

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

APPELLANTS' PETITION FOR REHEARING *EN BANC*

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INTRODUCTION AND RULE 35(b) STATEMENT

State standing often looks different in the Ninth Circuit depending on the policy position of the states involved. When immigration restrictions or contraceptive coverage are involved, the Court has been comfortable projecting the natural consequences of the federal government's actions and affording standing based on the harm that will flow to the states. But when a coalition of states (the Intervenor States) challenged the Food and Drug Administration's creation of a nationwide, mail-order abortion regime offering women in any state easy access to dangerous abortion drugs, the panel here refused to forecast the likely repercussions—now moved by a pressing concern that it should not engage in “speculation.” Op. 21.

The consequences of permitting doctors to remotely prescribe mifepristone into states that otherwise largely prohibit abortion are not speculative at all. The predictable result is that more women in the Intervenor States will use mifepristone, and more women will use it under unsafe conditions that could be prevented by an in-person physical examination. Given mifepristone's significant historical hospitalization rate, that means more women will head to the emergency room, where the Intervenor States will have to foot the bill through Medicaid. Under Ninth Circuit precedent, this anticipated harm should have been more than enough for standing. The panel's denial of standing creates an intra-circuit split. Fed R. App. P. 35(b)(1).

The panel repeated its error when addressing the harms to the Intervenor States' sovereign interest in enforcing their abortion laws and quasi-sovereign interest in

protecting the health of their citizens. Common sense indicates that these interests are certainly impaired by the FDA's action, but the panel denied standing by devising arbitrary limitations that directly contradict Supreme Court precedent.

The Court's vacillating approach to standing is particularly concerning here since it coincides with a parallel trend of selectively denying intervention. This case was originally brought by a different coalition of states seeking to force the FDA to eliminate *all* heightened restrictions on mifepristone. Because the suit had all the trappings of the “[s]ue-and-settle litigation [that] has plagued the federal regulatory system for decades,”¹ the Intervenor States brought their claims by moving to intervene in this case rather than bringing them separately. By refusing to allow the Intervenor States to participate, the panel continues its “troubling trend” of “denying intervention whenever it might upset a possible collusive settlement resulting in a favored policy.” *E. Bay Sanctuary Covenant v. Biden*, 102 F.4th 996, 1003 (9th Cir. 2024) (VanDyke, J., dissenting).

If the panel's decision is allowed to stand, it will not only disrupt uniformity in this Court's precedents, it may also enable a collusive settlement with nationwide effect that will foreclose any chance for the Intervenor States or other states to have their claims heard. *See All. for Hippocratic Med. v. FDA*, No. 2:22-cv-223-Z (N.D. Tex.). The Court should not let that happen; the panel's decision should be reheard *en banc*.

¹ Letter from James Comer, Chairman, Committee on Oversight and Accountability, to Michael S. Regan, Administrator EPA (Nov. 14, 2023), *available at* <https://tinyurl.com/53cx3mx3>.

BACKGROUND

I. The FDA jeopardizes maternal health by eliminating the requirement that mifepristone be dispensed in person.

Mifepristone is a drug with deadly potential—in more ways than one. The drug induces chemical abortions by blocking nutrients from reaching the unborn child and starving it to death; so by design, the drug is lethal to the unborn child. But its side effects can also be fatal or serious to women who ingest it, as the drug can cause urgent conditions like excessive bleeding or sepsis. *All. for Hippocratic Med. v. FDA*, 78 F.4th 210, 231 (5th Cir. 2023) (describing patient who “was at risk of bleeding to death”).² According to the FDA itself, “about 5-8 out of 100 women taking [mifepristone] will need a surgical procedure to end the pregnancy or to stop too much bleeding,” and 2.9 to 4.6% will visit the emergency room. 2011 Mifepristone REMS at 4;³ 2016 Mifepristone Label at 8.⁴

Based on the risks to women who take mifepristone, the FDA has always treated the drug as dangerous and has imposed heightened restrictions on the drug’s use since the day it was submitted for approval. *See FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 375-76 (2024). The “risk evaluation and mitigation strategy” (REMS) the FDA

² *See* Danco Letter at 1 (Nov. 12, 2004), <https://perma.cc/734R-LLSQ> (letter from mifepristone manufacturer to emergency rooms explaining that “some women who present to an emergency room [will have] serious and sometimes fatal infection and bleeding”).

³ *Available at* <https://tinyurl.com/53k8cf3m>.

⁴ *Available at* <https://tinyurl.com/yu8fd7fw>.

implemented in 2011 required that (1) mifepristone be prescribed and administered in person in a hospital, clinic, or medical office, (2) prescribers be certified, and (3) prescribers document serious adverse events. *Id.*; 2-ER-77 ¶ 26; *see* 21 U.S.C. § 355-1. The 2011 REMS also indicated that mifepristone is not safe for women who are more than seven weeks pregnant or have an ectopic pregnancy. 2011 Mifepristone REMS at 5.⁵ Given the likelihood of emergency complications, the REMS warned that women should not take mifepristone if they “cannot easily get emergency medical help [for] 2 weeks” after taking the drug. *Id.*

Then the FDA abruptly changed course. In 2021, although nothing about the drug’s risk profile had changed, the FDA announced that it would no longer enforce the requirement that mifepristone be prescribed and administered in person. *FDA*, 602 U.S. at 376. And in 2023, the FDA officially modified the REMS to eliminate this in-person dispensing requirement. 2-ER-78 ¶ 31. Its modification came without explanation and without requesting notice and comment—it simply issued a letter parroting the statutory standard for modifying a REMS. *Compare* 2-ER-96, *with* 21 U.S.C. § 355-1(g)(2)(C).

The result is a nationwide mail-order abortion drug regime with enormous risk to maternal health. Mifepristone can now be prescribed via telehealth, shipped directly

⁵ In 2016, the FDA extended the permissible gestational age to 10 weeks. *FDA*, 602 U.S. at 375.

to a patient’s home, and ingested without a woman ever being physically examined by a doctor. The dangers of this easy-access scheme are obvious—an in-person visit is the *only* way for a medical provider to accurately assess gestational age or check for ectopic pregnancies and other dangerous conditions.⁶ And initial in-person visits facilitate quick follow-up visits if concerning complications develop. In other words, because of the REMS modification, more women are bound to experience complications from misused mifepristone, catch those complications slower, and seek emergency-room treatment.

This increase in medical complications imposes significant costs on states, too. States have a quasi-sovereign “interest in the health and well-being . . . of its residents” that is obviously hampered when its citizens are sent to the emergency room at higher rates. *Alfred L. Snapp & Son, Inc. v. Puerto Rico, ex rel., Barez*, 458 U.S. 592, 593 (1982). States also suffer economic harm from increased emergency room trips, since they will have to pay for many such visits through Medicaid. And for states (like the Intervenor States) whose “legitimate interest[]” in the “preservation of prenatal life” has prompted them to pass laws prohibiting abortion in most circumstances, *Dobbs v. Jackson Women’s Health Org.*, 597 U.S. 215, 301 (2022), a mail-order mifepristone regime obliterates their ability to effectively enforce those laws.

⁶ About 1 in 50 pregnancies in the United States are ectopic. ACOG Practice Bulletin (Mar. 2018), <https://perma.cc/3AA3-CNQX>.

