No. 23-35294

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

STATE OF WASHINGTON, et al.,

Plaintiffs-Appellees,

v.

U.S. FOOD & 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

BRIEF FOR FEDERAL APPELLEES

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STATEMENT OF ISSUE

Seventeen States and the District of Columbia brought this suit to challenge a decision by the U.S. Food and Drug Administration (FDA) to retain certain conditions for the distribution and use of mifepristone for the termination of pregnancy. Seven additional States moved to intervene for the purpose of challenging FDA's decision to *remove* a different restriction on mifepristone. The question presented is whether the district court properly denied the motion to intervene.

STATEMENT OF THE CASE

A. Statutory And Regulatory Background

1. Congress has entrusted FDA with the authority and responsibility to determine whether a "new drug" is safe and effective before it is distributed. 21 U.S.C. §§ 321(p), 355; *see id.* § 393(b)(2)(B). The Federal Food, Drug, and Cosmetic Act (FDCA), *id.* § 301 *et seq.*, directs FDA to approve a new drug if, among other things, the sponsor's application contains evidence demonstrating that the drug is safe and effective for its intended use. *Id.* § 355(b), (d); *see* 21 C.F.R. §§ 314.50, 314.105(c).

In 2007, Congress codified and expanded FDA's existing regulatory regime by authorizing the agency to require a "risk evaluation and mitigation strategy," or REMS, when it determines that such a strategy is necessary to ensure that the benefits of a drug outweigh the risks. 21 U.S.C. § 355-1; *see* Food and Drug Administration Amendments Act of 2007 (FDAAA), Pub. L. No. 110-85, tit. IX, § 901, 121 Stat. 823, 922. Under the REMS framework, FDA's approval of a drug may include "elements to assure

safe use," such as a requirement that a drug's prescribers have particular training or that a drug be dispensed only in certain settings. 21 U.S.C. § 355-1(f)(3). FDA may require submission of a proposed modification to an approved REMS if it determines that the modification should be made to ensure the benefits of the drug outweigh the risks. Modifications may include changes to requirements previously imposed to assure safe use of the drug. *Id.* § 355-1(g)(4).

2. In 2000, FDA approved mifepristone under the brand name Mifeprex. 2-ER-32. Mifepristone is approved for use in a regimen with another drug, misoprostol, to end an early pregnancy. 2-ER-32. In approving mifepristone, FDA invoked regulations known as "Subpart H" to impose, among others, requirements that mifepristone be dispensed only "in a hospital, clinic, or medical office, by or under the supervision of a certified provider"; that "providers attest to their clinical abilities in a signed form kept on file by the manufacturer"; and that "prescribers and patients review and sign a form with information about the regimen and risks." 2-ER-32–33.[1]

When Congress adopted the REMS framework in 2007, it deemed each drug with existing Subpart H distribution restrictions, including mifepristone, to have an approved REMS imposing the same restrictions. FDAAA tit. IX, § 909(b), 121 Stat. at 950-951 (21 U.S.C. § 331 note). Since those amendments took effect, therefore, the

[1] Another drug with mifepristone as its active ingredient, called Korlym, is approved for the treatment of Cushing's syndrome. This litigation does not involve Korlym or its generic.

requirements to assure mifepristone's safe use have been governed by the statutory REMS framework.

FDA has since modified the conditions of mifepristone's distribution and use on several occasions. In 2016, for example, FDA increased the gestational age limit from seven to ten weeks; reduced the number of required in-person clinical visits from three to one; and approved a modification to the REMS to allow certain non-physician healthcare providers licensed under state law to prescribe and dispense drugs, such as nurse practitioners, to prescribe and dispense mifepristone. 2-ER-34–35. And in 2019, FDA approved "a generic version of mifepristone and established the Mifepristone REMS Program, which covered both Mifeprex and the generic drug." 2-ER-35.

