting that "[b]arriers to accessing mifepristone do not make care safer, are not based on medical evidence, and create barriers to patient access to essential reproductive health care."[56]

139. Further, in 2022, ACOG, along with 48 other organizations, submitted a citizen petition to FDA seeking to add miscarriage management as an indication to the drug's label, to eliminate or modify the REMS for that use, and more generally requesting the removal of the mifepristone REMS.[57]

140. The petition asked that "the Patient Agreement Form be removed entirely because it is medically unnecessary and repetitive of informed consent,

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[56]Letter from Maureen G. Phipps, Am. Coll. of Obstetricians & Gynecologists, to Robert Califf, MD (Jun. 21, 2022), https://searchlf.ama-assn.org/letter/documentDownload?uri=/unstructured/binary/letter/LETTERS/lfdr.zip/2022-6-21-Joint-ACOG-AMA-Letter-to-FDA-re-Mifepristone.pdf.

[57]Citizen Petition from Am. Coll. of Obstetricians & Gynecologists to Lauren Roth, Assoc. Comm'r for Pol'y, U.S. FDA (Oct. 4, 2022), https://emaaproject.org/wp-content/uploads/2022/10/Citizen-Petition-from-the-American-College-of-Obstetrician-and-Gynecologists-et-al-10.3.22-EMAA-website.pdf.

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as a previous review conducted by [FDA Center for Drug Evaluation and Research] determined in 2016."[58]

141. ACOG further explained that "the Certified Provider Requirement serves no benefit to patient safety," but is instead "redundant and unnecessary."[59] Moreover, ACOG noted that the provider-certification requirement has disproportionately affected rural patients because "clinicians who have already navigated mifepristone REMS compliance to provide abortion care . . . are almost always located in cities."[60] Making matters worse, "rural residents are more likely to lack access to OBGYNs, meaning that surgical management is also less likely to be an option."[61] Moreover, "clinicians might have reasonable reservations about opting into a prescription system that could, if their

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[58] *Id.* at 12.

[59] *Id.* at 13.

[60] *Id.* at 14 (citing Bearak JM, Burke KL, Jones RK. *Disparities and change over time in distance women would need to travel to have an abortion in the USA: a spatial analysis*. Lancet Public Health. 2017; 2:e493–500 and Committee on Health Care for Underserved Women. *Health Disparities in Rural Women. American College of Obstetricians and Gynecologists.* Obstet Gynecol. 2014;123:384-388).

[61] *Id.* (citation omitted).

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certification were leaked, suggest they were an abortion provider and open them up to violence and harassment."[62]

142. The ACOG's citizen petition also urged FDA not to include a pharmacy-certification requirement because "research . . . suggests that the pharmacy requirement is unnecessary to ensure that mifepristone's benefits outweigh its risks and unduly burden[s] access."[63] The petition pointed

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[62] *Id.*; *see also id.* ("Research has shown that without certification, more clinicians would prescribe mifepristone.") (citing Neill S, Goldberg AB, Janiak E., *Medication management of early pregnancy loss: the impact of the US Food and Drug Administration Risk Evaluation and Mitigation Strategy* [A289]. Obstet Gynecol. 2022 May;139: 83S; Calloway D, Stulberg DB, Janiak E. *Mifepristone restrictions and primary care: Breaking the cycle of stigma through a learning collaborative model in the United States.* Contraception. 2021 July; 104(1):24-28; *Mokashi M, Boulineaux C, Janiak E, Boozer M, Neill S. "There's only one use for it": stigma as a barrier to mifepristone use for early pregnancy loss in Alabama*. [A31]. Obstet Gynecol. 2022 May:139:9S-10S; and Razon N, Wulf S, Perez C, McNeil S, Maldonado L, et al. *Exploring the impact of mifepristone's risk evaluation and mitigation strategy (REMS) on the integration of medication abortion into US family medicine primary care clinics.* Contraception 2022;109(5):19-24).

[63] *Id.* at 15.

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specifically to a study "conducted . . . in California and Washington state suggest[ing] that pharmacies are already equipped to dispense the drug without special certification."[64] "As with the certified provider requirement," ACOG noted, "the burdens associated with the certified pharmacy requirement will also fall disproportionately on poor and rural [patients], contrary to the REMS statute."[65]

143. Finally, as ACOG pointed out, recent scholarship demonstrates that removing the REMS restrictions does not negatively affect patient safety:

> After Canada removed all restrictions on prescribing mifepristone for abortion, thereby allowing it to be prescribed and dispensed like any other drug ("normal prescribing"), there was no increase in complications from mifepristone use. [A] 2022 study . . . found no difference in the rate of any complication (0.67% vs. 0.69%) or in the rate of serious adverse events (0.03% vs. 0.04%) between the ten-month period when mifepristone was distributed with REMS-like restrictions and the twenty-eight-month period of normal prescribing after all such restrictions were lifted and mifepristone was prescribed with no special self-certification and dispensed routinely from pharmacies.[66]

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[64] *Id.* (citing Grossman D, Baba CF, Kaller S, Biggs MA, Raifman S, et al. *Medication abortion with pharmacist dispensing of mifepristone.* Obstet Gynecol 2021;137(4):613-622).

[65] *Id.* at 16.

[66] *Id.* at 17 (citing Schummers L, Darling EK, Dunn S, McGrail K, Gayowsky A, et al. *Abortion Safety and Use with Normally Prescribed Mifepristone in Canada*. N Engl J Med. 2022 Jan 6;386(1):57-67.)

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144. FDA rejected ACOG's citizen petition.[67]

145. In fact, FDA has repeatedly rejected the concerns raised by leading medical organizations and retained the medically unfounded REMS restrictions: renewing them in 2016,[68] 2019,[69] 2021,[70] and yet again in 2023.[71] FDA retained these restrictions notwithstanding its periodic reviews of the post-marketing data, which have not identified any new safety concerns with the use of mifepristone for medical termination of pregnancy through 70 days' gestation (10 weeks).[72]

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[67]U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Research, Letter from Patrizia Cavazzoni, M.D., Regarding Docket No. FDA-2022-P-2425, (Jan. 3, 2023), https://www.regulations.gov/document/FDA-2022-P-2425-0003, ECF No. 1-20.

[68]Danco Labs., LLC, Mifeprex REMS (Mar. 2016), https://www.fda.gov/media/164649/download.

[69]Danco Labs., LLC, Mifepristone REMS (Apr. 2019), https://www.fda.gov/media/164650/download.

[70]Danco Labs., LLC, Mifepristone REMS (May 2021), https://www.fda.gov/media/164651/download.

[71]ECF No. 1-13 (2023 REMS).

[72]U.S. Food & Drug Admin., *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation* (Jan. 4, 2023), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-

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146. Even as mifepristone has remained subject to the unduly burdensome REMS restrictions, a less safe mifepristone product for the treatment of Cushing's syndrome has been available for over a decade with no similar restrictions. In 2012, FDA approved Korlym (mifepristone) tablets, 300 mg, as treatment for Cushing's syndrome *without* a REMS.[73] This was done even though, as FDA noted in its 2016 Medical Review, Korlym "is taken in higher doses, in a chronic, daily fashion unlike the single 200 mg dose of Mifeprex . . . [and] the rate of adverse events with Mifeprex is much lower."[74] Patients who are prescribed Korlym take one to four pills *daily*—which is 1.5 to 6 times the recommended dose for Mifeprex.[75]

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providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation.

[73]HHS, Food & Drug Admin., Ctr. for Drug Evaluation & Research, *Application Number: 202107Orig1s000, Approval Letter* (Feb. 17, 2012), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/202107Orig1s000Approv.pdf.

[74]ECF No. 1-3 (2016 Medical Review) at 10.

[75]U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Research, *Application Number*: *202107Orig1s000, Labeling* (Feb. 17, 2012), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/202107Orig1s000Lbl.pdf.

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147. The risks associated with mifepristone are also lower than those of many other common medications, such as Viagra, Tylenol, anticoagulants (blood thinners), and penicillin. Again, since 2000, mifepristone has been used 5.6 million times with only 28 reported associated deaths, none of which can be causally attributed to mifepristone.[76] And in nearly all cases of fatal infections associated with mifepristone, FDA has acknowledged that "the critical risk factor" is not mifepristone but "pregnancy itself," as similar infections "have been identified both in pregnant women who have undergone medical abortion and those who have not[.]"[77]

148. By contrast, as the American Academy of Family Physicians has noted, "other drugs with higher complication rates, such as acetaminophen, aspirin, loratadine, and sildenafil, do not have REMS restrictions[.]"[78]

149. Medications for erectile dysfunction have a mortality rate more than six times greater than mifepristone, and penicillin has a mortality rate three times greater than mifepristone.[79]

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[76]ECF No. 1-2 (Mifepristone U.S. Post-Marketing Adverse Events Summary).

[77]ECF No. 1-7 at 26.

[78]*Supra* n.51.

[79]Greer Donley, *Medication Abortion Exceptionalism*, 107 CORNELL L. REV. 627, 651–52 (2022).

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150. Likewise, acetaminophen (Tylenol) toxicity is the most common cause of liver transplantation in the U.S. and is responsible for 56,000 emergency department visits, 2,600 hospitalizations, and 500 deaths per year in the United States.[80]

151. But none of these drugs is subject to a REMS.

152. And even though opioids are highly addictive and cause tens of thousands of fatalities per year from overdoses, the opioid REMS does not require providers to do anything; it only requires that opioid manufacturers *offer* optional training to healthcare providers who prescribe opioids, who may or may not choose to take it. FDA acknowledges that "[t]here is no mandatory federal requirement that prescribers or other [health care providers] take the training and no precondition to prescribing or dispensing opioid analgesics to patients."[81]

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[80]Suneil Agrawai and Babek Khazaeni, *Acetaminophen Toxicity*, National Library of Medicine (Aug. 1, 2022), https://www.ncbi.nlm.nih.gov/books/NBK441917/#:~:text=It%20is%20responsible%20for%2056%2C000,is%20contained%20in%20combined%20products.

[81]Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS), U.S. FOOD & DRUG ADMIN. (Sept. 2018), https://www.fda.gov/drugs/information-drug-class/opioid-analgesic-risk-evaluation-and-mitigation-strategy-rems.

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153. Mifepristone use is also far safer than continuing a pregnancy. A person who carries a pregnancy to term is at least fourteen times more likely to die than a person who uses mifepristone to end a pregnancy.[82] Unequal access to adequate health care exacerbates the risk for those with less privilege. For example, Black women are three to four times more likely than white women to die a pregnancy-related death in the U.S.[83]

154. The two risks listed on the mifepristone label are also associated with many common obstetrical and gynecological procedures, such as vaginal delivery, surgical or medical miscarriage management, or insertion of an intrauterine long-acting reversible contraceptive (IUD). As the Mifeprisone Medication Guide acknowledges: "Although cramping and bleeding are an

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[82]Elizabeth G. Raymond & David E. Grimes, *The Comparative Safety of Legal Induced Abortion and Childbirth in the United States*, 119 Obstetrics & Gynecology 215, 215 (2012).

[83]Elizabeth A. Howell, MD, MPP, *Reducing Disparities in Severe Maternal Morbidity and Mortality*, 61:2 Clinical Obstetrics & Gynecology 387, 387 (2018); *see also* Claire Cain Miller, Sarah Kliff, Larry Buchanan, *Childbirth is Deadlier for Black Families Even When They're Rich, Expansive Study Finds*, N.Y. Times (Feb. 12, 2023), https://www.nytimes.com/interactive/2023/02/12/upshot/child-maternal-mortality-rich-poor.html?smid=url-share.

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expected part of ending a pregnancy, rarely, serious and potentially life-threatening bleeding, infections, or other problems can occur following a *miscarriage*, *surgical abortion*, medical abortion, or *childbirth*." (Emphasis added.)[84]

G. The 2023 REMS Unduly Burdens Access to Healthcare

155. The mifepristone REMS have significantly impeded access to abortion care. And the 2023 REMS is even more unduly burdensome than prior REMS in light of dramatically restricted access to care across the United States.

156. Even before *Dobbs v. Jackson Women's Health Organization*, 142 S. Ct. 2228 (2022), only a small fraction of counties in the United States had a clinician providing surgical abortions.[85] Mifepristone offers the possibility of vastly increased access to care by enabling primary care physicians to integrate abortion care into the services they provide. But the mifepristone REMS impedes the availability of medication abortion care, and so abortion care remains beyond

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[84]ECF No. 1-19 (Mifepristone Medication Guide).

[85]Na'amah Razon, Sarah Wulf, et al., *Exploring the impact of mifepristone's risk evaluation and mitigation strategy (REMS) on the integration of medication abortion into US family medicine primary care clinics*, 109 Contraception 19 (May 2022), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9018589/.

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the reach of many—even in states like the Plaintiff States in which abortion care is lawful and protected in various ways.[86]

157. According to one recent study, approximately 40 percent of "family physicians interviewed . . . either named or described the REMS criteria as a barrier to providing medication abortion."[87] These family physicians explained that "the REMS impede their ability to provide medication abortion within primary care" because they "require substantial involvement of clinic administration, who can be unsupportive," and because "[t]he complexity of navigating the REMS results in physicians and clinic administration . . . viewing medication abortion as not worth the effort, since it is only a small component of services offered in primary care."[88]

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[86] *Id.*

[87] *Id.*

[88] *Id.*; *see also* Sara Neill, MD, et al., *Medication Management of Early Pregnancy Loss: The Impact of the U.S. Food and Drug Administration Risk Evaluation and Mitigation Strategy* (describing a survey of obstetrician-gynecologists in which "[n]early all interviewees (17 of 19, 89%) listed the REMS as a barrier to mifepristone use. Barriers included [the] belief that the REMS indicated mifepristone was not available to general ob-gyns . . . and concerns about signing the required prescriber agreement").

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158. Another recent study of primary care physicians and administrators noted that "[a]bortion with mifepristone is safe and effective" and "falls well within the scope of primary care in the United States, as it involves patient assessment and health education for which primary care providers are extensively trained." But, the article concluded, the REMS are the "linchpin of a cycle of stigmatization that continues to keep mifepristone out of primary care practice."[89]

159. This, in turn, harms patients. Under the REMS, a person who turns to their trusted health care provider—often a family doctor or primary care physician—for a medication abortion cannot obtain that care unless the clinician is specially certified (or is willing to become specially certified), and either the clinician has arranged to stock the drug or a pharmacy serving the patient's area has also gone through the process to be specially certified. This is so even though that same provider can simply write the same patient a prescription for misoprostol, the second drug in FDA's approved regimen for medication abortion, or virtually any other prescription drug that the clinician deems medically appropriate—and a pharmacy can simply dispense it—without the need for any special certifications.

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[89]Danielle Calloway, Debra B Stulberg, & Elizabeth Janiak, *Mifepristone restrictions and primary care: Breaking the cycle of stigma through a learning collaborative model in the United States*, 104 Contraception 24 (July 2021).

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160. Forcing patients to go to "specifically certified" providers, as opposed to their primary care or family physicians, disrupts continuity of care, stigmatizes routine health care, and discourages patients from making the best healthcare choices for themselves and their families. This burden is especially harsh for patients whose access to healthcare is already diminished by poverty, language barriers, lack of transportation, racial discrimination, or other factors. And it is particularly burdensome given the limited time window in which medication abortion is available.

161. This results in worse health outcomes for patients who might otherwise rely on mifepristone to safely terminate their pregnancies, but are unable to obtain a medication abortion given the limited number of REMS-certified prescribers or pharmacies.

162. Some patients will effectively be unable to access abortion, and will carry an unwanted pregnancy to term, due to the limited number of providers who are able to prescribe mifepristone because of the REMS. A landmark study shows that patients denied abortion are more likely to: experience serious complications from the end of pregnancy, including eclampsia and death; stay tethered to abusive partners; suffer anxiety and loss of self-esteem in the short term after being denied abortion; and experience poor physical health for years after the

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pregnancy, including chronic pain and gestational hypertension.[90]

163. Still others will opt for surgical abortion, which FDA describes as a more "invasive medical procedure that increases health risks for some patients and that may be otherwise inaccessible to others."[91] As FDA acknowledges, access to mifepristone is particularly critical "[f]or patients for whom mifepristone is the medically indicated treatment because of the patient's pre-existing health condition."[92]

164. "For example," FDA has explained:

> surgical abortion involves anesthesia, but people who are allergic to anesthesia can experience a sudden drop in blood pressure with cardiorespiratory arrest, and death. And . . . patient populations for whom medication abortion is more appropriate than a surgical abortion include patients who are survivors of abuse, including rape and incest, for whom pelvic exams can recreate severe trauma, adolescent patients, who have not yet had a pelvic exam, and patients in the intensive care unit or trauma patients who have difficulty with the positioning required for suction D&C.

(Internal quotations and citations omitted.)[93]

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[90]Our Studies, *The Turnaway Study*, Advancing New Standards in Reproductive Health, https://www.ansirh.org/research/ongoing/turnaway-study.

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

[92]*Id.* at 39.

[93]*Id.*

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165. Moreover, FDA itself has repeatedly confirmed and re-confirmed that mifepristone is safe and effective. According to FDA, mifepristone provides a "meaningful therapeutic benefit to patients" as compared to other treatments.

166. By unduly burdening patients' access to mifepristone through the 2023 REMS, FDA deprives patients of the therapeutic benefit of the drug without any scientific basis.

H. Injury to the Plaintiff States and Their Residents

Washington

167. The State of Washington's injuries exemplify those of other Plaintiff States caused by the mifepristone REMS.

168. In Washington, mifepristone is a critical medicine for providing safe and effective abortion care as well as for supporting miscarriage management.

169. In 2021 (the most recent year for which complete data is available), there were 15,358 abortions in Washington. Of those, 9,060—59%—were medication abortions using mifepristone. Fewer than 0.1% of mifepristone abortions in 2021 resulted in a complication that required hospitalization.

170. Washington providers have been hindered in providing care, and patients have been hindered in receiving care, due to the mifepristone REMS. The 2023 REMS requirements pose substantial challenges to providers and patients, and have resulted in significant expenses for state institutions, including the University of Washington (UW).

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171. The State of Washington, through the UW, its largest institution of higher education, operates UW Medicine, a group of multiple public and private nonprofit entities sharing the mission to improve the health of the public. This includes the UW's two campuses of the University of Washington Medical Center, the UW Medicine Primary Care Clinics, the UW Medical School, and through a contract with King County, Harborview Medical Center. As an owner and operator of medical facilities that provide reproductive health care services and pharmacies that dispense mifepristone, Washington is subject to and harmed by the January 2023 REMS.

172. At the UW, for instance, implementation of the 2023 REMS requirements is currently being overseen by a subcommittee of more than 20 UW physicians, administrators, and staff. To date, the subcommittee members have expended hundreds of hours on REMS implementation work, with many outstanding tasks still to complete. This is valuable time that these UW employees could otherwise spend treating patients, conducting research, or attending to other critical job functions.

173. One area in which UW has dedicated substantial resources is in its work to make the REMS-required Patient Agreement Form available to its telemedicine patients. The 2023 REMS continues to require that the Patient Agreement Form be signed by both the patient and a certified provider before a prescription can be filled by a certified pharmacy. Completing the form is usually a simple task in person, but it poses significant challenges in the

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telehealth setting. UW staff have worked more than 100 hours on both operational and technical elements to implement this REMS component, including making the Patient Agreement Form accessible to telemedicine patients in a HIPAA-compliant form and designing a method to securely transmit the form to the patient for their signature and then securely re-route the form back to the provider.

174. This work has been further complicated by the fact that some patients may not have access to or comfort with certain technologies (such as smartphones with scanning apps), making it challenging for UW to create a technology process that does not exacerbate inequities in patient access to abortion care.

175. Another area of significant time and expense has been implementation of the provider-certification requirement for telehealth providers. UW has hundreds of providers who are eligible to provide telehealth services. To ensure UW providers who may want to prescribe mifepristone are in compliance with the 2023 REMS requirements, UW is currently conducting outreach to ensure all interested, qualified providers are aware of the 2023 REMS requirements. UW operational staff then has to work with each provider who expresses an interest in prescribing mifepristone to ensure that the physician completes the Prescriber Agreement Form and transmits it to the UW Pharmacy. Providers then have to be trained on the new technology interfaces required for the Patient Agreement Form as well as the additional steps required in order to

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submit a mifepristone prescription for a medication abortion to a UW pharmacy. This outreach will likewise need to be done for UW's medical residents. This will require ongoing work as new healthcare providers and residents join UW.

176. UW has also had to devote significant time to designing electronic safeguards to help protect the safety of its providers. Some UW physicians, for instance, have expressed concern that by completing the Prescriber Agreement Form and having their name on a list of certified medication abortion prescribers, they could become a target of anti-abortion violence or harassment in the event the list were leaked or compromised.[94] Given the growing criminalization and

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[94]Abortion providers have long faced stigma, harassment, and violence. In 2021, 182 death threats were made against abortion providers. *See* National Abortion Federation, *2021 Violence & Disruption Statistics*, https://prochoice.org/wp-content/uploads/2021_NAF_VD_Stats_Final.pdf; *see also, e.g.*, U.S. Dep't of Justice, *Recent Cases on Violence Against Reproductive Health Care Providers* (Oct. 18, 2022), https://www.justice.gov/crt/recent-cases-violence-against-reproductive-health-care-providers; Megan Burbank, *Planned Parenthood awarded $110K after Spokane clinic protests*, CROSSCUT (Dec. 20, 2022), https://crosscut.com/news/2022/12/planned-parenthood-awarded-110k-after-spokane-clinic-protests]; Ted McDermott, *Windows smashed at Planned Parenthood in Spokane Valley; suspect arrested*, THE SPOKESMAN-REVIEW (July

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penalization of abortion following the *Dobbs* decision, these concerns are further heightened for doctors who hold medical licenses in multiple states (including states where abortion laws differ from Plaintiff States') and for medical residents who later intend to practice in states where abortion is illegal or heavily restricted.[95] While UW is working hard to protect its providers—by, for example, creating additional interfaces so that a telehealth appointment for a medication abortion can only be booked with a telehealth clinic (not a specific provider),

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5, 2021), https://www.spokesman.com/stories/2021/jul/05/windows-smashed-at-planned-parenthood-in-spokane-v/.

[95]Recognizing the reality of potential prosecution of Washington abortion providers, the Washington's Office of the Insurance Commissioner (OIC) recently approved coverage to reimburse physician policyholders for legal fees and expenses incurred in defending against a criminal action that comes from providing direct patient care, including abortions. As Insurance Commissioner Mike Kreidler explained, "As states like Texas threaten legal and criminal action against physicians, the OIC is determined to counter this by assisting medical malpractice insurers wherever we can." Press Release, Office of the Insurance Commissioner, New insurance coverage approved to help doctors who face criminal charges for providing legal abortions (Sept. 27, 2022), https://www.insurance.wa.gov/news/new-insurance-coverage-approved-help-doctors-who-face-criminal-charges-providing-legal.

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thereby ensuring that an individual provider's name is not made available before the appointment—many physicians remain concerned about having to become a "certified prescriber" of medication abortion. The provider-certification requirement thus creates additional, unnecessary risks for Washington employees, providers, and residents that would not exist without the REMS. These risks have become exponentially higher in the post-*Dobbs* era, even as Washington continues to protect the right to choose and provide abortion care.

177. FDA recognizes such concerns, but disregarded them in issuing the 2023 REMS. FDA shields the identities of its own employees whose work relates to mifepristone to protect their health and safety, in light of the violence and harassment surrounding the provision of abortion.

178. The January 2023 REMS also places a significant burden on UW's pharmacies. Prior to the January 2023 REMS, UW pharmacies did not distribute mifepristone for medication abortion, as those medications had to be provided directly to the patient by the provider at an in-patient visit in a UW clinic (or, during the COVID-19 pandemic, by the provider via mail). With the easing of the in-patient and provider-only distribution requirements, UW is now working to stock mifepristone at both its inpatient pharmacies and through its mail-order pharmacy for its telehealth patients. But the requirements associated with becoming a certified pharmacy have created a significant additional workload for UW pharmacy team members.

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179. Most significant is the requirement that UW pharmacies verify that each prescriber of mifepristone has a signed Prescriber Agreement Form on file with the pharmacy before a prescription can be filled. This has required extensive work by both UW operations and IT staff to determine how to host a dynamic list of certified providers in a secure but easily verifiable manner for UW pharmacy personnel.

180. Under the 2023 REMS program requirements, UW's pharmacies are also required to ensure that the drug is dispensed within four calendar days after the pharmacy receives the prescription (or the pharmacy must engage in additional consultation with the prescribing physician), which has required an additional workflow to ensure compliance. The same is true for the REMS requirement that authorized pharmacies record the National Drug Code (a unique identifier for drug packages) and lot number from each package of mifepristone dispensed. To date, UW pharmacy staff has expended approximately 80–100 hours on implementation work to comply with the 2023 REMS, and this work is not yet complete. The pharmacy needs additional hours to finalize these workflows and to train staff on the mifepristone REMS program requirements.