II. The Plaintiff States sue to eliminate the REMS altogether, and the Intervenor States are denied intervention.

Even though the 2023 REMS modification *relaxed* restrictions on prescribing mifepristone, a coalition of states led by Washington (the Plaintiff States) brought this action to challenge the FDA’s having a REMS *at all*. 3-ER-346. This “unusual” lawsuit—which seeks to somehow force further agency action, not set aside the action—“makes one wonder” if the Plaintiff States’ real motivation was to “engag[e] in ‘rulemaking-by-collective-acquiescence’” through a sue-and-settle tactic. *E. Bay Sanctuary Covenant*, 102 F.4th at 1006 (VanDyke, J., dissenting). In fact, one member of the Supreme Court has wondered as much out loud. *See Danco Labs., LLC v. All. for Hippocratic Med.*, 143 S. Ct. 1075, 1076 (2023) (Alito, J., dissenting from grant of stay) (suggesting that the FDA in this case “engaged in what has become the practice of leveraging district court injunctions as a basis for implementing a desired policy while evading both necessary agency procedures and judicial review”) (cleaned up). The Intervenor States moved to intervene both to foreclose this possibility and raise APA challenges of their own to the improper REMS modification, seeking to restore the in-person dispensing requirement. 2-ER-61-94.

The district court denied intervention for two reasons, both flawed. First, even though the Intervenor States challenged the exact same agency action as the Plaintiff States, they did so on grounds that were “not at issue in this case.” 1-ER-5-8. Raising distinct arguments, of course, is the precise reason why intervention exists. Second, the

district court reasoned that “resolution of this case will not affect State Intervenor’s claims” or “impair” their interests. 1-ER-7. That can’t possibly be true—if the Plaintiff States succeed in requiring the FDA to eliminate the REMS altogether, that decision would have effect within the Intervenor States’ boundaries and, if upheld on appeal, would foreclose the Intervenor States’ claims.

A three-judge panel of this Court affirmed, ruling that the Intervenor States lack standing. Writing for the panel, Judge Thomas reasoned that the Intervenor States’ economic injury was too speculative. The panel assumed that eliminating the in-person dispensing requirement would “cause more pregnant women to require emergency abortions,” but thought that it was too “difficult to predict” whether doctors would use telehealth or violate state laws by prescribing mifepristone into the Intervenor States—even though statistics show that doctors are doing both things *en masse*. Op. 22.

The panel also rejected the Intervenor States’ assertion of sovereign and quasi-sovereign injuries. The Intervenor States alleged that the REMS modification impaired their sovereign interest in enforcing their abortion laws by enabling out-of-state abortion providers to evade state law at will, but the panel held that a state’s sovereign interest in enforcing its laws is impacted only if there is formal, legal preemption. Op. 23-26. The panel also rejected the Intervenor States’ claim to a quasi-sovereign interest in the health and well-being of its citizens on the ground that the women and unborn children whose health is jeopardized by the REMS modification are “individual citizens,” so the harm to them does not “concern the state as a whole.” Op. 26-27.

ARGUMENT

I. The panel departed from Ninth Circuit precedent to reject the Intervenor States’ claim of economic harm.

For an imminent injury to confer standing, there must be “a substantial risk that the harm will occur.” *Clapper v. Amnesty Int’l USA*, 568 U.S. 398, 414 n.5 (2013) (cleaned up). A plaintiff does not need to show that the injury is “literally certain” to occur. *Id.* Rather, the plaintiff need only “demonstrate a realistic danger of sustaining a direct injury.” *Babbitt v. United Farm Workers Nat’l Union*, 442 U.S. 289, 298 (1979).

It is well-established that the threatened injury can result from a “predictable chain of events” involving “third parties [who] react in predictable ways.” *FDA*, 602 U.S. at 383-85. So states had standing to challenge a rule making “public-charge” inadmissibility turn on enrollment in federal assistance programs because immigrants would predictably respond by (1) unenrolling in federal assistance programs, then (2) enrolling in state-run assistance programs. *City & Cnty. of S.F. v. USCIS*, 981 F.3d 742, 754 (9th Cir. 2020). Or when the federal government issued rules exempting private employers from having to provide contraceptive coverage, states had standing to challenge those rules based on the prediction that women would (1) be denied coverage by employers, then (2) seek contraceptive care through state-run programs. *California v. Azar*, 911 F.3d 558, 571-73 (9th Cir. 2018).

This should have been an easy case under these precedents. The logical consequence of removing the in-person dispensing requirement is that more women

will experience serious complications—likely because they will be prescribed mifepristone without the doctor being able to physically verify their gestational age or lack of ectopic pregnancy—and more women will fail to obtain prompt and necessary follow-up care as those complications develop. As a result, there will be more emergency room visits that the Intervenor States will have to pay for through Medicaid. That is a classic “pocketbook injury” sufficient to establish standing. *California v. Texas*, 593 U.S. 659, 671 (2021).

This is not mere speculation. According to the FDA’s own numbers, since mifepristone was approved, “thousands of women, and as many as hundreds of thousands, have experienced serious adverse effects as a result of taking the drug, and required surgery or emergency care to treat those effects.” *All. For Hippocratic Med.*, 78 F.4th at 229-30. And thanks to the FDA’s removal of the in-person dispensing requirement, the drug will now be prescribed under less-safe conditions.

Allowing mifepristone to be prescribed remotely will also increase emergency room visits by increasing the sheer volume of women who use mifepristone within the Intervenor States’ boundaries. The Intervenor States prohibit doctors from performing abortions except for in certain circumstances, like incest, rape, and saving the life of the mother. *E.g.*, Idaho Code § 18-622(2)(a). But without an in-person dispensing requirement, out-of-state prescribers can administer chemical abortions from afar,

often claiming protection from prosecution through their states’ “shield laws.”⁷ The FDA predicts that 2.9 to 4.6% of all mifepristone users will visit the emergency room, *see* 2016 Mifepristone Label at 8,⁸ so this jump in mifepristone use across the seven Intervenor States is sure to translate into more emergency room visits.⁹

The panel declined to reach the straightforward result dictated by this Court’s precedents, instead demanding something more. Its decision directly conflicts with precedent from the Supreme Court and this Court. *See* Fed. R. App. P. 35(b)(1)(A).

The panel began by adding two “contingencies” to the Intervenor States’ injury, Op. 23, but those “contingencies” did nothing to render the injury speculative. First, it surmised that doctors may still decide to prescribe mifepristone in person even though they now have the “flexibility” not to. Op. 22. But that posed no problem in *Azar*, where employers were allowed—but not required—to decline coverage for contraceptives. 911 F.3d at 572. It was still “reasonably probable” that some employers would deny coverage. *Id.*

⁷ Nathaniel Weixel, *Red state abortion bans headed for clash with blue state shield laws*, The Hill (Apr. 20, 2024), <https://tinyurl.com/4b9e6up2>.

⁸ *Available at* <https://tinyurl.com/yu8fd7fw>.

⁹ Unlike the doctors in *FDA*, who presumably operate their practices with a profitable cost structure, states can only lose money as insurers when more women visit emergency rooms. 602 U.S. at 390.

Here, it's not just "reasonably probable" that abortion providers will prescribe mifepristone through telehealth—it's already happened. Telehealth abortions now account for nearly 1 in 5 abortions in the United States.¹⁰

The panel also believed it could not assume that out-of-state doctors would violate Intervenor State-law. Op. 22-23. Again, not so. In *Department of Commerce v. New York*, states had standing to challenge an immigration-status question on the census on the theory that it would (1) depress census response rates, then (2) decrease the states' political representation and entitlement to federal funds. 588 U.S. 752, 766-68 (2019). Failing to respond to the census is illegal, 13 U.S.C. § 221, but it was the "predictable effect of [the] Government[']s action" nonetheless. 588 U.S. at 768.

