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

THE STATE OF FLORIDA, *et al.*, *Plaintiffs*, v. U.S. FOOD AND DRUG ADMINISTRATION, *et al.*, *Defendants*, and DANCO LABORATORIES, LLC, *Intervenor-Defendant*.	No. 7:25-cv-00126-O Chief Judge Reed O'Connor

DANCO LABORATORIES, LLC'S REPLY IN SUPPORT OF ITS MOTION TO DISMISS

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INTRODUCTION

Nothing in the Plaintiff States' opposition shows that either Texas or Florida can litigate this case. First, and fundamentally, the Plaintiff States lack standing. That is a threshold constitutional defect requiring dismissal, *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992), not a token "procedural roadblock" that Danco (or any other defendant) "hide[s]" behind. Pls.' Resp., ECF No. 56 at 3, 6 (Opp.). Each State's alleged injuries are either directly foreclosed by the Supreme Court's decision in *FDA v. Alliance for Hippocratic Medicine*, 602 U.S. 367 (2024) (*Alliance*), or not cognizable under any existing doctrine. *See* Mot. Dismiss, ECF No. 53 at 1-8 (Danco MTD). The Plaintiff States' standing arguments misstate the law and have no limiting principle. Their other defenses fare no better. The Plaintiff States are not within the relevant zones of interests; they have not exhausted mandatory administrative remedies; their challenges to the 2000 and 2016 actions are facially and fatally time-barred; and their lawsuit is unripe because of FDA's ongoing review of all the challenged actions.

To be sure, a Fifth Circuit stay panel has recently taken a different view. On May 1, the Fifth Circuit stayed the 2023 mifepristone REMS pending appeal in a related challenge brought by Louisiana, finding that Louisiana had standing under financial and sovereign injury theories similar to those Florida and Texas assert here. *Louisiana v. FDA*, _ F.4th ___, No. 26-30203, 2026 WL 1194924 (5th Cir. May 1, 2026). Danco has sought further relief, and the Supreme Court has granted an administrative stay of the Court's order. *Danco Lab'ys, LLC v. Louisiana*, No. 25A1207 (U.S. May 2, 2026). Briefing in the Supreme Court is currently ongoing. Danco continues to preserve all its arguments for appeal.

ARGUMENT

I. The Plaintiff States Lack Article III Standing.

Just as was the case with the *Alliance* plaintiffs, nothing in the FDA's regulation of mifepristone requires the Plaintiff States to "prescribe or use mifepristone" or to "do anything or to refrain from doing anything" with mifepristone. *Alliance*, 602 U.S. at 385. That means, like the *Alliance* plaintiffs, the Plaintiff States have no non-attenuated, non-speculative injury-in-fact that

is "traditionally redressable in federal court." *Id.* at 379, 381 n.1 (citation omitted). None of the Plaintiff States' alleged economic, sovereign, or quasi-sovereign injuries satisfies Article III.[1]

A. The Plaintiff States' Alleged Economic Costs Are Legally Insufficient To Create Article III Standing.

The Opposition mischaracterizes the Supreme Court's decision in *Alliance*. *Alliance* did not hold only that the plaintiffs failed to plead adequate facts. Opp. at 17-18. After noting the doctors' lack of evidence, the Supreme Court continued: "In any event, and *perhaps more to the point*, . . . there is no Article III doctrine of 'doctor standing' that allows doctors to challenge general government safety regulations." *Alliance*, 602 U.S. at 386, 391 (emphasis added). The Court declined to "create such a novel standing doctrine out of whole cloth." *Id.*