181. As demonstrated by the hundreds of hours being spent by UW physicians and staff to implement the 2023 REMS program requirements, compliance with the REMS program creates an expensive and substantial burden for Washington's hospitals, clinics and pharmacies. This is a financial and

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administrative burden that many hospitals, clinics, and pharmacies in Washington—particularly small or family-operated ones—cannot shoulder.

182. As a result, the 2023 REMS requirements unnecessarily limit the number of providers in Washington who can prescribe mifepristone and the patients' options for filling a mifepristone prescription. These unnecessary limitations, in turn, unduly burden access to mifepristone for Washington patients.

183. In eastern Washington, the student medical center at Washington State University (WSU), Cougar Health Services, has no REMS-certified providers nor is its campus pharmacy REMS-certified. WSU students seeking medication abortion cannot obtain medication abortion services at the student medical center or have a mifepristone prescription filled at the campus pharmacy, but are instead referred off-campus. This referral process is time-sensitive, requires many students to establish care at a new facility, and often creates undue stress for the student attempting to access care.

184. As the WSU example highlights, the harms caused by the REMS are particularly pronounced in central and eastern Washington, where access to abortion is already limited by a smaller density of providers and more rural population. Of the 20 eastern Washington counties, only nine have abortion providers. By irrationally limiting who may prescribe and dispense mifepristone, the REMS ensure that abortion care remains unavailable to many rural Washingtonians.

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185. The REMS certification requirements pose particular hardships in eastern Washington for providers and pharmacies who serve patients from other states—including Idaho—or who may live in Idaho themselves. For these providers and pharmacists, putting themselves on a list of abortion providers raises serious concerns about criminal or civil liability under Idaho's draconian anti-abortion laws.

186. Moreover, the REMS pharmacy requirements also limit the number of specially certified pharmacies in Washington, thereby limiting drug availability for patients, particularly in rural communities underserved by large pharmacy chains. While mail-order prescriptions may be desirable for some, they may be infeasible or impossible for others, including patients experiencing housing insecurity; traveling from other states; close to the gestational limit; living in rural areas dependent on P.O. boxes for mail delivery—which are ineligible for mail-order prescriptions; or for whom receipt of abortion medication at home may trigger domestic violence or housing loss. For these patients, local pharmacy pick-up may be necessary—but unavailable due to the 2023 REMS requirements.

187. For patients receiving medical care in Washington, the Patient Agreement Form creates an additional, unnecessary risk. While medical institutions and providers have enacted safeguards to ensure the safety and privacy of all medical records, the simple fact that a patient has an additional document in their medical record attesting to their medication abortion creates an

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added risk for patients—particularly for those patients who travel to Washington for medical treatment from states where the abortion would be illegal. Abortion providers have been targets for hackers seeking to steal information about both patients and providers. In 2021, for example, hackers accessed data about roughly 400,000 patients from Planned Parenthood Los Angeles.[96] Here in Washington, providers report frequent phishing attacks aimed at illegally obtaining information about patients and providers.

188. This risk is compounded by the fact that providers are required to provide patients with a copy of the Patient Agreement Form, which could, in turn, be found by a patient's spouse, partner, or parent (who might otherwise be unaware of the patient's medication abortion), potentially putting the patient at risk of violence or abuse. And the Patient Agreement Form is uniquely problematic for patients who receive mifepristone for miscarriage management, as they must falsely attest that they are "decid[ing] . . . to end [their] pregnancy" and then have that document placed into their medical record. And again, all of these risks are compounded for individuals traveling to Washington to receive care they cannot access in their home state.

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[96]Gregory Yee and Christian Martinez, *Hack exposes personal information of 400,000 Planned Parenthood Los Angeles patients*, LOS ANGELES TIMES (Dec. 1, 2021), https://www.latimes.com/california/story/2021-12-01/data-breach-planned-parenthood-los-angeles-patients.

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Oregon

189. As in Washington, mifepristone is a critical medicine for providing safe and effective abortion care as well as for supporting miscarriage management in Oregon. The prescription and use of mifepristone with misoprostol is the standard of care for miscarriage management and medication abortion in Oregon.

190. According to state data for 2021, 4,246 medication abortions were administered by Oregon medical providers. Based on information available at the time of filing, it is likely that most of those medication abortions were effected with a mifepristone prescription.

191. Those 4,246 medication abortions constitute about 60 percent of abortions in Oregon in 2021. At the time of filing, the State of Oregon is not aware of any Oregon patient who has experienced serious adverse effects or death as the result of being prescribed and using mifepristone for miscarriage management or medication abortion.

192. Oregon providers have been hindered in providing care, and patients have been hindered in receiving care, due to the mifepristone REMS. Medical providers, hospital administrators, and staff spend many hours implementing REMS requirements, including making Patient Agreement Forms available to patients and protecting the security of Provider Agreement Forms.

193. The REMS requirements also add to the amount of provider time required for each patient. Even at a conservative estimate of two to three minutes

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per patient, over a hundred—potentially hundreds—of provider hours are spent each year for the review, discussion, and signing of the Patient Agreement Forms. That is valuable time that those medical providers could otherwise spend treating patients or attending to other important work.

194. Those requirements are also duplicative of the counseling that Oregon providers already provide to their patients, namely in discussing risks and benefits, explaining the treatment and alternatives, and obtaining informed consent.

195. Oregon patients seeking care for miscarriage management have also experienced the same issues as similarly situated Washington patients. Namely, because the Patient Agreement Form is written specifically for the context of medication abortion, it requires them to inaccurately attest that they have decided to "end [their] pregnancy." That causes unnecessary confusion for those patients.

196. In addition to the unnecessary (and sometimes frightening) confusion, the Patient Agreement Form has caused unwarranted additional anguish in some seeking care for miscarriage management. That is because the form does not distinguish between the use of mifepristone for miscarriage management and its use for the intentional termination of a pregnancy. Consequently, for those already dealing with the distress of losing a pregnancy, the medically unjustified REMS impose the additional emotional burden of requiring the patient to incorrectly attest that the pregnancy loss was intentional

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as a prerequisite for obtaining medically appropriate healthcare for their miscarriage.

197. The REMS requirements also reduce access to essential reproductive healthcare in Oregon. Namely, many rural providers in Oregon do not have the volume of patient care to justify the onerous steps required to comply with the REMS for mifepristone. As a result, rather than seek certification themselves, they often refer patients to other providers. That requires patients to see a second provider for something that their original provider otherwise could have handled quickly and safely, results in reduced patient choice, and also places the burden of additional patient loads on those certified providers that accept referrals.

198. And similar to Washington patients, the reduced access to essential reproductive health care results in additional delays to patients receiving healthcare. For example, it takes time for the patient to receive the referral from their primary provider. It takes time for the patient to establish care with the second provider. It can take additional time if the patient seeks in-person consultation and needs to travel for care. And it takes time for the patient to wait for any healthcare delays caused by the patient-load resulting from the number of referrals. Those are delays to healthcare for conditions for which time is of the essence. And those delays often contribute to patients having reduced availability of healthcare options and adverse effects to patient health.

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Arizona

199. Access to safe and effective medication abortion is critically important for Arizonans. Arizonans experience harms as a result of the 2023 REMS that are similar to those experienced by residents of the Plaintiff States.

Colorado

200. The State of Colorado, through the University of Colorado, its largest institution of higher education, operates a woman's health clinic. As an owner and operator of a medical clinic that provides reproductive health care services and dispenses mifepristone, Colorado is subject to and harmed by the January 2023 REMS.

201. Providers and staff at the University of Colorado have expended time and resources complying with the 2023 REMS requirement, including developing and processing the Prescriber Agreement Form and the Patient Agreement Form. Further, the 2023 REMS prevent non-certified providers from prescribing mifepristone to their patients. As a result, those patients often must make additional clinic visits—sometimes at different locations—to obtain mifepristone.

202. Further, patients in Colorado suffer the same harms experienced by patients in other states outlined above and below.

Connecticut

203. Access to safe and effective medication abortion is critically important for Connecticut residents. Connecticut residents experience harms as a

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result of the 2023 REMS that are similar to those experienced by residents of the Plaintiff States.

Delaware

204. Like Washington, Delaware residents rely on mifepristone to access safe and effective abortion care and management of miscarriages. Analysis of data from 2014 to 2020 shows that Delawareans have increasingly relied on medication abortion for early pregnancy termination. In 2014, there were 2,937 abortions in Delaware. Of those, 1,292—44%—were medical abortions using mifepristone. In 2020 (the most recent year for which complete data is available), there were 2,281 abortions in Delaware. Of those, 1,492—65.4%—were medical abortions using mifepristone.

205. Restricting access to mifepristone needlessly harms Delawareans who increasingly rely on it.

Illinois

206. In Illinois, mifepristone is a critical medicine for providing safe and effective abortion care as well as for supporting miscarriage management.

207. In 2020 (the most recent year for with public data), there were 46,243 reported abortions in Illinois. Of those, 23,765—51%—were medication abortions using mifepristone.

208. The mifepristone REMS requirements impede drug availability for Illinois residents by limiting the providers that can prescribe and the pharmacies

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that can dispense the medication, while creating additional barriers to patient access through the Patient Agreement Form requirement.

209. Limited access to abortion and miscarriage management medication increases other health care costs, including more expensive procedural or later-stage abortion care, emergency care, and care related to complications due to unwanted pregnancies, childbirth, and miscarriage.

210. A significant proportion of this cost is borne by the State, which is one of only 16 states that goes beyond federal Medicaid limits and uses state funds to cover abortion care for people enrolled in Medicaid. From January 2019 to May 2022, the State covered approximately 29,000 mifepristone prescriptions.

211. State Medicaid reimbursement rates are higher for procedural abortions and abortions taking place later in gestation. The bundled State Medicaid reimbursement rate for medication abortion is $558. In contrast, the lowest rate for a procedural abortion is $798. Because the 2023 REMS requirements artificially limit the number of providers who can prescribe mifepristone and the pharmacies that can fill prescriptions, fewer people have access to mifepristone abortions. This restriction results in more higher-cost procedural abortions. Broad mifepristone access is a critical tool for addressing the financial impact on the State.

212. As Illinois's neighboring states have curtailed abortion access, Illinois has seen a 28% increase in abortions from April 2022 to August 2022, creating additional strain on Illinois providers and healthcare systems. The

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REMS certification requirements pose particular hardships for Illinois providers and pharmacies because Illinois is an abortion oasis in the Midwest and a significant portion of patients seeking abortion care in Illinois are traveling from Indiana, Missouri, and other nearby states where abortion is restricted. For these providers and pharmacists, as well as patients traveling from out of state, the REMS certification requirements and Patient Agreement Form create additional risks of civil or criminal liability.

Attorney General of Michigan

213. Access to safe and effective medication abortion is critically important for Michiganders. Michiganders experience harms as a result of the 2023 REMS that are similar to those experienced by residents of the Plaintiff States.

Nevada

214. In Nevada, mifepristone is widely used in combination with misoprostol as a safe, effective, FDA-approved regimen for medication abortions. It is also used in the medical management of early pregnancy loss.

215. Medication abortions represent the largest share of pregnancy termination procedures performed in Nevada. From December 2021 to November 2022, 49% of all abortions performed in Nevada were medication abortions.

216. The Nevada Department of Health and Human Services, Division of Health Care Financing and Policy (DHHS) administers the Medicaid program in

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Nevada. It is responsible for ensuring high quality, cost-effective care to Medicaid recipients while maintaining compliance with federal Medicaid requirements.

217. Nevada Medicaid fee-for-service covers mifepristone.

218. The reduced availability of mifepristone will financially impact DHHS. Providers and patients will be forced to adopt alternatives including surgical abortions which are more invasive, costly, and can expose patients to higher health risks, e.g., excessive bleeding.

219. Since the *Dobbs* decision, Nevada has experienced a marked increase in out-of-state patients seeking abortion care in state. In 2021, Nevada experienced an average of 47 out-of-state patients per month over a six-month period. In the first half of 2022, the average increased to 55 out-of-state patients. Post-*Dobbs*, there was an immediate spike of 113 in July 2022, after which the average leveled to 80 out-of-state patients per month.

220. The reduced availability of mifepristone will financially burden Nevada reproductive healthcare providers attempting to service this increased patient load.

221. The Mifepristone REMS program imposes medically unnecessary barriers to the prescription, distribution, and use of mifepristone by Nevada clinicians and patients. The REMS Patient Agreement Form must be signed by both a patient and a certified provider before a prescription can be filled by a

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qualified pharmacy. This imposes a significant burden for telehealth patients or patients without access to smartphones or scanning apps.

222. A pharmacy can only become qualified by undergoing the REMS certification process which further limits the availability of mifepristone in Nevada.

223. The barriers created by the REMS program disproportionately burden people of color, low-income families, and communities within Nevada's large rural regions whose residents would have to travel long distances to seek alternative reproductive healthcare services.

224. These barriers interfere with Nevada's inherent authority to provide for the health and welfare of its residents.

New Mexico

225. New Mexico's injuries are exemplified in the sections discussing Washington's and the other Plaintiff States' injuries.

226. New Mexico repealed its antiquated prohibition of abortion in 2021.[97]

227. Nonetheless, many communities in New Mexico—particularly the rural communities—do not currently have adequate access to reproductive health care services.

[97]NMSA 1978, §§ 30-5-1 to -3 (repealed 2021).

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228. New Mexico's injuries are exacerbated by various local cities and counties in the State of New Mexico enacting ordinances attempting to regulate abortion, declaring unlawful the delivery of abortion medications, and creating a private cause of action against abortion clinics. New Mexico residents in these cities and counties, as well as in other rural communities in the State, are particularly subject to the harms described in this Complaint.

Rhode Island

229. In Rhode Island, mifepristone is a critical medicine for providing safe and effective abortion care as well as for supporting miscarriage management.

230. The mifepristone REMS requirements impede drug availability for Rhode Islanders by limiting the providers that can prescribe and the pharmacies that can dispense the medication, while creating additional barriers to patient access through the Patient Agreement Form requirement.

231. Limited access to abortion and miscarriage management medication increases other health care utilization costs, including emergency care, resulting from complications due to unwanted pregnancies, childbirth, and miscarriage. A significant proportion of this cost is borne by the state, in which over 30% of Rhode Islanders are enrolled in Medicaid.

232. Rhode Islanders are harmed when access to mifepristone is limited, including the emotional, financial, and social harms that individuals experience

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by having to carry an unwanted pregnancy to term or not having access to the benefit of miscarriage management medication.

Vermont

233. Medication abortion is critically important for Vermonters. In 2019, 59% of abortions in Vermont were medication abortions; in 2020, that number rose to 75%.[98]

234. The harms that the REMS cause are particularly acute in Vermont because the state's rurality makes it difficult for many Vermonters to access providers. Less than a third of Vermont counties have abortion providers—

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[98] Agency of Human Services, *Vermont 2019 Vital Statistics: 135th Report Relating to the Registry and Return of Births, Deaths, Marriages, Divorces, and Dissolutions* at 139, Vermont Department of Health (June 2021), https://www.healthvermont.gov/sites/default/files/documents/pdf/HS-VR-2019VSB_final.pdf; Agency of Human Services, *Vermont 2020 Vital Statistics: 136th Report Relating to the Registry and Return of Births, Deaths, Marriages, Divorces, and Dissolutions* at 142, Vermont Department of Health (July 2022) https://www.healthvermont.gov/sites/default/files/documents/pdf/Vital%20Statistics%20Bulletin%202020.pdf.

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meaning that 43% of women of reproductive age live in a county without an abortion provider.[99]

District of Columbia

235. In the District of Columbia, mifepristone is a critical medicine for providing safe and effective abortion care. The prescription and use of mifepristone with misoprostol is the standard of care for medication abortion in the District.

236. Medication abortion is critically important for District residents. In 2020, 2,358 medication abortions were administered by District medical providers, accounting for roughly 53% of all abortions in the District.[100]

237. The mifepristone REMS requirements impede drug availability for District residents by limiting the providers that can prescribe and the pharmacies that can dispense the medication. The certification process is onerous and can deter providers from undergoing the process, which in turn limits patients' access to medication abortion services. The REMS also create additional barriers to patient access through the Patient Agreement Form requirement.

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[99] Jesse Philbin, et al., *10 US States Would Be Hit Especially Hard by a Nationwide Ban on Medication Abortion Using Mifepristone*, GUTTMACHER INSTITUTE (Feb. 7, 2023), https://www.guttmacher.org/2023/02/10-us-states-would-be-hit-especially-hard-nationwide-ban-medication-abortion-using.

[100] https://www.cdc.gov/mmwr/volumes/71/ss/ss7110a1.htm#T12_down

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Hawaii

238. Patients in the State of Hawaii suffer the same harms experienced by patients in other Plaintiff States.

239. Access to safe and effective medication abortion is critically important for the State of Hawaii.

240. Limitation on access to safe and effective medication abortion increases other health care costs, including the more expensive procedural or later-stage abortion care, emergency care, and care related to complications due to unwanted pregnancies, childbirth, and miscarriage.

241. As Hawaii is a state of several islands, the aforementioned health care costs are further increased if a patient must travel to another island in order to seek the appropriate care.

Maine

242. Medication abortion is essential to reproductive health care in Maine. According to the Maine Centers for Disease Control, in 2021, a total of 1,915 abortions were performed in Maine. Of that total, 1,159 (more than 60%) were medication abortions using mifepristone.

243. According to the Maine Department of Health and Human Services, in 2021, the State paid for 770 abortions under the state-funded abortion services program. Of that total, 463 (about 60%) were medication abortions using mifepristone.

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244. Access to medication abortion – including provision of mifepristone via mail, is particularly important in Maine, which is a large rural state. Many Maine residents live far away from health care providers offering abortion services, and access to mifepristone via mail is critical to their healthcare.

245. The 2023 REMS makes it more difficult for pregnant people to access the abortion services to which they are entitled. This leads to delay in abortion services, which could require a person to obtain a surgical abortion, as well as increased health care costs, including emergency care, care related to complications due to unwanted pregnancies, childbirth, and miscarriage. Some of these costs are borne by the state through its Medicaid program, in which approximately 30% of Maine residents are enrolled as of October 2022.

246. Access to safe and effective medication abortion is critically important for Maine residents. Maine residents experience harms as a result of the 2023 REMS that are similar to those experienced by residents of the other Plaintiff States.

247. Maine provides state-funded abortion services to Medicaid-eligible pregnant people. The burdens and obstacles created by the 2023 REMS may result in increased state expenditures. For example, the delays imposed by the REMS could require a more complicated and expensive surgical abortion procedure.

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248. The 2023 REMS creates and maintains substantial and costly administrative burdens for health care and pharmaceutical services provided in the State of Maine.

Maryland

249. Access to safe and effective medication abortion is critically important for Maryland residents. Maryland residents experience harms as a result of the 2023 REMS that are similar to those experienced by residents of the Plaintiff States.

Minnesota

250. Mifepristone is critical to reproductive healthcare providers and patients in Minnesota. Minnesota residents rely on mifepristone to access safe and effective abortion care and miscarriage management. Medication abortions using mifepristone represent the majority of pregnancy termination procedures performed in Minnesota. Data from 2008 to 2021 shows that Minnesotan patients and providers have increasingly relied on medication for early pregnancy termination. In 2008, there were 12,948 abortions in Minnesota. Of those, 2,226—17%—were non-surgical medical abortions. In 2017, there were 10,177 abortions in Minnesota. Of those, 3,997—39%—were medication abortions using mifepristone. In 2021, there were 10,136 abortions in Minnesota. Of those, 5,894—58%—were medication abortions using mifepristone.

251. The 2023 REMS limits Minnesotans' access to reproductive healthcare by limiting the providers that can prescribe mifepristone and the

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pharmacies that can dispense it. It also creates additional barriers to patient access by requiring the Patient Agreement Form. As a result of this limited access, Minnesotan providers are sometimes forced to provide, and patients are sometimes forced to seek, alternative care. This alternative care includes surgical abortions and miscarriage management procedures which are more invasive, costly, and expose patients to additional medical risks.

252. The burden of this reduced availability disproportionately impacts people of color, low-income families, and rural Minnesota communities whose residents must travel long distances to seek alternative reproductive healthcare services.

253. Minnesotans are harmed because access to mifepristone is limited. These harms include the emotional, financial, and social harms that individuals may experience when they have to carry an unwanted pregnancy to term or when they do not have access to medication to manage a miscarriage.

254. Additionally, this limited access to medication abortion and medication miscarriage management increases other health care costs, including more expensive procedural or later-stage abortion care, emergency care, and care related to complications due to unwanted pregnancies, childbirth, and miscarriage. Some of this increased cost is paid by the State, which is one of 16 states that uses state funds to cover abortion care for people enrolled in Medicaid. Ensuring Minnesotans have access to mifepristone is critical to managing health care costs borne by the State.

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255. The 2023 REMS also puts additional demand pressure on the providers who are able to prescribe mifepristone and the pharmacies that are able to dispense it. Since the *Dobbs* decision, Minnesota has experienced a significant increase in out-of-state-patients seeking abortion care in the state. In the months after *Dobbs*, Minnesota's Planned Parenthood clinics reported a 150% surge in call center traffic, and a 13% increase in patients. Whole Woman's Health in Minnesota reported a 50% increase in patients. The reduced availability of mifepristone financially burdens Minnesotan reproductive healthcare providers working to meet this increased patient demand.

Pennsylvania

256. Medication abortion is vital to the reproductive health care of Pennsylvanians. According to the Centers for Disease Control and Prevention, approximately 51% of abortions in Pennsylvania in 2020 (the most recent year for which complete data is available) were medication abortions. Of the 18 existing abortion-service providers in Pennsylvania, 8 of them exclusively provide medication abortions, and most providers are located near larger cities in the eastern and western portions of the Commonwealth, limiting access to these services for residents in much of the Commonwealth. Restrictions on the use of mifepristone only serve to further limit access to safe and effective reproductive health to Pennsylvanians.

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V. FIRST CAUSE OF ACTION
(Administrative Procedure Act—Agency Action in Excess of Statutory Authority and Contrary to Law)

257. The Plaintiff States reallege and incorporate by reference the allegations set forth in each of the preceding paragraphs of this Complaint.

258. FDA's promulgation of the mifepristone 2023 REMS was a final agency action that is causing the Plaintiff States irreparable harm for which the States have no other adequate remedy under 5 U.S.C. § 704.

259. This Court must "hold unlawful and set aside agency action" that is, *inter alia*, "not in accordance with law," "in excess of statutory jurisdiction, authority, or limitations," or "without observance of procedure required by law[.]" 5 U.S.C. § 706(2).

260. Through their actions described above, Defendants violated 5 U.S.C. § 706(2)(C) by acting in excess of statutory jurisdiction, authority, limitations, and short of statutory right in promulgating the mifepristone 2023 REMS.

VI. SECOND CAUSE OF ACTION
(Administrative Procedure Act—Arbitrary and Capricious Agency Action)

261. The Plaintiff States reallege and incorporate by reference the allegations set forth in each of the preceding paragraphs of this Complaint.

262. FDA's promulgation of the mifepristone 2023 REMS was a final agency action that is causing the Plaintiff States irreparable harm for which the States have no other adequate remedy under 5 U.S.C. § 704.

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263. FDA's promulgation of the mifepristone 2023 REMS was arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law in violation of 5 U.S.C. § 706(2)(A).

VII. THIRD CAUSE OF ACTION
(Administrative Procedure Act—Action Contrary to Constitutional Right)

264. The Plaintiff States reallege and incorporate by reference the allegations set forth in each of the preceding paragraphs of this Complaint.

265. FDA's promulgation of the mifepristone 2023 REMS was a final agency action that is causing the Plaintiff States irreparable harm for which the States have no other adequate remedy under 5 U.S.C. § 704.

266. FDA's promulgation of the mifepristone 2023 REMS treated similarly situated parties differently without adequate justification, and therefore violates the constitutional guarantee of equal protection in violation of 5 U.S.C. § 706(2)(B).

VIII. FOURTH CAUSE OF ACTION
(Equal Protection)

267. The Plaintiff States reallege and incorporate by reference the allegations set forth in each of the preceding paragraphs of this Complaint.

268. Through their actions described above, Defendants violate the equal protection guarantee of the Due Process Clause of the Fifth Amendment to the United States Constitution.

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269. Through the 2023 REMS, FDA reduces access to a critical and time-sensitive health care service needed by pregnant people. And FDA treats providers, pharmacists, and patients who prescribe, dispense, or use mifepristone worse than providers, pharmacists, and patients who prescribe, dispense, or use nearly every other medication. FDA's actions are irrational and violate the Fifth Amendment under any standard of review.

