RAÚL R. LABRADOR
Attorney General
DAVID M.S. DEWHIRST (ID #12141)
Chief Deputy Attorney General
THEODORE J. WOLD (CA #289177)
Solicitor General
LINCOLN DAVIS WILSON (WA #53764)
Deputy Attorney General
Chief, Civil Litigation and Constitutional Defense Division
JOSHUA N. TURNER (MN #0400279)
Deputy Solicitor General
Office of the Attorney General
P.O. Box 83720
Boise, Idaho 83720-0010
Tel: (208) 334-2400
Fax: (208) 854-8071

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON

STATE OF WASHINGTON, et al.,

Plaintiffs,
v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, et al.

Defendants,

STATE OF IDAHO; STATE OF IOWA; STATE OF MONTANA; STATE OF NEBRASKA; STATE OF SOUTH CAROLINA; STATE OF TEXAS; STATE OF UTAH,

Plaintiffs-Intervenors,

Case No. 1:23-cv-03026

**REPLY IN SUPPORT OF PLAINTIFFS-INTERVENORS' MOTION TO INTERVENE**

State Intervenors' Motion is a routine example of Rule 24 intervention. State Intervenors assert the same claims against the FDA as Plaintiffs, dispute the same agency action, challenge the same REMS, allege many of the same harms, and seek—in part—the same relief. In opposition, the FDA and Plaintiffs rely on arguments this Court has already rejected and on basic misunderstandings of the law. They seek to impose heightened burdens that flout the Ninth Circuit's instruction that Rule 24 is construed "broadly in favor of proposed intervenors." *Wilderness Soc. v. U.S. Forest Service*, 630 F.3d 1173, 1179 (9th Cir. 2011). As this Court has recognized, such a slanted view must be rejected. *Jordan v. Nationstar Mortg., LLC*, No. 2:14-CV-0175-TOR, 2016 WL 7494297, at *2 (E.D. Wash. Oct. 14, 2016) (describing Rule 24 as a "liberal policy" whose "requirements are broadly interpreted in favor of intervention"). Intervention here is well supported; it will cause the existing parties no prejudice; and it will "prevent or simplify future litigation involving related issues." *See United States v. City of Los Angeles*, 288 F.3d 391, 397 (9th Cir. 2002).

## ARGUMENT

### I. State Intervenors Have Standing To Intervene.

The FDA assumes State Intervenors must separately establish standing and are asserting injuries that belong only to their citizens. It is incorrect on both counts.

***Separate Standing Not Required.*** The FDA begins with a fundamental misstep by arguing that the State Intervenors must show standing. That is not required because the Court has already found Plaintiffs have standing to challenge the 2023 mifepristone REMS under the APA. *See Massachusetts v. EPA*, 549 U.S. 497, 518 (2007) ("Only one of the petitioners needs to have standing to permit us to consider

the petition for review."). The FDA's position is at odds with Ninth Circuit precedent that "once the court determines that one of the plaintiffs has standing, it need not decide the standing of the others." *Leonard v. Clark*, 12 F.3d 885, 888 (9th Cir. 1993).

This standing rule makes sense. Article III limits a court's power to decide "Cases" or "Controversies." *Town of Chester, N.Y. v. Laroe Ests., Inc.*, 581 U.S. 433, 438 (2017). Once one plaintiff presents the court with a case or controversy, Article III imposes no further barrier on judicial power to reach the dispute. *Id.* Standing relates to a federal court's power over disputes; it has nothing to do with a court's power over litigants, which is instead a question of personal jurisdiction. This Court has established its jurisdiction to hear the dispute over the 2023 REMS.

The FDA thinks this rule inapplicable because State Intervenors seek different relief from that sought by Plaintiffs. Dkt. #92 at 5. But Plaintiffs' Amended Complaint contradicts the FDA: they too have brought APA claims to "hold unlawful and set aside" the 2023 REMS and otherwise invalidate it. Dkt. #35 at ¶¶ 257-66. That is the same relief State Intervenors seek—no more, no less. Dkt. #76-1 at ¶¶ 97-107.