Thus, *Alliance*'s holding was categorical: The "chain of causation" between FDA's "safety regulations" and people "show[ing] up at emergency rooms or in doctors' offices with follow-on injuries" is "simply too attenuated" for Article III purposes. *Id.* at 391-392. There is no basis for a different attenuation rule to apply based on who receives an invoice for the follow-up care. As a result, the Plaintiff States' claim to have pleaded "facts demonstrating concrete economic injury," Opp. at 12, changes nothing because *Alliance* expressly rejected higher "insurance costs" as a basis of standing. 602 U.S. at 391. For good reason. Those costs, like the other costs the *Alliance* doctors alleged, can happen after several layers of independent decision making by independent decisionmakers because all drugs sometimes cause complications or side effects. *Id.* at 392. The logical endpoint of the Plaintiff States' Medicaid-costs theory is that anyone who pays for health care has "standing to challenge virtually every government action that they do not like." *Id.*; *see also Washington v. FDA*, 108 F.4th 1163, 1176 (9th Cir. 2024) (recognizing this theory "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") (quotation omitted). The Supreme Court rejected that "unprecedented and limitless approach." *Alliance*, 602 U.S. at 391.

[1] The Plaintiff States do not dispute that Texas is the only plaintiff that makes venue proper in this district, so they cannot rely on Florida for standing. *See* Danco MTD at 15.

The Opposition's attempt to distinguish *United States v. Texas*, 599 U.S. 670 (2023) (*Priorities* decision), also fails. Opp. at 10-11. *Priorities* arose in a different factual context, to be sure. But the Supreme Court's decision cautioned against granting states standing based on "indirect effects on state revenues or state spending"—which are ever-present "in our system of dual federal and state sovereignty"—because doing so would erode "bedrock Article III constraints." 599 U.S. at 680 n.3; *see also* Danco MTD at 8 (collecting cases applying that limitation on state standing). While some types of financial harm can confer standing, *Alliance* establishes that Medicaid costs from FDA's regulation of a drug cannot.

None of the other cases the Plaintiff States invoke overcomes that principle. The "landmark Supreme Court precedent" they discuss, *Motor Vehicles Manufacturers Association of United States, Inc. v. State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29 (1983), was not a standing decision at all. Opp. at 10. It does not mention, let alone purport to analyze, Article III requirements. *State Farm*, 463 U.S. at 34. And the concurrence the Plaintiff States invoke (at 10) to suggest that *State Farm* should be understood to do so says no such thing. *See Corner Post, Inc. v. Bd. of Governors of Fed. Rsrv. Sys.*, 603 U.S. 799, 834 (2024) (Kavanaugh, J., concurring) (explaining that *State Farm* implicitly recognized the availability of vacatur as an APA remedy).

Biden v. Nebraska and *Texas v. United States* (*DAPA*) are also inapposite. *See* Opp. at 10 (citing *Nebraska*, 600 U.S. 477, 490 (2023), and *DAPA*, 809 F.3d 134, 152 (5th Cir. 2015)). The government action challenged in *Nebraska* cost a state $44 million per year in fees it otherwise would have earned under a contract with the federal government. 600 U.S. at 490. The federal government thus "directly injure[d]" the plaintiff state—not at the end of an attenuated chain. *Id.* at 489. And in *DAPA*, the government conceded that the challenged agency action would "directly" cost one plaintiff state several million dollars because it increased the overall population of people eligible for a state-paid benefit. *DAPA*, 809 F.3d at 155 & n.58. An FDA drug approval, in contrast, does not directly inflict any costs on a state. States speculating about whether they may be asked to pay for follow-up care for Medicaid beneficiaries after several layers of discretionary actions by third-parties is a complaint about a "distant (even if predictable) ripple effect[]"

of FDA's action that "cannot establish Article III standing" as a matter of law. *Alliance*, 602 U.S. at 383.

Nor can the Plaintiff States gain standing by incurring costs to investigate and prosecute an out-of-state provider who mails mifepristone to a patient in Texas. Courts "have never held that a logistical burden on [state] law enforcement"—like "mak[ing] mifepristone more difficult to police"—constitutes a cognizable Article III injury." *Washington*, 108 F.4th at 1177. The only case the Plaintiff States cite in support of their position was reversed by the Supreme Court on the grounds that those states' alleged injuries were not redressable. *See* Opp. at 12-13 (citing *Texas v. United States*, 40 F.4th 205, 216-217 (5th Cir. 2022), *rev'd*, 599 U.S. at 686). If that type of burden were sufficient for standing, states would have "standing to challenge any federal action" that they can allege would "increase[] crime or disorder, or impose[] indirect compliance costs for state law enforcement," including, for example, any loosening of regulations relating to firearms, the environment, or banking. *Washington*, 108 F.4th at 1177. That is not the law.

