

**UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
WICHITA FALLS DIVISION**

STATE OF FLORIDA and STATE OF TEXAS,

Plaintiffs,

v.

U.S. FOOD AND DRUG ADMINISTRATION, *et al.*,

Defendants.

Case No. 7:25-cv-00126-O

**INTERVENOR-DEFENDANT GENBIOPRO, INC.'S
REPLY IN SUPPORT OF ITS MOTION TO DISMISS**

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INTRODUCTION

Plaintiffs' opposition only confirms the complaint must be dismissed. Article III standing is lacking. At the threshold, Texas is precluded from rearguing the same theories of standing it litigated and lost in the Ninth Circuit. Plaintiffs' contention that Texas cannot be precluded because it was denied intervention misses the point: while denied intervenors are, of course, not bound by the outcomes of issues they were excluded from litigating, they are very much bound by holdings that underpin the denial of intervention. And Plaintiffs do not dispute that without Texas in the case as a co-plaintiff with Article III standing, there is no venue for Florida's claims.

Texas and Florida also lack Article III standing on a *de novo* analysis. In that regard, GenBioPro acknowledges that in *Louisiana v. FDA*, 2026 WL 1194924 (5th Cir. May 1, 2026), a motions panel of the Fifth Circuit granted Louisiana's motion to stay FDA's 2023 Risk Evaluation and Mitigation Strategy ("REMS") for mifepristone pursuant to 5 U.S.C. § 705 pending appeal, and in the course of doing so, found Louisiana had standing to challenge the 2023 REMS. However, GenBioPro believes *Louisiana* is wrongly decided and has sought an emergency stay of the Fifth Circuit's order from the U.S. Supreme Court. Regardless of whether the Supreme Court immediately stays the May 1 order, it is very likely that the motions panel's decision will not be the final word on the subject, given that the appeal has yet to be briefed and argued to a Fifth Circuit merits panel that will not be bound by the motions panel, as well as the prospect of Supreme Court review on certiorari. As such, the Court may find it efficient to hold this matter in abeyance until final guidance on these issues from the appellate courts in *Louisiana* crystallizes.

At any rate, even under the May 1 Fifth Circuit decision, most of the claims in this case would still fail for lack of Article III standing. The Fifth Circuit held that Louisiana had standing to challenge the 2023 REMS on the basis that the "goal of the regulation" was "ensuring out-of-state medical providers could prescribe mifepristone to women in states that restrict abortion" in

the wake of *Dobbs. Louisiana*, 2026 WL 1194924, at *5. While that holding is profoundly wrong, what matters here is that it has no conceivable applicability to Plaintiffs' challenges to FDA's 2000 and 2019 drug approvals and 2016 REMS changes: Plaintiffs do not plausibly allege that any of those actions were designed to undermine state abortion restrictions. Nor could they credibly allege such a motivation—throughout that time period, the right to abortion was protected by the federal Constitution and Plaintiffs were not able to enforce their restrictions on abortion anyway.

Plaintiffs' economic injury theory fares no better. The Fifth Circuit May 1 decision found standing to challenge the 2023 REMS because "Louisiana provided hard evidence" of pocketbook injury, namely "\$92,000 it paid in Medicaid costs from two women who needed emergency care in 2025 from complications caused by out-of-state mifepristone." *Id.* While GenBioPro disputes that holding and Louisiana's showing, what is relevant here is that Florida and Texas provide nothing of the sort. Their economic injury argument rests on a chain of contingencies even more attenuated than the one the Supreme Court rejected in *FDA v. Alliance for Hippocratic Medicine* ("*AHM*"), 602 U.S. 367, 390-91 (2024): independent prescribers and patients must choose to violate state law; those violations must produce medical complications; those complications must result in particular treatment costs; and those costs must be borne by the State. Plaintiffs have not established any of those links, let alone all of them.

Neither Plaintiffs' arguments in their opposition brief, nor the Fifth Circuit May 1 decision in *Louisiana*, excuses Plaintiffs' failure to exhaust in this case. And Plaintiffs' challenges to the 2000 and 2019 approvals and the 2016 changes are plainly untimely. While Plaintiffs try to avoid the limitations bar by insisting that they are not relying on injuries outside the limitations periods, that is not how statutes of limitation work. If Plaintiffs were injured at all by the FDA 2000, 2016, and 2019 actions in the way they allege they were (through availability of mifepristone causing

them economic harm), those injuries would have ensued when the 2000, 2016, and 2019 actions took effect, not years later. The complaint should be dismissed.