It's true that Plaintiffs seek additional relief, but all that matters is that the Court has found they have standing to seek the relief State Intervenors also seek. The Supreme Court has made this point clear: "an intervenor of right must demonstrate Article III standing when it seeks additional relief beyond that which the plaintiff requests." *Town of Chester*, 581 U.S. at 439. State Intervenors are not seeking "additional" relief "beyond" the relief already sought by Plaintiffs.

For this reason, the FDA misplaces reliance on *Oregon Prescription Drug Monitoring Program v. U.S. DEA*, 860 F.3d 1228 (9th Cir. 2017), where the intervenors

sought different relief on different legal grounds from the original plaintiff's complaint. *Id.* at 1234. Plaintiffs and State Intervenors, by contrast, pray for the same relief on the same legal grounds. That Plaintiffs seek to go further than State Intervenors is of no moment. And the FDA cannot unilaterally recharacterize the baseline relief Plaintiffs have prayed for in their Amended Complaint. Plaintiffs' Amended Complaint is "the best evidence of the relief [they] seek[]." *See Town of Chester*, 581 U.S. at 440. This Court has already found that Plaintiffs "claim that the 2023 REMS violated the Administrative Procedures Act." Dkt. #80 at 10. So do State Intervenors.

***The State Intervenors Have Independent Standing***. In any event, State Intervenors have shown their own standing. The FDA confuses distinct concepts of standing by arguing that State Intervenors are asserting *parens patriae* standing on behalf of their citizens. But that isn't so. State Intervenors assert their own sovereign and quasi-sovereign interests, which is very different than what *Mellon* bars. *See Kentucky v. Biden*, 23 F.4th 585, 596-99 (6th Cir. 2022) (explaining the difference); *Oregon v. Legal Servs.*, 552 F.3d 965, 971 (9th Cir. 2009) (drawing same distinction).

Those "sovereign-and-quasi-sovereign-interest theories" do not rest "on impermissible notions of third-party standing in which a state asserts in a purely vicarious manner the interests of its citizens." *Id.* They instead assert classic state interests that entitle them to "special solicitude" for standing purposes. *Massachusetts*, 549 U.S. at 520. The Ninth Circuit has also recognized that States can bring APA claims to vindicate these interests. *See Natl. Res. Defense v. U.S.*, 542 F.3d 1235, 1249 n.8 (9th Cir. 2008). The FDA ignores this binding precedent.

In this case, State Intervenors "may so sue . . . to vindicate [their] own sovereign and quasi-sovereign interests against the United States." *Id.* at 596. The 2023 REMS deregulate mifepristone and make it more likely for State Intervenors' citizens to unlawfully or improperly obtain the drug. Dkt. #76-1 at ¶¶ 46-52. Plaintiffs' Amended Complaint confirms as much, alleging that eliminating mifepristone's REMS will reduce the risk of criminal and civil enforcement by bordering States, like Idaho and Texas. Dkt. #35 at ¶¶ 130, 185. And deregulation will lead directly to citizen harm. Dkt. #76-1 at ¶¶ 41-51. State Intervenors' sovereign and quasi-sovereign interests provide them with standing. *See Massachusetts*, 549 U.S. at 520; *California v. Trump*, 963 F.3d 926, 936 (9th Cir. 2020) ("[A] state may sue to assert its quasi-sovereign interests in the health and well-being . . . of its residents in general.").

State Intervenors also have alleged direct harm to their own economic interests traceable directly to the 2023 REMS, which alone provides standing. *Hinojos v. Kohl's Corp.*, 718 F.3d 1098, 1104 n.4 (9th Cir. 2013). For example, Idaho alleges that "[t]he increased risk to Idaho women and unborn children [from the REMS] will [cause] it to incur additional medical care expenses, including emergency care, some of which is borne by Idaho through Medicaid expenditures." Dkt. #76-1 at ¶ 54. Plaintiffs asserted the same economic harms tied to the 2023 REMS, and this Court held such harms conferred standing. Dkt. #80 at 13-14. The result cannot be any different here.

