NO.23-35294

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

State of Washington, et al.,
Plaintiffs-Appellees,
v.

United States Food and Drug Administration, et al.,
Defendants-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

BRIEF OF PLAINTIFFS-APPELLEES

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Federal Statutes

State Statutes

Regulations

Rules

I. INTRODUCTION

In this lawsuit, a coalition of States challenge three restrictions the U.S. Food and Drug Administration placed on mifepristone, a medication used for termination of early pregnancy. The Plaintiff States argue that imposing these restrictions was arbitrary, capricious, and contrary to law. Among other things, the FDA's governing statute does not authorize the agency to impose such restrictions on exceptionally safe drugs like mifepristone, and mandates that the FDA consider factors related to health care access that the FDA did not consider here. In partially granting preliminary relief, the district court found serious questions going to the merits of Plaintiffs' argument.

Another group of States moved to intervene, and the district court denied both mandatory and permissive intervention. This Court should affirm. First, Proposed Intervenors assert only undifferentiated policy interests in the lawfulness of agency action generally, and they would favor reinstatement of a prior FDA restriction that is no longer in effect. But intervention as of right cannot be premised on an entity's broad policy preferences about the outcome of litigation. Instead, the applicant must show some direct stake in the case—which Proposed Intervenors cannot do here, since this case will not affect their ability to enact and enforce their own state laws restricting medication abortion.

Second, Proposed Intervenors' claims involve a separate and distinct agency action that is not at issue in this case, and they seek a completely different remedy: the reinstatement of a prior FDA restriction not at issue here. The Plaintiff States challenge the FDA's decision to *impose* three restrictions on mifepristone, and seek to have all of those restrictions lifted—but Proposed Intervenors seek only to challenge the FDA's *lifting* of the in-person dispensing restriction for mifepristone, and would ask the court to re-impose that prior restriction. If Proposed Intervenors have grounds for challenging that separate and distinct agency action, they are free to file their own lawsuit, or could have sought intervention in the lawsuit currently pending in Texas challenging that same agency action. They do not have a right to commandeer this lawsuit.

The district court also appropriately exercised its discretion in denying permissive intervention, finding it would turn this existing case into a different, vastly more complicated one, without any benefit. Granting permissive intervention would undermine, rather than protect, the goal of judicial economy that intervention is intended to serve. This Court should affirm the district court's decision.

II. JURISDICTIONAL STATEMENT

Plaintiff States agree with the statement of jurisdiction in Appellants' Opening Brief.

III. ISSUES PRESENTED FOR REVIEW

1. Did the district court correctly deny intervention as of right under Federal Rule of Civil Procedure 24(a)(2)?

2. Did the district court properly exercise its discretion in denying permissive intervention under Federal Rule of Civil Procedure 24(b)(1)?

IV. STATEMENT OF THE CASE

A. Plaintiff States File Suit to Preserve Access to Medication Abortion

1. The FDA imposes three primary restrictions on mifepristone

This lawsuit concerns three restrictions imposed in 2023 by the FDA on the prescribing and dispensing of mifepristone, a medicine used by the majority of women in the United States who choose to terminate an early pregnancy. 2-ER-203. Since the FDA approved mifepristone in 2000, it has been used approximately 5.6 million times in the United States. 2-ER-204. As the FDA has acknowledged, mifepristone's safety is "well-established by both research and experience, and serious complications have proven to be extremely rare." 2-ER-204.

Nonetheless, the FDA has singled out mifepristone for a unique set of restrictions known as a Risk Evaluation and Mitigation Strategy (REMS). The FDA most recently imposed a REMS on mifepristone in January 2023. At the same time, the FDA formally removed the requirement that mifepristone be dispensed in person, following a two-year period in which the FDA exercised its discretion not to enforce the requirement. 2-ER-234. However, the agency re-imposed other burdensome requirements and created new ones, imposing three primary hurdles to accessing the medication:

(1) *Provider Certification.* Like prior REMS, the 2023 REMS provides that mifepristone can be prescribed only by a health care provider who has obtained a "special certif[ication]." That provider certification must, in turn, be submitted to each qualified pharmacy to which the provider intends to submit mifepristone prescriptions to be filled, and to the medicine's distributor if the prescriber intends to dispense in-office. 2-ER-238.

(2) *Pharmacy Certification.* The 2023 REMS imposed a new requirement that dispensing pharmacies become "specially certified" by the medicine's sponsor, a process that involves communication, recordkeeping, and training regimes beyond what is required for the vast majority of prescription drugs. 2-ER-239-40.

(3) *Patient Agreement Form.* Like prior REMS, the 2023 REMS requires that each patient receiving a mifepristone prescription first sign a Patient Agreement Form certifying that they have "decided to take mifepristone and misopristol to end my pregnancy"; the form must also be signed by the provider and a copy must be placed into the patient's medical record. 2-ER-240.

