FILED
April 10, 2026
KAREN MITCHELL
CLERK, U.S. DISTRICT COURT

IN 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 MOTION TO DISMISS

Oral Argument Requested

Danco Laboratories, LLC moves to dismiss Plaintiffs' complaint under Rules 12(b)(1), 12(b)(3), and 12(b)(6) of the Federal Rules of Civil Procedure for lack of subject-matter jurisdiction, lack of venue with respect to Florida, and for failure to state a claim upon which relief can be granted. In support of this motion, Danco relies on the accompanying brief. A proposed order is also attached. In light of the history of the litigation over Mifeprex's approvals, Danco respectfully requests oral argument.

Danco agrees with the Federal Defendants' argument that the Plaintiffs lack Article III standing and thus would not be prejudiced by a stay of this action. *See* ECF No. 20-1. However, Danco respectfully submits that, in the absence of Article III jurisdiction, the more prudent course is to dismiss the action.

Respectfully submitted,

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Dated: March 13, 2026

CERTIFICATE OF SERVICE

I certify that on March 13, 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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BRIEF IN SUPPORT OF
DANCO LABORATORIES, LLC'S MOTION TO DISMISS

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INTRODUCTION

Two years ago, the Supreme Court unanimously rejected a doctors group's efforts to challenge the Food and Drug Administration's (FDA's) regulation of mifepristone. The Court's ruling was unambiguous: Nothing in FDA's regulation of mifepristone required those doctors to "prescribe or use mifepristone" or to "do anything or to refrain from doing anything," and their attenuated link to FDA's drug approvals did not satisfy Article III. *FDA v. Alliance for Hippocratic Med.*, 602 U.S. 367, 385 (2024). FDA's actions likewise do not require the Plaintiff States here—Florida and Texas—to prescribe or use mifepristone, nor compel those States to do or refrain from doing anything. Texas and Florida seek to bring a similar challenge as the *Alliance* doctors' suit based on similarly (and even more) attenuated allegations. The Plaintiff States' Complaint should be dismissed for lack of standing.

The Plaintiff States essentially assert that they suffer a traceable, redressable, and Article III cognizable injury from FDA's actions because FDA's actions do not align with their preferred policies and because other states have different state laws. But divergence in abortion policy is a natural result of the Supreme Court "return[ing]" abortion policy to the states. *Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215, 292 (2022). And states cannot challenge FDA's supposed under-regulation of a drug by asserting "downstream" financial or sovereign injury, as the Ninth Circuit recognized when holding that Idaho lacked standing in a similar lawsuit challenging one of the same FDA actions at issue here. *Washington v. FDA*, 108 F.4th 1163, 1175-76 (9th Cir. 2024). Indeed, *Alliance* held that doctors who said they provided follow-up care were too far removed to have Article III standing, yet the Plaintiff States premise their standing on an even more attenuated link in claiming that their state Medicaid programs may cover the cost of that follow-up medical care. Adding another layer of attenuation makes their theory less viable than the "doctor standing" theory the Supreme Court unanimously rejected in *Alliance*. And the Plaintiff States' alternative theories of sovereign harm are not "legally and judicially cognizable," because Florida and Texas do not identify any state restriction that they say FDA has preempted or assert that FDA prohibits them from enacting or enforcing restrictions on medication abortion

within their boundaries. *United States v. Texas*, 599 U.S. 670, 676 (2023) (*Priorities* decision).

The Plaintiff States' Complaint has other threshold defects. Although they seek review under the Administrative Procedure Act (APA), the Plaintiff States are not within the zone of interests for any of the underlying statutes they invoke. They have not administratively exhausted their claims, as FDA regulations require. Their challenges to the original 2000 mifepristone approval and 2016 changes are time-barred. And the Plaintiff States' challenge is not ripe given the ongoing FDA review.

For each and all of these reasons, dismissal of the Plaintiff States' Complaint is warranted.