3. In April 2021, FDA announced that, in light of potential COVID-19-related risks associated with the in-person dispensing requirement, FDA intended to exercise enforcement discretion as to that requirement during the COVID-19 public health emergency. 2-ER-35. This decision "was the result of a thorough scientific review by experts" who evaluated evidence including "clinical outcomes data and adverse event reports." 2-ER-102. FDA then announced a broader review of the Mifepristone REMS Program to determine whether any of its elements should be modified. SER-11.

In December 2021, following that review, FDA concluded that "certain elements of the Mifepristone REMS Program remain necessary to assure the safe use of mifepristone." SER-60. In particular, FDA maintained the prescriber certification and

patient agreement-form requirements. SER-76–78. But FDA concluded that "the REMS must be modified to remove the in-person dispensing requirement," so as to "allow, for example, dispensing of mifepristone by mail via certified prescribers or pharmacies." SER-89. FDA made that change on the basis of its determination that mifepristone would "remain safe and effective if the in-person dispensing requirement [were] removed," so long as "all the other requirements of the REMS [were] met and" a requirement for "pharmacy certification [was] added" to the Program. *Id.*

FDA explained its conclusions in a review memorandum. SER-4–53. It found no "difference in adverse events between periods during the COVID-19 [public health emergency] when the in-person dispensing requirement was being enforced and periods when the in-person dispensing requirement was not being enforced." SER-41. And it explained that, while the removal of the in-person dispensing requirement would allow mifepristone to be dispensed by pharmacies for the first time, the newly created pharmacy certification requirement would "incorporate[] pharmacies into the REMS, ensur[ing] that [they] are aware of and agree to follow applicable REMS requirements, and … that mifepristone is only dispensed pursuant to prescriptions that are written by certified prescribers." SER-43.

FDA directed the drugs' application holders to submit supplemental applications proposing conforming modifications to the REMS (SER-96–100; SER-102–105), and FDA approved those applications in January 2023 (SER-107–146).

B. This Action And Related Litigation

1. Shortly after FDA approved the January 2023 REMS modifications, plaintiffs brought this challenge to the REMS under the Administrative Procedure Act (APA). 2-ER-202–300 (amended complaint). Plaintiffs contend that it is improper for FDA to subject mifepristone to a REMS at all. 2-ER-206 ¶ 7. They challenge the three "hurdles to accessing mifepristone" that the REMS imposes: the prescriber certification requirement, the pharmacy certification requirement, and the patient agreement-form requirement. 2-ER-238–242 ¶¶ 115-124. Plaintiffs seek declaratory relief and an injunction against enforcement of the REMS, as well as an injunction barring "any action to remove mifepristone from the market or reduce its availability." 2-ER-291.

2. Seven States moved to intervene, bringing a wholly different claim: a challenge to the January 2023 elimination of the in-person dispensing requirement. 2-ER-61–70 (motion); 2-ER-72–94. Movants seek a declaratory judgment that the action was invalid, vacatur of the action, and an injunction against the enforcement of the 2023 REMS. 2-ER-91.

3. While the motion to intervene was pending, the district court granted in part plaintiffs' motion for a preliminary injunction, barring 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-59.

Meanwhile, a Texas district court issued an order staying FDA's original approval of mifepristone, as well as subsequent actions modifying its conditions of distribution.

Alliance for Hippocratic Med. v. FDA, 2023 WL 2825871 (N.D. Tex. Apr. 7, 2023). The Supreme Court stayed that order pending appeal to the Fifth Circuit and any subsequent Supreme Court proceedings. *Danco Labs., LLC v. Alliance for Hippocratic Med.*, 143 S. Ct. 1075 (2023). The Fifth Circuit subsequently affirmed the district court's order in part and vacated it in part, *Alliance for Hippocratic Med. v. FDA*, 78 F.4th 210 (5th Cir. 2023), and petitions for certiorari are now pending before the Supreme Court (Nos. 23-235, -236).