IX. PRAYER FOR RELIEF

WHEREFORE, Washington, Oregon, Arizona, Colorado, Connecticut, Delaware, Illinois, Attorney General of Michigan, Nevada, New Mexico, Rhode Island, Vermont, District of Columbia, Hawaii, Maine, Maryland, Minnesota, and Pennsylvania pray that the Court:

a. Declare, pursuant to 28 U.S.C. § 2201, that mifepristone is safe and effective and that Defendants' approval of mifepristone is lawful and valid;

b. Declare, pursuant to 28 U.S.C. § 2201, that the mifepristone REMS violates the Administrative Procedure Act;

c. Declare, pursuant to 28 U.S.C. § 2201, that the mifepristone REMS violates the United States Constitution;

d. Enjoin Defendants, pursuant to 28 U.S.C. § 2202, from enforcing or applying the mifepristone REMS;

e. Enjoin Defendants, pursuant to 28 U.S.C. § 2202, from taking any action to remove mifepristone from the market or reduce its availability; and

f. Award such additional relief as the interests of justice may require.

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DATED this 9th day of March, 2023.

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**Applications for pro hac vice admission forthcoming*

CERTIFICATE OF SERVICE

I hereby certify that on March 9, 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 9th day of March, 2023, at Seattle, Washington.

/s/Kristin Beneski
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No. 23-35294

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

UNITED STATES OF AMERICA ET AL.,
Plaintiff-Appellee,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, ET AL.,
Defendant-Appellees,

v.

STATE OF IDAHO, ET AL.
Movants-Appellants.

On Appeal from the United States District Court
for the Eastern District of Washington

No. 1:23-cv-03026-TOR
The Honorable Thomas O. Rice

MOVANTS-APPELLANTS' EXCERPTS OF RECORD VOLUME 3 OF 3

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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON

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

Plaintiffs,

v.

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

NO. 1:23-cv-03026

PLAINTIFF STATES' MOTION FOR PRELIMINARY INJUNCTION

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

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

Defendants.

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I. INTRODUCTION

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

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

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

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

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II. FACTS

A. Statutory Background

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

C. FDA Adopts Burdensome REMS for Mifepristone

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

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

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

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

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

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

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

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

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D. The 2023 REMS Unduly Burdens Access to Health Care

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

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

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

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

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Gold Decl. ¶¶ 17–19.

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

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

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

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

III. ARGUMENT

A. Legal Standard

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

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

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

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

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

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

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

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

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2. The 2023 REMS violates the APA

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

a. The 2023 REMS is contrary to law

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

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

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

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

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

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

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

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

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

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

b. The 2023 REMS is arbitrary and capricious

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

C. The States Will Suffer Irreparable Harm Absent Injunctive Relief

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

IV. CONCLUSION

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

DATED this 24th day of February 2023.

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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:

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

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

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

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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON

STATE OF WASHINGTON; STATE OF OREGON; STATE OF ARIZONA; STATE OF COLORADO; STATE OF CONNECTICUT; STATE OF DELAWARE; STATE OF ILLINOIS; ATTORNEY GENERAL OF MICHIGAN; STATE OF NEVADA; STATE OF NEW MEXICO; STATE OF RHODE ISLAND; and STATE OF VERMONT, Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION; ROBERT M. CALIFF, in his official capacity as Commissioner of Food and Drugs; UNITED STATES	NO. COMPLAINT

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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.

I. INTRODUCTION

1. The availability of medication abortion has never been more important. As states across the country have moved to criminalize and civilly penalize abortion, the Plaintiff States have preserved the right to access abortion care, and have welcomed people from other states who need abortion care. The extremely limited availability of abortion in other states, and the growing threat to abortion access nationwide, makes patients' access to medication abortion paramount. Medication abortion through a combination of mifepristone and misoprostol is the "gold standard" for early termination of pregnancy, used by the majority of people in the U.S. who choose to have an abortion.

2. More than 22 years ago, the United States Food and Drug Administration (FDA) approved mifepristone (under the brand name Mifeprex) to be used with the drug misoprostol, in a two-drug medication regimen to end an early pregnancy. Approval was based on a thorough and comprehensive review of the scientific evidence, which established that mifepristone is safe and effective.

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3. Since this regimen was approved in 2000, mifepristone has been used approximately 5.6 million times in the United States.[1] As FDA acknowledged in 2016, mifepristone "has been increasingly used as its efficacy and safety have become well-established by both research and experience, and serious complications have proven to be extremely rare."[2] Mifepristone is safer than many other common drugs FDA regulates, such as Viagra and Tylenol.

4. Medication abortion is now the most common method of abortion in the United States. For example, almost 60% of abortions in Washington State are medication abortions.

5. But FDA has continued to hamper access by singling out mifepristone—and the people in the Plaintiff States who rely on it for their reproductive health care—for a unique set of restrictions known as a Risk Evaluation and Mitigation Strategy (REMS). The restrictions on mifepristone are a particularly burdensome type of REMS known as Elements to

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[1]FDA, Mifepristone U.S. Post-Marketing Adverse Events Summary through 06/30/2022, https://www.fda.gov/media/164331/download ("Mifepristone U.S. Post-Marketing Adverse Events"), attached hereto as Ex. A.

[2]FDA, Ctr. for Drug Evaluation & Research, No. 020687Orig1s020, Mifeprex Medical Review(s) at 12 (Mar. 29, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf ("FDA 2016 Medical Review"), attached hereto as Ex. B.

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Assure Safe Use (ETASU), which strictly limit who can prescribe and dispense the drug. FDA's decision to continue these burdensome restrictions in January 2023 on a drug that has been on the market for more than two decades with only "exceedingly rare" adverse events has no basis in science. It only serves to make mifepristone harder for doctors to prescribe, harder for pharmacies to fill, harder for patients to access, and more burdensome for the Plaintiff States and their health care providers to dispense.[3] Not only that, but the REMS require burdensome documentation of the patient's use of mifepristone for the purpose of abortion, making telehealth less accessible and creating a paper trail that puts both patients and providers in danger of violence, harassment, and threats of liability amid the growing criminalization and outlawing of abortion in other states.

6. FDA has imposed REMS for only 60 of the more than 20,000[4] FDA-approved prescription drug products marketed in the U.S. These cover dangerous drugs such as fentanyl and other opioids, certain risky cancer drugs, and high-dose sedatives used for patients with psychosis.[5]

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[3]Ex. B (FDA 2016 Medical Review) at 47.

[4]Office of the Commissioner, *FDA at a Glance: FDA Regulated Products and Facilities*, FDA (Nov. 2021), https://www.fda.gov/media/154548/download.

[5]*Id.*

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7. This case is about whether it is improper and discriminatory for FDA to relegate mifepristone—a medication that has been used over 5 million times with very low rates of complications, very high rates of efficacy, and which is critical to the reproductive rights of the Plaintiff States' residents, as well as visitors who travel to the Plaintiff States to seek abortion care—to the very limited class of dangerous drugs that are subject to a REMS.

8. The Plaintiff States seek an order directing FDA to follow the science and the law. The Court should order FDA to remove the unnecessary January 2023 REMS restrictions that impede and burden patients' access to a safe, proven drug that is a core element of reproductive health care in the Plaintiff States.

II. JURISDICTION AND VENUE

9. The Court has subject matter jurisdiction under 28 U.S.C. § 1331, as this is a civil action arising under federal law, and under 5 U.S.C. § 702, as this is a civil action seeking judicial review of a final agency action.

10. This action for declaratory and injunctive relief is authorized by 28 U.S.C. §§ 2201 and 2202, by Federal Rules of Civil Procedure 57 and 65, and by the inherent equitable powers of this Court.

11. The Court has personal jurisdiction over Defendants pursuant to 28 U.S.C. § 1391(e) because Defendants are agencies and officers of the United States.

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12. Venue is proper in this district pursuant to 28 U.S.C. § 1391(a) because this is a judicial district in which Plaintiff State of Washington resides. Defendants' policies adversely affect the health and welfare of residents in the Plaintiff States, including in this district, and harm the financial interests of the Plaintiff States, including Washington. Abortion access is far more limited in Eastern Washington than in Western Washington, with the State's clinics concentrated in urban areas and the I-5 corridor.

III. PARTIES

Washington

13. The Attorney General is the chief legal adviser to the State. The Attorney General's powers and duties include acting in federal court on behalf of the State on matters of public concern.

14. As an operator of medical facilities that provide reproductive health care services and pharmacies that dispense mifepristone, Washington is directly subject to the January 2023 REMS and has standing to vindicate its proprietary interests in delivering high-quality patient care.

15. Washington also has standing because the 2023 REMS creates and maintains substantial and costly administrative burdens for State-operated hospitals, clinics, and pharmacies.

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16. Washington additionally brings this suit in its capacity as parens patriae to protect its quasi-sovereign interest in the health and well-being of Washington residents.

Oregon

17. Plaintiff State of Oregon is represented by its Attorney General, who is the chief law officer for the State. Oregon has a strong interest in the proper provision of health care within the state, particularly at public hospitals, and joins in its capacity as parens patriae to protect its quasi-sovereign interest in the health and well-being of Oregon residents.

Arizona

18. The Attorney General is the chief legal adviser to the State. The Attorney General's powers and duties include acting in federal court on behalf of the State on matters of public concern.

19. As the operator of facilities that provide reproductive health care and pharmaceutical services, Arizona is directly subject to the January 2023 REMS and has standing to vindicate it proprietary interests in delivering high-quality patient care.

20. Arizona also has standing because the 2023 REMS create and maintain substantial and costly administrative burdens for health care and pharmaceutical services provided in state owned or operated facilities.

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21. Arizona additionally brings this suit in it capacity as parens patriae to protect its quasi-sovereign interest in the health and well-being of Arizona residents.

Colorado

22. Plaintiff the State of Colorado is a sovereign state of the United States of America. This action is brought on behalf of the State of Colorado by Attorney General Phillip J. Weiser, who is the chief legal representative of the State of Colorado, empowered to prosecute and defend all actions in which the state is a party. Colo. Rev. Stat. § 24-31-101(1)(a).

Connecticut

23. The State of Connecticut is a sovereign state. The Attorney General is Connecticut's chief civil legal officer, responsible for supervising and litigating all civil legal matters in which Connecticut is an interested party, including federal court matters.

24. Medication abortion is indispensable to reproductive health care in Connecticut. According to the Centers for Disease Control, more than 65% of Connecticut abortions are medication abortions using mifepristone.

25. Access to mifepristone for medicated abortions is increasingly critical in Connecticut. An ongoing wave of hospital closures and consolidations threaten to leave swaths of the state without access to on-site reproductive

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healthcare, even as demand for abortion care has increased in the aftermath of *Dobbs*.

26. Connecticut is directly subject to the January 2023 REMS and has standing to vindicate its proprietary interests in delivering high-quality patient care. Connecticut funds and operates the John Dempsey Hospital of the University of Connecticut Health Center (UConn Health) and its associated pharmacy. The Hospital provides reproductive health services, including prescribing mifepristone for medication abortions. The pharmacy dispenses mifepristone to patients.

27. Connecticut also has standing because the 2023 REMS create and maintain substantial and costly administrative burdens, including burdens to UConn Health and its associated pharmacy.

28. Connecticut additionally brings this suit in its capacity as parens patriae to protect is quasi-sovereign interest in the health and well-being of Connecticut residents.

Delaware

29. Plaintiff the State of Delaware is a sovereign state of the United States of America. This action is brought on behalf of the State of Delaware by Attorney General Kathleen Jennings, the "chief law officer of the State." *Darling Apartment Co. v. Springer*, 22 A.2d 397, 403 (Del. 1941).

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Attorney General Jennings also brings this action on behalf of the State of Delaware pursuant to her statutory authority. Del. Code Ann. tit. 29, § 2504.

Illinois

30. Plaintiff the State of Illinois is a sovereign state of the United States of America. This action is brought on behalf of the State of Illinois by Attorney General Kwame Raoul, the State's chief legal officer. *See* Ill. Const. art. V, § 15; 15 ILCS 205/4.

31. Illinois has standing because the 2023 REMS create barriers to accessing medically necessary abortion and miscarriage care, leading to subsequent health care costs, including emergency care, some of which is borne by the state through Medicaid expenditures.

32. Illinois additionally brings this suit in its capacity as *parens patriae* to protect its quasi-sovereign interest in the health and well-being of Illinois residents.

Attorney General of Michigan

33. Attorney General Dana Nessel is the chief legal adviser to the State of Michigan. The Attorney General's powers and duties include acting in federal court on behalf of the State on matters of public concern.

34. The Attorney General brings this suit in her capacity as parens patriae to protect its quasi-sovereign interest in the health and well-being of Michigan residents.

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Nevada

35. Plaintiff State of Nevada is represented by its Attorney General. The Attorney General is the chief legal officer of the State.

36. The Nevada Attorney General may commence or defend a suit in state or federal court when in his opinion a suit is necessary to protect and secure the interest of the State.

37. Nevada provides reproductive healthcare services including medication abortions using mifepristone.

38. As a provider of reproductive healthcare services, Nevada is subject to the January 2023 REMS program.

39. Nevada has standing to challenge the REMS because it imposes financial and administrative burdens on Nevada reproductive healthcare service providers seeking to prescribe and distribute mifepristone for medication abortions.

40. Nevada also has standing to challenge the program because the program interferes with its inherent authority to provide for the health and welfare of its residents. It imposes medically unnecessary barriers to Nevada's provision of reproductive healthcare using the least intrusive and most cost-effective means.

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New Mexico

41. Plaintiff State of New Mexico, represented by and through its Attorney General, is a sovereign state of the United States of America. Attorney General Raúl Torrez is the chief legal officer of the State of New Mexico. He is authorized to prosecute all actions and proceedings on behalf of New Mexico when, in his judgment, the interest of the State requires such action. N.M. Stat. Ann. § 8-5-2(B). Likewise, he shall appear before federal courts to represent New Mexico when, in his judgment, the public interest of the state requires such action. N.M. Stat. Ann. § 8-5-2(J). This challenge is brought pursuant to Attorney General Torrez's statutory authority.

42. As an operator of medical facilities that provide reproductive health care services and pharmacies that dispense mifepristone, New Mexico is directly subject to the 2023 REMS and has standing to vindicate its proprietary interests in delivering high-quality patient care.

43. New Mexico also has standing because the 2023 REMS will impose substantial and costly administrative burdens for State-operated hospitals, clinics, and pharmacies.

44. New Mexico additionally brings this suit in its capacity as parens patriae to protect its quasi-sovereign interest in the health and well-being of New Mexico residents.

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Rhode Island

45. The Rhode Island Attorney General is the chief legal officer for the State of Rhode Island. The Rhode Island Attorney General's powers and duties include acting in federal court on behalf of the State on matters of public concern.

46. Rhode Island has standing because the 2023 REMS create barriers to accessing medically necessary abortion and miscarriage care, leading to subsequent health care utilization, including emergency care, some cost of which is borne by the state through Medicaid expenditures.

47. Rhode Island additionally brings this suit in its capacity as parens patriae to protect its quasi-sovereign interest in the health and well-being of Rhode Island residents.

Vermont

48. The Attorney General is the chief legal adviser to the State. The Attorney General's powers and duties include representing the State in civil causes when, in her judgment, the interests of the State so require.

49. Vermont brings this suit in its capacity as parens patriae to protect its quasi-sovereign interest in the health and well-being of Vermont residents.

Plaintiff States

50. The Plaintiff States collectively represent more than 59 million Americans with protected rights to abortion care.

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Defendants

51. Defendant United States Food and Drug Administration (FDA) is an agency of the federal government within the United States Department of Health and Human Services (HHS). FDA is responsible for administering the provisions of the federal Food, Drug, and Cosmetic Act that are relevant to this Complaint.

52. Robert M. Califf is the Commissioner of the United States Food and Drug Administration and is sued in his official capacity. He is responsible for administering FDA and its duties under the federal Food, Drug, and Cosmetic Act.

53. Defendant HHS is a federal agency within the executive branch of the federal government.

54. Defendant Xavier Becerra is the Secretary of HHS and is sued in his official capacity. He is responsible for the overall operations of HHS, including FDA.

IV. ALLEGATIONS

A. Statutory Background

55. Under the Food, Drug and Cosmetic Act (FDCA), a new drug cannot be marketed and prescribed until it undergoes a rigorous approval process to determine that it is safe and effective. *See generally* 21 U.S.C. § 355. An approved prescription medication is subject to robust safeguards to ensure that it is used safely and appropriately, including the requirement of a prescription by a

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licensed medical provider, patient informed-consent laws, scope of practice laws, professional and ethical guidelines, and state disciplinary laws regulating the practice of medicine and pharmacy, as well as additional warnings, indications, and instructions that FDA may impose specific to the medication.

56. FDA relies on this set of safeguards to ensure the safe and effective use of the *vast* majority of prescription drugs.

57. A "Risk Evaluation and Mitigation Strategy" (REMS) is an additional set of requirements, beyond the usual network of safeguards, that FDA may impose in the rare case when—and only when—"necessary to ensure that the benefits of the drug outweigh the risks of the drug[.]" 21 U.S.C. § 355-1(a)(1).

58. The most burdensome type of 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).

59. By statute, FDA may impose ETASU only for medications that demonstrate risks of serious side effects such as death, incapacity, or birth defects, and only where the risk of side effects is sufficiently severe that FDA could not approve, or would have to withdraw approval of, the medication, absent the ETASU. *Id.* §§ 355-1(b)(5), (f)(1)(A).

60. ETASU must not be "unduly burdensome on patient access to the drug, considering in particular . . . patients in rural or medically underserved

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areas," and must "minimize the burden on the health care delivery system[.]" *Id.* §§ 355-1(f)(2)(C)–(D).

61. In light of these stringent statutory limitations, REMS, and in particular an ETASU, are exceptionally rare: of the more than 20,000 prescription drug products approved by FDA and marketed in the U.S.,[6] there are only 60 REMS in place, 56 of which include an ETASU, covering dangerous drugs like fentanyl and other opioids.[7]

B. FDA's Approval of Mifepristone and the History of the Mifepristone REMS Program

62. The current FDA-approved regimen for the medical termination of early pregnancy involves two drugs: (1) *mifepristone*, which interrupts early pregnancy by blocking the effect of progesterone, a hormone necessary to maintain a pregnancy, and (2) *misoprostol*, which causes uterine contractions that expel the pregnancy from the uterus. Shortly after taking mifepristone and then misoprostol, a patient will experience a miscarriage.[8]

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[6] *Supra* n.5.

[7] Ex. C (FDA Approved REMS).

[8] Taken alone, misoprostol also acts as an abortifacient—but it is less effective and causes more negative side effects than the mifepristone/misoprostol regimen. Misoprostol, however, it is not subject to a REMS; patients may obtain it from any provider and have it filled at retail or mail-order pharmacies.

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63. Mifepristone was first approved for medical termination of early pregnancy in France in 1988 and its approval expanded to the United Kingdom and European countries throughout the 1990s.

64. In 1996, the Population Council, a non-profit organization based in the United States, sponsored a New Drug Application (NDA) for Mifeprex for use in combination with misoprostol for the medical termination of early pregnancy. In 1999, the Population Council contracted with Danco Laboratories, L.L.C. (Danco) to manufacture and market the medication.

65. FDA approved the marketing of mifepristone under the brand name Mifeprex in September 2000,[9] concluding that mifepristone is safe and effective for medical termination of intrauterine pregnancy through 49 days' gestation when used in a regimen with the already-approved drug, misoprostol. In granting its approval, FDA extensively reviewed the scientific evidence and determined that mifepristone's benefits outweigh any risks.[10]

66. FDA's review included three clinical trials that together involved 4,000 women: two French trials that were complete at the time of the application, and one then-ongoing trial in the United States for which summary data on

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[9]FDA NDA 20-687 Approval Memo, Sept. 28, 2000, attached hereto as Ex. D.

[10]Food and Drug Administration Approval and Oversight of the Drug Mifeprex, https://www.gao.gov/assets/gao-08-751.pdf, attached hereto as Ex. E.

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serious adverse events were available.[11] FDA has explained that "[t]he data from these three clinical trials . . . constitute substantial evidence that Mifeprex is safe and effective for its approved indication in accordance with the [FDCA]."[12] FDA also considered: (1) results from other European trials from the 1980s and 1990s in which mifepristone was studied alone or in combination with misoprostol or similar drugs; (2) a European postmarket safety database of over 620,000 women who used medication to terminate a pregnancy, approximately 415,000 of whom had received a mifepristone/misoprostol regimen[13]; and (3) data on the drug's chemistry and manufacturing.[14]

67. Despite the strong findings on the safety and efficacy of Mifeprex from clinical trials and European post-market experience, FDA originally approved Mifeprex under Subpart H of the FDCA regulations (the predecessor to the REMS statute) and imposed "restrictions to assure safe use"—a restricted

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[11] *Id.* at 5.

[12] 2016 FDA Letter to Am. Ass'n of Pro-Life Obstetricians & Gynecologists, Christian Medical & Dental Ass'ns, and Concerned Women for Am. denying 2002 Citizen Petition, Docket No. FDA-2002-P0364 (Mar. 29, 2016) (Citizen Petition Denial) at 8, Mar. 29, 2016, attached hereto as Ex. F.

[13] *Id.* at 8.

[14] Ex. E, supra n.11.

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distribution system—as a condition of approval.[15] For example, FDA imposed an in-person dispensing requirement (later "ETASU C," pursuant to 21 U.S.C. § 355-1(f)(3)(C)) and permitted the drug to be dispensed only in a hospital, clinic, or medical office, by or under the supervision of a "certified provider" (discussed more below), who at that time could only be a physician. FDA also imposed a prescriber-certification ETASU (later "ETASU A," pursuant to 21 U.S.C. § 355-1(f)(3)(A)), which prohibited health care providers from prescribing the drug unless they first attested to their clinical abilities in a signed form kept on file by the manufacturer, and agreed to comply with reporting and other REMS requirements. FDA also imposed a Patient Form ETASU (later "ETASU D," pursuant to 21 U.S.C. § 355-1(f)(3)(D)), requiring the prescriber and patient to review and sign a special form with information about the mifepristone regimen and risks, and required the prescriber to provide the patient with a copy and place a copy in the patient's medical record. The same information contained in the patient form is also included in the "Medication Guide" that is part of the FDA-approved labeling provided to patients with mifepristone.

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[15] Although the Subpart H regulations are sometimes referred to as FDA's "accelerated approval" regulations, FDA has explained elsewhere that its 2000 approval of Mifeprex, which occurred more than four years after the new drug application was submitted to FDA, did not involve an accelerated review.

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68. FDA's decision to subject Mifeprex to an ETASU under Subpart H was highly unusual. In the fifteen years from 1992 (the year the Subpart H regulations were promulgated) to February 2007 (just before the creation of the REMS statute), only seven NDAs, including Mifeprex, were approved subject to ETASU under Subpart H.[16] By comparison, FDA approved 961 NDAs with no additional restrictions in the roughly thirteen years from January 1993 to September 2005.[17]

69. The Food and Drug Administration Amendments Act of 2007 effectively replaced Subpart H of the FDCA regulations with the REMS statute. All drugs previously approved under Subpart H—including Mifeprex—were deemed by the Amendments Act to have a REMS in place. Following passage of the 2007 FDCA, Mifeprex continued to be subject to the same ETASU as before.

70. In 2011, FDA issued a new REMS for Mifeprex incorporating the same restrictions under which the drug was approved eleven years earlier.

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[16] *Id.* at 27.

[17] U.S. Gov't Accountability Off., *New Drug Development: Science, Business, Regulatory, and Intellectual Property Issues Cited as Hampering Drug Development Efforts*, GAO-07-49, 20 (Nov. 2006), http://www.gao.gov/assets/gao-07-49.pdf.

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71. In 2013, FDA reviewed the existing REMS and reaffirmed the restrictions already in place.[18]

72. In May 2015, Mifeprex's manufacturer (Danco) submitted a supplemental NDA proposing to update the label to reflect evidence-based practice across the country—mainly, the use of 200 mg of mifepristone instead of 600 mg. In July 2015, Danco also submitted its statutorily required REMS assessment, proposing minor modifications.

73. This submission prompted a review of the Mifeprex label and REMS by FDA in 2015-2016. As part of that review, FDA received letters from more than 40 medical experts, researchers, advocacy groups, and professional associations who asked, *inter alia*, that the REMS be eliminated in their entirety.

74. Signatories requesting that FDA eliminate the Mifeprex REMS included the American College of Obstetricians and Gynecologists (ACOG), the leading professional association of physicians specializing in the health care of women, which represents 58,000 physicians and partners in women's health; the American Public Health Association (APHA), the nation's leading public health organization; the Director of Stanford University School of Medicine's Division of Family Planning Services and Research; the Chair of the Department of Obstetrics and Gynecology at the University of New Mexico School of Medicine;

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[18]FDA Final Risk Evaluation and Mitigation Strategy (REMS) Review (Oct. 10, 2013), attached hereto as Ex. G.

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and the Senior Research Demographer in the Office of Population Research at Princeton University.