2. Plaintiff States challenge these restrictions as arbitrary, capricious, and contrary to law

The State of Washington filed this lawsuit against the FDA on February 23, 2023, along with 11 other states, seeking to preserve access to mifepristone by challenging the three requirements limiting access to the medicine—the provider certification, pharmacy certification, and patient agreement form—as contrary to the Federal Food, Drug, and Cosmetic Act (FDCA) and as arbitrary and capricious. 3-ER-346-432. They amended their complaint on March 9, 2023, adding five additional states and the District of Columbia. 2-ER-202-300.

Plaintiff States maintain that these restrictions are arbitrary, capricious, and contrary to law under the Administrative Procedure Act (APA) for three primary reasons. *First*, these restrictions fail to meet the FDCA's requirement that they be imposed only for drugs so "inherent[ly] toxic[] or potential[ly] harmful[]" that the FDA otherwise could not approve them. 21 U.S.C. § 355-1(f)(1); *see also* 21 U.S.C. § 355-1(f)(1)(A) (providing that REMS may be

imposed only for medications associated with a "serious adverse drug experience" like hospitalization or death). Nor are the restrictions "commensurate with" a "specific serious risk" such as "death" or "hospitalization," as required by statute. 21 U.S.C. §§ 355-1 (b)(4)(A) ,(f)(1)(A), (f)(2)(A); *see* 2-ER-242-244. *Second*, the FDA failed to consider the restrictions' impacts on patient access, including for "patients in rural or medically underserved areas," even though it is statutorily required to do so, *see id.* 21 U.S.C §§ 355-1(f)(2)(C)-(D)—and in fact, the FDA expressly "excluded" those factors from its consideration. 2-ER-238-42, 244-45, 257-62; SER 39-40. *Third*, the FDA disregarded scientific evidence that undermined the supposed safety rationale behind the restrictions. *See* 2-ER-245-57.

To preserve access to medication abortion within their borders, Plaintiff States moved for a preliminary injunction on February 24, 2023, the day after filing their initial complaint. 3-ER-302-345. The district court heard oral argument on that motion on March 28, 2023. 3-ER-449.

The district court granted the preliminary injunction in part on April 7, 2023, preliminarily enjoining the FDA from "altering the status quo and rights as it relates to the availability of Mifepristone under the current operative January 2023 [REMS] under 21 U.S.C. § 355-1 in Plaintiff States." 2-ER-059.

The district court found "serious issues going to the merits of Plaintiffs' APA claims" regarding the REMS requirements, including that the FDA appeared to have "failed to consider an important aspect" of whether mifepristone qualifies for REMS restrictions in the first place. 2-ER-050. By its terms, the preliminary injunction applies only within the Plaintiff States, and has no application within Proposed Intervenor States. 2-ER-059.

B. Proposed Intervenors Seek Intervention to Restrict Access to Medication Abortion and Challenge a Preliminary Injunction Order That Does Not Apply to Them

Proposed Intervenors moved to intervene on March 30, 2023, after the parties had already fully briefed and argued the preliminary injunction motion. 2-ER-061. Their proposed complaint sought to challenge the FDA's formal removal of the in-person dispensing requirement for mifepristone. 2-ER-072-094. It made no arguments regarding the claims at issue in this lawsuit—namely, Plaintiff States' challenges to the FDA's patient agreement form, provider certification, and pharmacy certification requirements. 2-ER-072-094. All parties—Plaintiff States, the FDA, and the other federal defendants—opposed intervention. 2-ER-011-029; SER 10-23.

Proposed Intervenors acknowledged that they sought intervention specifically to enable them to appeal any preliminary injunction order—even

though such an order would not affect the in-person dispensing issue that they sought to raise as intervenors. SER 24-27 (seeking expedited consideration of their motion to intervene "in advance of the deadline to appeal from the April 7, 2023 Preliminary Injunction Order"); SER 7-9 (clarifying that the basis for seeking expedited review was "to make sure that [Proposed Intervenors] are timely included with respect to any appeal rights that may run from the court's grant of preliminary relief").[1]

C. The District Court Denies Intervention

The district court denied intervention. 1-ER-002-009. As to intervention as of right, the district court held that it "is not enough that both groups assert APA claims against the FDA relating to the 2023 Mifepristone REMS Program." 1-ER-006. Rather, Proposed Intervenors' sole claim—challenging the removal of 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." 1-ER-007. Moreover, the district court noted that this case would not impair Proposed Intervenors' ability to enforce their own state laws that may regulate mifepristone more strictly than the FDA's requirements. 1-ER-007.

[1] The deadline to appeal the district court's preliminary injunction order expired on June 6, 2023. 2-ER-031-060; Fed. R. App. P. 4(a)(1)(B).

The district court also exercised its discretion to deny permissive intervention, finding no common question of law or fact under Fed. R. Civ. P. 24(b). 1-ER-008. The district court noted that this case asks whether the 2023 REMS violates the APA by imposing the patient agreement form, provider certification, and pharmacy certification requirements, whereas "the question [Proposed Intervenors] pose is whether the . . . 2023 REMS violates the APA by *not* imposing an in-person dispensing requirement." 1-ER-008. The district court further determined that adding additional "claims and relief not at issue would cause additional delay in this complex litigation." 1-ER-008. (citing *Cooper v. Newsom*, 13 F.4th 857, 868 (9th Cir. 2021)).

