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UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF WASHINGTON

STATE OF WASHINGTON, *et al.*, Plaintiffs, v. U.S. FOOD AND DRUG ADMINISTRATION, *et al.*, Defendants.	No. 1:23-cv-03026 DEFENDANTS' RESPONSE IN OPPOSITION TO STATE INTERVENORS' MOTION TO INTERVENE

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INTRODUCTION

Idaho and six other states (Intervenors) seek to intervene of right under Federal Rule of Civil Procedure 24(a)(2), or permissively under Rule 24(b)(1)(B). Because Intervenors seek a result not sought by any other party—specifically, that the U.S. Food and Drug Administration (FDA) reintroduce the in-person dispensing requirement for the drug mifepristone[1]—they must establish independent Article III standing to do so. They have not made that showing.

Intervenors offer three theories of standing, but each fails. First, contrary to Intervenors' assertion, they lack standing to sue the federal government as *parens patriae* on their residents' behalf. Second, while Intervenors ostensibly sue to vindicate their power to create and enforce state law, they have not identified any act by Defendants that interferes with that power. Third, Intervenors' prediction that removal of the in-person dispensing requirement will burden their Medicaid programs is mere speculation devoid of factual support. Because they have failed to establish independent Article III standing, Intervenors' motion should be denied.

[1] This brief uses the term "mifepristone" to refer to drug products that are approved for medical termination of early pregnancy, in both brand name and generic form. FDA has separately approved another manufacturer's drug, Korlym, which has mifepristone as its active ingredient and is approved for the treatment of Cushing's syndrome. This litigation does not affect Korlym or its generic.

BACKGROUND

The State of Washington and 11 other states filed this lawsuit on February 23, 2023, Compl., Dkt. 1, and they filed an Amended Complaint on March 9, 2023, with five additional states and the District of Columbia, Am. Compl., Dkt. 35. Among other things, Plaintiffs seek an order directing FDA to "remove" all of the Risk Evaluation and Mitigation Strategy (REMS) restrictions on the drug mifepristone. *Id.* ¶ 8. They also seek declaratory and injunctive relief that would bar Defendants from "enforcing or applying" the mifepristone REMS or "reduc[ing] [mifepristone's] availability." *Id.* at 90. On April 7, 2023, this Court preliminarily enjoined Defendants from "altering the status quo and rights as it relates to the availability of Mifepristone under the current operative January 2023 [REMS] under 21 U.S.C. § 355-1 in Plaintiff States." Order Granting in Part Plaintiffs' Motion for Preliminary Injunction, Dkt. 80, at 30 (Apr. 7, 2023).

Meanwhile, on March 30, 2023, Intervenors had moved to intervene. Mot. to Intervene, Dkt. 76. They challenge FDA's January 3, 2023 decision to remove a requirement that mifepristone be dispensed in clinics, medical offices, and hospitals, by or under the supervision of a certified provider (the in-person dispensing requirement). *See* Intervenors' Proposed Compl., Dkt. 76-1 (Intervenors' Compl.), ¶¶ 96, 102, 107. Thus, in contrast to Plaintiffs, Intervenors seek to increase, not reduce, restrictions on mifepristone. *Id.*

ARGUMENT

I. Intervenors May Not Intervene Of Right

Intervenors primarily seek intervention of right under Federal Rule of Civil Procedure 24(a)(2). *See* Mot. to Intervene 2. Under that rule, a court must permit intervention by a litigant that "claims an interest relating to the property or transaction that is the subject of the action, and is so situated that disposing of the action may as a practical matter impair or impede the movant's ability to protect its interest, unless existing parties adequately represent that interest." Fed. R. Civ. P. 24(a)(2). However, "an intervenor of right must have Article III standing in order to pursue relief that is different from" that sought by the original plaintiffs. *Town of Chester v. Laroe Estates, Inc*., 581 U.S. 433, 440 (2017); *accord Ore. Prescription Drug Monitoring Program v. U.S. Drug Enf't Admin.*, 860 F.3d 1228, 1234 (9th Cir. 2017) (*OPDMP*). This rule flows from the principle that standing must be established "for each claim" raised and "for each form of relief that is sought." *Town of Chester*, 581 U.S. at 439 (quotation marks and citation omitted).

Here, Intervenors seek relief that is wholly distinct from, and even irreconcilable with, that sought by Plaintiffs. As Intervenors acknowledge, "the existing Plaintiffs are seeking to eliminate mifepristone's REMS altogether," whereas Intervenors "are seeking to restore and strengthen mifepristone's REMS" by reviving the in-person dispensing requirement. Mot. to Intervene 5. And

apparently recognizing the need to establish their independent standing, Intervenors, like Plaintiffs, allege injuries tailored to their distinct claims. *Compare* Am. Compl. ¶¶ 168-70 (alleging that the mifepristone REMS injures Washington's residents by impairing access to a "critical medicine" that is "safe and effective"), *with* Intervenors' Compl. ¶¶ 39-56 (alleging that FDA's elimination of the in-person dispensing requirement will harm Idaho's residents by exposing them to "dangerous complications"). Thus, while both groups challenge FDA's January 2023 decision, "[w]hat Intervenors want is something very different" from what Plaintiffs want. *OPDMP*, 860 F.3d at 1234. Therefore, they "must establish independent Article III standing." *Id.*