And once again, the Court doesn't need a crystal ball to determine whether out-of-state abortion providers will prescribe mifepristone to women within the Intervenor States' boundaries. A simple Google search brings up multiple websites connecting residents in Idaho, for example, to doctors willing to prescribe them mifepristone from states with "shield laws."¹¹ Indeed, roughly half of all telehealth mifepristone prescriptions in 2023 were from states with shield laws.¹² From July 2023 to March

¹⁰ Deidre McPhillips, *Telehealth abortions now account for nearly 1 in 5 in US, with thousands accessed under shield laws each month, report says*, CNN (May 14, 2024), <https://tinyurl.com/2es6jzuy>.

¹¹ *Get an Abortion Pill Online in Idaho*, Aid Access, <https://tinyurl.com/3xfb4raw>; *Where people get abortion pills online in Idaho*, Plan C, <https://tinyurl.com/46m2de53>.

¹² See *supra* n.10, <https://tinyurl.com/2es6jzuy>.

2024, “shield-law groups provided more than 68,000 abortion kits by mail to residents in states with tight limits on the procedure or telemedicine.”¹³

The panel was therefore both legally and factually wrong to conclude that these extra “links in the chain” made the Intervenor States’ claim less probable. Op. 22. To the extent the panel simply wanted the Intervenor States to provide more evidence of standing at the motion to dismiss stage, that contradicts Circuit precedent too. *See Sm. Ctr. for Biological Diversity v. Berg*, 268 F.3d 810, 818-22 & n.3 (9th Cir. 2001) (“accept[ing] as true the non-conclusory allegations made in support of an intervention motion”).

Finally, the panel expressed concern that affording the Intervenor States standing would allow states and health insurance companies to challenge all FDA drug approvals. Op. 23. There is no slippery slope here—mifepristone poses proven risks that are not present in most other drugs. Moreover, it is not a “boundless conception” of standing to allow insurers to challenge a class of regulations that often affect them. *Id.* Auto-insurance companies can challenge car safety standards because they often foot the bill for unsafe vehicles. *See Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 39 (1983).

And the panel’s concern is selectively applied, to say the least. This panel had no qualms about opening the standing floodgates when it held that the *Plaintiff States* had

¹³ Scott Calvert, *The Parties Where Volunteers Pack Abortion Pills for Red-State Women*, WSJ (Aug. 12, 2024), <https://tinyurl.com/3f4e3ayw> (emphasis added).

standing to challenge the whole REMS based on their ownership of state-run health clinics. Op. 12, 22. Indeed, this Court has historically showed little concern when broadening states' standing to challenge immigration and pro-life regulations based on indirect costs to the state. But now that the Intervenor States are challenging a pro-abortion regulation, concerns about broad state standing carry the day. Respectfully, the same standing standards should apply to the Intervenor States regardless of the politics of the law they are challenging.

II. The panel contravened Supreme Court precedent by rejecting sovereign theories of standing.

The panel's analysis of the Intervenor States' injuries to their sovereign and quasi-sovereign interests involved more of the same. Its decision again placed arbitrary roadblocks in the Intervenor States' path to standing, clashing with Supreme Court precedent in the process. Fed. R. App. P. 35(b)(1).

"States are not normal litigants for the purposes of invoking federal jurisdiction" because they "have interests and capabilities beyond those of an individual by virtue of their sovereignty." *Oregon v. Legal Servs. Corp.*, 552 F.3d 965, 970 (9th Cir. 2009) (cleaned up). Thus, the Supreme Court has held that states have standing to assert both their sovereign interest in "the power to create and enforce a legal code" and their "quasi-sovereign interest in the health and well-being—both physical and economic—of [their] residents in general." *Snapp*, 458 U.S. at 601, 607. The Intervenor States have plainly

suffered harm to both types of interests here, yet the panel denied standing on both grounds.

1. Eliminating the in-person dispensing requirement wholly erodes the Intervenor States’ “power to . . . enforce a legal code” as it pertains to prohibiting abortion. *Snapp*, 458 U.S. at 601. As explained, out-of-state providers now prescribe mifepristone virtually and mail it into the Intervenor States without regard for state law, producing tens of thousands of abortions in states with tight abortion restrictions.

Yet the panel held that this mass evasion of state law was not a sovereign injury because the removal of the in-person dispensing requirement did not *formally* “preempt[]” or limit the Intervenor States’ legal “authority to enact or enforce restrictions on medical abortion”—it just placed “a logistical burden on law enforcement.” Op. 24-25. This is no mere “logistical burden”; the REMS modification has blasted a hole through the middle of the Intervenor States’ abortion prohibitions.

On the law, the panel is wrong that only formal preemption suffices and that a state suffers no injury when federal action vitiates the effect of state law. Nothing in the Supreme Court’s articulation of states’ sovereign interest in the “power to create *and enforce* a legal code” suggests that states’ interest is limited to the technical legal authority to enforce their laws. *Snapp*, 458 U.S. at 601 (emphasis added). That’s not how the Court treats the Sixth Amendment right to counsel, for example—instead, it says “the right to counsel is the right to the *effective* assistance of counsel.” *McMann v. Richardson*, 397 U.S. 759, 771 n.14 (1970) (emphasis added).

Nor has the panel’s “formal-preemption-only” limitation been suggested by any circuit. This Court previously granted California standing when the construction of a border wall “*undermine[d]* [the state’s] enforcement of its air quality standards.” *California v. Trump*, 963 F.3d 926, 938 (9th Cir. 2020) (emphasis added). And the Tenth Circuit granted Wyoming standing when federal action drained its misdemeanor expungement statute of its desired effect, even without any preemption. *Wyoming ex rel. Crank v. United States*, 539 F.3d 1236, 1241-42 (10th Cir. 2008).

By all accounts, the Intervenor States’ ability to effectively enforce their abortion restrictions has been utterly sapped, and that is sufficient for them to sue to set aside the federal action that caused that harm.¹⁴

2. The Intervenor States also should have had standing based on the harm to their “quasi-sovereign interest in the health and well-being . . . of [their] residents in general.” *Snapp*, 458 U.S. at 607. As explained, eliminating the in-person dispensing requirement threatens to compound the number of women sent to the emergency room, which clearly harms the “health, comfort and welfare” of the public. *Pennsylvania v. West Virginia*, 262 U.S. 553, 592 (1923).¹⁵

¹⁴ The panel was wrong to believe *United States v. Texas* has any relevance on the question of sovereign interests. 599 U.S. 670 (2023); Op. 25-26. That case never mentioned the operation of any state law; the passages the panel cited address only alleged *monetary* injuries.

¹⁵ The panel agreed that quasi-sovereign interests can be asserted against the United States. Op. 26; see *Kentucky v. Biden*, 23 F.4th 585, 596-98 (6th Cir. 2022) (exploring the doctrine at length).

The panel denied standing by imposing a limitation that fundamentally misunderstands quasi-sovereign interests altogether. According to the panel, a quasi-sovereign interest must “concern the state as a whole,” and eliminating the in-person dispensing requirement concerns only “pregnant women” and “unborn children.” Op. 26-27. But the Supreme Court has been clear that a state’s quasi-sovereign interests are implicated when there is an injury “to a sufficiently substantial segment of [the state’s] population.” *Snapp*, 458 U.S. at 607. That’s because when a large swath of the public is affected, the matter becomes one of “public concern,” so the state “as the representative of the public, has an interest apart from that of the individuals affected.” *Pennsylvania*, 262 U.S. at 592.

