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

SUPPLEMENTAL BRIEF OF APPELLANTS

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The Supreme Court recently decided *FDA v. Alliance for Hippocratic Medicine*, No. 23-235, 2024 WL 2964140 (U.S. June 13, 2024) ("*Alliance*"). The Court held that the private plaintiffs—individual doctors and medical organizations—lacked standing to challenge the FDA's actions related to mifepristone. *Id.* at *9-14. But the Court did not hold that the FDA's actions were unchallengeable, as the Solicitor General urged. *See* Transcript of Oral Argument at 6:19-15:19. In fact, the Court expressed doubt "that no one else would have standing to challenge FDA's relaxed regulation of mifepristone." 2024 WL 2964140 at *14. On the heels of that decision, the Panel requested supplemental briefing to address any impact of that ruling on this case.

Alliance **Did Not Address**
The State Intervenors' Unique Bases For Standing

The short answer to the Panel's question is that *Alliance* does not address the State Intervenors' theories of standing. None of the plaintiffs before the Court in *Alliance* were States. There were only "[f]our pro-life medical associations, as well as several individual doctors," whose standing was in question. 2024 WL 2964140 at *4. The Court's analysis therefore centered on what a "citizen" must do to show standing. *See id.* at *6-7, *12.

As a result, nothing in *Alliance* calls into question the State Intervenors' standing at the pleading stage. That last part is important. The applicable standard for the State Intervenors' complaint-in-intervention mirrors the standard that governs at the

pleading stage. *Sw. Ctr. for Biological Diversity v. Berg*, 268 F.3d 810, 818-22 & n.3 (9th Cir. 2001). In other words, the Panel must "accept as true the non-conclusory allegations made in support of an intervention motion." *Id.* at 819. That means that the State Intervenors need only support standing with "general factual allegations of injury." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992). They have done so here.

For example, the State Intervenors allege that the 2023 REMS deregulating mifepristone will increase the number of emergency room and urgent care visits of pregnant women who have taken mifepristone in the Intervenor States, and that increase in emergency medical services will cause State Intervenors "to incur additional medical care expenses." 2-ER-080-82, 086-88 at ¶¶ 41-54, 79, 84, 89. The State Intervenors also allege that the 2023 REMS harm their sovereign and quasi-sovereign interests, including their ability to enforce their laws and protect the health and well-being of pregnant women and unborn children within their territories. *See generally* 2-ER-080-88 at ¶¶ 39-91.

Those allegations well suffice at this stage. There will come a time when the State Intervenors will be required to prove that they have suffered an injury in fact and the FDA will have the opportunity to present evidence that the State Intervenors have suffered no injury. But for now, the State Intervenors' "allegations of economic injury" are enough. *See Hinojos v. Kohl's Corp.*, 718 F.3d 1098, 1104 n.4 (9th Cir. 2013). Add to that the classic State interests that are within the State Intervenors' "traditional prerogative to superintend" and that are impaired by the 2023 REMS, and the State

Intervenors have more than met their burden to allege standing at the pleading stage. *See Kentucky v. Biden*, 23 F.4th 585, 599 (6th Cir. 2022); *see also Nat. Res. Def. v. United States*, 542 F.3d 1235, 1248 n.8 (9th Cir. 2008). That is especially so given the "special solicitude" States have for standing purposes. *Massachusetts v. EPA*, 549 U.S. 497, 520 (2007); *see also California v. Trump*, 963 F.3d 926, 936 (9th Cir. 2020); *Arpaio v. Obama*, 797 F.3d 11, 27-28 (D.C. Cir. 2015) (Brown, J., concurring) (suggesting that there would have been standing to hear claims at issue if the plaintiff had been a State entitled to "special solicitude").

The Principles On Which *Alliance* Rests Confirm
The State Intervenors Have Sufficiently Alleged Standing

While it is true that *Alliance* does nothing to undermine the State Intervenors' standing here, it is also true that the principles the Supreme Court set out and applied to deny standing to the doctors and private medical associations in *Alliance* readily lead to the exact opposite outcome here.