FACTUAL BACKGROUND

2000 Mifeprex Approval. Danco, a small pharmaceutical company, holds the New Drug Application (NDA) for Mifeprex (mifepristone) Tablets for use in a regimen with misoprostol for the medical termination of intrauterine pregnancy. FDA approved Mifeprex in 2000 for use through 49 days gestation. ECF No. 1-4 at App. 479-481 (2000 Approval Letter); *see* 21 U.S.C. § 355; 21 C.F.R. § 314.105. The 1996 NDA for Mifeprex presented extensive data on the drug's efficacy and safety. *See* ECF No. 1-4 at App. 483. In approving Mifeprex as safe and effective, FDA imposed certain use restrictions under Subpart H, 21 C.F.R. § 314.520.[1] Among those restrictions was a requirement that Mifeprex be dispensed in person by a physician. ECF No. 1-5 at App. 596-597; *see also id.* (requiring three in-office visits for medication abortions). An independent review by the U.S. Government Accountability Office (GAO) confirmed that the approval and oversight process for Mifeprex was consistent with FDA's processes for other drugs with Subpart H use restrictions. GAO, GAO-08-751, *FDA: Approval and Oversight of the Drug Mifeprex* (2008), https://www.gao.gov/assets/gao-08-751.pdf.

In 2002, several groups filed a citizen petition asking FDA to stay and ultimately reverse its 2000 Mifeprex approval. ECF No. 1-4 at App. 375-469 (2002 Citizen Petition); Compl. ¶ 201.

[1] Prior to its REMS authority, the agency relied on Subpart H to impose use restrictions. Subpart H also allows FDA to accelerate approval for certain new drugs. FDA invoked Subpart H in its review of mifepristone solely for the use restrictions. *See* ECF No. 1-4 at App. 488, 490.

FDA denied that petition in 2016. ECF No. 1-5 at App. 540-572; Compl. ¶ 202. Neither Florida nor Texas was a party to the citizen petition, and they did not file their own petition.

In 2007, Congress amended the Food, Drug, and Cosmetic Act (FDCA) to give FDA authority to require a Risk Evaluation and Mitigation Strategy, or REMS, if the agency determines that one "is necessary to ensure that the benefits of the drug outweigh the risks of the drug." 21 U.S.C. § 355-1(a)(1). Mifeprex's original use restrictions were deemed a REMS, *see* 73 Fed. Reg. 16,313 (Mar. 27, 2008), and FDA approved Danco's supplemental NDA to set a REMS in 2011. ECF No. 1-5 at App. 528-538. FDA subsequently updated the REMS that governs Mifeprex's distribution several times.[2]

2016 Changes. In 2016, FDA approved a supplemental NDA that modified certain aspects of Mifeprex's label and REMS based on 15 years of data reflecting the drug's safety profile and dozens of studies reporting outcomes for tens of thousands of women under various combinations of the proposed changes. *See* ECF No. 1-3 at App. 9-36 (FDA March 29, 2016 Summary Review). "FDA deemed Mifeprex safe to terminate pregnancies up to 10 weeks," "approved a dosing regimen that reduced the number of required in-person visits [to] a single visit to receive Mifeprex," and "changed prescribers' adverse event reporting obligations to require prescribers to report only fatalities." *Alliance*, 602 U.S. at 375-376. GAO again found that FDA's approval process followed the agency's standard procedures. GAO, GAO-18-292, *FDA: Information on Mifeprex Labeling Changes and Ongoing Monitoring Efforts* (2018), https://www.gao.gov/assets/gao-18-292.pdf. In 2019, certain associations (but not Texas or Florida) filed a citizen petition requesting FDA undo the 2016 changes, which FDA ultimately denied in a detailed 40-page response. *See Alliance*, 602 U.S. at 376; Compl. ¶¶ 203-204; ECF No. 1-6 at App. 711-750. That petition did not ask FDA to rescind Mifeprex's original 2000 approval.

[2] FDA approved one generic version of mifepristone in 2019 and another in 2025. *See* ECF No. 1-6 at App. 695-700; FDA, *ANDA Approval Letter from FDA to Evita Solutions, LLC* (Sept. 30, 2025), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2025/216616s000ltr.pdf. The mifepristone REMS today applies to all three mifepristone products.

2021 Non-enforcement Decisions and 2023 REMS. In 2020, during the COVID-19 pandemic, the American College of Obstetricians and Gynecologists (ACOG) asked FDA to suspend enforcement of the in-person dispensing requirement because it unnecessarily put patients and providers at risk of COVID-19, delayed time-sensitive healthcare, and "served as a barrier to accessing this safe, effective medication." ECF No. 1-6 at App. 702-704.[3] In response, FDA analyzed medical literature, postmarketing adverse-event reporting from earlier in the pandemic, and information about deviations or noncompliance events associated with the REMS. ECF No. 1-6 at App. 706-707. FDA found no indication that forgoing in-person dispensing increased adverse events. *Id.* In April 2021, FDA announced that it would not enforce the in-person dispensing requirement during the public health emergency. *Id.* Neither Texas nor Florida filed a citizen petition challenging this action.