ARGUMENT

I. Texas Is Precluded from Relitigating Theories of Standing It Has Argued and Lost In Prior Mifepristone Litigation Against FDA

Texas cannot relitigate here the same theories of standing that it litigated and lost in *Washington v. FDA*, 108 F.4th 1163 (9th Cir. 2024). GBP Mot.8-10. Plaintiffs argue Texas is not precluded because, as a result of its motion to intervene being denied, it was “not a party” in the *Washington* case, and only “parties” to an action are subject to issue preclusion. Opp.7-8. But the “principles of res judicata are applicable to fully litigated issues raised by a motion to intervene,” including where the motion to intervene was denied. *Bhd. of Locomotive Firemen & Enginemen v. Seaboard Coast Line R. Co.*, 413 F.2d 19, 23-24 (5th Cir. 1969); accord *U.S. ex rel. Conner v. Mahajan*, 877 F.3d 264, 270-72 (7th Cir. 2017) (per curiam).

Plaintiffs’ principal cases do not hold otherwise. There, litigants sought to intervene to object to consent decrees, were denied intervention, and then appealed those denials. Affirming, the Fifth Circuit explained that inability to intervene did not prejudice the appellants because they would not be bound by the consent decrees they had been excluded from challenging. *Jones v. Caddo Parish School Bd.*, 704 F.2d 206, 217 (5th Cir. 1983); *United States v. Allegheny-Ludlum Indus., Inc.*, 517 F.2d 826, 845 (5th Cir. 1975).

The situation here is nothing like that. GenBioPro is not trying to bind Texas to a case outcome between *the parties* in the *Washington* case that Texas was excluded from litigating. Rather, GenBioPro seeks to hold Texas to “the same jurisdictional issue[s] decided [against it] in a prior case”—the Article III standing issue that was fully litigated *between Texas and FDA* in *Washington*, standing being just as necessary for intervention there as it is for Texas to sue here.

Bank of La. v. FDIC, 33 F.4th 836, 838 (5th Cir. 2022). Texas made a tactical choice to litigate its misguided standing theories in *Washington* and must abide the consequences of that choice.

Plaintiffs' attempts to play up minor differences between *Washington* and this case fall flat:

- While Plaintiffs object that this case challenges a broader set of FDA actions than those at issue in *Washington*, Opp.8 n.4, the underlying *standing* theories on which those challenges rest are precisely the same as those the Ninth Circuit rejected: economic injury from Medicaid payments; interference with sovereign interests in law enforcement; and quasi-sovereign *parens patriae* interests. Compare Opp.9-20, with *Washington*, 108 F.4th at 1174-78.
- Contrary to Plaintiffs' assertion that *Washington* did not address "whether Texas's increased investigatory and prosecutorial costs constitute economic injury," Opp.8 n.4, the Ninth Circuit squarely rejected Texas's bid for "standing to challenge federal action that ... mak[es] violations of state law more difficult *or costly* to detect." *Washington*, 108 F.4th at 1176 (emphasis added).
- While Texas asserts that its allegations about having "already incurred" Medicaid costs moot *Washington's* remarks about "speculative" allegations, Opp.8 n.4, *Washington* rejected the same theory because Texas's alleged "causal chain [was] too attenuated," even taking its "highly speculative allegations as true," 108 F.4th at 1174-76.
- Texas touts "new data" about state shield laws Texas believes impede enforcement of its laws. Opp.8-9 n.4. But *Washington's* holding that "a logistical burden on law enforcement" is not "a cognizable Article III injury" is a qualitative holding, not dependent on the *degree* of burden. 108 F.4th at 1177. If anything, Texas's emphasis on state shield laws detracts from its standing to sue FDA, as it makes clear its alleged injuries are traceable to policy decisions by coequal sovereign states, not to FDA's drug safety regulations.

In sum, Texas is barred from relitigating here the same Article III standing theories it litigated and lost in the *Washington* case.