B. The Plaintiff States Have Not Pled A Cognizable Sovereign Injury.

The Plaintiff States cannot circumvent *Alliance*'s central holding by recasting the downstream effects of FDA's regulation of mifepristone as "sovereign" injury. These supposed harms are not "'traditionally' recognized as providing a basis for a lawsuit in American courts." *TransUnion LLC v. Ramirez*, 594 U.S. 413, 424 (2021). The Fifth Circuit has held that states can suffer cognizable sovereign harm if the federal government exerts "substantial pressure on them to change their laws." *DAPA*, 809 F.3d at 153. But, as Danco explained in its opening brief, FDA's mifepristone decisions do not force the Plaintiff States to accede to federal policy, stop them from being independent sovereigns, or "compel the States to require or prohibit" any conduct. *See Printz v. United States*, 521 U.S. 898, 924 (1997).

The Plaintiff States do not engage with this basic problem. Instead, they continue to vaguely assert that FDA's actions "threaten to preempt" their abortion laws. Opp. at 14. But they

still fail to show that preemption is "imminent" or "certainly impending."[2] *See Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 410 (2013). Their brief points to a district court order enjoining a non-party state's medication abortion restrictions, Opp. at 14—but that injunction has no effect on Florida or Texas and so does not injure them. And they admit (at 14 n.7) that the relevant regional circuit has rejected the theory underlying the injunction. *GenBioPro, Inc. v. Raynes*, 144 F.4th 258 (4th Cir. 2025). Nor do the Plaintiff States allege that anyone is actively seeking to enjoin their abortion laws based on FDA's challenged actions. As FDA has explained, the federal government does not "assert[]" that the 2023 REMS preempts state laws (*contra* Opp. at 15). *See* FDA Mot. to Stay or Dismiss, ECF No. 20-1 at 12-13. These claims of injury are thus entirely speculative. Unlike the case the Plaintiff States cite, *Abbott v. Perez*, there is no current or imminent "injunction[] barring the State[s] from" enforcing their laws. 585 U.S. 579, 602 (2018).

That leaves the Plaintiff States to more generally claim that FDA's actions "inhibit[]" their ability to enforce their abortion regulations. Opp. at 15. But the Plaintiff States do not—and cannot—refute Danco's observation that this argument merely repackages their enforcement-costs theory as "sovereign" injury—and thus is foreclosed by *Alliance*. *See* Danco MTD at 12-13. Tellingly, the Plaintiff States cite no case finding that the mere imposition of additional costs constitutes a "sovereign" injury. *See* Opp. at 15-16.

Nor do the Plaintiff States refute the separate traceability problem with this claim. As Danco explained, the Plaintiff States' actual dispute is with discretionary decisions by independent third parties—their coequal sister states that have enacted shield laws and out-of-state medical providers—not with FDA. Danco MTD at 14-15. Nothing about the FDA's challenged actions compels or directs any third party to violate Florida or Texas law, speaks to extradition, or grants immunity to those who violate Florida or Texas law. And it was impossible for FDA to "predict" that some states would react to *Dobbs* by enacting shield laws when it first eliminated the in-person

[2] The Plaintiff States also state that they "do not agree that the Challenged Actions preempt any of their laws." Opp. at 15 n8. They can't have it both ways. Article III injuries must be actual, not hypothetical or conjectural. *E.g.*, *Lujan*, 504 U.S. at 560; *Clapper*, 568 U.S. at 410.

dispensing requirement in April 2021—over a year before *Dobbs* was decided, and indeed, before the Supreme Court even granted certiorari in that case. *See id.* at 14; Docket, *Dobbs v. Jackson Women's Health Org.*, No. 19-1392 (May 17, 2021).