To meet the "irreducible constitutional minimum of standing," *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992), Intervenors "must show (i) that [they] suffered an injury in fact that is concrete, particularized, and actual or imminent; (ii) that the injury was likely caused by the defendant[s]; and (iii) that the injury would likely be redressed by judicial relief," *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2203 (2021). An "injury-in-fact" must be "actual" or "certainly impending," *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013), not "conjectural" or "hypothetical," *Lujan*, 504 U.S. at 560. "'[A]llegations of possible future injury' are not sufficient." *Clapper*, 568 U.S. at 409 (quoting *Lujan*, 504 U.S. at 565 n.2). To satisfy the causation requirement, Intervenors must also show

that their alleged injuries are "fairly traceable to the challenged action of the defendant, and not the result of the independent action of some third party not before the court." *Lujan*, 504 U.S. at 560.

Intervenors offer three theories of standing; each fails. *First*, just as Defendants have argued with respect to Plaintiffs, *see* Defs.' PI Opp., Dkt. 51, at 18, Intervenors lack standing to sue the federal government as *parens patriae* on behalf of their residents. *See Alfred L. Snapp & Son, Inc. v. Puerto Rico ex rel. Barez*, 458 U.S. 592, 610 n.16 (1982) (citing *Massachusetts v. Mellon*, 262 U.S. 447, 485-86 (1923)). Intervenors suggest that they have a "quasi-sovereign interest in the health and well-being" of their residents, Mot. to Intervene 4, but the federal government is "the ultimate *parens patriae* of every American citizen." *S. Carolina v. Katzenbach*, 383 U.S. 301, 324 (1966); *see also Gov't of Manitoba v. Bernhardt*, 923 F.3d 173, 180-83 (D.C. Cir. 2019) (applying this rule to APA claims); Order, Dkt. 80, at 12 ("Courts have determined that the APA alone does not demonstrate congressional intent to authorize a state to sue the federal government as *parens patriae*."). Accordingly, any alleged injury to Intervenors' citizens cannot establish Intervenors' standing to challenge FDA's January 2023 action under the APA.

Second, while Intervenors contend that FDA's January 2023 action "undermines the State Intervenors' ability to enforce their laws," Mot. to Intervene 4, they fail to "clearly allege facts" in support of that contention, *Spokeo, Inc. v.*

Robins, 578 U.S. 330, 338 (2016). Instead, Intervenors allege that, "without the in-person dispensing requirement," Intervenors' residents may find it easier to violate those states' laws. *E.g.*, Intervenors' Compl. ¶¶ 52, 55. This theory relies on a "speculative chain of possibilities" about what could occur in the absence of the in-person dispensing requirement. *Clapper*, 568 U.S. at 414. For example, Idaho fears that (1) an out-of-state health care provider "*could* conduct a telehealth appointment with an Idaho resident and prescribe her mifepristone," (2) the resident "*could* travel [out of state] to have a mifepristone prescription filled," (3) such events "will result in an influx of mifepristone in Idaho," and (4) the State will be unable to stop this through enforcement of its laws. Intervenors' Compl. ¶ 52 (emphasis added). Such contingencies cannot establish a "certainly impending" injury, especially where they "rest on speculation about the decisions of independent actors"—here, unidentified physicians, pharmacists, and patients. *Clapper*, 568 U.S. at 414; *see also Lujan*, 504 U.S. at 561-62.

Moreover, Intervenors' theory is particularly suspect because it is premised on an assumption that independent actors will attempt to evade Intervenors' state laws. *Cf. City of Los Angeles v. Lyons,* 461 U.S. 95, 105-06 (1983). As an initial matter, Intervenors do not clearly explain what allegedly unlawful conduct the in-person dispensing requirement supposedly prevents. In any event, their mere supposition that removal of the in-person dispensing requirement "will lead to

increased unlawful behavior" by third parties is insufficient, given the difficulty in predicting how third parties not before the court will act. *See Arpaio v. Obama*, 797 F.3d 11, 22 (D.C. Cir. 2015) (rejecting as speculative plaintiff's inference that a change in federal immigration law would lead to an increase in crime); *see also Whitewater Draw Nat. Res. Conservation Dist. v. Mayorkas*, 5 F.4th 997, 1014-15 (9th Cir. 2021) (citing *Arpaio* with approval and rejecting a theory of standing that "hinges on an unreasonable response of third parties" to a federal policy).