Here, the REMS modification presents grave public concern because it threatens the health of thousands of pregnant women and unborn children within the Intervenor States’ boundaries—undoubtedly a substantial segment of the public. *Contra* Op. 27 (claiming that only the rights of “specific pregnant women” were implicated). The Supreme Court has explained that a “helpful indication” for whether the segment is substantial enough is whether “the injury is one that the State, if it could, would likely attempt to address through its sovereign lawmaking powers,” *Snapp*, 458 U.S. at 607, and the Intervenor States have legislated to set safety standards for mifepristone use. *E.g.*, Idaho Code § 18-617.

Indeed, Supreme Court precedent is replete with examples of quasi-sovereign interests in harms affecting only a substantial segment of the public. In *North Dakota v.*

Minnesota, flooding threatened only farmland on the west bank of the Bois de Sioux River. 263 U.S. 365, 371 (1923). In *Georgia v. Tenn. Copper Co.*, noxious gas from copper companies threatened crops in only “five counties” in Georgia. 206 U.S. 230, 236 (1907). And in *Georgia v. Pennsylvania Railroad Co.*, a railroad price-fixing scheme directly harmed only those in Georgia who wished to ship freight. 324 U.S. 439 (1945).

The panel’s decision runs roughshod over these binding precedents by demanding a state-wide harm, essentially collapsing quasi-sovereign interests into sovereign interests. In fact, it’s hard to see how a state could *ever* base standing on a quasi-sovereign interest under the panel’s reasoning. As the panel sees it, harms to the health “individual citizens”—anything short of every citizen in the state—may not be advanced by the state. Op. 27. Rehearing *en banc* is necessary to align the panel’s decision with Supreme Court precedent.¹⁶

CONCLUSION

The Court should grant rehearing *en banc*.

¹⁶ The panel compared the Intervenor States’ claim of standing to the claims in *Haaland v. Brackeen*, 599 U.S. 255 (2023) and *Murthy v. Missouri*, 144 S. Ct. 1972 (2024). But those states sought to vindicate citizens’ rights under the First Amendment and Equal Protection Clause, not to safeguard citizens’ health. That’s why neither of those cases mention quasi-sovereign interests once.

Respectfully Submitted,

HON. RAÚL R. LABRADOR
ATTORNEY GENERAL

Date: September 9, 2024

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UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

Form 11. Certificate of Compliance for Petitions for Rehearing/Responses

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9th Cir. Case Number(s)

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☒ P. 32(a)(4)-(6) and **contains the following number of words:** .

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CERTIFICATE OF SERVICE

I certify that on September 9, 2024, I electronically filed Appellants' Petition for Rehearing En Banc 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.

Date: September 9, 2024

/s/Michael A. Zarian

Michael A. Zarian

FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

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

Plaintiffs-Appellees,

v.

U.S. FOOD & DRUG
ADMINISTRATION; ROBERT M.
CALIFF, in his official capacity as
Commissioner of Food and Drugs;
UNITED STATES DEPARTMENT
OF HEALTH AND HUMAN
SERVICES; XAVIER BECERRA, in

No. 23-35294

D.C. No. 1:23-cv-
03026-TOR

OPINION

his official capacity as Secretary of the
Department of Health and Human
Service,

Defendants-Appellees,

v.

STATE OF IDAHO; STATE OF
IOWA; STATE OF MONTANA;
STATE OF NEBRASKA; STATE OF
SOUTH CAROLINA; STATE OF
TEXAS; STATE OF UTAH, Proposed
State Plaintiff-Intervenors,

Movants-Appellants.

Appeal from the United States District Court
for the Eastern District of Washington
Thomas O. Rice, District Judge, Presiding

Argued and Submission Deferred March 13, 2024
Submitted July 17, 2024
San Francisco, California

Filed July 24, 2024

Before: Sidney R. Thomas, M. Margaret McKeown, and
Morgan Christen, Circuit Judges.

Opinion by Judge Sidney R. Thomas

SUMMARY*

Article III Standing / Intervention

The panel affirmed the district court’s order denying Idaho’s motion to intervene as of right, and dismissed for lack of jurisdiction the portion of the appeal concerning the district court’s denial of permissive intervention, in the State of Washington’s lawsuit challenging the Food and Drug Administration’s imposition of safe-use restrictions on the abortion drug mifepristone.

The Food, Drug, and Cosmetic Act authorizes the FDA to restrict access to certain drugs by imposing a “risk evaluation and mitigation strategy” (“REMS”) when it concludes that doing so is necessary to ensure that the benefits of the drug outweigh the risks. In a 2023 REMS, the FDA eliminated in-person dispensing requirements for mifepristone and allowed certain pharmacies to dispense mifepristone at retail locations or by mail. Washington and a collation of states sued the FDA under the Administrative Procedure Act, arguing that the agency should have gone further to eliminate hurdles to accessing mifepristone. Idaho and a different coalition of states moved to intervene seeking injunctive relief that would effectively reimpose the previous REMS, including the in-person dispensing requirement.

* This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

The panel held that because Idaho sought different relief from Washington, it must independently satisfy the requirements of Article III standing.

The panel concluded that Idaho's complaint-in-intervention did not establish a cognizable injury-in-fact that was fairly traceable to the FDA's revised safe-use restrictions. Idaho could not establish standing based on the alleged costs to the state's finances because the asserted casual chain was too attenuated. The panel rejected Idaho's allegation that elimination of the in-person dispensing requirement would harm its sovereign interest in law enforcement by making illegal mifepristone use harder to detect because nothing in the REMS impaired Idaho's sovereign authority to enact or enforce its own laws regulating chemical abortion. Finally, the panel rejected Idaho's allegation that elimination of the in-person dispensing requirement would harm its "quasi-sovereign interest" in maternal health and fetal life because the allegations concern the interests of individual citizens—not the separate interests of the state itself.

Guided by the Supreme Court's recent decision on standing in *FDA v. Alliance for Hippocratic Medicine*, 602 U.S. 367 (2024), the panel held that because Idaho did not have standing to bring the claims in its complaint, it affirmed the denial of its motion to intervene. The panel did not reach any other issue raised in the district court or urged by the parties on appeal, including whether Idaho would be otherwise entitled to intervene under Fed. R. Civ. P. 24.

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OPINION

THOMAS, Circuit Judge:

In this appeal, we consider whether Idaho is entitled to intervene in Washington’s lawsuit challenging the Food and Drug Administration’s (“FDA”) imposition of safe-use restrictions on the abortion drug mifepristone. We conclude that, because Idaho seeks different relief than Washington, it must independently satisfy the requirements of Article III standing. We further conclude that Idaho’s complaint-in-intervention does not establish a cognizable injury-in-fact that is fairly traceable to FDA’s revised safe-use restrictions. We are guided in our decision by the Supreme Court’s recent decision on standing and the FDA’s regulation of mifepristone in *FDA v Alliance for Hippocratic Medicine*. 602 U.S. 367 (2024). Because Idaho does not have standing to bring the claims in its complaint, we affirm the denial of its motion to intervene.

I

A

The Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.*, tasks FDA with ensuring the safety and efficacy of all drugs that enter into interstate commerce. *See Wyeth v. Levine*, 555 U.S. 555, 566–67 (2009). Before a new drug is approved, the drug’s sponsor must submit an application that includes patent and manufacturing

information, the results of laboratory and clinical testing, and proposed labeling and instructions for use. 21 U.S.C. § 355(b). The statute instructs FDA to approve a new drug only when it determines that the drug is “safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling.” *Id.* § 355(d).