Because the district court determined that its findings regarding intervention were dispositive, it declined to address the issue of Proposed Intervenors' standing to bring their proposed claims. 1-ER-008

D. Proposed Intervenors' Claims Are Squarely at Issue in Separate Proceedings, Where Their Requested Relief Is Being Addressed

Separately, the Alliance for Hippocratic Medicine and other plaintiffs filed suit in federal district court in Texas in November 2022, challenging under the APA the FDA's initial approval of mifepristone in 2000, as well as subsequent FDA actions relating to the medication, including the decision not to enforce the in-person dispensing requirement. *See All. for Hippocratic Med. v.*

U.S. Food & Drug Admin., 78 F.4th 210 (5th Cir. 2023). On the plaintiffs' motion for a preliminary injunction, the district court "stayed" the "effective date" of all of the challenged FDA actions, including its 2000 approval of mifepristone. *All. for Hippocratic Med.*, 78 F.4th at 226-27. The U.S. Supreme Court granted a full stay of the district court's order pending appeal, including any proceedings in the Supreme Court. *Id.* at 227.

Following full briefing and argument, the Fifth Circuit vacated the district court's order as to the approval of mifepristone in 2000. *Id.* at 222. However, the Fifth Circuit affirmed the components of the stay order concerning later FDA actions generally loosening the restrictions on use of mifepristone, including the 2021 decision not to enforce the in-person dispensing requirement. *Id*. at 222-23. In doing so, the Court directly considered the plaintiffs' arguments regarding the legality of removing the in-person dispensing requirement. *Id*. at 249–51.

The Fifth Circuit decision thus addressed the precise relief that Proposed Intervenors seek here: it reinstated the in-person dispensing requirement. *Id*. at 256. The Supreme Court will determine whether this relief will ultimately be effectuated or not. *See* Petition for Writ of Certiorari, *FDA, et al. v. All. For Hippocratic Med.*, No. 23-235 (Sept. 12, 2023).

V. SUMMARY OF THE ARGUMENT

The district court correctly denied intervention. Proposed Intervenors have not asserted a significant, protectable interest in this case sufficient to warrant intervention as of right. Instead, they primarily assert a policy position against lifting the in-person dispensing requirement and in favor of the FDA generally following the law as they see it. As this Court has held, these generalized and undifferentiated concerns do not meet the requirements of Fed. R. Civ. P. 24(a)(2). And crucially, resolution of this case will not affect Proposed Intervenors' interests. The FDA's elimination of the in-person dispensing requirement is not at issue in this case (although it is the subject of a different pending lawsuit that Proposed Intervenors have not sought to join). Moreover, this lawsuit will have no effect on Proposed Intervenors' ability to enact and enforce state laws restricting medication abortion within their borders.

Second, the district court appropriately exercised its discretion in denying permissive intervention. As the district court correctly determined, there is no common question of law or fact warranting permissive intervention. Instead, while this case challenges the FDA's decision to impose certain restrictions on the availability of mifepristone, Proposed Intervenors seek instead to challenge the FDA's decision to *lift* a separate and distinct restriction—involving a

different factual record and legal analysis—currently being litigated elsewhere. The district court correctly concluded that allowing permissive intervention would entirely change the nature of this case, vastly complicating it without any benefit.

VI. ARGUMENT

A. Proposed Intervenors Do Not Have a Right to Commandeer This Lawsuit via Mandatory Intervention to Litigate Different Issues

Proposed Intervenors do not have a right to intervene in this case. Mandatory intervention protects those with significant interests at stake in the subject of a lawsuit. It does not allow the commandeering of existing litigation as a vehicle to prosecute new claims, turning the subject of the case on its head.

This Court "review[s] a district court's denial of a motion for intervention as of right *de novo*." *Donnelly v. Glickman*, 159 F.3d 405, 409 (9th Cir. 1998).[2] The federal rules permit intervention as of right only where the movant "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

[2] The exception is for a district court's determination of timeliness, which this Court reviews for abuse of discretion. *S. Cal. Edison Co. v. Lynch*, 307 F.3d 794, 802 (9th Cir. 2002). In this case, the district court did not reach the timeliness prong of the intervention as of right analysis.

impede the movant's ability to protect its interest, unless existing parties adequately represent that interest." Fed. R. Civ. P. 24(a)(2).

In considering whether that standard is met, this Court applies a four-part test. First, the movant must have a "'significantly protectable' interest relating to the property or transaction which is the subject of the action." *Cooper v. Newsom*, 13 F.4th 857, 864 (9th Cir. 2021), *cert. denied sub nom. San Bernardino Cnty. Dist. Att'y v. Cooper*, 143 S. Ct. 287 (2022). Second, the movant must be "so situated that the disposition of the action may as a practical matter impair or impede its ability to protect that interest." *Cooper*, 13 F.4th at 864. Third, the claimed interest must be inadequately represented by the existing parties. *Id*. Finally, the motion must be timely. *Id*. "Failure to satisfy any one of the requirements is fatal." *Perry v. Proposition 8 Official Proponents*, 587 F.3d 947, 950 (9th Cir. 2009).