II. Because Texas Lacks Standing, There Is No Venue for Florida's Claims

Because Texas lacks standing, there is no basis for venue in this district. GBP Mot.10; *Missouri v. FDA*, 2025 WL 2825980, at *12 (N.D. Tex. Sept. 30, 2025). Plaintiffs do not contest that venue for Florida's claims depends on Texas having standing and continuing as a co-plaintiff. Therefore, this point stands conceded, and the consequence of Texas being precluded from

relitigating standing is that the entire case must be dismissed. *Howard v. Maxum Indem. Co.*, 2017 WL 292424, at *3 (N.D. Tex. Jan. 23, 2017).

III. Both Plaintiffs Lack Standing

Independent of Texas being precluded from relitigating the standing theories it lost, Plaintiffs' standing theories fail under a *de novo* analysis. This will be true even if the Fifth Circuit's May 1 decision in *Louisiana* remains intact through further appellate review.

Sovereign and Quasi-Sovereign Injury. While the May 1 decision found Louisiana had sovereign-injury standing to challenge the 2023 REMS,¹ it did not consider standing to challenge any other FDA actions relating to mifepristone, and its rationale as to sovereign injury from the 2023 REMS is inapplicable to those other FDA actions. Nor did Louisiana even assert the farfetched quasi-sovereign injury theory pressed by the States in this case.

The reason the Fifth Circuit found standing to challenge the 2023 REMS was its (mistaken) belief that the "goal of the regulation" was "ensuring out-of-state medical providers could prescribe mifepristone to women in states that restrict abortion." *Louisiana*, 2026 WL 1194924, at *5 (citing Executive Order "in the wake of *Roe*'s overruling"); *id.* ("[T]he 2023 REMS sanctions and facilitates conduct with the express purpose of undermining Louisiana's legal restrictions on abortion."). That rationale, such as it is, makes no sense as to Plaintiffs' challenges to assorted pre-*Dobbs* actions by FDA, all of which were taken when States like Florida and Texas generally could not and did not legally restrict medication abortion. While *Roe* and *Casey* were binding precedent, the right to abortion was constitutionally protected and thus neither Florida nor Texas would have been able to enforce unduly burdensome restrictions on mifepristone to terminate a pregnancy.

¹ As noted, GenBioPro strongly disagrees with the May 1 order's holding as to sovereign-injury standing to challenge the 2023 REMS and is seeking further appellate review.

Plaintiffs' other theories of sovereign injury (unaddressed in *Louisiana*) are equally baseless. Plaintiffs assert (at 14-15) that FDA's actions "threaten to preempt" Texas and Florida law. A generalized possibility that a court might someday hold that one of the challenged FDA actions preempts some Texas or Florida law, "abstracted from any concrete actual or threatened harm, falls outside the scope of the constitutional words 'Cases' or 'Controversies.'" *Alvarez v. Smith*, 558 U.S. 87, 93 (2009). For their part, the States emphatically dispute that any of their laws are preempted. Opp.15 n.8. And although the FDA actions in question have been in effect for years (even a quarter century), the States identify no lawsuit challenging any of their laws on grounds of FDA preemption, no instance in which a defendant charged with violating any of those laws has asserted preemption as a defense, no instance of anyone stating that they refuse to comply with any Texas or Florida law on the grounds that the law is preempted, and no articulated threat of litigation raising preemption. Under these circumstances, the States come nowhere near sustaining what they admit is their burden of showing a "substantial risk" that the harm will occur. Opp.15 n.8 (quoting *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 414 n.5 (2013)).

As for quasi-sovereign harm, Plaintiffs concede that longstanding precedent generally bars states from suing the federal government as *parens patriae*. Opp.19-20 (acknowledging *Haaland, Snapp*, and *Mellon*). Plaintiffs imagine a non-existent exception to that rule for "a quasi-sovereign interest in ... preborn children" that the federal government has not itself recognized. Opp.19. The *Washington* court correctly rejected that "thinly veiled attempt to circumvent the limits on *parens patriae* standing." 108 F.4th at 1178 (quoting *Murthy v. Missouri*, 603 U.S. 43, 76 (2024)). Plaintiffs' allegations do not concern "a distinct interest of the state as a whole," and "[w]hile [Texas] has a legitimate interest in legislating to protect maternal health and fetal life, it does not

have standing to bring a lawsuit ‘on behalf of its citizens’ against a federal agency.’” *Id.* (quoting *Haaland v. Brackeen*, 599 U.S. 255, 294-95 (2023)).