The FDCA also authorizes FDA to restrict access to certain drugs by imposing a “risk evaluation and mitigation strategy” or “REMS” when it concludes that doing so is “necessary to ensure that the benefits of the drug outweigh the risks[.]” *Id.* § 355-1(a)(1).¹ A REMS may include restrictions on drug labeling and packaging, as well as more burdensome “safe use” restrictions, such as requirements that providers be specially certified or that patients be subjected to post-administration monitoring. *Id.* §§ 355-1(d)–355-1(f). Unlike package and labeling requirements, safe-use restrictions may only be imposed on drugs “with known serious risks” of a “serious adverse drug experience.” *Id.* § 355-1(f); *id.* § 355-1(b)(4). The statute instructs FDA to design safe-use restrictions to ensure that they are “commensurate with the specific serious risk” and do not “unduly burden[.]” patient access. *Id.* § 355-1(f)(2). Once safe-use restrictions have been imposed, FDA must periodically reevaluate them to ensure the restrictions are

¹ FDA’s authority to adopt additional restrictions was previously governed by 21 C.F.R. §§ 314.500–560 (“Subpart H”). FDA adopted Subpart H in 1992 to accelerate its approval of new drugs with the potential to treat “serious or life-threatening illnesses” by authorizing the agency to impose post-approval safety restrictions. 57 Fed. Reg. 58942, 58958–59 (Dec. 11, 1992). This authority was codified and expanded by the Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823, which replaced Subpart H with the statutory “REMS” framework. *See id.* § 505-1, 121 Stat. at 926–39.

well calibrated to balance safety, access, and “the burden on the health care delivery system.” *Id.* § 355-1(f)(5)(B).

B

Mifepristone is a medication that, when used in combination with another drug called misoprostol, can safely end an early pregnancy. FDA first authorized the marketing of mifepristone under the commercial name “Mifeprex” in 2000. As a condition of its approval, FDA stipulated that Mifeprex could only be dispensed in person, under the supervision of a physician with certain qualifications, after the patient had been advised of the drugs risks and had reviewed and signed a “patient agreement form.” *See All. for Hippocratic Med.*, 602 U.S. at 375–76 (describing original restrictions on Mifeprex approval).

In 2011, FDA reauthorized Mifeprex under the revised statutory framework that codified and expanded the agency’s authority to impose a REMS. FDA retained the original conditions on distribution, formulated as three discrete safe-use restrictions requiring (1) in-person dispensing, (2) prescriber certification, and (3) documentation of patient counseling and consent.

Between 2011 and 2019, FDA reviewed the Mifeprex REMS several times, authorizing a handful of changes to prescribing guidelines and, in 2019, approving a generic version of mifepristone. At the conclusion of each review FDA concluded it was necessary to retain the three safe-use restrictions with only minor adjustments. *See All. for Hippocratic Medicine*, 602 U.S. at 375–76.

In 2020, FDA was forced to temporarily suspend the in-person dispensing requirement in response to a lawsuit filed by healthcare providers during the COVID-19 pandemic.

Am. Coll. of Obstetricians & Gynecologists v. FDA, 472 F. Supp. 3d 183, 194–97 (D. Md. 2020). The suspension was in effect for six months, from July 2020 until January 2021, before the district court’s injunction was stayed by the Supreme Court. *See FDA v. Am. Coll. of Obstetricians & Gynecologists*, 141 S. Ct. 578 (2021). During this time, FDA observed no impact on patient safety. Based in part on this revelation, FDA voluntarily stopped enforcing the in-person dispensing requirement in April 2021 and initiated a full review of the Mifepristone REMS Program.

In December 2021, FDA announced the completion of the review and its conclusions that the in-person dispensing requirement should be permanently eliminated, thus allowing certain pharmacies to dispense mifepristone at retail locations or by mail. In place of in-person dispensing, FDA added a new REMS requirement that pharmacies be specially certified before dispensing the drug to ensure compliance with the other safe-use restrictions—prescriber certification and patient documentation—which FDA elected to retain. The new REMS was finalized in January 2023.

C

In February 2023, a coalition of states led by Washington sued FDA under the Administrative Procedure Act (APA), 5 U.S.C. § 706(2), arguing that the agency should have gone further to eliminate hurdles to accessing mifepristone.²

² The eighteen plaintiff jurisdictions are Washington, Oregon, Arizona, Colorado, Connecticut, Delaware, Illinois, Michigan, Nevada, New Mexico, Rhode Island, Vermont, D.C., Hawaii, Maine, Maryland, Minnesota, and Pennsylvania. Because the plaintiff states are similarly situated for the purpose of this appeal, we refer to them collectively as “Washington.”

Given the rarity of adverse events in the drug’s twenty-some year history, Washington argues that mifepristone should no longer be subject to *any* of the original safe-use restrictions. Washington alleges that it is harmed as a regulated provider of maternal health care and pharmacy dispensing, and is forced to incur significant costs and risk as a result of the certification and documentation requirements. Washington supports these allegations with numerous sworn declarations from providers and administrators who work for state healthcare facilities.

Washington’s operative complaint challenges the 2023 REMS as imposing “hurdles” to drug access “without any corresponding medical benefit,” in violation of the FDCA, 21 U.S.C. § 355-1(f)(2) and APA, 5 U.S.C. § 706(2). In its prayer for relief, Washington seeks a declaration that mifepristone is “safe and effective” and an injunction prohibiting FDA from enforcing the restrictions contained in the 2023 REMS or otherwise “taking any action . . . to reduce [mifepristone’s] availability.” Washington also filed a motion for preliminary injunction, requesting the district court to enjoin the FDA from enforcing the 2023 REMS or otherwise “caus[ing] the drug to become less available.”

In March 2023, a different coalition of states led by Idaho moved to intervene, arguing that Washington’s lawsuit jeopardizes their legally protected interests in regulating the use of mifepristone within their borders.³ Idaho argues that Washington’s lawsuit could impair its interest by making mifepristone easier to obtain and harder

³ The seven intervenor states are Idaho, Iowa, Montana, Nebraska, South Carolina, Texas, and Utah. Because the intervenor states are similarly situated for the purpose of this appeal, we refer to them collectively as “Idaho.”

to police, and by limiting Idaho's ability to challenge the REMS in a separate lawsuit.

Idaho filed a proposed complaint-in-intervention that, like Washington's, advances three causes of action under the APA and seeks broad declaratory relief concerning the legality of the 2023 REMS. Unlike Washington, however, Idaho seeks injunctive relief that would effectively reimpose the previous REMS, including the in-person dispensing requirement. Idaho predicts that elimination of the in-person dispensing requirement will lead to increased mifepristone use under conditions that are either dangerous or illegal. Idaho alleges this uptick will injure the state in three ways. First, Idaho alleges that more women will experience complications that require follow-up care, "some of which [will be] borne by Idaho through Medicaid expenditures." Second, Idaho alleges that elimination of the "controlled" in-person "delivery system" will "undermine Idaho's ability to enforce its laws." Third, Idaho alleges that increased mifepristone use will endanger women and prenatal life, in which Idaho has a "legitimate interest."

Washington and FDA both opposed intervention but advanced different arguments for why Idaho's motion should be denied. Washington argued that Idaho did not satisfy the requirements for intervention under Federal Rule of Civil Procedure 24 because its interest in reimposing the in-person dispensing requirement was not implicated in Washington's case, which concerns the legality of different safe-use restrictions. FDA argued the motion should be denied because Idaho did not satisfy a threshold requirement to demonstrate Article III standing to pursue relief that is different from the relief requested by the existing plaintiffs.