The Supreme Court reiterated that a party can establish standing by showing an indirect injury as long as the "line of causation between the illegal conduct and injury" is not "too attenuated." 2024 WL 2964140 at *7 (cleaned up). The link is sufficiently tight where there is "a predictable chain of events leading from the government action to the asserted injury." *Id.* at *8. In "many cases," the question of attenuation "can be answered chiefly by comparing the allegations of the particular complaint to those made in prior standing cases." *Id.* (cleaned up).

Here, the chain of events leading from the 2023 REMS to State Intervenors' monetary injury is tight and predictable. Because the REMS allow mifepristone to be prescribed without an in-person physician visit and shipped to patients without an in-person pharmacy visit, it is foreseeable that more women will experience harm from the drug and require more emergency room or urgent care visits. 2-ER-080-88 at ¶¶ 39-91. The FDA admits as much, and the State Intervenors allege just that. 2-ER-082 at ¶ 54; *All. for Hippocratic Med. v. FDA*, 78 F.4th 210, 229, 233 (5th Cir. 2023) (the FDA does "not dispute that a significant percentage of women who take mifepristone experience adverse effects," with up to about 5 percent requiring emergency room care). Since the State Intervenors indisputably pay for a portion of those visits through Medicaid and the like, *see* 2-ER-082, 087 at ¶¶ 54, 79, 84, their "monetary harms" are plainly foreseeable and, under established precedent, "readily qualify as concrete injuries under Article III." *TransUnion LLC v. Ramirez*, 594 U.S. 413, 425 (2021).

This predictable chain of events is no more attenuated than others that have been held sufficient to confer standing. For example, the Supreme Court in *Department of Commerce v. New York*—which the Court cited repeatedly in *Alliance*, *see* 2024 WL 2964140 at *7-8—held that New York had standing to challenge the inclusion of a question on the census regarding citizenship because the question was likely to depress census response rates, decrease the State's population count, and result in diminished political representation and federal funds. 588 U.S. 752, 766-68 (2019). Or take *City and County of San Francisco v. USCIS*, where a rule making aliens inadmissible as "public

charge[s]" based on enrollment in federal benefits was predicted (including by DHS itself) to decrease enrollment in those benefits and at the same time increase enrollment in state benefits. 981 F.3d 742, 754 (9th Cir. 2020). There, like here, the logical consequences of the government action are straightforward to forecast. *See also California v. Azar*, 911 F.3d 558, 571-73 (9th Cir. 2018).

The State Intervenors' additional Medicaid costs are sufficient on their own to confer standing regardless of any potential benefit (or "net" result) from the 2023 REMS. As a leading treatise explains, "[o]nce injury is shown, no attempt is made to ask whether the injury is outweighed by benefits the plaintiff has enjoyed from the relationship with the defendant." 13A Fed. Prac. & Proc. Juris. § 3531.4 (3d ed.) (collecting cases); *Denney v. Deutsche Bank AG*, 443 F.3d 253, 265 (2d Cir. 2006) ("the fact that an injury may be outweighed by other benefits, while often sufficient to defeat a claim for damages, does not negate standing"). This Circuit has regularly followed that principle. *See*, *e.g.*, *Aluminum Co. of Am. v. Bonneville Power Admin.*, 903 F.2d 585, 590 (9th Cir. 1989) (injury from high energy rates established standing notwithstanding that utilities actually saved money as a result of actions taken to counteract high rates); *City & Cnty. of San Francisco*, 981 F.3d at 754 ("immediate financial injury" was an injury in fact even if the challenged rule could ultimately result in "long-term cost savings").

To be sure, the Court in *Alliance* ultimately ruled that the doctors and associations there did not have standing. But those plaintiffs were situated differently than the State Intervenors in at least three key ways:

First, *Alliance* came to the Supreme Court on an appeal from a preliminary injunction. *See* 2024 WL 2964140 at *4. That's why the Court scrutinized the lack of "record support" for aspects of the plaintiffs' assertion of standing. *See id.* at *11. Here, as explained above, the State Intervenors are still at the pleading stage, where the Court is "required to accept as true the non-conclusory allegations made in support of an intervention motion." *Berg*, 268 F.3d at 819. That distinction in procedural posture makes a world of difference.