The FDA ignores that track record and tries again. It argues that State Intervenors haven't shown that their allegations of economic harms are beyond speculative. But it does so based on caselaw addressing standing at the summary judgment stage, which does not apply here. *See, e.g., Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 412

(2013) ("[A]t the summary judgment stage, such a party can no longer rest on mere allegations." (cleaned up)); *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992) (same). And the FDA's squabbling over what certain studies actually show or deference to its own "reasoned conclusion" proves the point. *See* Dkt. #92 at 10. "At the pleading stage, general factual allegations of injury resulting from the defendant's conduct may suffice" because courts "presum[e] that general allegations embrace those specific facts that are necessary to support the claim." *Lujan*, 504 U.S. at 561. The FDA's dispute over the merits of State Intervenors' alleged injuries is for another day. *Maya v. Centex Corp.*, 658 F.3d 1060, 1068 (9th Cir. 2011). At this early stage, "allegations of economic injury suffice," full stop. *Hinojos*, 718 F.3d at 1104 n.4.

The FDA's final effort is to label State Intervenors' injuries "unadorned speculation" and "merely incidental." Dkt. #92 at 11. Neither characterization holds up. This Court has already found that there is "a reasonably probable threat to [State] economic interests in the form of unrecoverable costs that are fairly traceable to the 2023 REMS." Dkt. #80 at 14. Similarly, State Intervenors allege the 2023 REMS removed necessary safeguards to protect women, which increases the medical expenses State Intervenors incur. *See* Dkt. #76-1 at ¶¶ 24-26, 29-30, 37-38, 41-44, 47-51, and 53-54.

The FDA relies on *Arizona v. Biden*, 40 F.4th 375 (6th Cir. 2022), but this case is nothing like it. The States' allegations in *Arizona* relied on contingent and speculative assumptions about how a Guidance document would impact noncitizen criminal activity. *Id.* at 383. As the court explained well, "[t]hat the National Government decides to remove or detain person A over person B does not establish that it will pursue fewer people." *Id.* Here, in contrast, State Intervenors and Plaintiffs have both

alleged that the 2023 REMS directly result in adverse health outcomes and that States will foot the bill for some of the increased medical expenses.

The Ninth Circuit in *California v. Azar* recently affirmed a nearly identical theory of standing. 911 F.3d 558 (9th Cir. 2018). Like the FDA does here, the agency in *Azar* argued that the economic injuries were too speculative. But the Ninth Circuit held that "the states have shown that the threat to their economic interest is reasonably probable." *Id.* at 573. True, a causal chain was involved, but "[j]ust because a causal chain links the states to the harm does not foreclose standing." *Id.* at 571.

State Intervenors need only generally allege injuries, and their generally alleged injuries are entitled to special solicitude. *California*, 963 F.3d at 936. At this stage, State Intervenors allege "a quintessential injury-in-fact." *Maya*, 658 F.3d at 1069.

## II. State Intervenors Have A Right To Intervene.

Plaintiffs try a different approach from the FDA, but their arguments fare no better. Their Rule 24 analysis cannot be squared with Ninth Circuit precedent. State Intervenors have shown each of the four factors are met here.