75. As one letter explained: "Although the FDA may have decided 15 years ago that the balance of risk and burden came out in favor of restricting mifepristone's indicated use and distribution, today both science and the current conditions surrounding patient access to abortion care call strongly for a reevaluation of the mifepristone label and REMS restrictions, especially its Elements to Assure Safe Use (ETASU)."[19] In asking FDA to "[e]liminate the REMS and ETASU for mifepristone," the letter specifically asked FDA to, among other things, (i) "[e]liminate the Prescriber Agreement certification requirement" and (ii) "remove the confusing and unnecessary Patient Agreement."[20]

76. The signatory organizations explained that the Prescriber Agreement certification requirement should be eliminated, because, among other things[21]:

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[19]Letter from SFP, *et al.*, to Stephen Ostroff, M.D., Robert M. Califf, M.D., & Janet Woodcock, M.D., 1 (Feb. 4, 2016) (SFP Letter to FDA), attached hereto as Ex. H.

[20]*Id.* at 2–4.

[21]*Id.* at 3.

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a. "*The Prescriber's Agreement is unnecessary for the safe dispensation of mifepristone*. . . . [H]ealth care professionals are already subject to many laws, policies, and ordinary standards of practice that ensure they can accurately and safely understand and prescribe medications. Provider certification is not required for health care professionals to dispense other drugs, including drugs that carry black box, or boxed, warnings about their medical risks. Accutane, for example, has a boxed warning that describes the potential risks of the drug, but Accutane prescribers are not required to submit a certification form in order to prescribe it. Mifeprex also has a boxed warning and there is no medical reason for a Prescriber's Agreement to be required in addition."

b. "*The Prescriber's Agreement forces providers to identify themselves as abortion providers to a centralized entity (Danco Laboratories) inspected and regulated by the FDA, which could discourage some from offering medication abortion care to their patients*. In 2014, more than half of U.S. health care facilities that provide abortions (52%) experienced threats and other types of targeted intimidation, and one in five experienced severe violence, such as blockades, invasions, bombings, arsons, chemical attacks, physical violence, stalking, gunfire, bomb threats, arson threats, or death threats. Robert Dear's November 27, 2015, standoff at a Planned Parenthood health center in Colorado, which resulted in three deaths, provides one recent and chilling example of anti-abortion violence. Given such escalating harassment and violence against known abortion providers, clinicians may be understandably reluctant to add their names to a centralized database of mifepristone providers."

c. "*The Prescriber's Agreement would be incompatible and unnecessary if there were an expanded distribution system*. If dispensing venues are expanded as proposed . . . ordinary standards of practice and state regulations would govern pharmacists' and providers' distribution of mifepristone, and a specific certification process would be unnecessary. Furthermore, a distribution system that incorporates the Prescriber's Agreement would be extremely difficult to maintain as a practical matter. Pharmacists would need to check the certification status of each prescriber before filling a prescription, which they do not normally have to do when filling other prescriptions."

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77. The organizations also argued that the Patient Agreement was unnecessary, explaining: "This requirement is medically unnecessary and interferes with the clinician-patient relationship. It should be eliminated entirely."[22]

78. The letter also urged FDA to "[c]onsider the current legal and social climate," explaining that "[t]he overall legal and social climate around abortion care intensifies all of the burdens that the mifepristone REMS places on patients and makes it even more critical that the FDA lift medically unnecessary restrictions on the drug."[23] The letter concludes:

> Mifepristone continues to hold immense promise for patient access to a safe and effective early abortion option, but medically unnecessary regulations are impeding its full potential. Extensive scientific and clinical evidence of mifepristone's safety and efficacy, and the ever-increasing burden on patient access to abortion care, clearly demonstrate that mifepristone's REMS program is not needed to protect patients. In light of the FDA's statutory mandate from Congress to consider the burden caused to patients by REMS, and the agency's own stated commitment to ensuring that the drug restrictions do not unduly burden patient access, we ask that the FDA lift mifepristone's REMS . . . .[24]

79. FDA summarized these "Advocacy Group Communications" as follows:

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[22] *Id.* at 4.

[23] *Id.* at 5.

[24] *Id.* at 6.

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> The Agency received three letters from representatives from academia and various professional organizations . . . . In general, these advocates requested FDA to revise labeling in a manner that would reflect current clinical practice, including the new dose regimen submitted by the Sponsor, and proposing to extend the gestational age through 70 days. Other requests were that the labeling not require that the drug-taking location for both Mifeprex and misoprostol be restricted to the clinic, and that labeling not specify that an in-person follow-up visit is required. The advocates also requested that any licensed healthcare provider should be able to prescribe Mifeprex and that the REMS be modified or eliminated, to remove the Patient Agreement and eliminate the prescriber certification, while allowing Mifeprex to be dispensed through retail pharmacies.[25]

80. A multidisciplinary FDA review team considered the requested changes. This review concluded that "no new safety concerns have arisen in recent years, and that the known serious risks occur rarely," and that "[g]iven that the numbers of . . . adverse events appear to be stable or decreased over time, it is likely that . . . serious adverse events will remain acceptably low."[26]

81. Following the multidisciplinary review team's analysis, FDA made several changes to Mifeprex's indication, labeling, and REMS. Relying on safety and efficacy data from multiple studies, FDA increased the gestational age limit from 49 to 70 days.[27] FDA also reduced the number of required in-person clinic

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[25]FDA, Ctr. for Drug Evaluation & Research, 020687Orig1s020, Cross Discipline Team Leader Review 25 (Mar. 29, 2016), attached as Ex. I.

[26]Ex. B (FDA 2016 Medical Review) at 9, 39, 47, 49.

[27]The overwhelming majority (80%) of abortions occur within the first 70 days (10 weeks) of pregnancy. Katherine Kortsmit, et al., *Abortion Surveillance*

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visits to one (whereas patients had previously been required to visit a clinic setting twice in order to receive the medication). FDA determined that at-home administration of misoprostol is safe because multiple studies showed that administration of the drug was "associated with exceedingly low rates of serious adverse events" and because administering misoprostol at home would more likely result in patients being in an "appropriate and safe location" when cramping and bleeding caused by the drug would begin.[28] FDA also found no significant difference in outcomes based on whether patients had follow-up appointments via phone call or in-person or based on the timing of those appointments. Additionally, FDA allowed a broader set of healthcare providers, rather than only physicians, to prescribe mifepristone, finding no serious risk to patients from expanding the types of healthcare providers who could become

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– *United States, 2020*, 71 CDC Morbidity & Mortality Weekly Report 10 at 12 (Nov. 25, 2022), https://www.cdc.gov/mmwr/volumes/71/ss/pdfs/ss7110a1-H.pdf.

[28]U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Research, 020687Orig1s020, Mifeprex Summary Review at 15 (Mar. 29, 2016) (2016 Summary Review), attached hereto as Ex. J.

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certified under the 2016 REMS.[29] But FDA still required that mifepristone, the first drug in the regimen, be administered in a clinic setting.

82. In addition, FDA expert review team and the Director of FDA's Center for Drug Evaluation and Research recommended eliminating the Patient Agreement Form because it contains "duplicative information already provided by each healthcare provider or clinic," "does not add to safe use conditions," and "is a burden for patients."[30] But they were overruled by the FDA Commissioner, who directed the Form be retained.[31] FDA retained the in-person dispensing requirement and provider certification as well.

83. In 2019, FDA approved a different manufacturer's abbreviated new drug application for a generic version of mifepristone. When it approved the

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[29]U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Research, 020687Orig1s020, Mifeprex REMS (Mar. 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020RemsR.pdf (hereinafter 2016 REMS).

[30]Ex. J (2016 Summary Review) at 25.

[31]U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Research, 020687Orig1s020, Mifeprex Risk Assessment and Risk Mitigation Review(s): Letter from Janet Woodcock, M.D., Ctr. for Drug Evaluation & Research, Regarding NDA 020687, Supp 20, 1 (Mar. 28, 2016) (hereinafter "Woodcock Patient Agreement Memo"), attached hereto as Ex. K.

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abbreviated NDA, FDA also established the Mifepristone REMS Program, which covers both Mifeprex and the generic.

84. In May 2020, the American College of Obstetricians and Gynecologists sued FDA, challenging the Mifepristone REMS Program's in-person dispensing requirement in light of the COVID-19 pandemic. *See Am. Coll. of Obstetricians & Gynecologists v. FDA*, 472 F. Supp. 3d 183 (D. Md. 2020), *stayed by FDA v. Am. Coll. of Obstetricians & Gynecologists*, 141 S. Ct. 578, 578 (2021) (mem.). Over FDA's objection that "based on FDA's scientific judgment, the In-Person Requirements are necessary to assure safe use of mifepristone and thus to protect patients' safety," *id.* at 228, the U.S. District Court for the District of Maryland preliminarily enjoined the in-person dispensing requirements, allowing healthcare providers to forgo it based on their medical judgment for the duration of the declared COVID-19 public health emergency. *Id.* at 233.

85. In April 2021, FDA suspended the in-person dispensing requirement during the COVID-19 public health emergency because, during the six-month period in which the in-person dispensing requirement had been enjoined, the availability of mifepristone by mail showed no increases in serious patient safety concerns. Thereafter, FDA commenced a formal REMS review.

86. Finally, on January 3, 2023, FDA modified the REMS by, *inter alia*, removing the in-person dispensing requirement entirely. However, as discussed

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further below, the Mifepristone REMS continue to impose both the Prescriber Agreement Form and the Patient Agreement Form. The 2023 REMS also added a new pharmacy-certification requirement.[32]

C. The Safety of Mifepristone

87. Mifepristone is extremely safe and effective for terminating early pregnancies.

88. As discussed above, FDA's approval of mifepristone in 2000 rested on a comprehensive evaluation of the scientific data, and FDA reasonably determined, in its expert judgment, that the evidence showed mifepristone is safe and effective for abortion of early pregnancy.

89. When FDA conducted another medical review of mifepristone in 2016 (based on the then 2.5 million uses of Mifeprex for medication abortion in the U.S. since the drug's 2000 approval) it found: "[Mifeprex] has been increasingly used as its efficacy and safety have become well established by both research and experience, and serious complications have proven to be extremely

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[32]FDA Risk Evaluation and Mitigation Strategy (REMS) Single Shared System for Mifepristone 200 MG (2023 REMS), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2023_01_03_REMS_Full.pdf, attached hereto as Ex. L.

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rare."[33] FDA observed at that time that "[m]ajor adverse events . . . are reported rarely in the literature on over 30,000 patients. The rates, when noted, are exceedingly rare, *generally far below 0.1%* for any individual adverse event."[34] The Agency further stated that "[t]he safety profile of Mifeprex is well-characterized and its risks well-understood after more than 15 years of marketing. Serious adverse events are rare and the safety profile of Mifeprex has not substantially changed."[35] Since that 2016 medical review, mifepristone has

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[33]Ex. B (FDA 2016 Medical Review) at 12; *see also* U.S. Food & Drug Admin., Full Prescribing Information for Mifeprex 7–8, Tables 1 & 2 (approved Mar. 2016), https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf ("Mifeprex Labeling"), attached hereto as Ex. M.

[34]Ex. B (FDA 2016 Medical Review) at 47 (emphasis added); *see also* Ex. M (Mifeprex Labeling) at 8, Table 2; *see also* Kelly Cleland et al., Significant Adverse Events and Outcomes After Medical Abortion, 121 OBSTETRICS & GYNECOLOGY 166, 166 (2013) ("Medical research has consistently demonstrated that mifepristone is safe and effective and that adverse events and outcomes are exceedingly rare, occurring in less than a fraction of 1% of cases.").

[35]U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Research, 020687Orig1s020, Mifeprex Risk Assessment and Risk Mitigation Review(s):

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been used an additional 3 million times in the United States for medication abortion.

90. From the time mifepristone was approved in 2000, there have only been 28 reported associated deaths out of 5.6 million uses—an associated fatality rate of .00005%.[36] Further, FDA acknowledges that *none* of these deaths can be causally attributed to mifepristone. The 28 reported deaths were included in the adverse events summary "regardless of causal attribution to mifepristone" and included cases of homicide, drug overdose, ruptured ectopic pregnancy, and sepsis (a life-threatening immune response to an infection).[37] And in its 2016 review, FDA noted that, while roughly half the deaths to that point were associated with Clostridial septic infections, "[t]here have been no Clostridial septic deaths reported in the US since 2009."[38]

91. In other cases of fatal infections associated with mifepristone, FDA has acknowledged that "the critical risk factor" is not mifepristone but

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REMS Modification Memorandum at 3 (Mar. 29, 2016) (hereinafter 2016 REMS Modification Memorandum), attached hereto as Ex. N.

[36]Ex. A (Mifepristone U.S. Post-Marketing Adverse Events Summary).

[37]*Id.*

[38]*Id.*

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"pregnancy itself," as similar infections "have been identified both in pregnant women who have undergone medical abortion and those who have not[.]"[39]

92. The specific serious complications identified in the FDA-approved labeling for Mifeprex are "Serious and Sometimes Fatal Infections or Bleeding." But the labeling specifies that such "serious and potentially life-threatening bleeding, infections, or other problems can occur following a miscarriage, surgical abortion, medical abortion or childbirth"—in other words, any time after the pregnant uterus is emptied—and that "[n]o causal relationship between the use of MIFEPREX and misoprostol and [infections and bleeding] has been established."[40]

D. The January 2023 Mifepristone REMS

93. Despite this undisputed evidence of safety and effectiveness, FDA continues to impose a 2023 REMS with ETASU for mifepristone.

94. The current REMS was approved in January 2023 (the 2023 REMS).[41]

95. The 2023 REMS imposes three primary hurdles to accessing mifepristone. Two of these are continuing restrictions and the third is a new

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[39]Ex. F at 26 n.69.

[40]Ex. M (Mifeprex Labeling) at 2, 16.

[41]Ex. L (2023 REMS).

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restriction. Each hurdle unduly restricts mifepristone access without any corresponding medical benefit.

96. ***First,*** the REMS continues to provide that mifepristone can only be prescribed by a health care provider who has undergone a "special[] certif[ication]" process in which they attest that they can accurately date a pregnancy, diagnose an ectopic pregnancy, and provide surgical intervention or referral in the event of any complications.[42] This "special certification" must be submitted to each certified pharmacy to which a provider intends to submit Mifreprex prescriptions, and must also be submitted to the distributor if a prescriber intends to dispense in-office.

97. For many healthcare providers, becoming specially certified is unduly burdensome and raises safety concerns. Some providers are deterred by the unusual step of having to become certified to prescribe the medication; others, misled by mifepristone's REMS designation, misperceive it is a dangerous medication or out of the prescriber's scope of practice; and still others are not comfortable having their names compiled in a list of medication abortion prescribers for fear that they or their families may be targeted by anti-abortion activists. This fear is particularly acute for doctors who hold medical licenses in multiple states (with abortion laws different from the Plaintiff States'), and for medical residents in the Plaintiff States who intend to eventually practice in a

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[42]Mifepristone Prescriber Agreement Forms, attached as Ex. O.

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state that heavily restricts abortion. These concerns, which FDA was made aware of as far back as 2016, are heightened now due to the growing criminalization and penalization of abortion, including laws that subject health care providers to criminal penalties and significant monetary liability.

98. ***Second,*** although the 2023 REMS allows mifepristone to be dispensed directly by pharmacies (as opposed to being dispensed by a provider in a healthcare clinic, as prior REMS required), the REMS unnecessarily requires dispensing pharmacies to be "specially certified" by the drug's sponsor.[43]

99. Special certification requires pharmacies to verify that mifepristone prescriptions are written only by "certified" providers and to adhere to additional burdensome communication, recordkeeping, and training requirements beyond what is required for the vast majority of prescription drugs. Under the REMS, a pharmacy cannot dispense mifepristone to a patient until it confirms that the provider who wrote the prescription is specially certified.[44] This hurdle creates new costs and administrative burdens for pharmacies—and worse, threatens unnecessary delay patients seeking time-sensitive medication.

100. Further, by limiting mifepristone dispensing to "certified" pharmacies, the REMS requires healthcare providers to track which pharmacies are certified to dispense mifepristone, rather than allowing patients to select their

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[43]Mifepristone Pharmacy Agreement Forms, attached as Ex. P.

[44]*Id.*

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pharmacy of choice. And the reverse is true as well—pharmacies that wish to dispense mifepristone must go through the added step of confirming that each mifepristone prescription comes from a "specially certified" provider.

101. ***Third***, the 2023 REMS retains the requirement that each patient sign a Patient Agreement Form in order to receive a mifepristone prescription.[45] This form, among other things, requires a patient to certify: "I have decided to take mifepristone and misoprostol to end my pregnancy."[46] This Patient Agreement Form must be signed by both the patient and provider, a copy must be placed into the patient's medical record, and a copy must be given to the patient along with the Medication Guide.

102. This Patient Agreement Form creates significant privacy and safety issues for both patients and providers. It specifically identifies the patient as taking the medication for the purpose of ending their pregnancy—as opposed to, for instance, miscarriage management, for which the medication is also frequently prescribed. Anyone who obtains access to the patient's medical record will thus have evidence that the patient received the medication for abortion, which is a particular concern for patients who receive care from a provider in a state where abortion is legal but reside in a state where abortion is illegal. Making matters worse, for patients who receive mifepristone for miscarriage

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[45]Mifepristone Patient Agreement Form, attached as Ex. Q.

[46]*Id.*

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management, the evidence will be false. The form also identifies the provider to anyone who obtains access to the patient's medical record or sees the copy of the form that must be provided to the patient—potentially including, for example, a patient's spouse, partner, or parent. This exposes providers and patients to threats of potential violence, threats of legal liability (even when the care provided is lawful in the relevant Plaintiff State), or other life-altering consequences. On top of that, because patients who take the medication for miscarriage management are also required to sign the Patient Agreement Form, it may be traumatizing for individuals experiencing a miscarriage to nonetheless have to attest that they are "decid[ing]" to "end [their] pregnancy."

103. None of the harms caused by the Patient Agreement Form is necessary, as the information contained on the form is duplicative of the information already provided to patients in the five-page Medication Guide that accompanies mifepristone. The comprehensive Medication Guide answers questions such as: "What symptoms should I be concerned with?"; "Who should not take Mifepristone tablets?"; "What should I tell my healthcare provider before taking Mifepristone tablets?"; "How should I take Mifepristone tablets?"; and "What are the possible side effects of Mifepristone tablets?"[47] The Patient Agreement Form is also duplicative of provider counseling, as medical

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[47]Mifepristone Medication Guide, attached as Ex. R.

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ethics require providers to counsel patients on the risks and benefits of all medications.

104. ***In sum***, although the 2023 REMS improved on the prior REMS by dropping the requirement to dispense mifepristone in person, the REMS nonetheless retains unduly burdensome, harmful, and unnecessary dispensing and prescribing requirements, continues to expose providers and patients to unnecessary privacy and safety risks, and creates new hurdles that further burden an already overstretched health care system.

E. The 2023 REMS Violate the FDCA

105. FDA's imposition of the burdensome 2023 REMS requirements is contrary to the FDCA.

106. As noted above, FDA may impose an ETASU on a medication only if the medication is "associated with a serious adverse drug experience," which the statute defines as one that "results in" death or "immediate risk of death," "inpatient hospitalization or prolongation of existing hospitalization," "persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions," or "a congenital anomaly or birth defect," or that "may jeopardize the patient and may require a medical or surgical intervention to prevent [such] an outcome . . . ." 21 U.S.C. §§ 355-1(f)(1)(A), (b)(4)(A)–(B). And an ETASU may be imposed only where "required . . . to mitigate a specific serious risk" of a serious adverse drug experience, and only where such risk is sufficiently severe

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that absent the ETASU, FDA would not approve or would withdraw approval of the medication. *Id.* §§ 355-1(b)(5), (f)(1)(A).

107. Mifepristone does not meet these stringent standards because it is not "associated with a serious adverse drug experience." To the contrary, FDA itself has concluded that serious adverse events following mifepristone use are "exceedingly rare."[48]

108. Since mifepristone was approved in 2000, there have been only 28 reported associated deaths out of 5.6 million uses—an associated fatality rate of .00005%. And not a single one of these deaths can be causally attributed to mifepristone.[49] By contrast, thousands of deaths have been associated with phosphodiesterase type-5 inhibitors for the treatment of erectile dysfunction (e.g., Viagra)—which are not subject to a REMS.[50] And "other drugs with higher

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[48]Ex. B (FDA 2016 Medical Review) at 47; *see also* Ex. A (Mifepristone U.S. Post-Marketing Adverse Events Summary).

[49]*Id.*

[50]Advancing New Standards in Reproductive Health , *Analysis of Medication Abortion Risk and the FDA report "Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2018"*, Mifepristone safety: Issue Brief (Apr. 2019), https://www.ansirh.org/sites/default/files/publications/files/mifepristone_safety_4-23-2019.pdf.

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complication rates, such as acetaminophen, aspirin, loratadine, and sildenafil, do not have REMS restrictions[.]"[51]

109. Moreover, the ETASU violates the FDCA's requirement that such restrictions not be "*unduly burdensome* on patient access to the drug, considering in particular . . . patients in rural or medically underserved areas," and must "minimize the burden on the health care delivery system[.]" 21 U.S.C. §§ 355-1(f)(2)(C)–(D) (emphasis added).[52]

110. As explained in more detail below, the 2023 REMS significantly burdens patient access to mifepristone without *any* appreciable safety benefits. These burdens fall particularly heavily on rural patients in the Plaintiff States because the vast majority of "specially certified" providers practice in cities. Plus, with a number of states imposing severe restrictions on access to abortion care that used to be constitutionally protected, many patients in these medically underserved areas of the country are turning to Plaintiff State providers for this care. This is particularly pronounced in Plaintiff States sharing borders with states

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[51]2018 Congress of Delegates, *Resolution No. 506 (Co-Sponsored C) – Removing Risk Evaluation and Mitigation Strategy (REMS) Categorization on Mifepristone*, Am. Acad. Of Fam. Physicians (2019), https://www.reproductiveaccess.org/wp-content/uploads/2019/02/Resolution-No.-506-REMS.pdf.

[52]*Supra* n.52.

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that allow little to no access—for example, in Washington, Oregon, and Nevada, which border Idaho, in Illinois, which borders Missouri and Indiana, and in New Mexico, which borders Texas. Against this backdrop, the 2023 REMS significantly and unduly burdens health care delivery in the Plaintiff States by imposing substantial, unjustified burdens on health care providers, clinics, pharmacies, and hospitals.

F. The 2023 REMS Are Unsupported by Science

111. The 2023 REMS requirements are not supported by scientific evidence.

112. First, the Patient Agreement Form remains in place even though the team of expert reviewers at FDA's Center for Drug Evaluation and Research (CDER) unanimously recommended eliminating it in 2016 because it is duplicative of informed consent laws and standards, "does not add to safe use conditions[,] . . . and is a burden for patients."[53] But this team of experts was overruled by the agency head.[54]

113. Similarly, the requirement that clinicians certify that they are competent to prescribe mifepristone provides no additional safety benefit beyond the numerous existing laws and safety standards already in place to ensure health care providers practice only within their competency. The certification

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[53]Ex. H (2016 Summary Review) at 25.

[54]Ex. I (Woodcock Patient Agreement Memo) at 1.

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requirement is also out of step with how FDA regulates other, less safe medications. Physicians are allowed to prescribe countless higher-risk drugs without first attesting to their competency to make an accurate diagnosis or provide follow-up care in the event of a complication.

114. The REMS requirement that pharmacies, too, must be "specially certified" in order to dispense mifepristone is similarly baseless. It requires pharmacies to confirm they have met the unnecessary provider-certification requirement before filling prescriptions, affords no patient safety benefits on top of the laws and standards governing the practice of pharmacy, and, instead, acts as a significant barrier to patient access to a time-sensitive medication.

115. Accordingly, the mifepristone REMS is opposed by leading medical organizations, including the American College of Obstetricians and Gynecologists (ACOG), the American Academy of Family Physicians (AAFP), and the American Medical Association (AMA).

116. Since at least 2016, ACOG's position has been "that a Risk Evaluation and Mitigation Strategy (REMS) is no longer necessary for mifepristone, given its history of safe use. The REMS requirement is inconsistent

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with requirements for other drugs with similar or greater risks, especially in light of the significant benefit that mifepristone provides to patients."[55]

117. And since at least 2018, AAFP's position has been that the REMS restrictions "are not based on scientific evidence"; are overly burdensome on practitioners and impede patient access to care, particularly "for patients who might prefer to go to their own physician and for rural patients who have no other access points beyond their local physician"; cause "delays in care, thereby increasing second-trimester and surgical abortions, both of which have increased complication rates"; and create "a barrier to safe and effective off-label uses of mifepristone, such as for anti-corticoid treatment of Cushing's disease, term labor induction, and miscarriage management[.]"[56]

118. In a June 21, 2022, letter to FDA Commissioner Califf, ACOG and AMA urged the Agency to "eliminate the requirement for patients to sign a form to get the drug" and "lift the requirement that prescribers acquire a certification from the manufacturer," noting that "[b]arriers to accessing mifepristone do not

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[55]Advocacy and Health Policy, *ACOG Statement on Medication Abortion*, ACOG (Mar. 30, 2016) https://www.acog.org/news/news-releases/2016/03/acog-statement-on-medication-abortion.

