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