Here, Proposed Intervenors fail at least three of these requirements. First, the agency action they seek to challenge is not at issue in this lawsuit to begin with, and their claimed interest in ensuring the FDA's actions are lawful under the APA is not "significantly protectable" under Fed. R. Civ. P. 24; to the contrary, it is so generic that it is presumably shared by most members of the population. Second, because the in-person dispensing requirement is not at issue

in this case, the disposition of this action will not impair or impede Proposed Intervenors' ability to challenge the elimination of that requirement (which is directly at issue in the Texas case). Nor will this lawsuit affect Proposed Intervenors' ability to enforce their existing state laws restricting the availability of mifepristone. Third, even if Proposed Intervenors had asserted an interest in the subject matter of this lawsuit—the legality of the January 2023 restrictions on mifepristone—they have not shown that the FDA will not adequately represent any interests they have in defending those restrictions.[3]

1. Proposed Intervenors lack a significant protectable interest in the subject of this lawsuit

Notwithstanding this Court's "liberal policy in favor of intervention," an applicant for intervention must still show two "core," "irreducible" elements of Fed. R. Civ. P. 24(a)(2)'s "significantly protectable interest" prong: that (1) "the asserted interest be protectable under some law," and (2) "there exist a relationship between the legally protected interest and the claims at issue." *Cal. Dep't of Toxic Substances Control v. Jim Dobbas, Inc.*, 54 F.4th 1078, 1088 (9th

[3] As Plaintiff States argued below, there are also serious questions regarding timeliness, since Proposed Intervenors admitted they sought intervention to appeal a potential ruling on Plaintiff States' motion for preliminary injunction, and yet waited until after that motion was fully briefed and argued to seek intervention. 2-ER-019–20.

Cir. 2022) (internal quotation marks omitted). If they cannot establish both elements, "a putative intervenor lacks *any* 'interest' under Rule 24(a)(2), *full stop*." *Cal. Dep't of Toxic Substances Control*, 54 F.4th at 1088 (emphasis added). Proposed Intervenors have not established either.

a. Proposed Intervenors do not assert any significant, protectable interest beyond generic policy preferences

Proposed Intervenors do not have a significantly protectable interest in this litigation. They claim only generalized interests in "ensur[ing] that the REMS governing mifepristone's marketing are lawful" and "in mifepristone's in-person dispensing requirement being restored." Opening Br. at 10, 13. Leaving aside the fact that the in-person dispensing requirement is not at issue in this lawsuit, this Court has made clear that such "'an undifferentiated, generalized interest in the outcome of an ongoing action is too porous a foundation on which to premise intervention as of right.'" *S. Cal. Edison Co. v. Lynch*, 307 F.3d 794, 803 (9th Cir. 2002) (quoting *Pub. Serv. Co. of N.H. v. Patch*, 136 F.3d 197, 205 (1st Cir. 1998)). Otherwise, any entity could intervene and radically expand the scope of any lawsuit simply by asserting a policy interest in the subject matter or, even more vaguely, in ensuring the legality of administrative action.

The importance of a particularized, concrete interest beyond high-level

policy concerns is illustrated by this Court's decision in *United States v. City of Los Angeles*, 288 F.3d 391 (9th Cir. 2002) (cited in Opening Br. at 11). That case involved a federal civil rights lawsuit against the Los Angeles Police Department; the Court affirmed denial of intervention to community groups but granted it to the police officers' union. As to the community groups, the Court acknowledged that they had asserted a generalized interest "related to the subject matter of the litigation," i.e., preventing unconstitutional acts by police officers. *City of Los Angeles*, 288 F.3d at 402. But this was not enough to establish a significant, protectable interest: the case did not prevent any group from filing its own lawsuit against police officers or the City, or from continuing work on police reform. *Id*.

By contrast, the Court reversed denial of intervention to the police union because it had asserted a concrete, particularized interest in the specific claims at issue in the litigation. Specifically, the United States' complaint accused union members of constitutional violations and sought injunctive relief against them, and the existing parties' proposed relief—a consent decree—would alter the "terms and conditions of [union] members' employment[,]" which the union had a protectable legal right to negotiate. *Id*. at 399–400.

Here, Proposed Intervenors may have "broader policy interests" in

restricting abortion access, but this "cannot serve as a basis for mandatory intervention." *See Am. Coll. of Obstetricians & Gynecologists (ACOG) v. FDA*, 467 F. Supp. 3d 282, 289 (D. Md. 2020) (denying intervention to ten states in action challenging FDA's in-person dispensing requirement). Where an applicant's asserted interest in the outcome of an action is no different from that of "a substantial portion of the population," it "is not a legally protectible interest that can support" intervention as of right. *Westlands Water Dist. v. United States*, 700 F.2d 561, 563 (9th Cir. 1983) (denying intervention to environmental group with general interest in water rights, but no concrete interests in the contracts at issue in the lawsuit); *see also S. Cal. Edison Co.*, 307 F.3d at 803 (denying intervention to trade association alleging generally that its members were "an integral part of the California economy" and had purchased electricity from the plaintiff).