In addition, Intervenors fail to explain how FDA's removal of the in-person dispensing requirement infringes upon the Intervenors' "power to create and enforce a legal code," Mot. to Intervene 4 (citing *Alfred L. Snapp & Son*, 458 U.S. at 601). Intervenors cite—and Defendants are aware of—no authority holding that the federal government injures a state's sovereign interest in enforcing its laws merely by eliminating a federal policy that states allege incidentally makes it harder to violate their laws. And Intervenors' conclusory assertion that "enforcement of [their] law[s] . . . depends on . . . an in-person dispensing requirement," *e.g.*, Intervenors' Compl. ¶ 55, fails to establish a cognizable injury.

Third, Intervenors' prediction that removal of the in-person dispensing requirement will cause an "increased risk" to patients, thereby necessitating "additional medical care" that could increase state "Medicaid expenditures," *e.g.*, Intervenors' Compl. ¶ 54, amounts to a "speculative fear" rather than a "certainly

impending" injury. *Clapper*, 568 U.S. at 410. This theory relies on the same chain of assumptions, discussed above, that Intervenors' residents will obtain mifepristone in another state and then use it in their home states.

To those assumptions, Intervenors add two more: (1) that the Intervenors' residents will experience adverse events from their use of mifepristone, and (2) that they will seek care covered by Medicaid. *See, e.g.*, Intervenors' Compl. ¶ 54. Ignoring FDA's reasoned conclusion that the in-person dispensing requirement was no longer necessary to ensure that the benefits of the drug outweigh the risks, *see* Dkt. 51-4, at 38-39, Intervenors rely (Intervenors' Compl. ¶¶ 35, 54) on FDA's discussion of three studies "suggest[ing] there *may* be more frequent [emergency department and] urgent care visits" when mifepristone is "dispensed by mail from [a] clinic." Intervenors' Compl. Ex. 2 at 34 (emphasis added). But FDA noted that these studies did *not* show an increase in serious adverse events associated with the lack of in-person dispensing. *Id.*; *see also id.* at 33.[2]

[2] Additionally, whereas mifepristone's labeling references only unplanned emergency department (ED) visits, two of the studies did not differentiate between ED and urgent care visits, so it was unclear whether the frequency of the former had actually increased. *See* Intervenors' Compl. Ex. 2 at 32 n.108. And one of those studies revealed that half of the visits resulted in no treatment. *Id.* at 32.

Moreover, such studies do not relieve Intervenors of their burden to "clearly allege facts" showing that increases in such visits are impending, so as to establish standing. *Spokeo*, 578 U.S. at 338. Tellingly, Intervenors fail to identify *even one* instance of a Medicaid expenditure that would have been prevented by the in-person dispensing requirement, despite their having had two years of experience to draw on. *See* Intervenors Compl. Ex. 2 at 5 (noting that FDA first suspended its enforcement of that requirement in April 2021). Intervenors' "unadorned speculation" about a contingent financial injury cannot establish their standing. *Diamond v. Charles*, 476 U.S. 54, 66 (1986).

Finally, Intervenors' Medicaid expenditures theory fails because a federal policy's mere incidental effect on state expenditures does not qualify as a cognizable injury. Rather, Intervenors' must allege a "*direct* injury" at the hands of the federal government. *Florida v. Mellon*, 273 U.S. 12, 18 (1927) (rejecting Florida's "remote and indirect" theory that a federal tax would harm the state by diminishing its tax base). Intervenors' "boundless theory"—whereby a state may sue to block a federal policy's purely derivative effects on that state's fisc—would eviscerate the "limits on state standing" because many federal actions that affect a state's residents can be associated with "peripheral costs" for that state. *Arizona v. Biden*, 40 F.4th 375, 386 (6th Cir. 2022). Because the hypothetical Medicaid expenditures of which Intervenors complain would be, at most, a "remote and

indirect" consequence of a federal policy, they are not a cognizable Article III injury. *Florida*, 273 U.S. at 18.

II. For The Same Reasons, Permissive Intervention Would Be Improper

Intervenors alternatively seek permissive intervention under Rule 24(b)(1)(B), which provides that a court "may permit" intervention by a litigant that "has a claim or defense that shares with the main action a common question of law or fact." *Id.* But because Article III requires that "[f]or all relief sought, there must be a litigant with standing," *Town of Chester*, 581 U.S. at 439, and because Intervenors seek relief sought by no other party, Intervenors' lack of standing makes permissive intervention improper. *See Cross Sound Cable Co., LLC v. Long Island Lighting Co*., 2022 WL 247996, *9 (E.D.N.Y. Jan. 27, 2022) (applying *Town of Chester* to permissive intervention); *see also Perry v. Schwarzenegger*, 630 F.3d 898, 906 (9th Cir. 2011) (affirming refusal to permit intervention where intervenors lacked standing to vindicate their "specific interest"); *cf. E.E.O.C. v. Nevada Resort Ass'n*, 792 F.2d 882, 886 (9th Cir. 1986) ("A party seeking permissive intervention … must establish a basis for federal subject matter jurisdiction independent of the court's jurisdiction over the underling action.").

CONCLUSION

For the foregoing reasons, the Court should deny Intervenors' Motion to Intervene.

April 13, 2023

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CERTIFICATE OF SERVICE

I hereby certify that, on April 13, 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.

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