Danco recognizes that the Fifth Circuit and the District Court in *Louisiana* disagreed with this argument. *See Louisiana*, 2026 WL 1194924, at *4-6; *Louisiana v. FDA*, No. 6:25-cv-1491, 2026 WL 936958, at *8-12 (W.D. La. Apr. 7, 2026). The Supreme Court administratively stayed the Fifth Circuit's ruling and is considering whether a stay is warranted. *United States v. Texas*, 144 S. Ct. 797, 798 (2023) (Barrett, J., concurring in denial of applications to vacate stay).

C. The States Do Not Have A Valid Quasi-Sovereign Interest.

The Plaintiff States' asserted quasi-sovereign injury likewise fails under established precedent. The Supreme Court has unequivocally held that a "State does not have standing as *parens patriae* to bring an action against the Federal Government" on behalf of third parties. *Haaland v. Brackeen*, 599 U.S. 255, 295 (2023); *see, e.g.*, *Murthy v. Missouri*, 603 U.S. 43, 76 (2024) (same). "[C]reative arguments" cannot get around that "settled rule[]," which has been in effect for over a century. *Brackeen*, 599 U.S. at 295; *see Massachusetts v. Mellon*, 262 U.S. 447, 484-486 (1923).

The Plaintiff States say that because the federal government does not formally recognize fetuses as "citizens or legal persons," states can sue as *parens patriae* on their behalf. Opp. at 19. That is nothing more than a "thinly veiled attempt to circumvent the limits on *parens patriae* standing." *Murthy*, 603 U.S. at 76 (quotation omitted); *see Washington*, 108 F.4th at 1177-78 (rejecting identical theory). A state's "quasi-sovereign interests in its citizens' health and well-being" is "wholly derivative of the personal . . . interests of its citizens" (however *citizen* may be defined) "and therefore not a valid quasi-sovereign interest at all." *Paxton v. Dettelbach*, 105 F.4th 708, 715-716 (5th Cir. 2024); *see Massachusetts v. EPA*, 549 U.S. 497, 520 n.17 (2007) (a state cannot "protect her citizens from the operation of federal statutes").

And, as discussed, Article III injuries must be tethered to historical practice. *Priorities*, 599 U.S. at 677-678. Yet the only case the Plaintiff States cite in support of their quasi-sovereign injury, *Texas v. Becerra*, 577 F. Supp. 3d 527, 559 (N.D. Tex. 2021), is a district court decision

that issued three years before the Fifth Circuit decided *Paxton*, and which contravenes the Supreme Court's consistent rejection of *parens patriae* standing. *See, e.g.*, *Brackeen*, 599 U.S. at 295. The Plaintiff States do not point to a single case holding that *parens patriae* standing turns on federal recognition of the third parties whom a state seeks to represent. *See* Opp. at 18-20. Because Florida and Texas do not have a legal right to assert interests in their citizens' health and well-being against the federal government, the Court has no reason to reach the Plaintiff States' theory of fetal personhood—one that they raise only in passing (at 19 n.11), is outside the scope of the Complaint, and is wrong as a matter of constitutional law.[3]

II. Other Threshold Grounds Bar The Plaintiff States' Claims.

The Opposition also does not—and cannot—overcome several other threshold defects.

A. The Plaintiff States Are Not Within The Zone Of Interests For The Comstock Act, FDCA, Or PREA.

The Plaintiff States claim to be in the relevant zones of interests by misstating the legal standard. *See* Opp. at 20-21. The zone-of-interests test does not ask whether this lawsuit is related to the general purposes of the FDCA, the Comstock Act, or PREA. The Supreme Court rejected that view decades ago: whether a plaintiff is within a statute's zone of interests is "determined *not* by reference to the overall purpose of the Act in question . . . but by reference to the particular provision" the plaintiff claims was violated. *Bennett v. Spear*, 520 U.S. 154, 175-176 (1997) (emphasis added). Although the zone of interests test is not "especially demanding," the Plaintiff States do not meet it. *Lexmark, Int'l v. Static Control Components, Inc.*, 572 U.S. 118, 130 (2014).