While Proposed Intervenors make the conclusory allegation that the outcome of this case may affect their "ability to enforce their laws and the safeguards available to protect their citizens" (Opening Br. at 13), they do not even attempt to explain why that is the case—and the claim is simply wrong. Proposed Intervenors argue that the district court erred by declining to accept this claim as true (Opening Br. at 13), but the district court's conclusion did not

turn on any factual findings. *See* 1-ER-007. Rather, it turned on the straightforward reality that nothing in this suit will limit Proposed Intervenors' efforts to use their own state laws—none of which are at issue in this case—to restrict medication abortion within their borders. Proposed Intervenors' brief makes no serious attempt to show otherwise.

And indeed, Proposed Intervenors have actively imposed their own state-law restrictions on medication abortion, ranging from requirements for in-person dispensing of medication abortion to bans on nearly all abortions, whether in person or not. *See, e.g.*, Neb. Rev. Stat. § 28-335(2) (requiring physicians to be physically present during medication abortions); Utah Code 76-7-301(1)(a), 76-7-302(3) (providing that an abortion, including a medication abortion, "may be performed only in a hospital" unless medical emergency requires it to be performed elsewhere); 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). Proposed Intervenors cite no authority for the proposition that these laws are in any way dependent upon the FDA's regulation of mifepristone.

That is because they are not. This case simply has no bearing on these

laws. Whether Plaintiff States are ultimately successful or not, "resolution of this case [will] not impair [Proposed Intervenors'] ability to enforce their own laws regulating mifepristone." *See ACOG*, 467 F. Supp. 3d at 286. Thus, to the extent Proposed Intervenors contend that access to mifepristone is inconsistent with their anti-abortion policies or their sovereign interests, *see, e.g.*, Opening Br. at 19, this suit has no bearing whatsoever on their state-law efforts to restrict abortion.[4] Just as in *ACOG*, "Plaintiffs do not seek the invalidation of the [Proposed Intervenors'] abortion laws." *ACOG*, 467 F. Supp. 3d at 289.[5]

b. Proposed Intervenors' asserted interest is not related to this litigation

Proposed Intervenors have not asserted any significant, protectable interest in this litigation beyond a generalized interest in its outcome. Further,

[4] Plaintiff States dispute Proposed Intervenors' claims of harms from mifepristone, which are wholly unsupported by the evidence. But following *Dobbs*, regulation of abortion access is to up to each State's legislature. *Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228, 2283 (2022).

[5] Proposed Intervenors do not argue in their brief that protecting access to mifepristone in the Plaintiff States will cause them any harm, and any such argument is consequently waived. *Padgett v. Wright*, 587 F.3d 983, 985 n.2 (9th Cir. 2009). Even if not waived, such speculative harms cannot support intervention. *United States v. Alisal Water Corp.*, 370 F.3d 915, 919 (9th Cir. 2004) (speculative interests insufficient to support a right to intervention); *Benny v. England*, 791 F.2d 712, 721 (9th Cir.1986) ("This possibility that our decision could affect [the applicants'] interests is too tenuous to entitle them to intervene [as] of right."); *see also Wash. Elec. Coop., Inc. v. Mass. Mun. Wholesale Elec. Co.*, 922 F.2d 92, 97 (2d Cir.1990) ("An interest . . . that is contingent upon the occurrence of a sequence of events before it becomes colorable, will not satisfy the rule.").

Proposed Intervenors' asserted interests fail for the additional reason that they are not sufficiently related to the subject matter of this case. To establish that relationship, it is not enough that an applicant simply seeks to pursue a similar claim to the plaintiff's or asserts an interest in the general subject matter of the case. *See Donnelly*, 159 F.3d at 409–11; *S. Cal. Edison Co.*, 307 F.3d at 803. Rather, the applicant must assert an interest in the *specific* legal dispute and show that "'the resolution of the plaintiff's claims actually will affect the applicant.'" *S. Cal. Edison Co.*, 307 F.3d at 803 (quoting *City of Los Angeles*, 288 F.3d at 397); *Westlands Water Dist.*, 700 F.2d at 563.

Proposed Intervenors have not asserted an interest in the dispute at issue here. Their claim that they seek to assert "the same APA claims against the same Federal Defendants over the same final agency action" (Opening Br. at 11) is straightforwardly wrong. Their proposed APA challenge to the FDA's decision to *eliminate* the in-person dispensing requirement necessarily involves a different factual record and different legal arguments from Plaintiff States' challenge to the FDA's decision to *impose* the patient agreement form and the provider and pharmacy certification requirements.