4. The district court then denied the motion to intervene, reasoning that movants had not shown "a significantly protectable interest relating to the subject of the action." 1-ER-5. The court explained that "[t]he 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-6–7. It concluded that the "resolution of this case will not affect" movants' "claims that FDA should have more restrictive limitations than the 2023 REMS," and thus that movants have no right to intervene under Federal Rule of Civil Procedure 24(a). *Id.*

The court also denied permissive intervention, explaining that the question movants seek to raise (the propriety of eliminating the in-person dispensing requirement) is not presented by plaintiffs' complaint, and thus that "there is no common question of law or fact within the meaning of Rule 24(b)." 1-ER-8. The court further observed that "the addition of State Intervenors who allege claims and relief not at issue would cause additional delay in this complex litigation." *Id.*

SUMMARY OF ARGUMENT

I. The district court's ruling should be affirmed because movants lack standing to challenge FDA's elimination of the in-person dispensing requirement.

A. "[A]n intervenor of right must demonstrate Article III standing when it seeks additional relief beyond that which the plaintiff requests." *Town of Chester v. Laroe Estates, Inc.*, 581 U.S. 433, 439 (2017). That is plainly true of movants. As their brief explains (at 13), movants want "mifepristone's in-person dispensing requirement" to "be[] restored," whereas "[p]laintiffs hope to eliminate mifepristone's REMS altogether." Movants do not dispute that they seek distinct relief.

Movants argue that they need not establish standing because plaintiffs have standing, but that argument is at odds with *Town of Chester*. It is immaterial that movants challenge the same agency action as plaintiffs do, because the relief that they seek in their challenge is fundamentally different.

B. Movants' brief asserts no basis for Article III standing. Movants first contend that the elimination of the in-person dispensing requirement will cause more of their citizens to obtain mifepristone and that some of those citizens will be harmed as a result. But the Supreme Court has repeatedly and recently emphasized that States lack standing to assert their citizens' rights in a suit against a federal agency.

Movants also claim that the elimination of the in-person dispensing requirement threatens to harm their economic interests, because their Medicaid programs will need to cover some of the medical costs of people who (movants believe) will require care

after using mifepristone. But as the Supreme Court recently made clear, that sort of attenuated injury—resting on the indirect effects that a challenged policy may have on a State's fisc—is an insufficient basis for standing.

II. Movants' lack of standing equally defeats their claim to permissive intervention, because the reasoning of *Town of Chester* applies to a permissive intervenor who seeks relief not sought by any existing parties.

In any event, movants' lack of standing is a proper basis to affirm the district court's exercise of its discretion not to allow permissive intervention. So is the district court's determination that movants' claims do not share a "common question of law or fact" with plaintiffs' claims, and its determination that intervention to expand the scope of the litigation "would cause additional delay." 1-ER-8.

STANDARD OF REVIEW

This Court "review[s] de novo a district court's denial of a motion to intervene as a matter of right, with the exception of a denial based on timeliness, which is reviewed for abuse of discretion." *Callahan v. Brookdale Senior Living Cmtys., Inc.*, 42 F.4th 1013, 1019 (9th Cir. 2022). The Court "review[s] a district court's denial of a motion for permissive intervention for abuse of discretion." *Id.* at 1020.

ARGUMENT

I. Movants Lack Standing To Challenge The Elimination Of The In-Person Dispensing Requirement

A. Because Movants Seek Distinct Relief, They Must Establish Standing Like Any Other Plaintiff

1. In *Town of Chester v. Laroe Estates, Inc.*, 581 U.S. 433 (2017), the Supreme Court held that, "at the least, an intervenor of right must demonstrate Article III standing when it seeks additional relief beyond that which the plaintiff requests." *Id.* at 439. That conclusion, the Court explained, "follows ineluctably" from the basic requirement that "[a]t least one plaintiff must have standing to seek each form of relief requested … , whether that litigant joins the lawsuit as a plaintiff, a coplaintiff, or an intervenor of right." *Id.*