[56]*Supra* n.52.

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make care safer, are not based on medical evidence, and create barriers to patient access to essential reproductive health care."[57]

119. Further, in 2022, ACOG, along with 48 other organizations, submitted a citizen petition to FDA seeking to add miscarriage management as an indication to the drug's label, to eliminate or modify the REMS for that use, and more generally requesting the removal of the mifepristone REMS.[58]

120. The petition asked that "the Patient Agreement Form be removed entirely because it is medically unnecessary and repetitive of informed consent, as a previous review conducted by [FDA Center for Drug Evaluation and Research] determined in 2016."[59]

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[57]Letter from Maureen G. Phipps, Am. Coll. of Obstetricians & Gynecologists, to Robert Califf, MD (Jun. 21, 2022), https://searchlf.ama-assn.org/letter/documentDownload?uri=/unstructured/binary/letter/LETTERS/lfdr.zip/2022-6-21-Joint-ACOG-AMA-Letter-to-FDA-re-Mifepristone.pdf.

[58]Citizen Petition from Am. Coll. of Obstetricians & Gynecologists to Lauren Roth, Assoc. Comm'r for Pol'y, U.S. FDA (Oct. 4, 2022), https://emaaproject.org/wp-content/uploads/2022/10/Citizen-Petition-from-the-American-College-of-Obstetrician-and-Gynecologists-et-al-10.3.22-EMAA-website.pdf.

[59]*Id.* at 12.

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121. ACOG further explained that "the Certified Provider Requirement serves no benefit to patient safety," but is instead "redundant and unnecessary."[60] Moreover, ACOG noted that the provider-certification requirement has disproportionately affected rural patients because "clinicians who have already navigated mifepristone REMS compliance to provide abortion care . . . are almost always located in cities."[61] Making matters worse, "rural residents are more likely to lack access to OBGYNs, meaning that surgical management is also less likely to be an option."[62] Moreover, "clinicians might have reasonable reservations about opting into a prescription system that could, if their certification were leaked, suggest they were an abortion provider and open them up to violence and harassment."[63]

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[60] *Id.* at 13.

[61] *Id.* at 14 (citing Bearak JM, Burke KL, Jones RK. *Disparities and change over time in distance women would need to travel to have an abortion in the USA: a spatial analysis*. Lancet Public Health. 2017; 2:e493–500 and Committee on Health Care for Underserved Women. *Health Disparities in Rural Women. American College of Obstetricians and Gynecologists.* Obstet Gynecol. 2014;123:384-388).

[62] *Id.* (citation omitted).

[63] *Id.*; *see also id.* ("Research has shown that without certification, more clinicians would prescribe mifepristone.") (citing Neill S, Goldberg AB, Janiak

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122. The ACOG's citizen petition also urged FDA not to include a pharmacy-certification requirement because "research . . . suggests that the pharmacy requirement is unnecessary to ensure that mifepristone's benefits outweigh its risks and unduly burden[s] access."[64] The petition pointed specifically to a study "conducted . . . in California and Washington state suggest[ing] that pharmacies are already equipped to dispense the drug without

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E., *Medication management of early pregnancy loss: the impact of the US Food and Drug Administration Risk Evaluation and Mitigation Strategy* [A289]. Obstet Gynecol. 2022 May;139: 83S; Calloway D, Stulberg DB, Janiak E. *Mifepristone restrictions and primary care: Breaking the cycle of stigma through a learning collaborative model in the United States.* Contraception. 2021 July; 104(1):24-28; *Mokashi M, Boulineaux C, Janiak E, Boozer M, Neill S. "There's only one use for it": stigma as a barrier to mifepristone use for early pregnancy loss in Alabama*. [A31]. Obstet Gynecol. 2022 May:139:9S-10S; and Razon N, Wulf S, Perez C, McNeil S, Maldonado L, et al. *Exploring the impact of mifepristone's risk evaluation and mitigation strategy (REMS) on the integration of medication abortion into US family medicine primary care clinics.* Contraception 2022;109(5):19-24).

[64] *Id.* at 15.

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special certification."[65] "As with the certified provider requirement," ACOG noted, "the burdens associated with the certified pharmacy requirement will also fall disproportionately on poor and rural [patients], contrary to the REMS statute."[66]

123. Finally, as ACOG pointed out, recent scholarship demonstrates that removing the REMS restrictions does not negatively affect patient safety:

> After Canada removed all restrictions on prescribing mifepristone for abortion, thereby allowing it to be prescribed and dispensed like any other drug ("normal prescribing"), there was no increase in complications from mifepristone use. [A] 2022 study . . . found no difference in the rate of any complication (0.67% vs. 0.69%) or in the rate of serious adverse events (0.03% vs. 0.04%) between the ten-month period when mifepristone was distributed with REMS-like restrictions and the twenty-eight-month period of normal prescribing after all such restrictions were lifted and mifepristone was prescribed with no special self-certification and dispensed routinely from pharmacies.[67]

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[65] *Id.* (citing Grossman D, Baba CF, Kaller S, Biggs MA, Raifman S, et al. *Medication abortion with pharmacist dispensing of mifepristone.* Obstet Gynecol 2021;137(4):613-622).

[66] *Id.* at 16.

[67] *Id.* at 17 (citing Schummers L, Darling EK, Dunn S, McGrail K, Gayowsky A, et al. *Abortion Safety and Use with Normally Prescribed Mifepristone in Canada*. N Engl J Med. 2022 Jan 6;386(1):57-67.)

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124. FDA rejected ACOG's citizen petition.[68]

125. In fact, FDA has repeatedly rejected the concerns raised by leading medical organizations and retained the medically unfounded REMS restrictions: renewing them in 2016,[69] 2019,[70] 2021,[71] and yet again in 2023.[72] FDA retained these restrictions notwithstanding its periodic reviews of the post-marketing data, which have not identified any new safety concerns with the use of mifepristone for medical termination of pregnancy through 70 days' gestation (10 weeks).[73]

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[68]U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Research, Letter from Patrizia Cavazzoni, M.D., Regarding Docket No. FDA-2022-P-2425, (Jan. 3, 2023), https://www.regulations.gov/document/FDA-2022-P-2425-0003, attached hereto as Ex. S.

[69]Danco Labs., LLC, Mifeprex REMS (Mar. 2016), https://www.fda.gov/media/164649/download.

[70]Danco Labs., LLC, Mifepristone REMS (Apr. 2019), https://www.fda.gov/media/164650/download.

[71]Danco Labs., LLC, Mifepristone REMS (May 2021), https://www.fda.gov/media/164651/download.

[72]Ex. L (2023 REMS).

[73]U.S. Food & Drug Admin., *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation* (Jan. 4, 2023), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-

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126. Even as mifepristone has remained subject to the unduly burdensome REMS restrictions, a less safe mifepristone product for the treatment of Cushing's syndrome has been available for over a decade with no similar restrictions. In 2012, FDA approved Korlym (mifepristone) tablets, 300 mg, as treatment for Cushing's syndrome *without* a REMS.[74] This was done even though, as FDA noted in its 2016 Medical Review, Korlym "is taken in higher doses, in a chronic, daily fashion unlike the single 200 mg dose of Mifeprex . . . [and] the rate of adverse events with Mifeprex is much lower."[75] Patients who are prescribed Korlym take one to four pills *daily*—which is 1.5 to 6 times the recommended dose for Mifeprex.[76]

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providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation.

[74]HHS, Food & Drug Admin., Ctr. for Drug Evaluation & Research, *Application Number: 202107Orig1s000, Approval Letter* (Feb. 17, 2012), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/202107Orig1s000Approv.pdf.

[75]Ex. B (2016 Medical Review) at 10.

[76]U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Research, *Application Number*: *202107Orig1s000, Labeling* (Feb. 17, 2012), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/202107Orig1s000Lbl.pdf.

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127. The risks associated with mifepristone are also lower than those of many other common medications, such as Viagra, Tylenol, anticoagulants (blood thinners), and penicillin. Again, since 2000, mifepristone has been used 5.6 million times with only 28 reported associated deaths, none of which can be causally attributed to mifepristone.[77] And in nearly all cases of fatal infections associated with mifepristone, FDA has acknowledged that "the critical risk factor" is not mifepristone but "pregnancy itself," as similar infections "have been identified both in pregnant women who have undergone medical abortion and those who have not[.]"[78]

128. By contrast, as the American Academy of Family Physicians has noted, "other drugs with higher complication rates, such as acetaminophen, aspirin, loratadine, and sildenafil, do not have REMS restrictions[.]"[79]

129. Medications for erectile dysfunction have a mortality rate more than six times greater than mifepristone, and penicillin has a mortality rate three times greater than mifepristone.[80]

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[77]Ex. A (Mifepristone U.S. Post-Marketing Adverse Events Summary).

[78]Ex. F at 26.

[79]*Supra* n.52.

[80]Greer Donley, *Medication Abortion Exceptionalism*, 107 CORNELL L. REV. 627, 651–52 (2022).

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130. Likewise, acetaminophen (Tylenol) toxicity is the most common cause of liver transplantation in the U.S. and is responsible for 56,000 emergency department visits, 2,600 hospitalizations, and 500 deaths per year in the United States.[81]

131. But none of these drugs is subject to a REMS.

132. And even though opioids are highly addictive and cause tens of thousands of fatalities per year from overdoses, the opioid REMS does not require providers to do anything; it only requires that opioid manufacturers *offer* optional training to healthcare providers who prescribe opioids, who may or may not choose to take it. FDA acknowledges that "[t]here is no mandatory federal requirement that prescribers or other [health care providers] take the training and no precondition to prescribing or dispensing opioid analgesics to patients."[82]

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[81]Suneil Agrawai and Babek Khazaeni, *Acetaminophen Toxicity*, National Library of Medicine (Aug. 1, 2022), https://www.ncbi.nlm.nih.gov/books/NBK441917/#:~:text=It%20is%20responsible%20for%2056%2C000,is%20contained%20in%20combined%20products.

[82]Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS), U.S. FOOD & DRUG ADMIN. (Sept. 2018), https://www.fda.gov/drugs/information-drug-class/opioid-analgesic-risk-evaluation-and-mitigation-strategy-rems.

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133. Mifepristone use is also far safer than continuing a pregnancy. A person who carries a pregnancy to term is at least fourteen times more likely to die than a person who uses mifepristone to end a pregnancy.[83] Unequal access to adequate health care exacerbates the risk for those with less privilege. For example, Black women are three to four times more likely than white women to die a pregnancy-related death in the U.S.[84]

134. The two risks listed on the mifepristone label are also associated with many common obstetrical and gynecological procedures, such as vaginal delivery, surgical or medical miscarriage management, or insertion of an intrauterine long-acting reversible contraceptive (IUD). As the Mifeprisone Medication Guide acknowledges: "Although cramping and bleeding are an

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[83]Elizabeth G. Raymond & David E. Grimes, *The Comparative Safety of Legal Induced Abortion and Childbirth in the United States*, 119 Obstetrics & Gynecology 215, 215 (2012).

[84]Elizabeth A. Howell, MD, MPP, *Reducing Disparities in Severe Maternal Morbidity and Mortality*, 61:2 Clinical Obstetrics & Gynecology 387, 387 (2018); *see also* Claire Cain Miller, Sarah Kliff, Larry Buchanan, *Childbirth is Deadlier for Black Families Even When They're Rich, Expansive Study Finds*, N.Y. Times (Feb. 12, 2023), https://www.nytimes.com/interactive/2023/02/12/upshot/child-maternal-mortality-rich-poor.html?smid=url-share.

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expected part of ending a pregnancy, rarely, serious and potentially life-threatening bleeding, infections, or other problems can occur following a *miscarriage*, *surgical abortion*, medical abortion, or *childbirth*." (Emphasis added.)[85]

G. The 2023 REMS Unduly Burdens Access to Healthcare

135. The mifepristone REMS have significantly impeded access to abortion care. And the 2023 REMS is even more unduly burdensome than prior REMS in light of dramatically restricted access to care across the United States.

136. Even before *Dobbs v. Jackson Women's Health Organization*, 142 S. Ct. 2228 (2022), only a small fraction of counties in the United States had a clinician providing surgical abortions.[86] Mifepristone offers the possibility of vastly increased access to care by enabling primary care physicians to integrate abortion care into the services they provide. But the mifepristone REMS impedes the availability of medication abortion care, and so abortion care remains beyond

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[85]Ex. R (Mifepristone Medication Guide).

[86]Na'amah Razon, Sarah Wulf, et al., *Exploring the impact of mifepristone's risk evaluation and mitigation strategy (REMS) on the integration of medication abortion into US family medicine primary care clinics*, 109 Contraception 19 (May 2022), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9018589/.

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the reach of many—even in states like the Plaintiff States in which abortion care is lawful and protected in various ways.[87]

137. According to one recent study, approximately 40 percent of "family physicians interviewed . . . either named or described the REMS criteria as a barrier to providing medication abortion."[88] These family physicians explained that "the REMS impede their ability to provide medication abortion within primary care" because they "require substantial involvement of clinic administration, who can be unsupportive," and because "[t]he complexity of navigating the REMS results in physicians and clinic administration . . . viewing medication abortion as not worth the effort, since it is only a small component of services offered in primary care."[89]

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[87] *Id.*

[88] *Id.*

[89] *Id.*; *see also* Sara Neill, MD, et al., *Medication Management of Early Pregnancy Loss: The Impact of the U.S. Food and Drug Administration Risk Evaluation and Mitigation Strategy* (describing a survey of obstetrician-gynecologists in which "[n]early all interviewees (17 of 19, 89%) listed the REMS as a barrier to mifepristone use. Barriers included [the] belief that the REMS indicated mifepristone was not available to general ob-gyns . . . and concerns about signing the required prescriber agreement").

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138. Another recent study of primary care physicians and administrators noted that "[a]bortion with mifepristone is safe and effective" and "falls well within the scope of primary care in the United States, as it involves patient assessment and health education for which primary care providers are extensively trained." But, the article concluded, the REMS are the "linchpin of a cycle of stigmatization that continues to keep mifepristone out of primary care practice."[90]

139. This, in turn, harms patients. Under the REMS, a person who turns to their trusted health care provider—often a family doctor or primary care physician—for a medication abortion cannot obtain that care unless the clinician is specially certified (or is willing to become specially certified), and either the clinician has arranged to stock the drug or a pharmacy serving the patient's area has also gone through the process to be specially certified. This is so even though that same provider can simply write the same patient a prescription for misoprostol, the second drug in FDA's approved regimen for medication abortion, or virtually any other prescription drug that the clinician deems medically appropriate—and a pharmacy can simply dispense it—without the need for any special certifications.

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[90]Danielle Calloway, Debra B Stulberg, & Elizabeth Janiak, *Mifepristone restrictions and primary care: Breaking the cycle of stigma through a learning collaborative model in the United States*, 104 Contraception 24 (July 2021).

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140. Forcing patients to go to "specifically certified" providers, as opposed to their primary care or family physicians, disrupts continuity of care, stigmatizes routine health care, and discourages patients from making the best healthcare choices for themselves and their families. This burden is especially harsh for patients whose access to healthcare is already diminished by poverty, language barriers, lack of transportation, racial discrimination, or other factors. And it is particularly burdensome given the limited time window in which medication abortion is available.

141. This results in worse health outcomes for patients who might otherwise rely on mifepristone to safely terminate their pregnancies, but are unable to obtain a medication abortion given the limited number of REMS-certified prescribers or pharmacies.

142. Some patients will effectively be unable to access abortion, and will carry an unwanted pregnancy to term, due to the limited number of providers who are able to prescribe mifepristone because of the REMS. A landmark study shows that patients denied abortion are more likely to: experience serious complications from the end of pregnancy, including eclampsia and death; stay tethered to abusive partners; suffer anxiety and loss of self-esteem in the short term after

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being denied abortion; and experience poor physical health for years after the pregnancy, including chronic pain and gestational hypertension.[91]

143. Still others will opt for surgical abortion, which FDA describes as a more "invasive medical procedure that increases health risks for some patients and that may be otherwise inaccessible to others."[92] As FDA acknowledges, access to mifepristone is particularly critical "[f]or patients for whom mifepristone is the medically indicated treatment because of the patient's pre-existing health condition."[93]

144. "For example," FDA has explained:

> surgical abortion involves anesthesia, but people who are allergic to anesthesia can experience a sudden drop in blood pressure with cardiorespiratory arrest, and death. And . . . patient populations for whom medication abortion is more appropriate than a surgical abortion include patients who are survivors of abuse, including rape and incest, for whom pelvic exams can recreate severe trauma, adolescent patients, who have not yet had a pelvic exam, and patients in the intensive care unit or trauma patients who have difficulty with the positioning required for suction D&C.

(Internal quotations and citations omitted.)[94]

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[91]Our Studies, *The Turnaway Study*, Advancing New Standards in Reproductive Health, https://www.ansirh.org/research/ongoing/turnaway-study.

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

[93]*Id.* at 39.

[94]*Id.*

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145. Moreover, FDA itself has repeatedly confirmed and re-confirmed that mifepristone is safe and effective. According to FDA, mifepristone provides a "meaningful therapeutic benefit to patients" as compared to other treatments.

146. By unduly burdening patients' access to mifepristone through the 2023 REMS, FDA deprives patients of the therapeutic benefit of the drug without any scientific basis.

H. Injury to the Plaintiff States and Their Residents

Washington

147. The State of Washington's injuries exemplify those of other Plaintiff States caused by the mifepristone REMS.

148. In Washington, mifepristone is a critical medicine for providing safe and effective abortion care as well as for supporting miscarriage management.

149. In 2021 (the most recent year for which complete data is available), there were 15,358 abortions in Washington. Of those, 9,060—59%—were medication abortions using mifepristone. Fewer than 0.1% of mifepristone abortions in 2021 resulted in a complication that required hospitalization.

150. Washington providers have been hindered in providing care, and patients have been hindered in receiving care, due to the mifepristone REMS. The 2023 REMS requirements pose substantial challenges to providers and patients, and have resulted in significant expenses for state institutions, including the University of Washington (UW).

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151. The State of Washington, through the UW, its largest institution of higher education, operates UW Medicine, a group of multiple public and private nonprofit entities sharing the mission to improve the health of the public. This includes the UW's two campuses of the University of Washington Medical Center, the UW Medicine Primary Care Clinics, the UW Medical School, and through a contract with King County, Harborview Medical Center. As an owner and operator of medical facilities that provide reproductive health care services and pharmacies that dispense mifepristone, Washington is subject to and harmed by the January 2023 REMS.

152. At the UW, for instance, implementation of the 2023 REMS requirements is currently being overseen by a subcommittee of more than 20 UW physicians, administrators, and staff. To date, the subcommittee members have expended hundreds of hours on REMS implementation work, with many outstanding tasks still to complete. This is valuable time that these UW employees could otherwise spend treating patients, conducting research, or attending to other critical job functions.

153. One area in which UW has dedicated substantial resources is in its work to make the REMS-required Patient Agreement Form available to its telemedicine patients. The 2023 REMS continues to require that the Patient Agreement Form be signed by both the patient and a certified provider before a prescription can be filled by a certified pharmacy. Completing the form

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is usually a simple task in person, but it poses significant challenges in the telehealth setting. UW staff have worked more than 100 hours on both operational and technical elements to implement this REMS component, including making the Patient Agreement Form accessible to telemedicine patients in a HIPAA-compliant form and designing a method to securely transmit the form to the patient for their signature and then securely re-route the form back to the provider.

154. This work has been further complicated by the fact that some patients may not have access to or comfort with certain technologies (such as smartphones with scanning apps), making it challenging for UW to create a technology process that does not exacerbate inequities in patient access to abortion care.

155. Another area of significant time and expense has been implementation of the provider-certification requirement for telehealth providers. UW has hundreds of providers who are eligible to provide telehealth services. To ensure UW providers who may want to prescribe mifepristone are in compliance with the 2023 REMS requirements, UW is currently conducting outreach to ensure all interested, qualified providers are aware of the 2023 REMS requirements. UW operational staff then has to work with each provider who expresses an interest in prescribing mifepristone to ensure that the physician completes the Prescriber Agreement Form and transmits it to the UW Pharmacy.

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Providers then have to be trained on the new technology interfaces required for the Patient Agreement Form as well as the additional steps required in order to submit a mifepristone prescription for a medication abortion to a UW pharmacy. This outreach will likewise need to be done for UW's medical residents. This will require ongoing work as new healthcare providers and residents join UW.

156. UW has also had to devote significant time to designing electronic safeguards to help protect the safety of its providers. Some UW physicians, for instance, have expressed concern that by completing the Prescriber Agreement Form and having their name on a list of certified medication abortion prescribers, they could become a target of anti-abortion violence or harassment in the event the list were leaked or compromised.[95] Given the growing criminalization and

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[95]Abortion providers have long faced stigma, harassment, and violence. In 2021, 182 death threats were made against abortion providers. *See* National Abortion Federation, *2021 Violence & Disruption Statistics*, https://prochoice.org/wp-content/uploads/2021_NAF_VD_Stats_Final.pdf; *see also, e.g.*, U.S. Dep't of Justice, *Recent Cases on Violence Against Reproductive Health Care Providers* (Oct. 18, 2022), https://www.justice.gov/crt/recent-cases-violence-against-reproductive-health-care-providers; Megan Burbank, *Planned Parenthood awarded $110K after Spokane clinic protests*, CROSSCUT (Dec. 20, 2022), https://crosscut.com/news/2022/12/planned-parenthood-awarded-110k-after-spokane-clinic-protests]; Ted McDermott, *Windows smashed at Planned*

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penalization of abortion following the *Dobbs* decision, these concerns are further heightened for doctors who hold medical licenses in multiple states (including states where abortion laws differ from Plaintiff States') and for medical residents who later intend to practice in states where abortion is illegal or heavily restricted.[96] While UW is working hard to protect its providers—by, for example, creating additional interfaces so that a telehealth appointment for a medication

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Parenthood in Spokane Valley; suspect arrested, THE SPOKESMAN-REVIEW (July 5, 2021), https://www.spokesman.com/stories/2021/jul/05/windows-smashed-at-planned-parenthood-in-spokane-v/.

[96]Recognizing the reality of potential prosecution of Washington abortion providers, the Washington's Office of the Insurance Commissioner (OIC) recently approved coverage to reimburse physician policyholders for legal fees and expenses incurred in defending against a criminal action that comes from providing direct patient care, including abortions. As Insurance Commissioner Mike Kreidler explained, "As states like Texas threaten legal and criminal action against physicians, the OIC is determined to counter this by assisting medical malpractice insurers wherever we can." Press Release, Office of the Insurance Commissioner, New insurance coverage approved to help doctors who face criminal charges for providing legal abortions (Sept. 27, 2022), https://www.insurance.wa.gov/news/new-insurance-coverage-approved-help-doctors-who-face-criminal-charges-providing-legal.

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abortion can only be booked with a telehealth clinic (not a specific provider), thereby ensuring that an individual provider's name is not made available before the appointment—many physicians remain concerned about having to become a "certified prescriber" of medication abortion. The provider-certification requirement thus creates additional, unnecessary risks for Washington employees, providers, and residents that would not exist without the REMS. These risks have become exponentially higher in the post-*Dobbs* era, even as Washington continues to protect the right to choose and provide abortion care.

157. FDA recognizes such concerns, but disregarded them in issuing the 2023 REMS. FDA shields the identities of its own employees whose work relates to mifepristone to protect their health and safety, in light of the violence and harassment surrounding the provision of abortion.

158. The January 2023 REMS also places a significant burden on UW's pharmacies. Prior to the January 2023 REMS, UW pharmacies did not distribute mifepristone for medication abortion, as those medications had to be provided directly to the patient by the provider at an in-patient visit in a UW clinic (or, during the COVID-19 pandemic, by the provider via mail). With the easing of the in-patient and provider-only distribution requirements, UW is now working to stock mifepristone at both its inpatient pharmacies and through its mail-order pharmacy for its telehealth patients. But the requirements

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associated with becoming a certified pharmacy have created a significant additional workload for UW pharmacy team members.

159. Most significant is the requirement that UW pharmacies verify that each prescriber of mifepristone has a signed Prescriber Agreement Form on file with the pharmacy before a prescription can be filled. This has required extensive work by both UW operations and IT staff to determine how to host a dynamic list of certified providers in a secure but easily verifiable manner for UW pharmacy personnel.