Under this Court's precedent, an intervenor must assert a "direct" and "non-contingent" interest in the dispute forming the subject of the lawsuit. For

example, where an environmental group had no asserted interest in the legal interpretation of contracts to which the group was not a party, this Court held that the group's general interest in water rights was insufficient. *Westlands Water Dist.*, 700 F.2d at 563. Likewise, an applicant's interest in pursuing a related but distinct claim is not enough. *See Dilks v. Aloha Airlines*, 642 F.2d 1155, 1157 (9th Cir. 1981) (junior pilots had no legally protectable interest in senior pilot's wrongful discharge suit); *United States v. Alpine Land & Reservoir Co.*, 431 F.2d 763, 768–69 (9th Cir. 1970) (tribe's interest in Truckee River waters could not support intervention in suit about Carson River waters). Similarly, in *Donnelly v. Glickman*, where female plaintiffs raised sex discrimination claims and male employees sought to intervene to raise similar claims against the same employer, this Court denied intervention because the male employees' claims were "unrelated" to the plaintiffs' "*particular* claims of 'hostile-work-environment' discrimination." *Donnelly*, 159 F.3d at 409–11. None of the plaintiffs' remedies—aimed at ending harassment of women—would directly or necessarily affect the applicants' claimed interest in preventing discrimination against men. *Id*.

Proposed Intervenors attempt to wave aside the fact that they seek to challenge an entirely different agency action as a mere "technical" issue.

Opening Br. at 10. But they do not cite a single case where a court has found a right to intervene to allow an applicant without a concrete stake in a lawsuit to advance a distinct factual and legal claim not already at issue in the litigation. Instead, Proposed Intervenors' cited cases demonstrate the opposite, allowing intervention by applicants with concrete interests who sought to challenge or defend the statute, rule, or action *already* at issue in the litigation.

For instance, in *City of Los Angeles*, discussed above, the police officers' union sought to intervene to defend its members against the claims already at issue in the litigation: namely, the federal government's allegations that union members had committed constitutional violations; by contrast, community groups' generalized interest in police reform was not enough for intervention. *City of Los Angeles,* 288 F.3d at 398–99 (cited in Opening Br. at 11).

In *Fresno County v. Andrus*, the lawsuit sought to suspend the federal government's ability to move forward with excess land sales to allow local farmers to buy land at nonspeculative prices. *Fresno County v. Andrus,* 622 F.2d 436, 438 (9th Cir. 1980) (cited in Opening Br. at 10). The intervenors were local farmers who sought to defend the federal government's ability to do so; they were "precisely those Congress intended to protect" with the reclamation acts governing the sales, and "precisely those who will be injured" if the lawsuit

succeeded and the federal government did not act expeditiously. *Andrus,* 622 F.2d at 438

In *California ex rel. Lockyer v. United States*, the lawsuit challenged a federal law protecting medical providers who refused to provide abortion services; the Court permitted providers, who were "conceded[ly] . . . the intended beneficiaries of th[e] law," and for whom the law "provide[d] an important layer of protection against state criminal prosecution or loss of their medical licenses," to intervene to defend the law. *California ex rel. Lockyer v. United States,* 450 F.3d 436, 441–45 (9th Cir. 2006) (cited in Opening Br. at 12).

In *Western Watersheds Project v. Haaland*, the parties conceded that an energy company had a significantly protectable interest in a lawsuit challenging that very company's oil and gas leases with the federal government; the company sought to defend the leases, and the only questions were whether the motion to intervene was timely and the government adequately represented the company's interests. *W. Watersheds Project v. Haaland,* 22 F.4th 828, 834 (9th Cir. 2022) (cited in Opening Br. at 11).

And in *Citizens for Balanced Use v. Montana Wilderness Association*, all parties conceded that the proposed intervenors—a conservation group that sought to defend a regulation limiting motorized vehicle use in a wilderness area

against plaintiffs' challenge, and whose prior lawsuit had actually led to the regulation being promulgated—had a protectable interest in defending the regulation. *Citizens for Balanced Use v. Mont. Wilderness Ass'n,* 647 F.3d 893, 897 (9th Cir. 2011) (cited in Opening Br. at 12).[6]

Each of these cases, in short, involved an applicant seeking to defend a challenged government action because the action directly and concretely affected *its own direct interests*. Here, by contrast, Proposed Intervenors assert no direct interest in the challenged regulations—the patient agreement form, provider certification requirement, and pharmacy certification requirement—and seek intervention not to defend those requirements, but instead to assert new claims about a different requirement altogether. Because Proposed Intervenors have not shown a significant, protectable interest relating to the subject matter of this action, intervention as of right is not warranted.

[6] Proposed Intervenors also cite *Wilderness Society v. U.S. Forest Service*, in which this Court overturned the previous categorical rule that precluded all private parties and state and local governments from intervening as of right as defendants on the merits in National Environmental Protection Act actions. *Wilderness Soc'y v. U.S. Forest Serv.*, 630 F.3d 1173, 1177 (9th Cir. 2011). This previous rule, unique to NEPA, had denied intervention even to entities with a "significant economic stake" in the outcome of the case. *Id*. The Court did not eliminate the basic requirement of a significant protectable interest in the outcome of the litigation.