Movants indisputably "pursue relief that is different from that which is sought by" plaintiffs, *Town of Chester*, 581 U.S. at 440. As discussed above, plaintiffs seek to prevent FDA from subjecting the distribution and use of mifepristone to *any* special conditions, including the in-person dispensing requirement. *See, e.g.*, 2-ER-242–245 ¶¶ 125-130 (explaining why, in plaintiffs' view, the Mifepristone REMS Program is beyond FDA's statutory authority). Consistent with that theory, plaintiffs seek an injunction barring FDA "from taking any action to … reduce" the "availability" of mifepristone. 2-ER-291. Movants, by contrast, argue that FDA acted unlawfully in *loosening* the conditions on mifepristone's distribution by eliminating the in-person dispensing requirement. *See, e.g.*, 2-ER-89–91 ¶¶ 99-107. They seek, among other forms of relief,

"[v]acat[ur]" of FDA's action eliminating the in-person dispensing requirement. 2-ER-91. In other words, as their brief explains (at 13), movants want "mifepristone's in-person dispensing requirement" to "be[] restored," whereas "[p]laintiffs hope to eliminate mifepristone's REMS altogether." The relief that movants seek is squarely at odds with the relief that plaintiffs seek.

2. In explaining (Br. 17-19) why they do not believe that they must establish standing, movants do not dispute that plaintiffs seek different relief than they do. But they argue (Br. 17) that they need not establish standing "because [p]laintiffs have standing to challenge the 2023 mifepristone REMS under the APA, and only one plaintiff needs standing to provide a federal court with jurisdiction to decide a case or controversy."

That argument is squarely at odds with *Town of Chester*, which applied the settled rule that "[a]t least one plaintiff must have standing to seek *each form of relief* requested in the complaint." 581 U.S. at 439 (emphasis added). That "ineluctable requirement is not vitiated simply because an intervenor is raising a new or different claim for relief in the context of an existing case rather than bringing an original suit." *Oregon Prescription Drug Monitoring Program v. DEA*, 860 F.3d 1228, 1233 (9th Cir. 2017); *see also California Dep't of Toxic Substances Control v. Jim Dobbas, Inc.*, 54 F.4th 1078, 1085 (9th Cir. 2022) ("[i]ntervenors that seek relief that is broader than or different from the relief sought by existing parties to the case must possess constitutional standing," even though "intervenors that seek the same relief sought by at least one existing party to the case need

not do so"). It is immaterial that movants challenge the same agency action as plaintiffs do, because the relief that they seek in their challenge is fundamentally different and the district court lacks jurisdiction to grant such relief absent a party with standing to seek it. Movants' argument flouts the basic principle that "standing is not dispensed in gross." *Town of Chester*, 581 U.S. at 439 (quotation marks omitted).

B. Movants Have Not Established Any Article III Injury

Neither of the injuries asserted in movants' brief is sufficient to establish standing to challenge the elimination of the in-person dispending requirement.

First, movants argue (Br. 18) that the elimination of the requirement will "make it more likely" that their citizens obtain mifepristone, including by obtaining it in neighboring States. And they claim that the increased use of mifepristone by their citizens "will lead directly to citizen harm." *Id.* (citing 2-ER-80–81 ¶¶ 41-51). Movants rely, for example, on the allegation that "[w]ithout the in-person dispensing requirement, women in Idaho will be exposed to the dangerous complications caused by [mifepristone] and will be left without any professional medical oversight or prompt medical assistance" for those complications. 2-ER-80 ¶ 45.

But even if those allegations were factually plausible, that sort of harm is an injury to movants' *citizens*, not to movants themselves. The Supreme Court has repeatedly and recently emphasized that States cannot assert their citizens' rights in a suit against a federal agency, "because '[a] State does not have standing as *parens patriae* to bring an action against the Federal Government.'" *Haaland v. Brackeen*, 143 S. Ct. 1609,

1640 (2023) (quoting *Alfred L. Snapp & Son, Inc. v. Puerto Rico ex rel. Barez*, 458 U.S. 592, 610 n.16 (1982)). Movants' asserted interest in preventing harm to their citizens closely resembles the interest held insufficient for standing in *Brackeen*—a State's interest in safeguarding the constitutional rights of "non-Indian families," 143 S. Ct. at 1640 n.11. The Supreme Court described the State's reliance on that interest as "a thinly veiled attempt to circumvent the limits on *parens patriae* standing." *Id.* The same is true of movants' theory here.