***Timeliness.*** State Intervenors filed their Motion to Intervene exactly three weeks after Plaintiffs filed their Amended Complaint, just five weeks after Plaintiffs commenced this action, and before the FDA answered or this Court issued any scheduling order. Yet Plaintiffs contend that State Intervenors' Motion is untimely. *See* Dkt. #93 at 8-9. Tellingly, they cite no case finding that a motion to intervene filed within five weeks of case commencement is untimely. That's because caselaw uniformly says the opposite. *See, e.g., Kalbers v. US DOJ*, 22 F.4th 816, 822 (9th Cir. 2021) (intervention timely when filed "just a few weeks" after intervenor learned of

need to intervene); *Los Angeles*, 288 F.3d at 398 (intervention timely when "filed only approximately one and half months after the suit was filed"). Nor does the Court's entry of a preliminary injunction make State Intervenors' Motion untimely. *BNSF Ry. Co. v. Tri-City & Olympia R.R. Co. LLC*, 2010 WL 11527085, at *1 (E.D. Wash. Mar. 8, 2010) (allowing intervention "although a preliminary injunction is in place").

Notably, Plaintiffs have not claimed they would be prejudiced by State Intervenors' entry, which "is the most important consideration in deciding whether a motion for intervention is untimely." *Smith v. L.A. Unified Sch. Dist.*, 830 F.3d 843, 857 (9th Cir. 2016). State Intervenors moved to intervene swiftly when they learned that this litigation implicated their interests. In fact, State Intervenors acted more quickly than Plaintiffs, who've argued that "[t]aking seven weeks to assemble a multi-state coalition and gather evidence following this final agency action hardly evinces a 'lack of urgency.'" Dkt. #60 at 17. State Intervenors motion is just as timely.

***Protectable Interest.*** Plaintiffs are just plain wrong that State Intervenors lack an interest "protectable under some law" that is related to "the claims at issue." *Wilderness Soc*, 630 F.3d at 1176. It is not plausible that, as Plaintiffs suggest, the only valid State interest in the mifepristone REMS is the one that seeks to invalidate it. State Intervenors also have an interest in safe mifepristone REMS, an interest that is legally protected by the APA. And State Intervenors' interest is related to Plaintiffs' claims, which also challenge the mifepristone REMS. Nothing more is needed to satisfy this factor. *Calif. Dep't of Toxic Substances Control v. Jim Dobbas, Inc.*, 54 F.4th 1078, 1092 (9th Cir. 2022) (reversing and finding protectable interest).

Plaintiffs only dispute that State Intervenors' interests are unrelated to their claims. Dkt. #93 at 4. They characterize State Intervenors' interest as "solely" concerning the in-person dispensing requirement, but that is not the case. State Intervenors have a broader interest in ensuring lawful and safe mifepristone REMS. Dkt. #76-1 at ¶¶ 1, 17-27. This case shares a direct relationship with that interest because it challenges the same 2023 REMS at issue in State Intervenors' Complaint. Even if State Intervenors' interest were "solely" about the in-person dispensing requirement, Plaintiffs are wrong that such an interest is unrelated to their claims. They seek to invalidate the 2023 REMS, which, as the Court noted, may be inconsistent with other further relief they seek, but Plaintiffs are entitled to plead inconsistent relief. *Oki America, Inc. v. Microtech International, Inc.*, 872 F.2d 312, 314 (9th Cir. 1989).

Nor does the ability to regulate medication abortion defeat State Intervenors' interests here. State Intervenors are not asserting an interest based on a connection between their laws and the mifepristone REMS, which was the case in *ACOG v. FDA*, 467 F. Supp. 3d 282 (D. Md. 2020). State Intervenors have a right to vindicate their interests under the APA, which are squarely at issue here. Because "resolution of the plaintiff's claims actually will affect [State Intervenors]," the relationship requirement is satisfied. *See Donnelly v. Glickman*, 159 F.3d 405, 410 (9th Cir. 1998)

***Impairment of Interest.*** Once an intervenor demonstrates a protectable interest, courts have "little difficulty concluding that the disposition of the case may, as a practical matter, affect it." *Citizens for Balanced Use v. Montana Wilderness Ass'n*, 647 F.3d 893, 898 (9th Cir. 2011). Plaintiffs' goal of eliminating mifepristone's REMS would apply to mifepristone's availability nationally. And even were it confined to

Plaintiffs' borders, State Intervenors' interests would still be impaired. As Plaintiffs admit, eliminating the REMS impacts State Intervenors' ability to enforce its laws and the safeguards available to protect their citizens. Dkt. #35 at ¶¶ 130, 185.