While the motion to intervene was pending, the district court ruled on Washington's motion for preliminary injunction, granting the motion in part and enjoining FDA from altering the status quo availability of mifepristone in the eighteen plaintiff jurisdictions. In evaluating the motion, the district court concluded that Washington had standing to challenge the 2023 REMS based on its allegations of direct harm to the state's health care system, practice restrictions on state employees, and "unrecoverable" compliance costs. The district court declined to enjoin the 2023 REMS in its entirety because doing so would have the perverse effect of reimposing the previous REMS, which would "run[] directly counter" to Washington's apparent aim.

On April 21, 2023, the district court denied Idaho's motion to intervene. The district court concluded that Idaho was not entitled to intervene as a matter of right because it did not have a "significantly protectable interest" that would be impaired by the litigation since its complaint concerned different features of the 2023 REMS. *See* Fed. R. Civ. P. 24(a). The district court also declined to permit Idaho to intervene permissively based on its conclusion that Idaho's APA claims did not share any questions of law or fact with Washington's claims. *See* Fed. R. Civ. P. 24(b). Idaho timely appealed the denial of its motion to intervene.

II

We have jurisdiction to review the denial of a motion to intervene as of right under 28 U.S.C. § 1291, and our review is *de novo*, except for the element of timeliness, which we review for abuse of discretion. *W. Watersheds Project v. Haaland*, 22 F.4th 828, 835 (9th Cir. 2022). "We have jurisdiction over a district court's denial of permissive intervention only if we conclude that the district court

abused its discretion.” *Cooper v. Newsom*, 13 F.4th 857, 868 (9th Cir. 2021) (citation omitted).

When the party attempting to intervene—whether as of right or permissively—seeks different relief than the original plaintiff, we review whether the intervening party has Article III standing to pursue the claims advanced in its complaint. *Or. Prescription Drug Monitoring Program v. U.S. Drug Enf’t Admin.*, 860 F.3d 1228, 1233–34 (9th Cir. 2017) (hereafter “*OPDMP*”). We review questions of standing *de novo*. *Isaacson v. Mayes*, 84 F.4th 1089, 1095 (9th Cir. 2023). Like any party invoking federal jurisdiction, the party seeking to intervene has the burden of demonstrating standing “with the manner and degree of evidence required” at the relevant stage of litigation. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992).

III

The threshold issue in this appeal is whether Idaho must separately establish standing to intervene. Because Idaho seeks relief that is fundamentally different from that sought by Washington, the answer is yes.

“Article III of the Constitution limits the exercise of the judicial power to ‘Cases’ and ‘Controversies.’” *Town of Chester v. Laroe Estates, Inc.*, 581 U.S. 433, 438 (2017) (quoting U.S. Const. art. III, § 2, cl. 1). The purpose of this “fundamental limitation” is to prevent courts from “intrud[ing] upon the powers given to the other branches” in our tripartite system. *Id.* (citation omitted). To establish Article III standing, a plaintiff must demonstrate that they have suffered a concrete “injury in fact” that is traceable to the defendant and is likely redressable by judicial relief. *TransUnion LLC v. Ramirez*, 594 U.S. 413, 423 (2021). These requirements “screen[] out plaintiffs who might have

only a general legal, moral, ideological, or policy objection to a particular government action,” and “prevents the federal courts from becoming a ‘vehicle for the vindication of the value interests of concerned bystanders.’” *All. for Hippocratic Medicine*, 602 U.S. at 381–82 (quoting *Allen v. Wright*, 468 U.S. 737, 756 (1984)).

The Supreme Court has repeatedly confirmed that “[s]tanding is not dispensed in gross,” *Davis v. Fed. Election Comm’n*, 554 U.S. 724, 734 (2008) (citation omitted), which means that “[f]or all relief sought, there must be a litigant with standing[.]” *Town of Chester*, 581 U.S. at 439. Thus, when a party moves to intervene in a case and “seek[s] to obtain different relief than the original plaintiff, the [i]ntervenor[] must establish independent Article III standing.” *OPDMP*, 860 F.3d at 1233–34. By contrast, “intervenor[s] that seek the same relief sought by at least one existing party . . . need not do so.” *Cal. Dep’t of Toxic Substances Control v. Jim Dobbas, Inc.*, 54 F.4th 1078, 1085 (9th Cir. 2022); *see also Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 591 U.S. 657, 674 n.6 (2020) (explaining that the court below “erred by inquiring into [i]ntervenor[s]’ independent Article III standing” where they sought the same relief as the federal government, which “clearly had standing”).

In this case, application of *Town of Chester*’s intervenor standing requirement turns on whether or not Idaho is seeking the “same relief” as Washington. Idaho argues that it is seeking the same relief because its complaint, like Washington’s, asks the court to “hold unlawful and set aside” the 2023 REMS. FDA disagrees, emphasizing the states’ antipodal objectives with respect to the in-person dispensing requirement: Washington seeks to loosen restrictions even further while Idaho seeks to strengthen

them. FDA argues that superficial similarities in the form of the parties' pleadings are "immaterial" when the ultimate outcomes they seek are "fundamentally different."

To assess whether Idaho and Washington seek the same relief, we look to the parties' complaints, which is the "best evidence of the relief [they] seek[]." *Town of Chester*, 581 U.S. at 440. In so doing, we consider not just the legal form of the parties' claims, but also their ultimate objectives. *See, e.g., In re Volkswagen "Clean Diesel" Mktg., Sales Pracs., & Prod. Liab. Litig.*, 894 F.3d 1030, 1044 (9th Cir. 2018); *OPDMP*, 860 F.3d at 1234. As the Supreme Court explained in *Town of Chester*, for example, two parties bringing "substantively identical" claims should nonetheless be understood as "seek[ing] different relief" when they seek separate judgments. 581 U.S. at 437, 440.

Applying *Town of Chester*, we have repeatedly held that an intervenor whose claims arise under a different legal theory "seeks different relief." In *OPDMP*, for example, we considered an attempt by the ACLU Foundation of Oregon to intervene in a lawsuit brought by the state of Oregon. 860 F.3d at 1231. The state plaintiffs sought a declaratory judgment that, under state law, the U.S. Drug Enforcement Administration ("DEA") was required to obtain a court order before accessing state prescription drug records. 860 F.3d at 1233–34. The ACLU, by contrast, sought declaratory and injunctive relief "founded on the Fourth Amendment" ordering the DEA to obtain a warrant before it could access the same records. *Id.* at 1234. We concluded that because the ACLU wanted "something very different" than the original plaintiffs, it "must establish independent Article III standing." *Id.* Likewise, in *In re Volkswagen "Clean Diesel" Marketing*, we concluded that an injunction requiring Volkswagen to rescind the sale of vehicles

programmed to cheat on emissions tests would be “completely different” relief than an injunction requiring Volkswagen to stop installing the software in the future, notwithstanding the fact that both claims were founded on alleged violations of the Clean Air Act. 894 F.3d at 1044.

This case is somewhat different in that both Washington’s and Idaho’s complaints advance claims under the APA, which provides a generic cause of action for persons aggrieved by agency action. *See* 5 U.S.C. §§ 701–706. Invoking the broad scope of relief authorized by the APA, *id.* § 706(2), both complaints ask the court to declare the 2023 REMS unlawful and enjoin FDA from “enforcing or applying” its requirements. Beyond these superficial features, however, the two complaints have little in common and are, in many respects, diametrically opposed.