Movants rely (Br. 18) on this Court's statement in *California v. Trump*, 963 F.3d 926, 936 (9th Cir. 2020), quoting from *Snapp*, 458 U.S. at 607, that "a state may sue to assert its 'quasi-sovereign interests in the health and well-being—both physical and economic—of its residents in general.'" But in *California*, the plaintiff States were asserting their *own* interests in "the environment and wildlife" within their borders, a type of "'interest independent of'" their residents'. *Id.* (quoting *Georgia v. Tennessee Copper Co.*, 206 U.S. 230, 237 (1907)); *see also Natural Res. Def. Council v. EPA*, 542 F.3d 1235, 1249 n.8 (9th Cir. 2008) (recognizing States' "interest in protecting in-state waterways from pollution originating outside their borders"). And to the extent that this Court's quotation from *Snapp* could be read to support movants' theory that they have standing to assert the interests of their residents, it would conflict with *Snapp* itself. The Supreme Court held in that case that a State "must" assert a quasi-sovereign injury to have *parens patriae* standing, 458 U.S. at 601, but that *even then* it cannot sue the federal government on such a theory, *id.* at 610 n.16. In any event, to the extent that *California* would

otherwise have been binding, it has been abrogated on this point by the Supreme Court's intervening decision in *Brackeen*. *See Miller v. Gammie*, 335 F.3d 889, 893 (9th Cir. 2003) (en banc).

Second, movants assert (Br. 19) that the elimination of the in-person dispensing requirement threatens "direct harm to their own economic interests." Their theory is that the elimination of the requirement will cause "'increased risk to … women and unborn children'"; that that increased risk will lead to "'additional medical care expenses, including emergency care'"; and that "'some of'" those "'additional medical care expenses'" will be "'borne by [States] through Medicaid expenditures.'" *Id.* (quoting 2-ER-82 ¶ 54). Movants argue that the district court accepted a similar theory as to the plaintiffs in the underlying suit. *See* 2-ER-42–43.

But to the extent the district court did so,[2] that reasoning does not survive the Supreme Court's subsequent decision in *United States v. Texas*, 143 S. Ct. 1964 (2023). There, two States asserted standing to challenge federal immigration-enforcement guidelines on the theory that the guidelines "impose[d] costs on the States," such as by requiring them to "continue to incarcerate or supply social services such as healthcare and education to noncitizens." *Id.* at 1969. The district court accepted that theory, *id.*,

[2] It is unclear whether the district court's finding of "a reasonably probable threat to [plaintiffs'] economic interests" rested on the prospect that plaintiffs would face "unrecoverable costs" to their "Medicaid and other state-funded health care programs"—akin to the one that movants allege—as opposed to the costs of "implementing systems to comply with the 2023 REMS' patient agreement and licensure requirements," which movants do not assert. 2-ER-42–43.

but the Supreme Court reversed. It explained that the States' challenge to the enforcement guidelines was "not the kind redressable by a federal court," *id.* at 1971, and emphasized more generally that "federal courts must remain mindful of bedrock Article III constraints in cases brought by States against an executive agency or officer," *id.* at 1972 n.3. In particular, the Court described as "attenuated" theories of state standing resting on claims that a federal policy "has produced only" "indirect effects on state revenues or state spending." *Id.* "To satisfy the causality element for Article III standing, … '[t]he line of causation between the defendant's action and the plaintiff's harm must be more than attenuated.'" *Washington Env't Council v. Bellon*, 732 F.3d 1131, 1141 (9th Cir. 2013); *see also, e.g.*, *Arizona v. Biden*, 40 F.4th 375, 386 (6th Cir. 2022) (a "boundless theory of standing," "in which all peripheral costs imposed on States by actions of the [federal government] create a cognizable Article III injury," "'would make a mockery … of the constitutional requirement of case or controversy'").