Second, the State Intervenors' injury is more direct and concrete than the injuries asserted by the doctors in *Alliance*. Neither the *Alliance* plaintiffs' conscience injury nor their claims of diverted time and resources treating additional women who visit the emergency room due to mifepristone complications were monetary injuries. As a Medicaid insurer, the State Intervenors can only lose money when extra women visit the emergency room. And those plaintiffs' other asserted injuries—added risk of liability suits and higher insurance premiums because of those suits—require attenuated steps beyond the emergency room visits themselves that are absent here.

Third, the State Intervenors, unlike the private *Alliance* plaintiffs, are sovereigns who can assert, and have asserted, sovereign injuries. Those injuries are unique to a sovereign and wholly absent from the Supreme Court's analysis in *Alliance*. Binding Ninth Circuit precedent recognizes the validity of the sovereign and quasi-sovereign interests the State Intervenors have asserted here. *See Trump*, 963 F.3d at 936; *Nat. Res. Def.*, 542 F.3d at 1248 n.8. Aside from the harm to health and welfare, *see supra*, the

FDA's actions also harm the State Intervenors' "sovereign interests" in "the power to create and enforce a legal code." *Alfred L. Snapp & Son, Inc. v. Puerto Rico, ex rel., Barez*, 458 U.S. 592, 601 (1982). "[F]ederal interference with the enforcement of state law" creates standing. *Texas v. United States*, 809 F.3d 134, 153 (5th Cir. 2015). That is because "a State clearly has a legitimate interest in the continued enforceability of its own statutes." *Maine v. Taylor*, 477 U.S. 131, 137 (1986). The State Intervenors have alleged a substantial risk of federal interference with enforcement of state law by the "FDA-approved pipeline" permitting abortion pills to be mailed into all 50 States. *See*, *e.g.*, 2-ER-81–88 at ¶¶ 52, 69, 73-76, 85, 90.[1] Such interests were not part of the *Alliance* decision.

All of that is consistent with the district court's standing holdings below, which necessarily determined that both the Plaintiff States and the State Intervenors have standing. The court held that the Plaintiffs had "shown a reasonably probable threat to their economic interests in the form of unrecoverable costs that are fairly traceable to the 2023 REMS." 2-ER-043. The only two unrecoverable costs the Plaintiffs alleged were: (1) Medicaid costs based on consumer response to mifepristone regulation (*i.e.*, the same cost that the State Intervenors allege); and (2) costs to implement systems to comply with the 2023 REMS. 2-ER-042-43. Given that the Ninth Circuit has never

[1] *See* Rebecca Grant, *Group Using 'Shield Laws' to Provide Abortion Care in States That Ban It*, The Guardian (July 23, 2023), https://www.theguardian.com/world/2023/jul/23/shield-laws-provide-abortion-care-aid-access.

determined that that type of compliance costs is sufficient to create standing, the Plaintiffs' standing must rest on the same ground as the State Intervenors' standing, and both groups' standing must rise and fall together.[2]

CONCLUSION

Because the district court's Rule 24 analysis is wrong, and because *Alliance* confirms that the State Intervenors have standing, the Panel should reverse and remand.

[2] The district court likewise appeared to base its decision on unrecoverable Medicaid costs—its sole analysis was a citation to *California v. Azar*, 911 F.3d 558, 571-73 (9th Cir. 2018), with a parenthetical noting that *Azar* found "standing due to economic interests where state was responsible for reimbursing women who will seek contraceptive care through state-run programs." 2-ER-043.

Respectfully Submitted,

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Date: June 27, 2024

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CERTIFICATE OF COMPLIANCE

I am the attorney representing Appellants. This brief contains 1,986 words, including 0 words manually counted in any visual images, and excluding the items exempted by FRAP 32(f). The brief's type size and typeface comply with FRAP 32(a)(5) and (6).

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Date: June 27, 2024

/s/ Joshua N. Turner
Joshua N. Turner

CERTIFICATE OF SERVICE

I certify that on June 27, 2024, I electronically filed Appellants' Supplemental Brief with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

Date: June 27, 2024 *<u>/s/ Joshua N. Turner</u>*
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