160. Under the 2023 REMS program requirements, UW's pharmacies are also required to ensure that the drug is dispensed within four calendar days after the pharmacy receives the prescription (or the pharmacy must engage in additional consultation with the prescribing physician), which has required an additional workflow to ensure compliance. The same is true for the REMS requirement that authorized pharmacies record the National Drug Code (a unique identifier for drug packages) and lot number from each package of mifepristone dispensed. To date, UW pharmacy staff has expended approximately 80–100 hours on implementation work to comply with the 2023 REMS, and this work is not yet complete. The pharmacy needs additional hours to finalize these workflows and to train staff on the mifepristone REMS program requirements.

161. As demonstrated by the hundreds of hours being spent by UW physicians and staff to implement the 2023 REMS program requirements,

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compliance with the REMS program creates an expensive and substantial burden for Washington's hospitals, clinics and pharmacies. This is a financial and administrative burden that many hospitals, clinics, and pharmacies in Washington—particularly small or family-operated ones—cannot shoulder.

162. As a result, the 2023 REMS requirements unnecessarily limit the number of providers in Washington who can prescribe mifepristone and the patients' options for filling a mifepristone prescription. These unnecessary limitations, in turn, unduly burden access to mifepristone for Washington patients.

163. In eastern Washington, the student medical center at Washington State University (WSU), Cougar Health Services, has no REMS-certified providers nor is its campus pharmacy REMS-certified. WSU students seeking medication abortion cannot obtain medication abortion services at the student medical center or have a mifepristone prescription filled at the campus pharmacy, but are instead referred off-campus. This referral process is time-sensitive, requires many students to establish care at a new facility, and often creates undue stress for the student attempting to access care.

164. As the WSU example highlights, the harms caused by the REMS are particularly pronounced in central and eastern Washington, where access to abortion is already limited by a smaller density of providers and more rural population. Of the 20 eastern Washington counties, only nine have abortion

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providers. By irrationally limiting who may prescribe and dispense mifepristone, the REMS ensure that abortion care remains unavailable to many rural Washingtonians.

165. The REMS certification requirements pose particular hardships in eastern Washington for providers and pharmacies who serve patients from other states—including Idaho—or who may live in Idaho themselves. For these providers and pharmacists, putting themselves on a list of abortion providers raises serious concerns about criminal or civil liability under Idaho's draconian anti-abortion laws.

166. Moreover, the REMS pharmacy requirements also limit the number of specially certified pharmacies in Washington, thereby limiting drug availability for patients, particularly in rural communities underserved by large pharmacy chains. While mail-order prescriptions may be desirable for some, they may be infeasible or impossible for others, including patients experiencing housing insecurity; traveling from other states; close to the gestational limit; living in rural areas dependent on P.O. boxes for mail delivery—which are ineligible for mail-order prescriptions; or for whom receipt of abortion medication at home may trigger domestic violence or housing loss. For these patients, local pharmacy pick-up may be necessary—but unavailable due to the 2023 REMS requirements.

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167. For patients receiving medical care in Washington, the Patient Agreement Form creates an additional, unnecessary risk. While medical institutions and providers have enacted safeguards to ensure the safety and privacy of all medical records, the simple fact that a patient has an additional document in their medical record attesting to their medication abortion creates an added risk for patients—particularly for those patients who travel to Washington for medical treatment from states where the abortion would be illegal. Abortion providers have been targets for hackers seeking to steal information about both patients and providers. In 2021, for example, hackers accessed data about roughly 400,000 patients from Planned Parenthood Los Angeles.[97] Here in Washington, providers report frequent phishing attacks aimed at illegally obtaining information about patients and providers.

168. This risk is compounded by the fact that providers are required to provide patients with a copy of the Patient Agreement Form, which could, in turn, be found by a patient's spouse, partner, or parent (who might otherwise be unaware of the patient's medication abortion), potentially putting the patient at risk of violence or abuse. And the Patient Agreement Form is uniquely

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[97]Gregory Yee and Christian Martinez, *Hack exposes personal information of 400,000 Planned Parenthood Los Angeles patients*, LOS ANGELES TIMES (Dec. 1, 2021), https://www.latimes.com/california/story/2021-12-01/data-breach-planned-parenthood-los-angeles-patients.

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problematic for patients who receive mifepristone for miscarriage management, as they must falsely attest that they are "decid[ing] . . . to end [their] pregnancy" and then have that document placed into their medical record. And again, all of these risks are compounded for individuals traveling to Washington to receive care they cannot access in their home state.

Oregon

169. As in Washington, mifepristone is a critical medicine for providing safe and effective abortion care as well as for supporting miscarriage management in Oregon. The prescription and use of mifepristone with misoprostol is the standard of care for miscarriage management and medication abortion in Oregon.

170. According to state data for 2021, 4,246 medication abortions were administered by Oregon medical providers. Based on information available at the time of filing, it is likely that most of those medication abortions were effected with a mifepristone prescription.

171. Those 4,246 medication abortions constitute about 60 percent of abortions in Oregon in 2021. At the time of filing, the State of Oregon is not aware of any Oregon patient who has experienced serious adverse effects or death as the result of being prescribed and using mifepristone for miscarriage management or medication abortion.

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172. Oregon providers have been hindered in providing care, and patients have been hindered in receiving care, due to the mifepristone REMS. Medical providers, hospital administrators, and staff spend many hours implementing REMS requirements, including making Patient Agreement Forms available to patients and protecting the security of Provider Agreement Forms.

173. The REMS requirements also add to the amount of provider time required for each patient. Even at a conservative estimate of two to three minutes per patient, over a hundred—potentially hundreds—of provider hours are spent each year for the review, discussion, and signing of the Patient Agreement Forms. That is valuable time that those medical providers could otherwise spend treating patients or attending to other important work.

174. Those requirements are also duplicative of the counseling that Oregon providers already provide to their patients, namely in discussing risks and benefits, explaining the treatment and alternatives, and obtaining informed consent.

175. Oregon patients seeking care for miscarriage management have also experienced the same issues as similarly situated Washington patients. Namely, because the Patient Agreement Form is written specifically for the context of medication abortion, it requires them to inaccurately attest that they have decided to "end [their] pregnancy." That causes unnecessary confusion for those patients.

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176. In addition to the unnecessary (and sometimes frightening) confusion, the Patient Agreement Form has caused unwarranted additional anguish in some seeking care for miscarriage management. That is because the form does not distinguish between the use of mifepristone for miscarriage management and its use for the intentional termination of a pregnancy. Consequently, for those already dealing with the distress of losing a pregnancy, the medically unjustified REMS impose the additional emotional burden of requiring the patient to incorrectly attest that the pregnancy loss was intentional as a prerequisite for obtaining medically appropriate healthcare for their miscarriage.

177. The REMS requirements also reduce access to essential reproductive healthcare in Oregon. Namely, many rural providers in Oregon do not have the volume of patient care to justify the onerous steps required to comply with the REMS for mifepristone. As a result, rather than seek certification themselves, they often refer patients to other providers. That requires patients to see a second provider for something that their original provider otherwise could have handled quickly and safely, results in reduced patient choice, and also places the burden of additional patient loads on those certified providers that accept referrals.

178. And similar to Washington patients, the reduced access to essential reproductive health care results in additional delays to patients receiving

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healthcare. For example, it takes time for the patient to receive the referral from their primary provider. It takes time for the patient to establish care with the second provider. It can take additional time if the patient seeks in-person consultation and needs to travel for care. And it takes time for the patient to wait for any healthcare delays caused by the patient-load resulting from the number of referrals. Those are delays to healthcare for conditions for which time is of the essence. And those delays often contribute to patients having reduced availability of healthcare options and adverse effects to patient health.

Arizona

179. Access to safe and effective medication abortion is critically important for Arizonans. Arizonans experience harms as a result of the 2023 REMS that are similar to those experienced by residents of the Plaintiff States.

Colorado

180. The State of Colorado, through the University of Colorado, its largest institution of higher education, operates a woman's health clinic. As an owner and operator of a medical clinic that provides reproductive health care services and dispenses mifepristone, Colorado is subject to and harmed by the January 2023 REMS.

181. Providers and staff at the University of Colorado have expended time and resources complying with the 2023 REMS requirement, including developing and processing the Prescriber Agreement Form and the

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Patient Agreement Form. Further, the 2023 REMS prevent non-certified providers from prescribing mifepristone to their patients. As a result, those patients often must make additional clinic visits—sometimes at different locations—to obtain mifepristone.

182. Further, patients in Colorado suffer the same harms experienced by patients in other states outlined above and below.

Connecticut

183. Access to safe and effective medication abortion is critically important for Connecticut residents. Connecticut residents experience harms as a result of the 2023 REMS that are similar to those experienced by residents of the Plaintiff States.

Delaware

184. Like Washington, Delaware residents rely on mifepristone to access safe and effective abortion care and management of miscarriages. Analysis of data from 2014 to 2020 shows that Delawareans have increasingly relied on medication abortion for early pregnancy termination. In 2014, there were 2,937 abortions in Delaware. Of those, 1,292—44%—were medical abortions using mifepristone. In 2020 (the most recent year for which complete data is available), there were 2,281 abortions in Delaware. Of those, 1,492—65.4%—were medical abortions using mifepristone.

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185. Restricting access to mifepristone needlessly harms Delawareans who increasingly rely on it.

Illinois

186. In Illinois, mifepristone is a critical medicine for providing safe and effective abortion care as well as for supporting miscarriage management.

187. In 2020 (the most recent year for with public data), there were 46,243 reported abortions in Illinois. Of those, 23,765—51%—were medication abortions using mifepristone.

188. The mifepristone REMS requirements impede drug availability for Illinois residents by limiting the providers that can prescribe and the pharmacies that can dispense the medication, while creating additional barriers to patient access through the Patient Agreement Form requirement.

189. Limited access to abortion and miscarriage management medication increases other health care costs, including more expensive procedural or later-stage abortion care, emergency care, and care related to complications due to unwanted pregnancies, childbirth, and miscarriage.

190. A significant proportion of this cost is borne by the State, which is one of only 16 states that goes beyond federal Medicaid limits and uses state funds to cover abortion care for people enrolled in Medicaid. From January 2019 to May 2022, the State covered approximately 29,000 mifepristone prescriptions.

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191. State Medicaid reimbursement rates are higher for procedural abortions and abortions taking place later in gestation. The bundled State Medicaid reimbursement rate for medication abortion is $558. In contrast, the lowest rate for a procedural abortion is $798. Because the 2023 REMS requirements artificially limit the number of providers who can prescribe mifepristone and the pharmacies that can fill prescriptions, fewer people have access to mifepristone abortions. This restriction results in more higher-cost procedural abortions. Broad mifepristone access is a critical tool for addressing the financial impact on the State.

192. As Illinois's neighboring states have curtailed abortion access, Illinois has seen a 28% increase in abortions from April 2022 to August 2022, creating additional strain on Illinois providers and healthcare systems. The REMS certification requirements pose particular hardships for Illinois providers and pharmacies because Illinois is an abortion oasis in the Midwest and a significant portion of patients seeking abortion care in Illinois are traveling from Indiana, Missouri, and other nearby states where abortion is restricted. For these providers and pharmacists, as well as patients traveling from out of state, the REMS certification requirements and Patient Agreement Form create additional risks of civil or criminal liability.

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Attorney General of Michigan

193. Access to safe and effective medication abortion is critically important for Michiganders. Michiganders experience harms as a result of the 2023 REMS that are similar to those experienced by residents of the Plaintiff States.

Nevada

194. In Nevada, mifepristone is widely used in combination with misoprostol as a safe, effective, FDA-approved regimen for medication abortions. It is also used in the medical management of early pregnancy loss.

195. Medication abortions represent the largest share of pregnancy termination procedures performed in Nevada. From December 2021 to November 2022, 49% of all abortions performed in Nevada were medication abortions.

196. The Nevada Department of Health and Human Services, Division of Health Care Financing and Policy (DHHS) administers the Medicaid program in Nevada. It is responsible for ensuring high quality, cost-effective care to Medicaid recipients while maintaining compliance with federal Medicaid requirements.

197. Nevada Medicaid fee-for-service covers mifepristone.

198. The reduced availability of mifepristone will financially impact DHHS. Providers and patients will be forced to adopt alternatives including

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surgical abortions which are more invasive, costly, and can expose patients to higher health risks, e.g., excessive bleeding.

199. Since the *Dobbs* decision, Nevada has experienced a marked increase in out-of-state patients seeking abortion care in state. In 2021, Nevada experienced an average of 47 out-of-state patients per month over a six-month period. In the first half of 2022, the average increased to 55 out-of-state patients. Post-*Dobbs*, there was an immediate spike of 113 in July 2022, after which the average leveled to 80 out-of-state patients per month.

200. The reduced availability of mifepristone will financially burden Nevada reproductive healthcare providers attempting to service this increased patient load.

201. The Mifepristone REMS program imposes medically unnecessary barriers to the prescription, distribution, and use of mifepristone by Nevada clinicians and patients. The REMS Patient Agreement Form must be signed by both a patient and a certified provider before a prescription can be filled by a qualified pharmacy. This imposes a significant burden for telehealth patients or patients without access to smartphones or scanning apps.

202. A pharmacy can only become qualified by undergoing the REMS certification process which further limits the availability of mifepristone in Nevada.

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203. The barriers created by the REMS program disproportionately burden people of color, low-income families, and communities within Nevada's large rural regions whose residents would have to travel long distances to seek alternative reproductive healthcare services.

204. These barriers interfere with Nevada's inherent authority to provide for the health and welfare of its residents.

New Mexico

205. New Mexico's injuries are exemplified in the sections discussing Washington's and the other Plaintiff States' injuries.

206. New Mexico repealed its antiquated prohibition of abortion in 2021.[98]

207. Nonetheless, many communities in New Mexico—particularly the rural communities—do not currently have adequate access to reproductive health care services.

208. New Mexico's injuries are exacerbated by various local cities and counties in the State of New Mexico enacting ordinances attempting to regulate abortion, declaring unlawful the delivery of abortion medications, and creating a private cause of action against abortion clinics. New Mexico residents in these cities and counties, as well as in other rural communities in the State, are particularly subject to the harms described in this Complaint.

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[98]NMSA 1978, §§ 30-5-1 to -3 (repealed 2021).

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Rhode Island

209. In Rhode Island, mifepristone is a critical medicine for providing safe and effective abortion care as well as for supporting miscarriage management.

210. The mifepristone REMS requirements impede drug availability for Rhode Islanders by limiting the providers that can prescribe and the pharmacies that can dispense the medication, while creating additional barriers to patient access through the Patient Agreement Form requirement.

211. Limited access to abortion and miscarriage management medication increases other health care utilization costs, including emergency care, resulting from complications due to unwanted pregnancies, childbirth, and miscarriage. A significant proportion of this cost is borne by the state, in which over 30% of Rhode Islanders are enrolled in Medicaid.

212. Rhode Islanders are harmed when access to mifepristone is limited, including the emotional, financial, and social harms that individuals experience by having to carry an unwanted pregnancy to term or not having access to the benefit of miscarriage management medication.

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Vermont

213. Medication abortion is critically important for Vermonters. In 2019, 59% of abortions in Vermont were medication abortions; in 2020, that number rose to 75%.[99]

214. The harms that the REMS cause are particularly acute in Vermont because the state's rurality makes it difficult for many Vermonters to access providers. Less than a third of Vermont counties have abortion providers—meaning that 43% of women of reproductive age live in a county without an abortion provider.[100]

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[99]Agency of Human Services, *Vermont 2019 Vital Statistics: 135th Report Relating to the Registry and Return of Births, Deaths, Marriages, Divorces, and Dissolutions* at 139, Vermont Department of Health (June 2021), https://www.healthvermont.gov/sites/default/files/documents/pdf/HS-VR-2019VSB_final.pdf; Agency of Human Services, *Vermont 2020 Vital Statistics: 136th Report Relating to the Registry and Return of Births, Deaths, Marriages, Divorces, and Dissolutions* at 142, Vermont Department of Health (July 2022) https://www.healthvermont.gov/sites/default/files/documents/pdf/Vital%20Statistics%20Bulletin%202020.pdf.

[100]Jesse Philbin, et al., *10 US States Would Be Hit Especially Hard by a Nationwide Ban on Medication Abortion Using Mifepristone*, GUTTMACHER

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V. FIRST CAUSE OF ACTION
(Administrative Procedure Act—Agency Action in Excess of Statutory Authority and Contrary to Law)

215. The Plaintiff States reallege and incorporate by reference the allegations set forth in each of the preceding paragraphs of this Complaint.

216. FDA's promulgation of the mifepristone 2023 REMS was a final agency action that is causing the Plaintiff States irreparable harm for which the States have no other adequate remedy under 5 U.S.C. § 704.

217. This Court must "hold unlawful and set aside agency action" that is, *inter alia*, "not in accordance with law," "in excess of statutory jurisdiction, authority, or limitations," or "without observance of procedure required by law[.]" 5 U.S.C. § 706(2).

218. Through their actions described above, Defendants violated 5 U.S.C. § 706(2)(C) by acting in excess of statutory jurisdiction, authority, limitations, and short of statutory right in promulgating the mifepristone 2023 REMS.

INSTITUTE (Feb. 7, 2023), https://www.guttmacher.org/2023/02/10-us-states-would-be-hit-especially-hard-nationwide-ban-medication-abortion-using.

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VI. SECOND CAUSE OF ACTION
(Administrative Procedure Act—Arbitrary and Capricious Agency Action)

219. The Plaintiff States reallege and incorporate by reference the allegations set forth in each of the preceding paragraphs of this Complaint.

220. FDA's promulgation of the mifepristone 2023 REMS was a final agency action that is causing the Plaintiff States irreparable harm for which the States have no other adequate remedy under 5 U.S.C. § 704.

221. FDA's promulgation of the mifepristone 2023 REMS was arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law in violation of 5 U.S.C. § 706(2)(A).

VII. THIRD CAUSE OF ACTION
(Administrative Procedure Act—Action Contrary to Constitutional Right)

222. The Plaintiff States reallege and incorporate by reference the allegations set forth in each of the preceding paragraphs of this Complaint.

223. FDA's promulgation of the mifepristone 2023 REMS was a final agency action that is causing the Plaintiff States irreparable harm for which the States have no other adequate remedy under 5 U.S.C. § 704.

224. FDA's promulgation of the mifepristone 2023 REMS treated similarly situated parties differently without adequate justification, and therefore violates the constitutional guarantee of equal protection in violation of 5 U.S.C. § 706(2)(B).

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VIII. FOURTH CAUSE OF ACTION
(Equal Protection)

225. The Plaintiff States reallege and incorporate by reference the allegations set forth in each of the preceding paragraphs of this Complaint.

226. Through their actions described above, Defendants violate the equal protection guarantee of the Due Process Clause of the Fifth Amendment to the United States Constitution.

227. Through the 2023 REMS, FDA reduces access to a critical and time-sensitive health care service needed by pregnant people. And FDA treats providers, pharmacists, and patients who prescribe, dispense, or use mifepristone worse than providers, pharmacists, and patients who prescribe, dispense, or use nearly every other medication. FDA's actions are irrational and violate the Fifth Amendment under any standard of review.

IX. PRAYER FOR RELIEF

WHEREFORE, Washington, Oregon, Arizona, Colorado, Connecticut, Delaware, Illinois, Attorney General of Michigan, Nevada, New Mexico, Rhode Island, and Vermont pray that the Court:

a. Declare, pursuant to 28 U.S.C. § 2201, that mifepristone is safe and effective and that Defendants' approval of mifepristone is lawful and valid;

b. Declare, pursuant to 28 U.S.C. § 2201, that the mifepristone REMS violates the Administrative Procedure Act;

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c. Declare, pursuant to 28 U.S.C. § 2201, that the mifepristone REMS violates the United States Constitution;

d. Enjoin Defendants, pursuant to 28 U.S.C. § 2202, from enforcing or applying the mifepristone REMS;

e. Enjoin Defendants, pursuant to 28 U.S.C. § 2202, from taking any action to remove mifepristone from the market or reduce its availability; and

f. Award such additional relief as the interests of justice may require.

DATED this 23rd day of February 2023.

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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,

STATE OF IDAHO; STATE OF IOWA; STATE OF MONTANA; STATE OF NEBRASKA; STATE OF SOUTH CAROLINA; STATE OF TEXAS; STATE OF UTAH,

Plaintiffs-Intervenors,

Case No. 1:23-cv-03026

NOTICE OF APPEAL

The States of Idaho, Iowa, Montana, Nebraska, South Carolina, Texas, and Utah ("State Intervenors") hereby appeal to the United States Court of Appeals for the Ninth Circuit from the Order Denying State Intervenors' Motion to Intervene, Dkt. #104, entered April 21, 2023.

Pursuant to Ninth Circuit Rule 3-2, State Intervenors' Representation Statement is attached hereto.

Dated: April 26, 2023

/s/ Lincoln Davis Wilson

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CERTIFICATE OF SERVICE

I hereby certify that, on April 26, 2023, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

/s/ Lincoln Davis Wilson
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RULE 3-2 REPRESENTATION STATEMENT

Pursuant to Ninth Circuit Rule 3-2(b) and in satisfaction of Federal Rule of Appellate Procedure 12(b), State Intervenors provide the following statement of the parties to this appeal and their respective counsel:

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APPEAL,LC01

Eastern District of Washington
U.S. District Court (Yakima)
CIVIL DOCKET FOR CASE #: 1:23-cv-03026-TOR

State of Washington et al v. United States Food and Drug Administration et al
Assigned to: Judge Thomas O. Rice
Case in other court: Ninth Circuit, 23-35294
Cause: 5:702 Administrative Procedure Act - Right of Review

Date Filed: 02/23/2023
Jury Demand: None
Nature of Suit: 899 Other Statutes: Administrative Procedures Act/Review or Appeal of Agency Decision
Jurisdiction: U.S. Government Defendant

Date Filed	#	Docket Text
02/23/2023	1	COMPLAINT against All Defendants (Filing fee $ 402; Receipt # AWAEDC-4234043) Filed by All Plaintiffs. (Attachments: # 1 Exhibit Table of Contents, # 2 Exhibit A, # 3 Exhibit B, # 4 Exhibit C, # 5 Exhibit D, # 6 Exhibit E, # 7 Exhibit F, # 8 Exhibit G, # 9 Exhibit H, # 10 Exhibit I, # 11 Exhibit J, # 12 Exhibit K, # 13 Exhibit L, # 14 Exhibit M, # 15 Exhibit N, # 16 Exhibit O, # 17 Exhibit P, # 18 Exhibit Q, # 19 Exhibit R, # 20 Exhibit S, # 21 Summons FDA, # 22 Summons Califf, # 23 Summons HHS, # 24 Summons Becerra, # 25 Civil Cover Sheet)(Beneski, Kristin) (Entered: 02/23/2023)
02/23/2023		Notice of Judge Assignment. Judge Thomas O. Rice assigned to case. (TNC, Case Administrator) (Entered: 02/24/2023)
02/24/2023	2	MOTION for Leave to File Excess Pages *for Plaintiff States' Motion for Preliminary Injunction* by All Plaintiffs. Motion Hearing set for **3/27/2023** Without Oral Argument before Chief Judge Stanley A Bastian. (Attachments: # 1 Text of Proposed Order) (Beneski, Kristin) (Entered: 02/24/2023)
02/24/2023	3	MOTION for Preliminary Injunction by All Plaintiffs. Motion Hearing set for **3/27/2023** at **10:00 AM** in Yakima Courtroom 203 before Chief Judge Stanley A Bastian. (Attachments: # 1 Text of Proposed Order)(Beneski, Kristin) (Entered: 02/24/2023)
02/24/2023	4	DECLARATION by Plaintiff States in Support re 3 MOTION for Preliminary Injunction filed by All Plaintiffs. (Attachments: # 1 Exhibit 1-19)(Beneski, Kristin) (Entered: 02/24/2023)
02/24/2023	5	MOTION to Appear Pro Hac Vice re Attorney: YoungWoo Joh. Filing fee $ 200, receipt number AWAEDC-4234593. by State of Oregon. Motion Hearing set for **3/27/2023** Without Oral Argument before Chief Judge Stanley A Bastian. (Hull, Sander) (Entered: 02/24/2023)
02/24/2023	6	Summons Issued as to All Defendants. (Attachments: # 1 Summons US Department of Health and Human Services, # 2 Summons Robert Califf, # 3 Summons Xavier Becerra) (TNC, Case Administrator) (Entered: 02/24/2023)
02/24/2023	7	MOTION to Appear Pro Hac Vice re Attorney: Julia C. Harvey. Filing fee $ 200, receipt number AWAEDC-4234894 by State of Rhode Island ~~Washington~~. Motion Hearing set for **3/27/2023** Without Oral Argument before Chief Judge Stanley A Bastian. (Hughes,

