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 EASTERN DISTRICT OF WASHINGTON AT YAKIMA

No. 1:23-cv-03026-TOR The Honorable Thomas O. Rice, United States District Court Judge

SUPPLEMENTAL BRIEF OF PLAINTIFFS-APPELLEES

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I. INTRODUCTION

The Supreme Court's *Alliance* decision underscores the impropriety of intervention here. Idaho and two other states are now the sole plaintiffs in *Alliance*, challenging, among other things, the Food and Drug Administration's removal of mifepristone's in-person dispensing requirement. Idaho and its aligned states cannot seriously assert a need to intervene here to seek precisely the same relief. There is no precedent for allowing a party litigating a claim in one venue to intervene and add the same claim to a different lawsuit. This maneuver defies the basic principles underlying intervention.

Moreover, the Supreme Court's decision makes clear that Proposed Intervenors have no legally protectable interest in their requested relief—a core requirement for intervention. Proposed Intervenors' only claimed interest is the legality under the Administrative Procedure Act of the FDA's removal of certain restrictions on mifepristone. But, as with the former plaintiffs in *Alliance*, Proposed Intervenors do not claim an interest relating to taking, prescribing, or dispensing mifepristone. Accordingly, the FDA does not require them to do anything or refrain from doing anything. Insofar as Proposed Intervenors want to restrict women in *other* states from accessing mifepristone, they may, as the Supreme Court stated, "express their views . . . in the political and electoral

processes." *Food & Drug Admin. v. All. for Hippocratic Med.*, 602 U.S. ___, 2024 WL 2964140, at *14 (June 13, 2024) (*Alliance*).

Following *Alliance*, it is even clearer that no grounds for intervention exist. If Proposed Intervenors continue to claim that they have standing to seek their requested relief, the correct forum to do so is *Alliance*, where their requested relief is already at issue, and Idaho and other states are the sole remaining plaintiffs. There is no basis to inject their attenuated and speculative claims into the Plaintiff States' existing lawsuit. The district court's denial of intervention should be affirmed.

II. THE SUPREME COURT'S DECISION IN ALLIANCE

The *Alliance* case is an Administrative Procedure Act (APA) lawsuit originally brought in the U.S. District Court for the Northern District of Texas against the FDA by anti-abortion doctors and medical associations. *Alliance*, 2024 WL 2964140, at *4. The complaint challenged the FDA's approval of mifepristone for marketing in the United States, its changing of certain regulations on the drug in 2016, and its decision not to enforce the in-person dispensing requirement in 2021. *Id.*¹ The district court, agreeing with the

¹ The FDA's 2021 decision was formalized in the 2023 REMS changes, which removed the in-person dispensing requirement. *See* 2-ER-234.

Plaintiffs, effectively enjoined the FDA's approval of mifepristone; the Supreme Court stayed that order. *Alliance*, 2024 WL 2964140, at *4. Subsequently, the Fifth Circuit ruled that the plaintiffs had standing, that the claims challenging the FDA's approval of mifepristone were time-barred, but that its 2016 and 2021 actions were likely unlawful. *Id.* at *5. The FDA petitioned for certiorari. *Id.*

Idaho, Missouri, and Kansas then moved to intervene in the Texas district court, nearly a year after the litigation started, arguing that if the Supreme Court denied standing to the existing plaintiffs, intervention would allow Idaho et al. to continue the case.² The district court granted intervention.³ Idaho et al. also sought to intervene in the Supreme Court, claiming their entry into the case below meant if the Court denied standing to the private plaintiffs, it would have no authority to reverse the lower courts' grant of preliminary relief.⁴ The Supreme Court denied intervention.⁵

² The States of Missouri, Kansas, & Idaho's Suggestions in Support of their Mot. to Intervene, *All. for Hippocratic Med. v. U.S. Food & Drug Admin.*, 668 F. Supp. 3d 507 (N.D. Tex. 2023) (No. 22-cv-223-Z), ECF No. 152; The States of Missouri, Kansas, & Idaho's Reply in Support of their Mot. to Intervene, *All. for Hippocratic Med.*, 668 F. Supp. 3d 507 (No. 22-cv-223-Z), ECF No. 172.