Washington and Idaho allege that different features of the 2023 REMS are unlawful. Washington’s complaint concerns the legality of FDA’s retention of the provider certification and patient documentation requirements, as well as the agency’s broader determination that mifepristone meets the “stringent standards” for the imposition of safe-use restrictions in the first place. Idaho’s complaint, by contrast, focuses entirely on FDA’s elimination of the in-person dispensing requirement, alleging that the change was inadequately explained, contrary to medical science, and violative of 21 U.S.C. § 355-1(a)(1).

Washington and Idaho also seek different remedies. Washington asks the court to enjoin the enforcement of *any* safe-use restrictions based on its view that they are not justified by any “known serious risk.” *See* 21 U.S.C. § 355-1(f)(2). Idaho seeks “something very different,” *OPDMP*, 860 F.3d at 1234, asking the court to declare the 2023

changes to the REMS unlawful, vacate the revision, and effectively reinstate the prior status quo, including the in-person dispensing requirement. As the district court recognized, reinstating the status quo would “run[] directly counter to [Washington’s] request” by reducing the availability of mifepristone. Indeed, the text of Washington’s complaint, which declares that “the 2023 REMS improved on” the previous regime clearly reveals the chasm between the parties’ preferred outcomes.

Given the deep and obvious conflict between the parties’ objectives, we cannot conclude that Idaho seeks the “same relief” as Washington. Under *Town of Chester*, Idaho must independently establish Article III standing to intervene.

IV

We next consider whether the allegations in Idaho’s complaint establish standing to challenge FDA’s elimination of the in-person dispensing requirement. Idaho’s complaint alleges three kinds of injury caused by the 2023 REMS: increased Medicaid costs, interference with state law enforcement, and harms to women and fetal life. Where, as here, the propriety of intervention “must be determined before discovery,” we generally accept “all well-pleaded, nonconclusory allegations” in the proposed complaint as true. *Sw. Ctr. for Biological Diversity v. Berg*, 268 F.3d 810, 819–20 (9th Cir. 2001); *see also Lujan*, 504 U.S. at 561 (“At the pleading stage, general factual allegations of injury resulting from the defendant’s conduct may suffice [to establish standing.]”). We conclude that none of the allegations contained in Idaho’s complaint constitute a cognizable injury-in-fact to the state’s own interests.

In assessing Idaho’s standing, we are mindful of both the general requirements for Article III standing set forth in

Lujan, 504 U.S. at 560–61, as well as prudential limits on states’ ability to sue the federal government on behalf of their citizens. *See Haaland v. Brackeen*, 599 U.S. 255, 294–95 (2023) (“Texas lacks standing to . . . assert equal protection claims on behalf of its citizens because a State does not have standing as *parens patriae* to bring an action against the Federal Government.” (cleaned up)); *Massachusetts v. Mellon*, 262 U.S. 447, 485–86 (1923) (“While the state, under some circumstances, may sue . . . for the protection of its citizens, it is no part of its duty or power to enforce their rights in respect of their relations with the federal government.” (internal citation omitted)). We heed the Supreme Court’s reminder to “remain mindful of bedrock Article III constraints in cases brought by States against an executive agency or officer.” *United States v. Texas*, 599 U.S. 670, 680 n.3 (2023).

A

Idaho first alleges that elimination of the in-person dispensing requirement will cause the state economic injury in the form of increased costs to the state’s Medicaid system. At oral argument, Idaho stated that this is its “strongest basis” for standing. Even taking Idaho’s highly speculative allegations as true, the complaint does not demonstrate an injury-in-fact because it depends on an attenuated chain of healthcare decisions by independent actors that will have only indirect effects on state revenue.

Like any party, a state has standing to challenge federal action that directly harms the state’s economic interests or interferes with its operations as a service provider, market participant, or employer. *See, e.g., Dept. of Com. v. New York*, 588 U.S. 752, 766–68 (2019); *City & Cnty. of San Francisco v. U.S. Citizenship & Immigr. Servs.*, 981 F.3d

742, 754 (9th Cir. 2020); *Washington v. Trump*, 847 F.3d 1151, 1159-61 (9th Cir. 2017) (per curiam). To establish standing based on an alleged “pocketbook injur[y],” the state must allege a concrete impact on state revenues that is caused by the defendant’s allegedly unlawful conduct. *California v. Texas*, 593 U.S. 659, 674 (2021). While the injury need not be direct, there must be a strong “causal chain” that “links” the federal action to the alleged harm. *California v. Azar*, 911 F.3d 558, 571–72 (9th Cir. 2018). “[P]laintiffs attempting to show causation generally cannot ‘rely on speculation about the unfettered choices made by independent actors not before the courts.’” *All. for Hippocratic Medicine*, 602 U.S. at 383 (quoting *Clapper v. Amnesty Int’l USA*, 568 U.S. 398, 415 n.5 (2013)).

In recent years, the Supreme Court has specifically cautioned us to be wary of theories of state standing that rely on the “indirect effects” of federal policy on state revenue or state spending. *United States v. Texas*, 599 U.S. at 680 n.3; *see also California v. Texas*, 593 U.S. at 675–78. As the Sixth Circuit has explained, a theory of state standing “in which all peripheral costs imposed on the States by actions of the [executive branch]” constitute cognizable injuries would “make a mockery” of Article III. *Arizona v. Biden*, 40 F.4th 375, 386 (6th Cir. 2022) (citation omitted).

In this case, Idaho alleges that it will sustain economic injury in the form of downstream medical costs that will borne by the state. Specifically, Idaho alleges that elimination of the in-person dispensing requirement will cause more providers to dispense mifepristone to women “with contraindications,” which in turn will lead more women to experience complications that require follow-up care, which will harm the state because some portion of the aggregate cost of that follow-up care will be “borne by Idaho

through Medicaid expenditures.” The complaint does not clearly explain what form these expenditures will take, but we infer from the complaint that Idaho means it will be forced to reimburse providers for care delivered to those women enrolled in state-sponsored health plans. In other words, Idaho’s allegations of economic harm refer to the costs it will incur as an insurer of women who use mifepristone. Unlike Washington, Idaho does not allege that it will incur these costs directly as the object of regulation, but indirectly as the result of “the government’s allegedly unlawful . . . lack of regulation of *someone else*.” *Lujan*, 504 U.S. at 562 (cleaned up). Accordingly, “much more is needed” to establish causation and redressability. *Id.*

As the Supreme Court recently explained in *Alliance for Hippocratic Medicine*, the causal chain between FDA’s regulation of mifepristone and downstream medical outcomes is highly attenuated, “even assuming for the sake of argument” that the 2023 REMS will “cause more pregnant women to require emergency abortions.” 602 U.S. at 387–93. The links in this chain depend on the independent actions of doctors and pregnant women whose medical decisionmaking is informed by a wide range of individualized considerations that are difficult to predict. The 2023 REMS does not require doctors to prescribe mifepristone to certain patients; it simply provides doctors and patients with increased flexibility to choose how to dispense the drug based on their assessment of risk in each individual case. Nor does the 2023 REMS prevent Idaho from prohibiting medical abortion within its borders under circumstances the state deems contrary to public policy. For example, under current law, women in Idaho will only be “exposed” to the alleged risks of mifepristone when one or more independent actors decides to break state law. *See*

Idaho Code §§ 18-604, 18-608, 18-622. Given these contingencies, any marginal increase in the rate at which pregnant women require additional medical care is too attenuated to establish the requisite causal connection.