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

Because 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 such an interest. *See, e.g.*, *S. Cal. Edison Co.*, 307 F.3d at 802 (denying intervention based on the lack of a significantly protectable interest without proceeding to the impairment prong); *Westlands Water Dist.*, 700 U.S. at 563 (same). But even if Proposed Intervenors had such an interest, they fail to establish impairment. To meet this burden, an applicant must show that the "relief sought by plaintiffs will have direct, immediate, and harmful effects upon [its] legally protectable interests." *Forest Conservation Council v. U.S. Forest Serv.*, 66 F.3d 1489, 1494 (9th Cir. 1995), *abrogated on other grounds by Wilderness Soc'y. v. U.S. Forest Serv.*, 630 F.3d 1173 (9th Cir. 2011).

First, as discussed above, a decision on the legality of the January 2023 REMS will not affect Proposed Intervenors' ability to regulate and restrict medication abortion within their borders. *See supra* pp. 17–19.

Second, Proposed Intervenors assert that any appellate decision in this case may have a *stare decisis* effect on future litigation concerning

mifepristone's REMS, but every case has the potential to create new legal precedent or persuasive authority; mandatory intervention requires more. Proposed Intervenors' reliance on *Lockyer* (Opening Br. at 15–16) is misplaced; in that case, the applicants were *barred* from bringing "a separate suit where they could argue" their position. *Lockyer*, 450 F.3d at 443. Similarly, in *United States v. Oregon*, the applicants were residents of a state institution sued by the federal government for failure to provide adequate care—and clearly had interests in the relief requested (better conditions in the facility) and risk of impairment if a precedential ruling came down without considering their related claims. *United States v. Oregon,* 839 F.2d 635, 639 (9th Cir. 1988).

Here, there is no such bar because Proposed Intervenors have "other means by which [they] may protect" their claimed interest. *Alisal Water Corp.*, 370 F.3d at 921. Proposed Intervenors may, for instance, assert their purported interests via their own lawsuit. Or they could have sought to intervene in the separate, active lawsuit in which the legality of the in-person dispensing requirement under the APA is currently being litigated. Compl., *All. for Hippocratic Med. v. U.S. Food & Drug Admin.*, No. 2:22-cv-00223-Z (N.D. Tex.), ECF No. 1 ¶ 394. The fact that Proposed Intervenors have other ways to pursue their legal interests only underscores that this case will not impair any

significant protectable interest. *See City of Los Angeles*, 288 F.3d at 402 (denying intervention where it was "doubtful" that police reform advocates' "interests are impaired by" order relating to LAPD constitutional violations, and because "[t]he litigation does not prevent any individual from initiating suit against LAPD officers who engage in unconstitutional practices").

Finally, Proposed Intervenors contradict themselves in attempting to show an impairment of their claimed interest. On the one hand, as discussed above, they claim that if Plaintiff States are successful, it would impair their interests in restoring the in-person dispensing requirement because Plaintiff States "want the opposite." Opening Br. at 13. In the same breath, they bizarrely contend that their interest will be impaired because the in-person dispensing requirement *will* be restored if Plaintiff States are successful—even though that is the relief they claim to want. Opening Br. at 14. It is uncontested, however, that no party in this suit seeks reinstatement of the in-person dispensing requirement contained in the 2016 REMS. Instead, Plaintiff States seek to permanently enjoin the FDA from enforcing the patient agreement form, provider certification requirement, and pharmacy certification requirement as restrictions on mifepristone. 2-ER-291. No principle of administrative law requires that this requested relief lead also to the reinstatement of a restriction that the agency has already eliminated. As the

district court correctly noted, the in-person dispensing requirement "will neither be eliminated nor reinstated as a result of this litigation." 1-ER-007.

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

As made clear by the proposed complaint, 2-ER-72–137, Proposed Intervenors' claims solely concern the FDA's elimination of the in-person dispensing requirement, not the restrictions challenged by 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 purpose of mandatory intervention. *See Donnelly*, 159 F.3d at 409–11; *Dilks*, 642 F.2d at 1157; *Alpine Land & Reservoir Co.*, 431 F.2d at 768-69; *Rosebud Coal Sales Co. v. Andrus*, 644 F.2d 849, 850-51 (10th Cir. 1981).

Even if Proposed Intervenors had asserted an interest in the existing subject matter of this litigation—the legality of the challenged restrictions—the FDA adequately represents it. The FDA has every incentive and ability to defend its own decision on the REMS requirements challenged here, and indeed is vigorously doing so. *See* 2-ER-165–201; *see also Cedars-Sinai Med. Ctr. v. Shalala*, 125 F.3d 765, 768 (9th Cir. 1997); *Am. Fed'n of State, Cnty. & 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."). Proposed Intervenors do not even assert an interest in the FDA restrictions that are actually at issue here, much less explain why the government's defense of its own actions is inadequate. For this reason, too, mandatory intervention is inappropriate.

B. The District Court Properly Exercised Its Discretion to Deny Permissive Intervention That Would Dramatically Expand the Scope of This Lawsuit

Proposed Intervenors' arguments on permissive intervention fare no better. Because the district court found intervention would vastly complicate this case without any benefit, the court properly exercised its discretion to deny intervention here. *See S. Cal. Edison Co.*, 307 F.3d at 804 (permissive intervention is "not intended to allow the creation of whole new lawsuits by the intervenors").