³ Order, *All. for Hippocratic Med.*, 668 F. Supp. 3d 507 (No. 22-cv-223-Z), ECF No. 175.

⁴ Notice of Intervention Below, & Mot. of Missouri, Idaho, & Kansas to Intervene (Jan. 22, 2024), *Alliance*, 602 U.S. (2024) (No. 23-235).

⁵ Order Denying Intervention (Feb. 20, 2024), *Alliance*, 602 U.S. (2024) (No. 23-235)

The Supreme Court issued its decision in *Alliance* on June 13, 2024, holding that the plaintiff doctors and medical associations lacked Article III standing. *Alliance*, 2024 WL 2964140, at *4. The Court noted that the challenged FDA regulations do not apply to the plaintiffs, who do not prescribe or use mifepristone. *Id.* at *9. As unregulated parties, the plaintiffs would therefore have to show how the FDA's regulation of others caused them concrete and non-speculative injury. *Id.* The Court held that the plaintiffs' causation theories failed to connect the FDA's actions to any of the plaintiffs' alleged injuries. *Id.* at *9-14. Instead, their "legal, moral, ideological, and policy objections" to medication abortion "do not establish a justiciable case or controversy in federal court." *Id.* at *14. Idaho et al. are now the sole remaining plaintiffs in *Alliance*.

III. ARGUMENT

The Supreme Court's decision in *Alliance* reinforces why intervention was correctly denied. Proposed Intervenors' central premise is that intervention is necessary to allow them to pursue their claimed interest in challenging the FDA's removal of the in-person dispensing requirement under the APA—a claim that is not otherwise at issue in this case. But Idaho is already pursuing that claim (with Missouri and Kansas) as the sole remaining plaintiffs in *Alliance*. Reversing the district court's denial of intervention below would allow

Proposed Intervenors to introduce a new claim into this lawsuit that Idaho is already litigating in a separate lawsuit, serving none of the purposes underlying intervention. *Alliance* also underscores that Proposed Intervenors' claimed policy interest in restricting access to mifepristone cannot suffice to allow these states to inject themselves into this case.

A. Proposed Intervenors have no need to intervene in this lawsuit to advance their claims.

To demonstrate entitlement to intervention as of right, an applicant must be "so situated" that disposition of the lawsuit may "as a practical matter" impair their ability to protect their claimed interest. *Cooper v. Newsom*, 13 F.4th 857, 864 (9th Cir. 2021). Intervention is properly denied where the applicant has "other means" to protect their interest, *United States v. Alisal Water Corp.*, 370 F.3d 915, 921 (9th Cir. 2004), including an "alternative forum" to advance their arguments. *California ex rel. Lockyer v. United States*, 450 F.3d 436, 442 (9th Cir. 2006).

When the briefs were filed in this appeal, the Plaintiff States noted that the Proposed Intervenors here had an alternative forum because they "could have sought to intervene" in *Alliance*, "in which the legality of the in-person dispensing requirement under the APA is currently being litigated." Br. of Pls.-

Appellees at 26 (DktEntry 34). Subsequently, Idaho and other states *did* intervene in *Alliance*. *See* Pls.-Appellees' FRAP 28(j) letter (DktEntry 57).

Following the Supreme Court's decision, Idaho and aligned states are now the sole remaining plaintiffs in *Alliance*. Those states' explicit reason for intervening in *Alliance* was to carry that case forward in the event the Supreme Court denied standing to the private plaintiffs. Thus, to the extent Idaho and aligned states seek to assert state standing to challenge the FDA's removal of the in-person dispensing requirement, the appropriate forum is the case in which Idaho is already litigating that exact issue.