		Andrew) Modified on 3/3/2023 to correct the filing party (LAS, Case Administrator). (Entered: 02/24/2023)
02/24/2023	8	NOTICE by All Plaintiffs re 2 MOTION for Leave to File Excess Pages *for Plaintiff States' Motion for Preliminary Injunction*, 3 MOTION for Preliminary Injunction (Beneski, Kristin) (Entered: 02/24/2023)
02/24/2023	9	PROOF OF SERVICE by All Plaintiffs re All Defendants. (Beneski, Kristin) (Entered: 02/24/2023)
02/24/2023	10	PROOF OF SERVICE by All Plaintiffs re All Defendants. (Beneski, Kristin) (Entered: 02/24/2023)
02/24/2023		Reset Motion Hearings for **3/27/2023** Without Oral Argument before Judge Thomas O. Rice re: 3 MOTION for Preliminary Injunction , 7 MOTION to Appear Pro Hac Vice re Attorney: Julia C. Harvey. 2 MOTION for Leave to File Excess Pages *for Plaintiff States' Motion for Preliminary Injunction*, 5 MOTION to Appear Pro Hac Vice re Attorney: YoungWoo Joh. (CLP, Case Administrator Team Lead) (Entered: 02/24/2023)
02/24/2023	11	CERTIFICATE OF SERVICE *re All Defendants* filed by All Plaintiffs. (Beneski, Kristin) (Entered: 02/24/2023)
02/27/2023	12	ORDER granting 2 Motion for Leave to File Excess Pages. Plaintiffs' Motion for Preliminary Injunction is accepted as filed. Signed by Judge Thomas O. Rice. TEXT ONLY ORDER; NO PDF WILL ISSUE. (BF, Paralegal) (Entered: 02/27/2023)
02/27/2023	13	ORDER granting 5 Motion for Leave to Appear Pro Hac Vice. Attorney YoungWoo Joh added for State of Oregon. Signed by Judge Thomas O. Rice. TEXT ONLY ORDER; NO PDF WILL ISSUE. (BF, Paralegal) (Entered: 02/27/2023)
02/27/2023	14	ORDER granting 7 Motion for Leave to Appear Pro Hac Vice. Attorney Julia C. Harvey added for State of Washington. Signed by Judge Thomas O. Rice. TEXT ONLY ORDER; NO PDF WILL ISSUE. (BF, Paralegal) (Entered: 02/27/2023)
02/28/2023	15	NOTICE of Appearance by Noah T Katzen on behalf of Xavier Becerra, Robert M Califf, United States Department of Health and Human Services, United States Food and Drug Administration (Attorney Noah T Katzen added to party Xavier Becerra(pty:dft), Attorney Noah T Katzen added to party Robert M Califf(pty:dft), Attorney Noah T Katzen added to party United States Department of Health and Human Services(pty:dft), Attorney Noah T Katzen added to party United States Food and Drug Administration(pty:dft))(Katzen, Noah) (Entered: 02/28/2023)
02/28/2023	16	MOTION for Extension of Time to File Response/Reply by Xavier Becerra, Robert M Califf, United States Department of Health and Human Services, United States Food and Drug Administration. Motion Hearing set for **3/30/2023** Without Oral Argument before Judge Thomas O. Rice. (Katzen, Noah) (Entered: 02/28/2023)
02/28/2023	17	Unopposed MOTION to Expedite by Xavier Becerra, Robert M Califf, United States Department of Health and Human Services, United States Food and Drug Administration. Motion Hearing set for **3/7/2023** Without Oral Argument before Judge Thomas O. Rice. (Katzen, Noah) (Entered: 02/28/2023)
03/01/2023	18	ORDER: For good cause shown, Defendants' 17 Unopposed Motion to Expedite is GRANTED. Plaintiffs shall file a response to Defendants' 16 Motion for Extension of Time no later than **March 6, 2023**. A hearing on the motion is set for **March 7, 2023** without oral argument. Signed by Judge Thomas O. Rice. TEXT ONLY ORDER - NO PDF ATTACHED. (HH, Law Clerk) (Entered: 03/01/2023)

03/01/2023		Set/Reset Motion Hearing as to 16 MOTION for Extension of Time to File Response/Reply. Motion Hearing set for **3/7/2023** without oral argument before Judge Thomas O. Rice. (HH, Law Clerk) (Entered: 03/01/2023)
03/01/2023	19	RESPONSE to Motion re 16 MOTION for Extension of Time to File Response/Reply filed by All Plaintiffs. (Beneski, Kristin) (Entered: 03/01/2023)
03/02/2023	20	ORDER: For good cause shown, Defendants' 16 Motion for Extension of Time is **GRANTED in part**. Defendants shall respond to Plaintiffs' 3 Motion for Preliminary Injunction on or before **3/17/2023**. Plaintiffs' Reply, if any, is due on or before **3/24/2023**. The hearing on the motion is RESET to **3/28/2023 at 8:30 AM** in Spokane Courtroom 902 before Judge Thomas O. Rice. Signed by Judge Thomas O. Rice. TEXT ONLY ORDER; NO PDF ATTACHED. (BF, Paralegal) (Entered: 03/02/2023)
03/02/2023		Reset Motion Hearing as to 3 MOTION for Preliminary Injunction. Motion Hearing reset for **3/28/2023 at 8:30 AM** in Spokane Courtroom 902 before Judge Thomas O. Rice. (BF, Paralegal) (Entered: 03/02/2023)
03/03/2023	21	MOTION to Appear Pro Hac Vice re Attorney: Aletheia Allen. Filing fee $ 200, receipt number AWAEDC-4240057, by State of New Mexico ~~Washington~~. Motion Hearing set for **4/3/2023** Without Oral Argument before Judge Thomas O. Rice. (Hughes, Andrew) Modified on 3/3/2023 to correct the filing party (CV, Courtroom Deputy). (Entered: 03/03/2023)
03/03/2023	22	MOTION to Appear Pro Hac Vice re Attorney: Eric R. Olson. Filing fee $ 200, receipt number AWAEDC-4240068. by State of Colorado. Motion Hearing set for **4/3/2023** Without Oral Argument before Judge Thomas O. Rice. (Hughes, Andrew) (Entered: 03/03/2023)
03/03/2023	23	MOTION to Appear Pro Hac Vice re Attorney: Michael D. McMaster. Filing fee $ 200, receipt number AWAEDC-4240182. by State of Colorado. Motion Hearing set for **4/3/2023** Without Oral Argument before Judge Thomas O. Rice. (Hughes, Andrew) (Entered: 03/03/2023)
03/03/2023	24	MOTION to Appear Pro Hac Vice re Attorney: Stephanie M. Service. Filing fee $ 200, receipt number AWAEDC-4240190. by Attorney General of Michigan. Motion Hearing set for **4/3/2023** Without Oral Argument before Judge Thomas O. Rice. (Hughes, Andrew) (Entered: 03/03/2023)
03/03/2023	25	MOTION to Appear Pro Hac Vice re Attorney: Luci D. Davis. Filing fee $ 200, receipt number AWAEDC-4240264. by State of Arizona. Motion Hearing set for **4/3/2023** Without Oral Argument before Judge Thomas O. Rice. (Hughes, Andrew) (Entered: 03/03/2023)
03/03/2023	26	MOTION to Appear Pro Hac Vice re Attorney: Daniel C. Barr. Filing fee $ 200, receipt number AWAEDC-4240270. by State of Arizona. Motion Hearing set for **4/3/2023** Without Oral Argument before Judge Thomas O. Rice. (Hughes, Andrew) (Entered: 03/03/2023)
03/06/2023	27	NOTICE of Appearance by Carla Scott on behalf of State of Oregon (Attorney Carla Scott added to party State of Oregon(pty:pla))(Scott, Carla) (Entered: 03/06/2023)
03/06/2023	28	NOTICE of Appearance *of Counsel* by Tera M Heintz on behalf of State of Washington (Attorney Tera M Heintz added to party State of Washington(pty:pla))(Heintz, Tera) (Entered: 03/06/2023)
03/07/2023	29	ORDER granting 21 Motion for Leave to Appear Pro Hac Vice. Attorney Aletheia Allen added for Plaintiff State of New Mexico. Signed by Judge Thomas O. Rice. TEXT ONLY

		ORDER; NO PDF WILL ISSUE. (BF, Paralegal) (Entered: 03/07/2023)
03/07/2023	30	ORDER granting 22 Motion for Leave to Appear Pro Hac Vice. Attorney Eric R. Olson added for Plaintiff State of Colorado. Signed by Judge Thomas O. Rice. TEXT ONLY ORDER; NO PDF WILL ISSUE. (BF, Paralegal) (Entered: 03/07/2023)
03/07/2023	31	ORDER granting 23 Motion for Leave to Appear Pro Hac Vice. Attorney Michael D. McMaster added for Plaintiff State of Colorado. Signed by Judge Thomas O. Rice. TEXT ONLY ORDER; NO PDF WILL ISSUE. (BF, Paralegal) (Entered: 03/07/2023)
03/07/2023	32	ORDER granting 24 Motion for Leave to Appear Pro Hac Vice. Attorney Stephanie M. Service added for Plaintiff Attorney General of Michigan. Signed by Judge Thomas O. Rice. TEXT ONLY ORDER; NO PDF WILL ISSUE. (BF, Paralegal) (Entered: 03/07/2023)
03/07/2023	33	ORDER granting 25 Motion for Leave to Appear Pro Hac Vice. Attorney Luci D. Davis added for Plaintiff State of Arizona. Signed by Judge Thomas O. Rice. TEXT ONLY ORDER; NO PDF WILL ISSUE. (BF, Paralegal) (Entered: 03/07/2023)
03/07/2023	34	ORDER granting 26 Motion for Leave to Appear Pro Hac Vice. Attorney Daniel C. Barr added for Plaintiff State of Arizona. Signed by Judge Thomas O. Rice. TEXT ONLY ORDER; NO PDF WILL ISSUE. (BF, Paralegal) (Entered: 03/07/2023)
03/09/2023	35	AMENDED COMPLAINT against All Defendants. Filed by All Plaintiffs.(Beneski, Kristin) (Entered: 03/09/2023)
03/09/2023	36	MOTION to Appear Pro Hac Vice re Attorney: Jill M. Graziano. Filing fee $ 200, receipt number AWAEDC-4244559. by Commonwealth of Pennsylvania. Motion Hearing set for **4/10/2023** Without Oral Argument before Judge Thomas O. Rice. (Hughes, Andrew) (Entered: 03/09/2023)
03/09/2023	37	MOTION to Appear Pro Hac Vice re Attorney: Jennifer Olson. Filing fee $ 200, receipt number AWAEDC-4244590. by State of Minnesota. Motion Hearing set for **4/10/2023** Without Oral Argument before Judge Thomas O. Rice. (Hughes, Andrew) (Entered: 03/09/2023)
03/09/2023	38	MOTION to Appear Pro Hac Vice re Attorney: Liz Kramer. Filing fee $ 200, receipt number AWAEDC-4244593. by State of Minnesota. Motion Hearing set for **4/10/2023** Without Oral Argument before Judge Thomas O. Rice. (Hughes, Andrew) (Entered: 03/09/2023)
03/09/2023	39	MOTION to Appear Pro Hac Vice re Attorney: Caitlyn G. McEllis. Filing fee $ 200, receipt number AWAEDC-4244596. by State of Illinois. Motion Hearing set for **4/10/2023** Without Oral Argument before Judge Thomas O. Rice. (Hughes, Andrew) (Entered: 03/09/2023)
03/09/2023	40	ORDER granting 36 Motion for Leave to Appear Pro Hac Vice. Attorney Jill M. Graziano added for Plaintiff Commonwealth of Pennsylvania. Signed by Judge Thomas O. Rice. TEXT ONLY ORDER; NO PDF WILL ISSUE. (BF, Paralegal) (Entered: 03/09/2023)
03/09/2023	41	ORDER granting 37 Motion for Leave to Appear Pro Hac Vice. Attorney Jennifer Olson added for Plaintiff State of Minnesota. Signed by Judge Thomas O. Rice. TEXT ONLY ORDER; NO PDF WILL ISSUE. (BF, Paralegal) (Entered: 03/09/2023)
03/09/2023	42	ORDER granting 38 Motion for Leave to Appear Pro Hac Vice. Attorney Liz Kramer added for Plaintiff State of Minnesota. Signed by Judge Thomas O. Rice. TEXT ONLY ORDER; NO PDF WILL ISSUE. (BF, Paralegal) (Entered: 03/09/2023)

03/09/2023	43	ORDER granting 39 Motion for Leave to Appear Pro Hac Vice. Attorney Caitlyn G. McEllis for Plaintiff State of Illinois. Signed by Judge Thomas O. Rice. TEXT ONLY ORDER; NO PDF WILL ISSUE. (BF, Paralegal) (Entered: 03/09/2023)
03/10/2023	44	MOTION to Appear Pro Hac Vice re Attorney: Nicole S. Hill. Filing fee $ 200, receipt number AWAEDC-4245466. by District of Columbia. Motion Hearing set for **4/10/2023** Without Oral Argument before Judge Thomas O. Rice. (Hughes, Andrew) (Entered: 03/10/2023)
03/10/2023	45	MOTION to Appear Pro Hac Vice re Attorney: Vanessa L. Kassab. Filing fee $ 200, receipt number AWAEDC-4245806. by State of Delaware. Motion Hearing set for **4/10/2023** Without Oral Argument before Judge Thomas O. Rice. (Hughes, Andrew) (Entered: 03/10/2023)
03/13/2023	46	ORDER granting 44 Motion for Leave to Appear Pro Hac Vice. Attorney Nicole S. Hill added for Plaintiff District of Columbia. Signed by Judge Thomas O. Rice. TEXT ONLY ORDER; NO PDF WILL ISSUE. (BF, Paralegal) (Entered: 03/13/2023)
03/13/2023	47	ORDER granting 45 Motion for Leave to Appear Pro Hac Vice. Attorney Vanessa L. Kassab added for Plaintiff Delaware. Signed by Judge Thomas O. Rice. TEXT ONLY ORDER; NO PDF WILL ISSUE. (BF, Paralegal) Modified on 4/28/2023 to correct the State. (LAS, Case Administrator). (Entered: 03/13/2023)
03/15/2023	48	Consent MOTION for Leave to File Excess Pages by Xavier Becerra, Robert M Califf, United States Department of Health and Human Services, United States Food and Drug Administration. Motion Hearing set for **4/14/2023** Without Oral Argument before Judge Thomas O. Rice. (Katzen, Noah) (Entered: 03/15/2023)
03/15/2023	49	Consent MOTION to Expedite by Xavier Becerra, Robert M Califf, United States Department of Health and Human Services, United States Food and Drug Administration. Motion Hearing set for **3/22/2023** Without Oral Argument before Judge Thomas O. Rice. (Katzen, Noah) (Entered: 03/15/2023)
03/16/2023	50	ORDER: For good cause shown, Defendants' 48 Consent Motion for Leave to File Excess Pages and 49 Consent Motion to Expedite are GRANTED. Defendants' response to Plaintiffs' 3 Motion for Preliminary Injunction shall not exceed 35 pages. Signed by Judge Thomas O. Rice. TEXT ONLY ORDER - NO PDF ATTACHED. (HH, Law Clerk) (Service of Notice on parties not registered as users of the Court CM/ECF system accomplished via USPS mail.) (Entered: 03/16/2023)
03/17/2023	51	MEMORANDUM of Points and Authorities in Opposition re 3 MOTION for Preliminary Injunction filed by Xavier Becerra, Robert M Califf, United States Department of Health and Human Services, United States Food and Drug Administration. (Attachments: # 1 Affidavit Katzen Declaration, # 2 Exhibit A, # 3 Exhibit B, # 4 Exhibit C, # 5 Exhibit D, # 6 Exhibit E, # 7 Exhibit F, # 8 Exhibit G, # 9 Exhibit H, # 10 Exhibit I, # 11 Exhibit J, # 12 Exhibit K)(Katzen, Noah) (Entered: 03/17/2023)
03/22/2023	52	MOTION for Leave to File *AMICUS CURIAE BRIEF* by Legal Voice. Motion Hearing set for **4/21/2023** Without Oral Argument before Judge Thomas O. Rice. (Attachments: # 1 Text of Proposed Order)(Beane, Amanda) (Entered: 03/22/2023)
03/22/2023	53	AMICUS BRIEF by Legal Voice. (Beane, Amanda) (Entered: 03/22/2023)
03/22/2023	54	MOTION for Leave to File Excess Pages *for Reply in Support of Motion for Preliminary Injunction* by All Plaintiffs. Motion Hearing set for **3/23/2023** Without Oral Argument before Judge Thomas O. Rice. (Beneski, Kristin) (Entered: 03/22/2023)

03/22/2023	55	MOTION to Expedite *Motion to Exceed Page Limits* by All Plaintiffs. Motion Hearing set for **3/23/2023** Without Oral Argument before Judge Thomas O. Rice. (Beneski, Kristin) (Entered: 03/22/2023)
03/23/2023	56	ORDER: For good cause shown, Plaintiffs' Unopposed 54 Motion for Leave to File Excess Pages and 55 Motion to Expedite are GRANTED. Plaintiffs' reply shall not exceed 17 pages. Signed by Judge Thomas O. Rice. TEXT ONLY ORDER - NO PDF ATTACHED. (HH, Law Clerk) (Entered: 03/23/2023)
03/23/2023	57	MOTION to Appear Pro Hac Vice re Attorney: Halliday Moncure. Filing fee $ 200, receipt number CWAEDC-4254390. by State of Maine. Motion Hearing set for **4/24/2023** Without Oral Argument before Judge Thomas O. Rice. (Hughes, Andrew) (Entered: 03/23/2023)
03/23/2023	58	ORDER granting 57 Motion for Leave to Appear Pro Hac Vice. Attorney Halliday Moncure added for Plaintiff State of Maine. Signed by Judge Thomas O. Rice. TEXT ONLY ORDER; NO PDF WILL ISSUE. (BF, Paralegal) (Entered: 03/23/2023)
03/24/2023	59	NOTICE of Appearance by Daniel M Weiskopf on behalf of American College of Obstetricians and Gynecologists, American Medical Association, Society for Maternal-Fetal Medicine, American Academy of Family Physicians, American Academy of Pediatrics, American College of Nurse-Midwives, American Gynecological and Obstetrical Society, American Society for Reproductive Medicine, Council of University Chairs of Obstetrics & Gynecology, North American Society for Pediatric and Adolescent Gynecology, Society of General Internal Medicine, Society of Gynecologic Oncology, Society of Gynecologic Surgeons, Society of OB/GYN Hospitalists, Washington State Medical Association (Attorney Daniel M Weiskopf added to party American College of Obstetricians and Gynecologists(pty:am), Attorney Daniel M Weiskopf added to party American Medical Association(pty:am), Attorney Daniel M Weiskopf added to party Society for Maternal-Fetal Medicine(pty:am), Attorney Daniel M Weiskopf added to party American Academy of Family Physicians(pty:am), Attorney Daniel M Weiskopf added to party American Academy of Pediatrics(pty:am), Attorney Daniel M Weiskopf added to party American College of Nurse-Midwives(pty:am), Attorney Daniel M Weiskopf added to party American Gynecological and Obstetrical Society(pty:am), Attorney Daniel M Weiskopf added to party American Society for Reproductive Medicine(pty:am), Attorney Daniel M Weiskopf added to party Council of University Chairs of Obstetrics & Gynecology(pty:am), Attorney Daniel M Weiskopf added to party North American Society for Pediatric and Adolescent Gynecology(pty:am), Attorney Daniel M Weiskopf added to party Society of General Internal Medicine(pty:am), Attorney Daniel M Weiskopf added to party Society of Gynecologic Oncology(pty:am), Attorney Daniel M Weiskopf added to party Society of Gynecologic Surgeons(pty:am), Attorney Daniel M Weiskopf added to party Society of OB/GYN Hospitalists(pty:am), Attorney Daniel M Weiskopf added to party Washington State Medical Association(pty:am))(Weiskopf, Daniel) (Entered: 03/24/2023)
03/24/2023	60	REPLY MEMORANDUM re 3 MOTION for Preliminary Injunction filed by All Plaintiffs. (Beneski, Kristin) (Entered: 03/24/2023)
03/24/2023	61	DECLARATION by Andrew Hughes in Support re 3 MOTION for Preliminary Injunction filed by All Plaintiffs. (Attachments: # 1 Exhibit A, # 2 Exhibit B, # 3 Exhibit C, # 4 Exhibit D, # 5 Exhibit E, # 6 Exhibit F, # 7 Exhibit G, # 8 Exhibit H, # 9 Exhibit I, # 10 Exhibit J, # 11 Exhibit K, # 12 Exhibit L, # 13 Exhibit M)(Beneski, Kristin) (Entered: 03/24/2023)
03/24/2023	62	DECLARATION by Karen Nelson in Support re 3 MOTION for Preliminary Injunction filed by All Plaintiffs. (Beneski, Kristin) (Entered: 03/24/2023)

03/24/2023	63	DECLARATION by Courtney Schreiber, M.D., M.P.H. in Support re 3 MOTION for Preliminary Injunction filed by All Plaintiffs. (Beneski, Kristin) (Entered: 03/24/2023)
03/24/2023	64	MOTION to Appear Pro Hac Vice re Attorney: Adam Aukand-Peck. Filing fee $ 200, receipt number AWAEDC-4256420. by American Academy of Family Physicians, American Academy of Pediatrics, American College of Nurse-Midwives, American College of Obstetricians and Gynecologists, American Gynecological and Obstetrical Society, American Medical Association, American Society for Reproductive Medicine, Council of University Chairs of Obstetrics & Gynecology, North American Society for Pediatric and Adolescent Gynecology, Society for Maternal-Fetal Medicine, Society of General Internal Medicine, Society of Gynecologic Oncology, Society of Gynecologic Surgeons, Society of OB/GYN Hospitalists, Washington State Medical Association. Motion Hearing set for **4/24/2023** Without Oral Argument before Judge Thomas O. Rice. (Attachments: # 1 Text of Proposed Order)(Weiskopf, Daniel) (Entered: 03/24/2023)
03/24/2023	65	MOTION to Appear Pro Hac Vice re Attorney: Jessica Morris. Filing fee $ 200, receipt number AWAEDC-4256443. by American Academy of Family Physicians, American Academy of Pediatrics, American College of Nurse-Midwives, American College of Obstetricians and Gynecologists, American Gynecological and Obstetrical Society, American Medical Association, American Society for Reproductive Medicine, Council of University Chairs of Obstetrics & Gynecology, North American Society for Pediatric and Adolescent Gynecology, Society for Maternal-Fetal Medicine, Society of General Internal Medicine, Society of Gynecologic Oncology, Society of Gynecologic Surgeons, Society of OB/GYN Hospitalists, Washington State Medical Association. Motion Hearing set for **4/24/2023** Without Oral Argument before Judge Thomas O. Rice. (Attachments: # 1 Text of Proposed Order)(Weiskopf, Daniel) (Entered: 03/24/2023)
03/24/2023	66	MOTION to Appear Pro Hac Vice re Attorney: Megan McGuiggan. Filing fee $ 200, receipt number AWAEDC-4256448. by American Academy of Family Physicians, American Academy of Pediatrics, American College of Nurse-Midwives, American College of Obstetricians and Gynecologists, American Gynecological and Obstetrical Society, American Medical Association, American Society for Reproductive Medicine, Council of University Chairs of Obstetrics & Gynecology, North American Society for Pediatric and Adolescent Gynecology, Society for Maternal-Fetal Medicine, Society of General Internal Medicine, Society of Gynecologic Oncology, Society of Gynecologic Surgeons, Society of OB/GYN Hospitalists, Washington State Medical Association. Motion Hearing set for **4/24/2023** Without Oral Argument before Judge Thomas O. Rice. (Attachments: # 1 Text of Proposed Order)(Weiskopf, Daniel) (Entered: 03/24/2023)
03/24/2023	67	MOTION to Appear Pro Hac Vice re Attorney: Molly Meegan. Filing fee $ 200, receipt number AWAEDC-4256450. by American Academy of Family Physicians, American Academy of Pediatrics, American College of Nurse-Midwives, American College of Obstetricians and Gynecologists, American Gynecological and Obstetrical Society, American Medical Association, American Society for Reproductive Medicine, Council of University Chairs of Obstetrics & Gynecology, North American Society for Pediatric and Adolescent Gynecology, Society for Maternal-Fetal Medicine, Society of General Internal Medicine, Society of Gynecologic Oncology, Society of Gynecologic Surgeons, Society of OB/GYN Hospitalists, Washington State Medical Association. Motion Hearing set for **4/24/2023** Without Oral Argument before Judge Thomas O. Rice. (Attachments: # 1 Text of Proposed Order)(Weiskopf, Daniel) (Entered: 03/24/2023)
03/24/2023	68	MOTION to Appear Pro Hac Vice re Attorney: Shannon R. Selden. Filing fee $ 200, receipt number AWAEDC-4256453. by American Academy of Family Physicians, American Academy of Pediatrics, American College of Nurse-Midwives, American College of Obstetricians and Gynecologists, American Gynecological and Obstetrical Society, American Medical Association, American Society for Reproductive Medicine,