Start with the FDCA. The Plaintiff States cite the Act's general policy, but that is irrelevant. *Contra* Opp. at 21. They also gesture at the FDCA's new drug provision, 21 U.S.C. § 355, but that provision—like the FDCA overall—was designed to safeguard and advance public health by protecting consumers from taking drugs that have not been FDA-approved, not to protect states

[3] The American public did not consider fetuses to be constitutional "persons" when the Fourteenth Amendment was ratified. *See, e.g.*, Aaron Tang, *After* Dobbs*: History, Tradition, and the Uncertain Future of a Nationwide Abortion Ban*, 75 Stan. L. Rev. 1091, 1150, 1152-55 (2023) (majority of states permitted abortions when the Fourteenth Amendment was ratified and there is "no evidence from the time" that those states "were violating the Constitution").

from economic, sovereign, or quasi-sovereign harms. The same is true of the PREA, 21 U.S.C. § 355c. That the Plaintiff States also regulate drugs shows that they have an interest in supplementing these federal statutes, not that they have an in interest in enforcing them. Their curt response falls far short of showing that Congress intended to permit states to bring private suits to challenge FDA's determination of whether a particular drug is safe and effective under its approved label for adult or pediatric use. *See Lexmark Int'l*, 572 U.S. at 130.

The Plaintiff States' Comstock Act argument is equally flawed. Again, the policy animating the Act is irrelevant to the zone-of-interests test. *Contra* Opp. at 21. And a state cannot invoke its "interests in promoting public morals" or a "symmetry of interests" to enforce federal criminal law against others. *See Priorities*, 599 U.S. at 686; *contra* Opp. at 21. Nothing in the Comstock Act suggests that Congress has authorized states (or any third party) to act as private enforcers.

B. The Plaintiff States Cannot Excuse Their Failure To Exhaust Administrative Remedies.

FDA's regulations required the Plaintiff States to submit citizen petitions before seeking judicial review. 21 C.F.R. § 10.45; *see Darby v. Cisneros*, 509 U.S. 137, 146, 153 (1992). Neither did so, and their counterarguments do not excuse this failure.

The Plaintiff States are correct that administrative action generally is deemed final for purposes of the APA regardless of whether additional administrative review mechanisms are available. Opp. at 22 (citing 5 U.S.C. § 704). But the "doctrine of exhaustion of administrative remedies is conceptually distinct from the doctrine of finality." *Darby*, 509 U.S. at 144. And FDA's regulations require exhaustion by specifying that any interested person who "wishes to rely upon information or views not included in the administrative record" must independently "submit . . . a new petition to modify the action under § 10.25(a)." 21 C.F.R. § 10.45(f). The Plaintiff States do not show that the third-party citizen petitions they invoke relied on the same evidence or made the same claims that they now bring, so section 10.45(f) applies. And the unpublished out-of-circuit district court that the Plaintiffs cite (at 23)—which goes against the great weight of authority, *see* Danco MTD at 18—did not actually decide whether a citizen petition was necessary under the

circumstances, and instead dismissed the plaintiff's claims as unripe "until the administrative process runs its course." *Vanda Pharms., Inc. v. FDA*, No. 23-cv-2812, 2024 WL 4133623, at *18 (D.D.C. Sept. 10, 2024). The Plaintiff States should not be rewarded for skipping the line, especially where many other interested parties—including other states—followed FDA's process.[4]

C. The Plaintiff States' Challenges To The 2000 And 2016 Actions Are Time-Barred.

The Plaintiff States also attempt to evade the APA's six-year statute of limitations for their challenges to FDA's 2000 and 2016 actions. None of their arguments holds water.