Movants assert exactly the sort of harm that the Supreme Court described as "attenuated," *Texas*, 143 S. Ct. at 1972 n.3—a theory that, to the extent the elimination of the in-person dispensing requirement makes their citizens more likely to obtain mifepristone within or outside their borders, and to the extent their citizens require medical care as a result, the State might wind up paying for that care under Medicaid. Even if those allegations were factually plausible, federal courts lack jurisdiction to address harms whose connection to the challenged policy is so speculative and indirect.

II. The District Court Did Not Abuse Its Discretion In Denying Permissive Intervention

1. Where a litigant seeks permissive intervention to participate in an action on substantially the same terms as the original parties, and seeks relief not sought by any existing parties, the "simple rule" applied in *Town of Chester* applies just as it does in the context of intervention by right: "For all relief sought, there must be a litigant with standing," regardless of how that litigant joins the suit. 581 U.S. at 439. For that reason, numerous courts have concluded that the reasoning of *Town of Chester* applies when permissive intervenors seek distinct relief, just as when of-right intervenors seek distinct relief. *See, e.g.*, *1199SEIU United Healthcare Workers E. v. PSC Cmty. Servs.*, 597 F. Supp. 3d 557, 567 n.7 (S.D.N.Y. 2022); *United States v. RaPower-3, LLC*, 341 F.R.D. 311, 317 (D. Utah 2022); *Franciscan All., Inc. v. Azar*, 414 F. Supp. 3d 928, 938 n.3 (N.D. Tex. 2019).[3]

The denial of movants' request for permissive intervention therefore should be affirmed on the same ground as the denial of intervention by right.

2. Even if *Town of Chester*'s logic did not apply to permissive intervention, moreover, this Court's standard for permissive intervention has long taken account of the proposed intervenors' "'standing to raise relevant legal issues.'" *Perry v. Schwarzenegger*, 630 F.3d 898, 905 (9th Cir. 2011) (per curiam) (quoting *Spangler v. Pasadena Bd. of*

[3] Article III standing may not be required in circumstances where district courts place "highly restrictive conditions" on permissive intervention, *Stringfellow v. Concerned Neighbors in Action*, 480 U.S. 370, 382 n.1 (1987) (Brennan, J., concurring in part and concurring in the judgment). Here, however, movants seek permissive intervention without such limits.

Educ., 552 F.2d 1326, 1329 (9th Cir. 1977)). Movants' failure to establish standing would therefore be an appropriate basis on which to affirm the district court's exercise of its "broad discretion," *id.* at 905-906, whether to allow permissive intervention.

This district court was equally justified in denying permissive intervention on the ground that movants' challenge to the elimination of the in-person dispensing requirement does not share a "common question of law or fact" with plaintiffs' challenge to the restrictions maintained by the January 2023 REMS modifications, and that "the addition of State Intervenors who allege claims and relief not at issue would cause additional delay in this complex litigation." 1-ER-8. In seeking to combine their challenge to the elimination of the in-person dispensing requirement with plaintiffs' challenge to the maintenance of *any* REMS program for mifepristone, movants asked the district court to resolve two fundamentally different claims in a single action. The district court acted well within its discretion in declining to do that.

CONCLUSION

The district court's denial of intervention should be affirmed.

Respectfully submitted,

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STATEMENT OF RELATED CASES

I am unaware of any related case pending in this Court.

/s/ Daniel Winik
Daniel Winik

CERTIFICATE OF COMPLIANCE

9th Cir. Case Number(s) No. 23-35294

I am the attorney or self-represented party.

This brief contains 3,993 **words,** excluding the items exempted by Fed. R. App. P. 32(f). The brief's type size and typeface comply with Fed. R. App. P. 32(a)(5) and (6).

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