Further, an alleged uptick in Medicaid costs is exactly the kind of “indirect effect[] on . . . state spending” that the Supreme Court has rejected as a basis for standing. *United States v. Texas*, 599 U.S. at 680 n.3. As the Supreme Court has explained, “virtually all drugs come with complications, risks, and side effects,” which means that changes in prescription drug guidelines will frequently “yield more visits to doctors to treat complications or side effects.” *All. for Hippocratic Medicine*, 602 U.S. at 392. Allowing Idaho to proceed based on predictions of increased emergency-room visits alone would give not just states, but every entity that provides health insurance or subsidized medical care, standing “to challenge any FDA decision approving a new drug.” *Id.* We decline to endorse this boundless conception of Article III’s injury requirement. Idaho cannot establish standing based on the alleged costs to the state’s finances because the asserted causal chain is too attenuated.

B

Idaho next alleges that elimination of the in-person dispensing requirement will harm its sovereign interest in law enforcement by making illegal mifepristone use harder to detect. This allegation is insufficient to convey standing because nothing in the 2023 REMS impairs Idaho’s sovereign authority to enact or enforce its own laws regulating chemical abortion.

States have standing to vindicate their authority as sovereign entities with a governing prerogative that is separate from the federal government. *Alfred L. Snapp &*

Son, Inc. v. Puerto Rico, ex rel., Barez, 458 U.S. 592, 600–02 (1982). A state has a “sovereign interest” in the retention of its authority to “exercise . . . sovereign power over individuals and entities within [its] jurisdiction,” including “the power to create and enforce a legal code.” *Id.* at 601; *see also Bowen v. Pub. Agencies Opposed to Soc. Sec. Entrapment*, 477 U.S. 41, 50 n.17 (1986) (acknowledging a state’s “judicially cognizable interest in the preservation of its own sovereignty”). This interest is sufficient to convey standing to defend a state statute against a legal challenge in federal court, *Diamond v. Charles*, 476 U.S. 54, 62 (1986); *Maine v. Taylor*, 477 U.S. 131, 136 (1986), or challenge a federal statute that preempts or nullifies state law, *see generally, e.g., Colorado v. Toll*, 268 U.S. 228 (1925); *Oregon v. Ashcroft*, 192 F. Supp. 2d 1077, 1087 (D. Or. 14 2002); *see also Kentucky v. Biden*, 23 F.4th 585, 598–99 (6th Cir. 2022) (collecting cases). This cognizable interest in the preservation of sovereign authority, however, does not convey standing to challenge federal action that affects state law enforcement indirectly, by making violations of state law more difficult or costly to detect.

Here, Idaho alleges an injury to its sovereign interest in enforcing state abortion laws, which make mifepristone illegal to use under most circumstances. *See Idaho Code* §§ 18-602, 18-604, 18-617, 18-622; *Moyle v. United States*, 144 S.Ct. 2015, 2016–17 (2024) (Kagan, J., concurring) (describing Idaho’s abortion laws). Idaho alleges that elimination of the in-person dispensing requirement will impede the state’s ability to enforce those laws by making it easier for Idaho residents to obtain and use mifepristone illegally. Idaho does not, however, allege that the 2023 REMS preempts or otherwise interferes with the state’s

authority to enact or enforce restrictions on medical abortion within its boundaries.

These allegations are insufficient to demonstrate standing for two reasons. First, Idaho’s prediction that elimination of the in-person dispensing requirement will lead to illegal use of mifepristone depends heavily on speculation that doctors and pregnant women will break state law. As we have previously explained, speculation about the decisions of independent actors, without more, is not a proper basis for standing. *Clapper*, 568 U.S. at 414. Second, even if the availability of retail and mail-order dispensing does make mifepristone more difficult to police, we have never held that a logistical burden on law enforcement constitutes a cognizable Article III injury. Holding otherwise would greatly expand state standing to challenge any federal action that allegedly increases crime or disorder, or imposes indirect compliance costs for state law enforcement.

In *United States v. Texas*, the Supreme Court has declined to take the federal judiciary down this “uncharted path.” 599 U.S. at 681. In that case, Texas sued the Department of Homeland Security, arguing that the agency’s revised enforcement guidelines, which deprioritized the deportation of noncitizens convicted of nonviolent offenses, violated federal law. *Id.* at 673–75. Texas alleged that it was injured by the increased costs of “incarcerat[ing]” and “supply[ing] social services” to individuals who “should be (but are not being) arrested.” *Id.* at 674. The Supreme Court forcefully rejected this “novel standing argument,” noting that holding otherwise would lead to an increase in “complaints in future years about alleged Executive Branch under-enforcement” of other laws, including “drug laws, gun laws, obstruction of justice laws, or the like.” *Id.* at 681.

This slippery slope concern is just as salient for Idaho's theory of injury, which similarly lacks a limiting principle.

Because Idaho does not allege that the 2023 REMS encroaches on its authority to govern, it does not have standing based on "law enforcement injury."

C

Finally, Idaho alleges that elimination of the in-person dispensing requirement will harm its "quasi-sovereign interest" in maternal health and fetal life. Idaho cannot sue FDA on this basis because the allegations concern the interests of individual citizens—not the separate interests of the state itself.

In *Massachusetts v. EPA*, the Supreme Court explained that states have standing to sue the federal government based on their "quasi-sovereign interests," that "concern the state as a whole." 549 U.S. 497, 520 n.17 (2007) (citation omitted). These interests include the "health and welfare" of state residents generally, which may be endangered by harms to the land or environment within a state's sovereign territory. *See id.* at 519–23; *California v. Trump*, 963 F.3d 926, 936 (9th Cir. 2020); *Nat. Res. Def. Council v. EPA*, 542 F.3d 1235, 1248 n.8 (9th Cir. 2008). However, states do not have standing to sue the federal government in a third-party *parens patriae* capacity based on alleged injuries "to an identifiable group of individual residents." *Snapp*, 458 U.S. at 607. This is because, with respect to the relationship between citizens and federal action, the federal government, not the states, is the sovereign entity that acts as the ultimate "parent of the country." *See id.* at 600 ("*Parens patriae* means literally 'parent of the country.'"); *Mellon*, 262 U.S. at 485–86.

Here, Idaho alleges that elimination of the in-person dispensing requirement will endanger specific pregnant women who take the drug and “unborn children” subjected to its effects. These allegations concern the well-being of individual citizens—not a distinct interest of the state as a whole. *See Snapp*, 458 U.S. at 607 (“the State must articulate an interest apart from the interests of particular private parties”). While Idaho has a legitimate interest in legislating to protect maternal health and fetal life, *Dobbs v. Jackson Women’s Health Org.*, 597 U.S. 215, 262 (2022), it does not have standing to bring a lawsuit “on behalf of its citizens” against a federal agency, *Brackeen*, 599 U.S. at 294–95. Idaho’s characterization of the medical risks of mifepristone as harms to the state itself is a “thinly veiled attempt to circumvent the limits on *parens patriae* standing.” *Murthy v. Missouri*, 144 S.Ct. 1972, 1996–97 (2024) (quoting *Brackeen*, 599 U.S. at 295 n.11).

V

In sum, Idaho does not have standing in this case to challenge the 2023 REMS based on the allegations contained in its complaint. Having failed to establish independent standing, Idaho cannot intervene to pursue separate relief. Because this appeal is confined to that narrow issue, we need not—and do not—reach any other issue raised in the district court or urged by the parties on appeal, including whether Idaho would otherwise be entitled to intervene under Federal Rule of Civil Procedure 24. We affirm the district court’s order denying Idaho’s motion to intervene as of right. We dismiss for lack of jurisdiction that portion of the appeal concerning the district court’s denial of permissive intervention.

AFFIRMED in part and DISMISSED in part.