		Council of University Chairs of Obstetrics & Gynecology, North American Society for Pediatric and Adolescent Gynecology, Society for Maternal-Fetal Medicine, Society of General Internal Medicine, Society of Gynecologic Oncology, Society of Gynecologic Surgeons, Society of OB/GYN Hospitalists, Washington State Medical Association. Motion Hearing set for **4/24/2023** Without Oral Argument before Judge Thomas O. Rice. (Attachments: # 1 Text of Proposed Order)(Weiskopf, Daniel) (Entered: 03/24/2023)
03/24/2023	69	Unopposed MOTION for Leave to File *Amicus Brief in Support of Plaintiffs' Amended Complaint and Motion for Preliminary Injunction* by American Academy of Family Physicians, American Academy of Pediatrics, American College of Nurse-Midwives, American College of Obstetricians and Gynecologists, American Gynecological and Obstetrical Society, American Medical Association, American Society for Reproductive Medicine, Council of University Chairs of Obstetrics & Gynecology, North American Society for Pediatric and Adolescent Gynecology, Society for Maternal-Fetal Medicine, Society of General Internal Medicine, Society of Gynecologic Oncology, Society of Gynecologic Surgeons, Society of OB/GYN Hospitalists, Washington State Medical Association. Motion Hearing set for **3/30/2023** Without Oral Argument before Judge Thomas O. Rice. (Attachments: # 1 Amicus Brief, # 2 Text of Proposed Order)(Weiskopf, Daniel) (Entered: 03/24/2023)
03/28/2023	70	Minute Entry for proceedings held before Judge Thomas O. Rice: Motion Hearing held on 3/28/2023. (Reported by: Allison Anderson) (BF, Paralegal) (Entered: 03/28/2023)
03/29/2023	71	Supplemental NOTICE by Xavier Becerra, Robert M Califf, United States Department of Health and Human Services, United States Food and Drug Administration (Katzen, Noah) (Entered: 03/29/2023)
03/30/2023	72	RESPONSE *to Notice of Supplemental Information* by All Plaintiffs. (Attachments: # 1 Appendix A)(Beneski, Kristin) (Entered: 03/30/2023)
03/30/2023	73	MOTION to Appear Pro Hac Vice re Attorney: Heidi Parry Stern. Filing fee $ 200, receipt number AWAEDC-4260631. by State of Nevada. Motion Hearing set for **5/1/2023** Without Oral Argument before Judge Thomas O. Rice. (Hughes, Andrew) (Entered: 03/30/2023)
03/30/2023	74	MOTION to Appear Pro Hac Vice re Attorney: Steven M. Sullivan. Filing fee $ 200, receipt number AWAEDC-4260645. by State of Maryland. Motion Hearing set for **5/1/2023** Without Oral Argument before Judge Thomas O. Rice. (Hughes, Andrew) (Entered: 03/30/2023)
03/30/2023	75	MOTION to Appear Pro Hac Vice re Attorney: Eleanor Spottswood. Filing fee $ 200, receipt number AWAEDC-4260649. by State of Vermont. Motion Hearing set for **5/1/2023** Without Oral Argument before Judge Thomas O. Rice. (Hughes, Andrew) (Entered: 03/30/2023)
03/30/2023	76	MOTION to Intervene by State of Idaho, State of Iowa, State of Montana, State of Nebraska, State of South Carolina, State of Texas, State of Utah. Motion Hearing set for **5/1/2023** Without Oral Argument before Judge Thomas O. Rice. (Attachments: # 1 Complaint)(Wilson, Lincoln) (Entered: 03/30/2023)
03/30/2023	77	MOTION to Appear Pro Hac Vice re Attorney: Joshua N. Turner. Filing fee $ 200, receipt number AWAEDC-4260708. by State of Idaho, State of Iowa, State of Montana, State of Nebraska, State of South Carolina, State of Texas, State of Utah. Motion Hearing set for **5/1/2023** Without Oral Argument before Judge Thomas O. Rice. (Wilson, Lincoln) (Entered: 03/30/2023)
04/04/2023	78	NOTICE OF FILING OF OFFICIAL TRANSCRIPT of Preliminary Injunction Motion Hearing. Proceedings held on 3/28/2023 in Spokane, Washington before Judge Thomas

		O. Rice. Page Numbers: 1 - 28 Parties have seven (7) business days to file with the court a Notice of Intent to Request Redaction of this transcript. If no such Notice is filed, the transcript may be made remotely electronically available to the public without redaction after 90 calendar days. Transcript may be viewed at the court public terminal or purchased through the Court Reporter/Transcriber before the deadline for Release of Transcript Restriction. After that date it may be obtained through PACER. Information regarding the policy can be found on the court website at www.waed.uscourts.gov. To purchase a copy of the transcript contact Court Reporter/Transcriber Allison Anderson at 509-458-3465 or Allison_Anderson@waed.uscourts.gov. Redaction Request due 4/25/2023. Redacted Transcript Deadline set for 5/5/2023. Release of Transcript Restriction set for 7/3/2023. (Anderson, Allison) (Entered: 04/04/2023)
04/06/2023	79	MOTION to Appear Pro Hac Vice re Attorney: Peter M. Torstensen, Jr.. Filing fee $ 200, receipt number AWAEDC-4265245. by State of Montana. Motion Hearing set for **5/8/2023** Without Oral Argument before Judge Thomas O. Rice. (Wilson, Lincoln) (Entered: 04/06/2023)
04/07/2023	80	ORDER denying ECF No. 52 Motion for Leave to File Amicus Curiae Brief; denying ECF No. 69 Motion for Leave to File Amicus Curiae Brief; granting in part and denying in part ECF No. 3 Motion for Preliminary Injunction. Signed by Judge Thomas O. Rice. (Entered: 04/07/2023)
04/10/2023	81	MOTION to Clarify by Xavier Becerra, Robert M Califf, United States Department of Health and Human Services, United States Food and Drug Administration. Motion Hearing set for **5/10/2023** Without Oral Argument before Judge Thomas O. Rice. (Katzen, Noah) (Entered: 04/10/2023)
04/10/2023	82	MOTION to Expedite by Xavier Becerra, Robert M Califf, United States Department of Health and Human Services, United States Food and Drug Administration. Motion Hearing set for **4/17/2023** Without Oral Argument before Judge Thomas O. Rice. (Katzen, Noah) (Entered: 04/10/2023)
04/10/2023	83	MOTION to Appear Pro Hac Vice re Attorney: Joshua Perry. Filing fee $ 200, receipt number AWAEDC-4267047. by State of Connecticut. Motion Hearing set for **5/10/2023** Without Oral Argument before Judge Thomas O. Rice. (Hughes, Andrew) (Entered: 04/10/2023)
04/10/2023	84	RESPONSE to Motion re 82 MOTION to Expedite filed by All Plaintiffs. (Beneski, Kristin) (Entered: 04/10/2023)
04/11/2023	85	MOTION to Appear Pro Hac Vice re Attorney: Thomas T. Hydrick. Filing fee $ 200, receipt number AWAEDC-4267782. by State of South Carolina. Motion Hearing set for **5/11/2023** Without Oral Argument before Judge Thomas O. Rice. (Wilson, Lincoln) (Entered: 04/11/2023)
04/11/2023	86	REPLY MEMORANDUM re 82 MOTION to Expedite filed by Xavier Becerra, Robert M Califf, United States Department of Health and Human Services, United States Food and Drug Administration. (Katzen, Noah) (Entered: 04/11/2023)
04/11/2023	87	MOTION to Appear Pro Hac Vice re Attorney: Eric H. Wessan. Filing fee $ 200, receipt number AWAEDC-4267873. by State of Iowa. Motion Hearing set for **5/11/2023** Without Oral Argument before Judge Thomas O. Rice. (Wilson, Lincoln) (Entered: 04/11/2023)

04/11/2023	88	MOTION to Appear Pro Hac Vice re Attorney: Leif A. Olson. Filing fee $ 200, receipt number AWAEDC-4267976. by State of Texas. Motion Hearing set for **5/11/2023** Without Oral Argument before Judge Thomas O. Rice. (Wilson, Lincoln) (Entered: 04/11/2023)
04/11/2023	89	MOTION to Appear Pro Hac Vice re Attorney: Christopher A. Bates. Filing fee $ 200, receipt number AWAEDC-4267990. by State of Utah. Motion Hearing set for **5/11/2023** Without Oral Argument before Judge Thomas O. Rice. (Wilson, Lincoln) (Entered: 04/11/2023)
04/11/2023	90	MOTION to Expedite by State of Idaho, State of Iowa, State of Montana, State of Nebraska, State of South Carolina, State of Texas, State of Utah. Motion Hearing set for **4/18/2023** Without Oral Argument before Judge Thomas O. Rice. (Wilson, Lincoln) (Entered: 04/11/2023)
04/13/2023	91	ORDER granting ECF No. 81 Motion to Clarify; granting ECF No. 82 Motion to Expedite. Signed by Judge Thomas O. Rice. (Entered: 04/13/2023)
04/13/2023	92	MEMORANDUM in Opposition re 76 MOTION to Intervene filed by Xavier Becerra, Robert M Califf, United States Department of Health and Human Services, United States Food and Drug Administration. (Katzen, Noah) (Entered: 04/13/2023)
04/13/2023	93	RESPONSE to Motion re 76 MOTION to Intervene filed by All Plaintiffs. (Beneski, Kristin) (Entered: 04/13/2023)
04/13/2023	94	DECLARATION by Kristin Beneski in Opposition re 76 MOTION to Intervene filed by All Plaintiffs. (Attachments: # 1 Exhibit A)(Beneski, Kristin) (Entered: 04/13/2023)
04/17/2023	95	Consent MOTION for Extension of Time to File Answer by Xavier Becerra, Robert M Califf, United States Department of Health and Human Services, United States Food and Drug Administration. Motion Hearing set for **5/17/2023** Without Oral Argument before Judge Thomas O. Rice. (Katzen, Noah) (Entered: 04/17/2023)
04/18/2023	96	ORDER: For good cause shown, the Proposed Intervenors' unopposed 90 Motion to Expedite is GRANTED. The Proposed Intervenors shall file a reply to the 76 Motion to Intervene on or before **April 20, 2023**. A hearing is set for the 76 Motion to Intervene and 77 79 85 87 88 89 Motions to Appear Pro Hac Vice on **April 21, 2023** without oral argument. Signed by Judge Thomas O. Rice. TEXT ONLY ORDER - NO PDF ATTACHED. (HH, Law Clerk) (Entered: 04/18/2023)
04/18/2023		Set/Reset Motion Hearing as to 76 MOTION to Intervene , 77 MOTION to Appear Pro Hac Vice re Attorney: Joshua N. Turner, 79 MOTION to Appear Pro Hac Vice re Attorney: Peter M. Torstensen, Jr., 85 MOTION to Appear Pro Hac Vice re Attorney: Thomas T. Hydrick, 87 MOTION to Appear Pro Hac Vice re Attorney: Eric H. Wessan, 88 MOTION to Appear Pro Hac Vice re Attorney: Leif A. Olson, and 89 MOTION to Appear Pro Hac Vice re Attorney: Christopher A. Bates. Motion Hearing set for **4/21/2023** without oral argument before Judge Thomas O. Rice. (HH, Law Clerk) (Entered: 04/18/2023)
04/18/2023	97	MOTION to Appear Pro Hac Vice re Attorney: Erin N. Lau. Filing fee $ 200, receipt number AWAEDC-4272595. by State of Hawaii. Motion Hearing set for **5/18/2023** Without Oral Argument before Judge Thomas O. Rice. (Hughes, Andrew) (Entered: 04/18/2023)
04/19/2023	98	ORDER granting 64 Motion for Leave to Appear Pro Hac Vice. Attorney Adam Aukland-Peck added for American Academy of Family Physicians; American Academy of Pediatrics; American College of Nurse-Midwives; American College of Obstetricians and Gynecologists; American Gynecological and Obstetrical Society; American Medical

		Association; American Society for Reproductive Medicine; Council of University Chairs of Obstetrics & Gynecology; North American Society for Pediatric and Adolescent Gynecology; Society for Maternal-Fetal Medicine; Society of General Internal Medicine; Society of Gynecologic Oncology; Society of Gynecologic Surgeons; Society of OB/GYN Hospitalists; and Washington State Medical Association. TEXT ONLY ORDER; NO PDF WILL ISSUE. Signed by Judge Thomas O. Rice. (BF, Paralegal) Modified on 5/11/2023 to correct the spelling of the last name. (LAS, Case Administrator). (Entered: 04/19/2023)
04/19/2023	99	ORDER granting 65 Motion for Leave to Appear Pro Hac Vice. Attorney Jessica Morris added for American Academy of Family Physicians; American Academy of Pediatrics; American College of Nurse-Midwives; American College of Obstetricians and Gynecologists; American Gynecological and Obstetrical Society; American Medical Association; American Society for Reproductive Medicine; Council of University Chairs of Obstetrics & Gynecology; North American Society for Pediatric and Adolescent Gynecology; Society for Maternal-Fetal Medicine; Society of General Internal Medicine; Society of Gynecologic Oncology; Society of Gynecologic Surgeons; Society of OB/GYN Hospitalists; and Washington State Medical Association. TEXT ONLY ORDER; NO PDF WILL ISSUE. Signed by Judge Thomas O. Rice. (BF, Paralegal) (Entered: 04/19/2023)
04/19/2023	100	ORDER granting 66 Motion for Leave to Appear Pro Hac Vice. Attorney Megan McGuiggan added for American Academy of Family Physicians; American Academy of Pediatrics; American College of Nurse-Midwives; American College of Obstetricians and Gynecologists; American Gynecological and Obstetrical Society; American Medical Association; American Society for Reproductive Medicine; Council of University Chairs of Obstetrics & Gynecology; North American Society for Pediatric and Adolescent Gynecology; Society for Maternal-Fetal Medicine; Society of General Internal Medicine; Society of Gynecologic Oncology; Society of Gynecologic Surgeons; Society of OB/GYN Hospitalists; and Washington State Medical Association. TEXT ONLY ORDER; NO PDF WILL ISSUE. Signed by Judge Thomas O. Rice. (BF, Paralegal) (Entered: 04/19/2023)
04/19/2023	101	ORDER granting 67 Motion for Leave to Appear Pro Hac Vice. Attorney Molly Meegan added for American Academy of Family Physicians; American Academy of Pediatrics; American College of Nurse-Midwives; American College of Obstetricians and Gynecologists; American Gynecological and Obstetrical Society; American Medical Association; American Society for Reproductive Medicine; Council of University Chairs of Obstetrics & Gynecology; North American Society for Pediatric and Adolescent Gynecology; Society for Maternal-Fetal Medicine; Society of General Internal Medicine; Society of Gynecologic Oncology; Society of Gynecologic Surgeons; Society of OB/GYN Hospitalists; and Washington State Medical Association. TEXT ONLY ORDER; NO PDF WILL ISSUE. Signed by Judge Thomas O. Rice. (BF, Paralegal) (Entered: 04/19/2023)
04/19/2023	102	ORDER granting 68 Motion for Leave to Appear Pro Hac Vice. Attorney Shannon Rose Selden added for American Academy of Family Physicians; American Academy of Pediatrics; American College of Nurse-Midwives; American College of Obstetricians and Gynecologists; American Gynecological and Obstetrical Society; American Medical Association; American Society for Reproductive Medicine; Council of University Chairs of Obstetrics & Gynecology; North American Society for Pediatric and Adolescent Gynecology; Society for Maternal-Fetal Medicine; Society of General Internal Medicine; Society of Gynecologic Oncology; Society of Gynecologic Surgeons; Society of OB/GYN Hospitalists; and Washington State Medical Association. TEXT ONLY

		ORDER; NO PDF WILL ISSUE. Signed by Judge Thomas O. Rice. (BF, Paralegal) (Entered: 04/19/2023)
04/19/2023	103	REPLY MEMORANDUM re 76 MOTION to Intervene filed by State of Idaho, State of Iowa, State of Montana, State of Nebraska, State of South Carolina, State of Texas, State of Utah. (Wilson, Lincoln) (Entered: 04/19/2023)
04/21/2023	104	ORDER DENYING 76 MOTION TO INTERVENE. Proposed State Plaintiff-Intervenors' State of Montana, State of Nebraska, State of South Carolina, State of Texas, State of Utah, State of Idaho and State of Iowa are terminated; granting 77 Motion for Leave to Appear Pro Hac Vice. Added Attorney Joshua N Turner for State of Idaho; granting 79 Motion for Leave to Appear Pro Hac Vice. Added Peter M Torstensen, Jr for State of Montana; granting 85 Motion for Leave to Appear Pro Hac Vice. Added Attorney Thomas T Hydrick for State of South Carolina; granting 87 Motion for Leave to Appear Pro Hac Vice. Added Attorney Eric H Wessan for State of Iowa; granting 88 Motion for Leave to Appear Pro Hac Vice. Added Attorney Leif A Olson for State of Texas; granting 89 Motion for Leave to Appear Pro Hac Vice. Added Attorney Christopher A Bates for State of Utah. Signed by Judge Thomas O. Rice. (TNC, Case Administrator) (Entered: 04/21/2023)
04/24/2023	105	ORDER: For good cause shown, Defendants' 95 Consent Motion for Extension of Time is GRANTED. Defendants shall respond to the Amended Complaint on or before **May 15, 2023**. Signed by Judge Thomas O. Rice. TEXT ONLY ORDER - NO PDF ATTACHED. (HH, Law Clerk) (Entered: 04/24/2023)
04/26/2023	106	LODGED NOTICE OF APPEAL from District Court decision as to 104 Order on Motion to Intervene,,,, Order on Motion for Leave to Appear Pro Hac Vice,,,,,,,,,,,,,,,,,,,,,,,, by State of Idaho, State of Iowa, State of Montana, State of Nebraska, State of South Carolina, State of Texas, State of Utah. Filing fee $ 505, receipt number AWAEDC-4279245. (Wilson, Lincoln) (Entered: 04/26/2023)
04/26/2023	107	NOTICE OF INTERLOCUTORY APPEAL as to 104 Order on Motion to Intervene/Order on Motion for Leave to Appear Pro Hac Vice filed 4/21/2023 by State of Idaho, State of Iowa, State of Montana, State of Nebraska, State of South Carolina, State of Texas and State of Utah. (TNC, Case Administrator) Modified on 5/1/2023 **9CCA: 23-35294** (TNC, Case Administrator). (Entered: 04/26/2023)
04/26/2023	108	Letter from Appeal Deputy Clerk to Lincoln Davis Wilson dated 4/26/2023. (Attachments: # 1 Notice of Interlocutory Appeal, # 2 Docket Report)(TNC, Case Administrator) (Entered: 04/26/2023)
04/27/2023	109	ORDER granting 73 Motion for Leave to Appear Pro Hac Vice. Attorney Heidi Parry Stern added for State of Nevada. Signed by Judge Thomas O. Rice. TEXT ONLY ORDER; NO PDF WILL ISSUE. (BF, Paralegal) (Entered: 04/27/2023)
04/27/2023	110	ORDER granting 74 Motion for Leave to Appear Pro Hac Vice. Attorney Steven M Sullivan added for State of Maryland. Signed by Judge Thomas O. Rice. TEXT ONLY ORDER; NO PDF WILL ISSUE. (BF, Paralegal) (Entered: 04/27/2023)
04/27/2023	111	ORDER granting 75 Motion for Leave to Appear Pro Hac Vice. Attorney Eleanor Spottswood added for State of Vermont. Signed by Judge Thomas O. Rice. TEXT ONLY ORDER; NO PDF WILL ISSUE. (BF, Paralegal) (Entered: 04/27/2023)
04/27/2023	112	ORDER granting 83 Motion for Leave to Appear Pro Hac Vice. Attorney Joshua Perry added for State of Connecticut. Signed by Judge Thomas O. Rice. TEXT ONLY ORDER; NO PDF WILL ISSUE. (BF, Paralegal) (Entered: 04/27/2023)

04/27/2023	113	ORDER granting 97 Motion for Leave to Appear Pro Hac Vice. Attorney Erin N Lau added for State of Hawaii. Signed by Judge Thomas O. Rice. TEXT ONLY ORDER; NO PDF WILL ISSUE. (BF, Paralegal) Modified on 4/27/2023 to correct the docket text (LAS, Case Administrator). (Entered: 04/27/2023)
04/27/2023	114	MOTION to Appear Pro Hac Vice re Attorney: Sabrena K. Clinton. Filing fee $ 200, receipt number AWAEDC-4280602. by State of Nevada. Motion Hearing set for **5/30/2023** Without Oral Argument before Judge Thomas O. Rice. (Hughes, Andrew) (Entered: 04/27/2023)
04/28/2023	115	ORDER granting 114 Motion for Leave to Appear Pro Hac Vice. Attorney Sabrena K Clinton added for State of Nevada. Signed by Judge Thomas O. Rice. TEXT ONLY NOTICE; NO PDF WILL ISSUE. (BF, Paralegal) (Entered: 04/28/2023)
05/01/2023	116	9CCA Appeal Time Schedule and Case Number: 23-35294 for 107 Notice of Interlocutory Appeal, filed by State of Utah, State of Texas, State of Nebraska, State of Iowa, State of Montana, State of South Carolina, State of Idaho. Designation Due: 5/30/2023. Transcript Due: 6/30/2023. Opening Brief Due: 8/7/2023. Appellees Brief Due: 9/7/2023. Mediation Questionnaire Due: 5/8/2023. (TNC, Case Administrator) Modified on 5/1/2023 as to docket text (TNC, Case Administrator). (Entered: 05/01/2023)
05/10/2023	117	Joint MOTION for Extension of Time to File Answer *and to Set Deadline to Produce Administrative Record* by Xavier Becerra, Robert M Califf, United States Department of Health and Human Services, United States Food and Drug Administration. Motion Hearing set for **6/9/2023** Without Oral Argument before Judge Thomas O. Rice. (Katzen, Noah) (Entered: 05/10/2023)
05/10/2023	118	Joint MOTION to Expedite by Xavier Becerra, Robert M Califf, United States Department of Health and Human Services, United States Food and Drug Administration. Motion Hearing set for **5/17/2023** Without Oral Argument before Judge Thomas O. Rice. (Katzen, Noah) (Entered: 05/10/2023)
05/11/2023	119	ORDER: For good cause shown, the parties' 117 Joint Motion for Extension of Time to Answer *and to Set Deadline to Produce Administrative Record* and 118 Joint Motion to Expedite are GRANTED. Defendants shall respond to the Amended Complaint on or before **June 23, 2023**. Defendants shall produce the administrative record at issue on or before **September 1, 2023**. Signed by Judge Thomas O. Rice. TEXT ONLY ORDER - NO PDF ATTACHED. (HH, Law Clerk) (Entered: 05/11/2023)
06/15/2023	120	Joint MOTION for Extension of Time to File Answer re 35 Amended Complaint by Xavier Becerra, Robert M Califf, United States Department of Health and Human Services, United States Food and Drug Administration. Motion Hearing set for **7/17/2023** Without Oral Argument before Judge Thomas O. Rice. (Katzen, Noah) (Entered: 06/15/2023)
06/15/2023	121	Joint MOTION to Expedite by Xavier Becerra, Robert M Califf, United States Department of Health and Human Services, United States Food and Drug Administration. Motion Hearing set for **6/22/2023** Without Oral Argument before Judge Thomas O. Rice. (Katzen, Noah) (Entered: 06/15/2023)
06/16/2023	122	ORDER: The Parties' Joint Motion to Modify Deadlines and Expedite are GRANTED. ECF Nos. 120 and 121 . Defendants' deadline to respond to the Amended Complaint set forth in ECF No. 119 is deferred until after the Court rules on any motions for summary judgment and two weeks following the Court's ruling on any motions for summary judgment, the parties shall file a joint status report proposing a new deadline to answer

		the Amended Complaint. Signed by Judge Thomas O. Rice. TEXT ORDER ONLY - NO PDF ATTACHED (Entered: 06/16/2023)
06/28/2023	123	MOTION to Appear Pro Hac Vice re Attorney: Shannon Stevenson. Filing fee $ 200, receipt number AWAEDC-4324228. by State of Colorado. Motion Hearing set for **7/28/2023** Without Oral Argument before Judge Thomas O. Rice. (Hughes, Andrew) (Entered: 06/28/2023)
07/06/2023	124	ORDER granting 123 Motion for Leave to Appear Pro Hac Vice. Attorney Shannon Stevenson added for State of Colorado. Signed by Judge Thomas O. Rice. TEXT ONLY ORDER - NO PDF ATTACHED. (HH, Law Clerk) (Entered: 07/06/2023)
08/02/2023	125	Unopposed MOTION to Withdraw as Attorney (atty Leif A. Olson) by State of Texas. Motion Hearing set for **9/1/2023** Without Oral Argument before Judge Thomas O. Rice. (Attachments: # 1 Text of Proposed Order)(Olson, Leif) (Entered: 08/02/2023)

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