Economic Injury. Plaintiffs’ economic injury theory also fails. Plaintiffs argue they have expended “Medicaid funds to treat adverse events suffered by women as a result of FDA-approved abortion drugs.” Opp.10. While the Fifth Circuit order found Louisiana had standing to challenge the 2023 REMS on account of what the panel called “hard evidence” of its alleged economic injury (a declaration alleging \$92,000 “paid in Medicaid costs from two women who needed emergency care in 2025 from complications caused by out-of-state mifepristone”), neither State here has submitted anything comparable. 2026 WL 1194924, at *5.² While Florida alleges two instances of its Medicaid program paying “to treat complications from a chemical abortion,” Compl. ¶¶ 287-88 & nn.220-21, those allegations do not even identify the drug at issue, let alone attempt to draw any causal link from any of the particular FDA regulatory actions Florida challenges.

These huge gaps bring into sharp relief that Plaintiffs’ economic injury theory rests on a chain of contingencies even more attenuated than the one the Supreme Court rejected in *AHM*. Under the 2016 REMS, for example, before Plaintiffs’ Medicaid programs would spend a dime for complications stemming from a patient’s use of mifepristone in violation of State law, all of the following would need to occur: a patient who chooses to obtain an abortion must travel to a clinic outside of Florida or Texas; the patient must choose to have a medication abortion; the out-of-state provider must choose to prescribe mifepristone; the patient must travel back to Florida or Texas; the patient must experience a rare complication; the patient must seek care for that complication; the patient must be enrolled in Medicaid; and the provider must bill Texas or Florida

² GenBioPro respectfully submits that the May 1 Fifth Circuit order reached this conclusion in error and disputes the sufficiency of Louisiana’s allegations, but the point for present purposes is that Texas and Florida would not even pass the May 1 order’s standard.

Medicaid. Article III does not permit standing to rest on that kind of multi-step causal chain. “[T]heories that require guesswork as to how independent decisionmakers will exercise their judgment” are insufficient. *Clapper*, 568 U.S. at 413.

IV. Plaintiffs Failed to Exhaust Administrative Remedies

Plaintiffs dispute neither that FDA’s regulations require parties to file citizen petitions with FDA “before any legal action is filed in a court complaining of the action or failure to act,” 21 C.F.R. § 10.45(b), nor that they have filed no citizen petition. *See* Opp.22-23.

Darby v. Cisneros is inapposite. *Darby* addresses “whether federal courts have the authority to require that a plaintiff exhaust available administrative remedies ... where neither the statute nor agency rules specifically mandate exhaustion.” 509 U.S. 137, 138 (1993). FDA’s regulations mandate exhaustion. 21 C.F.R. § 10.45(b). *Darby*’s discussion of the finality requirement embedded in 5 U.S.C. § 704 is irrelevant. Section 704 governs when an agency action is sufficiently “final” for APA review notwithstanding the availability of further intra-agency review. FDA’s citizen-petition framework is not the type of optional intra-agency appeal addressed by *Darby*.³

The May 1 Fifth Circuit order does not relieve Plaintiffs’ obligation to exhaust. The order allowed Louisiana to sue over the 2023 REMS without first exhausting on the ground that resort to FDA would be “clearly useless.” 2026 WL 1194924, at *3-4. But here, Plaintiffs acknowledge that in FDA’s ongoing review, “FDA is substantively reconsidering all the Challenged Actions” and agreed to a time-limited stay pending that review—a position it would make no sense for

³ The narrow exception Plaintiffs derive from dicta in *Vanda Pharmaceuticals Inc. v. FDA*, 2024 WL 4133623 (D.D.C. Sept. 10, 2024), is inapplicable. *See* Opp.22-23. The *Vanda* exception does not apply to claims relying on “information or views” that “were never presented to the FDA” and lie “beyond the administrative record.” *Id.* at *18 (quoting 21 C.F.R. § 10.45(f)). Plaintiffs’ complaint relies upon a report published in April 2025, *see* Compl. ¶ 208 & n.151, well after FDA resolved the citizen petitions by other parties that Plaintiffs cite.