Proposed Intervenors have cited no case in which an applicant was granted intervention to bring a claim that they are already litigating in another venue. In responding to Plaintiffs-Appellees' Rule 28(j) letter on their successful intervention in *Alliance*, Proposed Intervenors attempted to distinguish between the two cases by pointing to their own litigation decisions—that different states chose to join Idaho in seeking intervention in *Alliance*, and that those states (to date) have not chosen to bring a notice-and-comment claim in *Alliance*. Appellants' Response to Pls.-Appellees' Rule 28(j) letter (DktEntry 61). But

⁶ The States of Missouri, Kansas, & Idaho's Reply in Support of their Mot. to Intervene, *Alliance*, *supra* note 2, at 2-7, ECF No. 172.

these are irrelevant. Mandatory intervention only protects those with significant interests at stake in the subject of a lawsuit from suffering "direct, immediate, and harmful effects" without the ability to be heard. *See 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). It does not protect the ability to bring the same claim in two venues at the same time.

Moreover, as Proposed Intervenors have previously noted (*see* Reply Br. of Appellants at 15 (DktEntry 46)), intervention exists to promote the "efficient resolution of issues," *Wilderness Soc. v. U.S. Forest Serv.*, 630 F.3d 1173, 1179 (9th Cir. 2011), and to "prevent or simplify future litigation involving related issues," *United States v. City of Los Angeles*, 288 F.3d 391, 398 (9th Cir. 2002). Permitting intervention here would turn those purposes on their head by introducing distinct issues that are not currently part of this case—thus requiring expansion of the already-filed administrative record,⁷ and significantly

⁷ During the pendency of this appeal, the parties engaged in motions practice over the scope of the administrative record. Those issues have been resolved by the district court, and the complete administrative record was filed on April 12, 2024. Pls.-Appellees' Second Supplemental Excerpts of Record 1-SSER-1-50, 1-SSER-51-71, 1-SSER-72-90, 1-SSER-91-106, 1-SSER-107-25.

complicating the issues to be briefed and adjudicated—while requiring duplicative work by two district courts to adjudicate the same parallel claims.

Finally, Proposed Intervenors claimed in responding to the Plaintiff States' 28(i) letter that the interests at stake here are "distinct" from Alliance because the Plaintiff States seek elimination of the existing mifepristone REMS. Appellants' Resp. to Pls.-Appellees' Rule 28(j) letter (DktEntry 61). But Proposed Intervenors explicitly sought intervention to reinstate the in-person dispensing requirement, *not* to join the FDA in defending the existing restrictions challenged by the Plaintiff States. 2-ER-72-94; see also Reply Br. of Appellants at 11-12 (DktEntry 46) (Proposed Intervenors claiming it would be "mighty odd" to suggest the FDA could adequately represent their interests "given [Proposed] Intervenors are proposing to sue the Federal Defendants"). Proposed Intervenors' first mention of wanting to "defend" the existing restrictions came after the Plaintiff States noted Idaho's successful intervention in Alliance. Appellants' Response to Pls.-Appellees' Rule 28(j) letter (DktEntry 61).

To the extent Proposed Intervenors now claim they seek intervention to defend the existing restrictions, there is no reason why the FDA cannot adequately represent that interest. *See* Br. of Pls.-Appellees at 28-29 (DktEntry 34). As the Plaintiff States have noted, "[t]he FDA has every incentive and

ability to defend its own decision on the REMS requirements challenged here, and indeed is vigorously doing so." *Id.* at 28 (citing 2-ER-165-201).

B. Proposed Intervenors cannot show a protectable interest in reinstating the FDA's in-person dispensing requirement.

The Supreme Court's decision in *Alliance* also demonstrates further that Proposed Intervenors have no significant protectable interest in the FDA's regulation of mifepristone, an "irreducible" requirement of intervention as of right under Rule 24(a)(2). *Cal. Dep't of Toxic Substances Control v. Jim Dobbas, Inc.*, 54 F.4th 1078, 1088 (9th Cir. 2022) (internal quotation marks omitted).

Proposed Intervenors claim a generalized interest in the FDA following the law under the APA. Opening Br. of Appellants at 10 (DktEntry 17); Reply Br. of Appellants at 8-9 (DktEntry 46) ("State Intervenors have asserted a specific interest—safe, effective, and lawful mifepristone REMS—that is protectable under a specific federal statute—the APA."). This does not suffice to demonstrate a protectable interest warranting intervention as of right.