This Court "review[s] the district court's denial of permissive intervention for abuse of discretion." *Id.* at 802 (citing *Venegas v. Skaggs,* 867 F.2d 527, 529 (9th Cir. 1989)). As this Court has explained, in the case of permissive intervention, the abuse of discretion standard is jurisdictional: "[i]f the district court did not abuse its discretion, [the Court] must dismiss the appeal for lack of jurisdiction." *Cooper v. Newsom*, 13 F.4th 857, 868 (9th Cir. 2021); *see also*

League of United Latin Am. Citizens v. Wilson, 131 F.3d 1297, 1307–08 (9th Cir. 1997).

"An applicant who seeks permissive intervention must prove that it meets three threshold requirements: (1) it shares a common question of law or fact with the main action; (2) its motion is timely; and (3) the court has an independent basis for jurisdiction over the applicant's claims." *Donnelly*, 159 F.3d at 412. "Even if an applicant satisfies those threshold requirements, the district court has discretion to deny permissive intervention." *Id*; *see also Orange County v. Air Cal.,* 799 F.2d 535, 539 (9th Cir. 1986) ("Permissive intervention is committed to the broad discretion of the district court.").

Proposed Intervenors fail to show that the district court abused its discretion in denying their request to dramatically expand the scope of this lawsuit. Rather, the district court correctly concluded that there is no "common question of law or fact" between the existing claims and the lifting of the in-person dispensing requirement such that intervention under Fed. R. Civ. P. 24(b)(1)(B) is warranted. Proposed Intervenors assert that their claims are "grounded in the same law and facts" as the Plaintiff States' claims (Opening Br. at 20), but as already discussed, Proposed Intervenors in fact seek to bring a separate claim challenging a different FDA action and seek a separate

remedy against that distinct agency action that is not at issue in this suit. 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 lawsuit only about retaliation); *see also Cooper*, 13 F.4th at 868 (denying intervention by district attorneys seeking to enforce execution protocol where they did not draft the protocol and were not authorized to defend its constitutionality, the issue in the "main action"); *S. Cal. Edison*, 307 F.3d at 804 (denying intervention by creditors asserting a future interest in plaintiff's recovery).

As the district court found, "in practical application . . . there is no common question of law or fact" between Plaintiff States' claims that the FDA erred by imposing burdensome restrictions on mifepristone and Proposed Intervenors' claim that the FDA erred by *not* imposing additional, separate burdens. 1-ER-008. Proposed Intervenors' response—that "there is no requirement of complete identity up and down the pleadings," Opening Br. at 20—is true as far as it goes, but it is beside the point. The fundamental problem is that Proposed Intervenors are trying to introduce and challenge an agency

action that simply is not at issue in this suit. Because the in-person dispensing requirement is not at issue here, Proposed Intervenors do not raise a common issue of fact or law. And even if they did, the district court undoubtedly had discretion to deny their request to inject their tangential claims into this suit.

Further, as the district court found, "the addition of State Intervenors who allege claims and relief not at issue would cause additional delay in this complex litigation," 1-ER-008, providing yet another well-supported ground to deny permissive intervention. Fed. R. Civ. P. 24(b)(3); *Perry*, 587 F.3d at 955–56. The legality of the in-person dispensing requirement is already at issue in what is also a "complicated administrative law" case requiring "extensive briefing and oral argument." *All. for Hippocratic Med.*, 78 F.4th at 222, 247–51. Adding Proposed Intervenors to this case would unnecessarily intertwine that case with this one, compounding the complexities of the claims at issue in both cases. The district court here did not abuse its discretion in declining to twist together two opposing claims.

Moreover, as the *ACOG* court recognized in a similar case, "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." *ACOG*, 467 F. Supp. 3d at 292 ("intervention would require

the Court to grapple with issues of the laws of ten different states"); *accord* 2-ER-72–94 at ¶¶ 55, 71, 80, 85, 90, 100 (Proposed Intervenors' proposed complaint alleging the FDA's elimination of the in-person dispensing requirement upset reliance interests related to their various state laws).

In short, the district court acted well within its discretion to deny Proposed Intervenors' request that the Court manage two distinct cases under one 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"). Permissive intervention was properly denied under Fed. R. Civ. P. 24(b)(1)(B).

VII. CONCLUSION

Plaintiff States respectfully request that this Court affirm the district court's order denying intervention.

RESPECTFULLY SUBMITTED this 10th day of October 2023.

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CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32 (a)(7)(C), and Ninth Circuit Rule 32-1, I certify that the attached response brief is proportionately spaced, has a typeface of 14 points or more, and contains 6718 words.

Dated this 10th day of October 2023.

s/Emma Grunberg
Emma Grunberg

STATEMENT OF RELATED CASES

Pursuant to Ninth Circuit Rule 28-2.6, counsel for Appellants is aware of no related cases pending before this Court.

Dated this 10th day of October 2023

s/Emma Grunberg
Emma Grunberg

CERTIFICATE OF SERVICE

I certify that on October 10, 2023, I electronically filed Appellees' Response Brief with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF sytem.

Dated this 10th of October 2023

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