The Supreme Court has been emphatically clear that the APA's statute of limitations begins to run when a cause of action first accrues. *Corner Post*, 603 U.S. at 812. The Plaintiff States cannot get around that fundamental rule by artificially claiming that their injuries started later. For example, they allege that neither Florida nor Texas suffered an economic injury from any of the challenged actions until six years before they filed this lawsuit. Opp. at 24. That is incoherent, and contrary to the allegations they included in the complaint. Based on their own statistical data, there is no basis to accept that the Plaintiff States' Medicaid systems first began paying for post-medication-abortion emergency care only in 2022, after *Dobbs* issued, instead of in 2000, when mifepristone was first approved. *E.g.*, Compl. ¶¶ 210 (pointing to a studies finding that 7-10% of women who have medication abortions "will need follow-up medical treatment"), 224 (characterizing mifepristone-related deaths and injuries as a "direct consequence of the FDA's [2000] approval of mifepristone"); 241, 242 (both asserting that the 2016 changes increased the "failure rate" of medication abortions); 341 ("under the 2000 measures to assure safe use," women would travel to other states to obtain medication abortions and then return to Florida and Texas while the medication took effect). Accepting the Plaintiff States' blatant attempt to evade the APA's statute of limitations would eviscerate that statute—not only in this context, but in every case.

[4] The three exceptions that the Plaintiff States raise in a footnote also get them nowhere. Opp. at 23 n.12. The first two are conclusory and amount to a blatant appeal to policy. The third totally misses the point. That FDA is reconsidering its mifepristone decisions in response to citizen petitions shows that submitting a petition is *not* futile.

The Plaintiff States also attempt (at 24-25) to invoke the "reopening doctrine." This doctrine has not been applied by any court outside of the D.C. Circuit. *See Biden v. Texas*, 597 U.S. 785, 809 n.8 (2022) (noting that "this Court has never adopted" the doctrine); *Alliance for Hippocratic Med. v. FDA*, 78 F.4th 210, 242 n.6, 244 (5th Cir. 2023), *rev'd on other grounds*, 602 U.S. 367 (2024) (same). In any event, the reopening doctrine is a narrow exception to exhaustion that applies when an agency treats its existing decision "as a proposed regulation" and then solicits and responds to comments in re-examining the existing decision. *Sierra Club v. EPA*, 551 F.3d 1019, 1024 (D.C. Cir. 2008) (quotation omitted). FDA's ongoing review of its mifepristone decisions has not yet concluded, so there is no basis for this Court to determine that FDA has already realtered "[t]he basic regulatory scheme" in a way that constitutes constructive reopening. *Natural Res. Def. Council v. EPA*, 571 F.3d 1245, 1266 (D.C. Cir. 2009) (per curiam). Even under the most sweeping interpretation of the doctrine, the Plaintiff States' untimeliness cannot be excused.

D. The Plaintiff States' Challenge Is Unripe In Light Of The Ongoing FDA Review.

Relatedly, FDA's decisions are not ripe for this Court's review. The Opposition acknowledges that FDA is substantively reconsidering each action challenged in the complaint. Opp. at 3, 5-6. It says FDA "clearly" has an "'intention to put the [Challenged Actions] back on the chopping block and rethink things,'" *id.* at 25 (quoting *Texas v. Biden*, 20 F.4th 928, 955 (5th Cir. 2021), *rev'd*, 597 U.S. 785), and this Court should not interfere with FDA's review. *Id.* at 6. Agency decisions are not "necessarily ripe," as the Plaintiff States claim, when a challenge post-dates the agency's announced review. *See id.* at 25 (quoting *Sierra Club v. Peterson*, 185 F.3d 349, 362 n.16 (5th Cir. 1999)); Danco MTD at 30. When a plaintiff's claims are unripe, the court lacks jurisdiction to review them, and the only appropriate outcome is dismissal. *Pierce v. Holder*, 614 F.3d 158, 160 (5th Cir. 2010) (per curiam). The Court should take that approach here.

CONCLUSION

For all the reasons discussed, the Court should dismiss the Complaint.

Respectfully submitted,

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Dated: May 8, 2026

CERTIFICATE OF SERVICE

I certify that on May 8, 2026, I electronically filed the foregoing using the CM/ECF system. Notice of this filing will be sent by operation of the Court's electronic filing system to all counsel of record.

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