Washington and other Plaintiff States are directly regulated by, and harmed by, the REMS. *See* 5 U.S.C. § 702 (to obtain judicial review under the APA, a party must have suffered a legal wrong or been otherwise harmed by the challenged agency action). Specifically, the REMS impose requirements on health care providers who prescribe mifepristone and pharmacists who dispense

it. See Alliance, 2024 WL 2964140, at *7. Washington and other Plaintiff States employ doctors and pharmacists who directly prescribe and dispense mifepristone and must spend hundreds of hours complying with the REMS' complex certification requirements—requirements that apply to virtually no other drug in the country. See Pls.-Appellees' Second Supplemental Excerpts of Record 1-SSER-184-92 (Decl. of UW pharmacy administrator Sumona DasGupta); 1-SSER-221-45 (Decl. of UW obstetrician Dr. Emily Godfrey); 2-SSER-406-22 (Decl. of UW obstetrician Dr. Sarah Prager); 2-SSER-468-74 (Decl. of UW medical administrator Brian Reed); 2-SSER-480-97 (Decl. of UW reproductive health clinic director Dr. Grace Shih); see also 2-ER-43 (district court finding these are "unrecoverable costs that are fairly traceable to the 2023 REMS").

By contrast, Proposed Intervenors, like the plaintiffs who lacked standing in *Alliance*, do not claim an interest relating to prescribing or dispensing mifepristone. Accordingly, the FDA is "not requiring them to do or refrain from doing anything." *Alliance*, 2024 WL 2964140, at *4. And as the Plaintiff States noted, "this lawsuit will have no effect on Proposed Intervenors' ability to enact

and enforce state laws restricting medication abortion within their borders." Br. of Pls.-Appellees at 18 (DktEntry 34).8

Further, the preliminary injunction does not affect Proposed Intervenors because it applies only to the Plaintiff States: the district court declined to issue a nationwide injunction because of the "potential for competing litigation." 2-ER-57-58. This fact is critical because as Proposed Intervenors candidly acknowledged below, they sought intervention specifically so that they might appeal any preliminary injunction order. Pls.-Appellees' SER 7-9, 24-27. As the Supreme Court held in *Alliance*, however, a party's "desire to make a drug less available *for others*" is not enough. *Alliance*, 2024 WL 2964140, at *4. If Proposed Intervenors want to restrict access to mifepristone in their sister states, they may, as the Court stated, "take their concerns to the Executive and Legislative Branches." *Id.* at *12.

The *Alliance* decision also confirms that Proposed Intervenors' asserted economic interests are insufficient. Proposed Intervenors advance a similar

⁸ In moving to intervene, Proposed Intervenors stated that they "are not asserting an interest based on a connection between their laws and the mifepristone REMS" (Pls.-Appellees' SSER-134), and on appeal they say their "interest in enforcing their laws" is "not the only—or even the principal—interest threatened with impairment." Opening Br. of Appellants at 13 (DktEntry 17).

theory to the former plaintiffs in *Alliance*: that the FDA's 2021 decision will lead to some small fraction of women experiencing exceedingly rare, serious adverse events requiring emergency care for which Proposed Intervenors may pay some portion of the remaining costs. See 2-ER-82; Opening Br. of Appellants at 19 (DktEntry 17). The Court held in *Alliance* that this was "too speculative or otherwise too attenuated" to show causation between the FDA's regulatory actions and the alleged harm. Alliance, 2024 WL 2964140, at *11. It is similarly insufficient to show a protectable interest under Rule 24 here. For intervention purposes, "a claim based only on an indirect economic effect of some action is rarely considered the same as a protectable right or interest sufficient to justify intervention." 6 James WM. Moore, Moore's Federal Practice § 24.03(2)(b) at 24–32 n.33 (Matthew Bender 3d ed. 2017); see also State of Montana v. U.S. E.P.A., 137 F.3d 1135, 1142 (9th Cir. 1998) ("[A] speculative and purely economic interest does not create a protectable interest in litigation concerning a statute that regulates environmental, not economic, interests.").