Plaintiffs' principal response is that State Intervenors can assert their interests in a separate lawsuit. Dkt. #93 at 6-7. But this view discounts the effect of judgment here and at the Ninth Circuit. *See United States v. Oregon*, 839 F.2d 635, 639 (9th Cir. 1988) (citing precedents "recognizing practical limitations on the ability of intervention applicants to protect interests in the subject of the litigation after court-ordered equitable remedies are in place"). The impairment "analysis focuses on the *future* effect pending litigation will have on the intervenors' interests." *Klamath Siskiyou Wildlands Ctr. v. U.S. BLM*, 2019 WL 6749411, at *2 (D. Or. Dec. 11, 2019). Here, it isn't difficult to see that a future decision from this Court or the Ninth Circuit may impair or impede State Intervenors' interest. In the Ninth Circuit, "such a stare decisis effect is an important [impairment] consideration." *Oregon*, 839 F.2d at 638.

Plaintiffs' go-file-your-own-lawsuit answer also disregards Rule 24's well-recognized purpose to promote the "efficient resolution of issues." *Wilderness Soc.*, 630 F.3d at 1179. This is why Rule 24 is liberally construed "in favor of intervention." *Id.* Intervention exists to "prevent or simplify future litigation involving related issues." *City of Los Angeles*, 288 F.3d at 398. But Plaintiffs turn this purpose on its head and ask this Court to deny intervention so that litigation can be multiplied. That disrespects constrained judicial resources and ignores Rule 24's primary purpose.

***Inadequate Representation.*** Plaintiffs do not dispute that they do not adequately represent State Intervenors' interests. And that's true. There is an obvious

misalignment of interests. Still, they contend that the "FDA adequately represents" State Intervenors' interests. They do not say how the FDA is a fit representative to advance State Intervenors' claims against itself. Nor has the FDA claimed that it would do so. It seems too obvious to have to say much more, but a party who an intervenor proposes to sue will not adequately represent the intervenors' interests. State Intervenors need only show that representation of their "interest may be inadequate—a 'minimal' burden." *See Kalbers*, 22 F.4th at 828. They've done so.

### III. State Intervenors May Permissively Intervene.

Both the FDA and Plaintiffs oppose permissive intervention on the same grounds as they oppose intervention as of right. Their arguments are addressed above and won't be rehashed here. One final point bears mention. State Intervenors' participation in this case will not "unduly delay or prejudice the adjudication of the original parties' rights." Fed. R. Civ. P. 24(b)(3). Neither the FDA nor Plaintiffs have argued that intervention here will prejudice their rights. Plaintiffs baldly assert that intervention will "unduly delay" this case, but their assertion is based on the erroneous belief that State Intervenors seek to advance "tangential claims." Dkt. #93 at 11. State Intervenors will instead provide the Court with an unrepresented perspective and so "will significantly contribute to full development of the underlying factual issues in the suit and to the just and equitable adjudication of the legal questions presented." *Spangler v. Pasadena City Bd. of Educ.*, 552 F.2d 1326, 1329 (9th Cir. 1977).

### CONCLUSION

State Intervenors request the Court grant their Motion to Intervene.

Dated: April 19, 2023

*/s/ Lincoln Davis Wilson*
LINCOLN DAVIS WILSON (#53764)
Deputy Attorney General
Chief, Civil Litigation and
Constitutional Defense Division
Office of the Attorney General
P.O. Box 83720
Boise, Idaho 83720-0010
Tel: (208) 334-2400
Fax: (208) 854-8071
Lincoln.Wilson@ag.idaho.gov

**CERTIFICATE OF SERVICE**

I hereby certify that, on April 19, 2023, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

*/s/Lincoln Davis Wilson*
LINCOLN DAVIS WILSON (WA #53764)