Plaintiffs to take if FDA's mind were already made up and further consideration were useless. Opp.6. Because Plaintiffs admit exhaustion would not be useless, the Fifth Circuit's rationale for letting Louisiana out of the exhaustion requirement does not apply here.

V. The States' Challenges to FDA's 2000, 2016, and 2019 Actions Are Time-Barred

Plaintiffs assert that FDA has regulated mifepristone unlawfully since 2000, causing harm to both States. Opp.2 & n.1. 28 U.S.C. § 2401(a) requires suit within six years after the right of action "first accrues." Yet Plaintiffs waited twenty-five years to challenge the 2000 approval, and more than nine and six years, respectively, to challenge the 2016 changes and the 2019 ANDA approval. Plaintiffs' attempts to overcome this glaring limitations problem fall flat.

Plaintiffs acknowledge an APA claim accrues when the plaintiff is first "injured by final agency action" and "has a complete and present cause of action." *Corner Post, Inc. v. Bd. of Govs. of Fed. Res. Sys.*, 603 U.S. 799, 804, 813, 817 (2024). Plaintiffs allege economic injury on the theory that FDA's approval of branded and generic mifepristone, and the 2016 changes, increased their Medicaid spending. If any of those actions had that effect, it would have begun as soon as the approvals or changes went into effect. By Plaintiffs' own account, each of those actions allowed mifepristone to enter (or remain in) the market on more permissive terms than would otherwise have applied: the 2000 approval permitted mifepristone sales for the first time; the 2016 changes broadened the universe of permissible prescribers and dispensing protocols; and the 2019 approval added a generic competitor. Although GenBioPro disputes that any of those actions caused Plaintiffs any injury, Plaintiffs' own theory of injury is that each action increased mifepristone usage, and therefore Medicaid claims, from the date it took effect. *E.g.*, Compl. ¶¶ 275-82 (alleging 2019 generic approval increased mifepristone use). On Plaintiffs' theory, then, the first dollar of asserted harm flowed years before the limitations window. Plaintiffs therefore had a "complete

and present cause of action,” *Corner Post*, 603 U.S. at 813, on September 28, 2000 for the 2000 approval; on March 29, 2016 for the 2016 changes; and on April 11, 2019 for the generic approval.

Plaintiffs try to evade limitations by taking the position that their complaint specifically alleges only economic injuries starting “in 2020” (for Florida) and within “six years prior to the suit” (for Texas). Opp.24. But if a plaintiff could plead around a statute of limitations by confining its express injury allegations to the limitations period—when its theory of harm necessarily would mean injury reaching back much further—statutes of limitations would be meaningless.⁴

Plaintiffs also maintain that “FDA’s ongoing review ... reopened the Challenged Actions.” Opp.24. This makes no sense. To the extent the “reopening doctrine” is a valid exception to the statute of limitations at all, *but see Biden v. Texas*, 597 U.S. 785, 809 n.8 (2022) (Supreme Court “has never adopted it”), only “the agency’s second action (the reaffirmance) is reviewable,” *Texas v. Biden*, 20 F.4th 928, 951 (5th Cir. 2021), *rev’d on other grounds*, 597 U.S. 785 (2022). Whether an action has been reopened turns on a retrospective examination of the “entire context” of the agency’s review to assess whether the agency undertook “a serious, substantive reconsideration” of the regulation. *Id.* at 951-52. Because FDA’s review is ongoing, there is no “reaffirmance” to review and no basis to assess whether FDA substantively reconsidered the prior actions.

CONCLUSION

The Court should dismiss the complaint. In the alternative, it should hold the case in abeyance until final guidance on these issues from the appellate courts in *Louisiana* crystallizes.

⁴ Plaintiffs also assert in the statute-of-limitations section of their brief that their sovereign and quasi-sovereign injuries did not start until Texas’s Human Life Protection Act took effect in 2022 and Florida’s Heartbeat Protection Act took effect in 2024. Opp.24. However, the standing section of their opposition asserts injury based on “many” State abortion regulations, not just the 2022 and 2024 laws. Opp.14. In any event, under *Corner Post* the statute started to run when the States first experienced *any* form of alleged injury—including the economic injury they rely on—and did not reset when they say a new form of alleged injury (sovereign injury) ensued.

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