Further, Proposed Intervenors—like the former plaintiffs in *Alliance*—fail to back up their assertion with any record evidence. *Alliance*, 2024 WL 2964140, at *11 (plaintiffs' theory "lacks record support and is highly speculative."). Proposed Intervenors claim that patients' ability to access mifepristone in retail

pharmacies or by mail will lead to increased serious complications. But the FDA stopped enforcing the in-person dispensing requirement in 2021, and its 2023 review concluded that "there does not appear to be a difference in adverse events between periods when the in-person dispensing requirement was being enforced and periods when [it] was not being enforced." Pls.-Appellees' SER-51. Despite the availability of evidence since 2021 as to how removal of the requirement has impacted emergency care, Proposed Intervenors—like the plaintiffs in *Alliance*—"have not offered evidence tending to suggest that FDA's deregulatory actions have . . . caused an increase in the number of pregnant women seeking treatment" or "any persuasive evidence or reason to believe that the future will be different." *Alliance*, 2024 WL 2964140, at *11.

Washington and other Plaintiff States, which prescribe mifepristone and are thus directly regulated by the FDA in that capacity, brought this case to challenge existing restrictions imposing significant burdens on the States that are contrary to statute, harmful to patients, and have no basis in the medical evidence. By contrast, as the Supreme Court's decision reinforces, Proposed Intervenors have asserted no protectable interest in attempting to reinstate the inperson dispensing requirement, let alone in doing so within the Plaintiff States.

C. Alliance reinforces the inappropriateness of permissive intervention.

Federal Rule of Civil Procedure 24(b)(3) requires courts to consider, on permissive intervention, "whether the intervention will unduly delay or prejudice the adjudication of the original parties' rights." Denial is appropriate where intervention would "only serve to undermine the efficiency of the litigation process." *Donnelly v. Glickman*, 159 F.3d 405, 412 (9th Cir. 1998).

The Court's decision in *Alliance*, because it leaves Idaho and aligned states as the sole remaining plaintiffs in *Alliance*, reinforces the inappropriateness of permissive intervention under these standards. The parties to this case, the Plaintiff States and the FDA, have already litigated the scope of the administrative record based on the existing claims and will proceed next to summary judgment. Intervention, however, would require the district court to essentially start over with the addition of a new claim, second administrative record, and new requested relief—relief that is already being sought in *Alliance*.

Adding Proposed Intervenors to this litigation would also complicate proceedings substantially by requiring the district court to address those states' theories of standing. Proposed Intervenors cannot use this case as an end-run around standing; an applicant for intervention seeking to pursue different relief from the existing plaintiffs must show Article III standing to pursue that relief.

Town of Chester v. Laroe Estates, Inc., 581 U.S. 433, 439-40 (2017). As explained, the Supreme Court's decision in Alliance underscores the speculative and attenuated nature of Proposed Intervenors' standing theories here. Idaho and its aligned states will have to advance those arguments in order to proceed in Alliance—in fact, that was an explicit reason for their intervention in that case. There is no purpose served by requiring the district court here to address those same standing theories in this case as well.

As the Plaintiff States noted, permissive intervention would require the district court to manage two distinct cases under one docket number. And it would do so even as another court is already hearing Proposed Intervenors' same claims. This is wasteful and improper.

* * *

As the Plaintiff States have maintained, Proposed Intervenors do not meet the requirements for intervention as of right, and the district court appropriately exercised its discretion in denying permissive intervention. The Supreme Court's decision in *Alliance* reinforces the lack of any basis for intervention here—both because Idaho and aligned states are now the sole remaining plaintiffs in *Alliance*

⁹ The States of Missouri, Kansas, & Idaho's Reply in Support of their Mot. to Intervene at 7-12, *Alliance*, *supra* note 2, at 2-7, ECF No. 172.

and have no need to intervene here, and because the Court's decision underlines the lack of any protectable interest in restricting others from accessing mifepristone.

IV. CONCLUSION

This Court should affirm the district court's denial of Proposed Intervenors' motion to intervene.

RESPECTFULLY SUBMITTED this 27th day of June 2024.

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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 2972 words.

Dated this 27th of June 2024.

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 27th of June 2024

s/Emma Grunberg Emma Grunberg

CERTIFICATE OF SERVICE

I certify that on June 27, 2024, 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 system.

Dated this 27th of June 2024

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