FDA came to the same conclusion in its December 2021 response to the 2019 citizen petition seeking to undo the 2016 changes: "[M]ifepristone may be safely used without in-person dispensing," ECF No. 1-6 at App. 737, and in-person dispensing was "no longer necessary to ensure" the drug's benefits outweigh the risks, *id.* at App. 735. FDA relied on safety data from the nonenforcement period, which showed "no indication" that suspending in-person dispensing "contributed to" adverse events. *Id.* at App. 707. FDA also pointed to three studies analyzing pharmacy-mail dispensing and five studies analyzing clinic-mail dispensing, all of which supported finding that mifepristone remains safe and effective without in-person dispensing. *Id.* at App. 737-739.

Based on its analysis, FDA directed Danco to submit a supplemental NDA proposing

[3] Before FDA responded, ACOG sued to enjoin the in-person dispensing requirement. *ACOG v. FDA*, 472 F. Supp. 3d 183 (D. Md. 2020). Several states (not including Texas and Florida) moved to intervene. The district court denied the states' intervention motion because the states had not demonstrated a "direct and substantial interest" in the litigation. *ACOG v. FDA*, 467 F. Supp. 3d 282, 288 (D. Md. 2020). State laws, the court explained, were not "linked in any way to the enforcement of the FDA's" in-person dispensing requirement, so the "case would not impair those States' ability to enforce their own laws." *Id.* at 286. Nor would any judgment "eliminate any state's ability to continue to regulate medication abortion, as they choose, above and beyond the FDA's requirements." *Id.* at 289.

modifications to the REMS to remove the in-person dispensing requirement. Danco complied, and FDA approved Danco's supplemental NDA in January 2023. *See* ECF No. 1-3 at App. 38-211. The Plaintiff States did not file a citizen petition challenging this action, either.

2025 HHS Letter and Court Remand. Responding to inquiries from state attorneys general, the Department of Health and Human Services (HHS) Secretary Robert Kennedy stated on September 19, 2025, that HHS is conducting "a study of the current [mifepristone] REMS, in order to determine whether modifications are necessary." Letter from Secretary Robert F. Kennedy, Jr. to State Attorneys General (Sept. 19, 2025), https://perma.cc/UT7C-NXHV (Kennedy Letter). One month later, a federal district court in Hawaii held unlawful certain restrictions in the 2023 REMS because FDA "fail[ed] to provide a reasoned explanation for its *restrictive* treatment of the drug" in light of the available evidence that mifepristone is objectively safe. *Purcell v. Kennedy*, No. 1:17-cv-00493, 2025 WL 3101785, at *2 (D. Haw. Oct. 30, 2025) (emphasis added). FDA has received multiple citizen petitions asking the agency to reconsider its decisions around mifepristone, including requests to suspend the original Mifeprex approval. ECF No. 20-1 at 8 (listing pending citizen petitions).

PROCEDURAL HISTORY

In November 2022, a group of physicians who oppose abortion challenged FDA's 2000 approval of Mifeprex, 2016 labeling changes, and 2021 non-enforcement decisions under the APA. *See Alliance for Hippocratic Med. v. FDA*, No. 2:22-cv-00223 (N.D. Tex.). The Supreme Court unanimously held that the *Alliance* Plaintiffs "lack standing to challenge FDA's actions." *Alliance*, 602 U.S. at 374. The Supreme Court rejected all of the *Alliance* Plaintiffs' theories of standing as a matter of law, including because "the law has never permitted" plaintiffs "to challenge the government's loosening of general public safety requirements simply because more individuals might then show up at emergency rooms or in doctors' offices with follow-on injuries." *Id.* at 391.

Over a year after the Supreme Court's decision—and almost three years after the *Alliance* suit was filed—Florida and Texas moved to intervene in the *Alliance* suit, as had three other states, Missouri, Kansas, and Idaho. *Alliance* ECF Nos. 151, 254, 255. Before Danco or FDA responded

to Florida's and Texas's motion, the district court denied that motion as moot and transferred the other three states' complaint to the Eastern District of Missouri, without addressing whether those states had standing. *Alliance* ECF No. 273; *see Missouri v. FDA*, No. 4:25-cv-01580 (E.D. Mo.). FDA and Danco have since moved to dismiss that suit for lack of standing and other reasons. *Missouri* ECF Nos. 293, 294, 295.

Another state, Louisiana, filed suit in September 2025 alongside an individual plaintiff. That suit challenges only the 2023 REMS. *Louisiana v. FDA*, No. 6:25-cv-01491 (W.D. La.). Around the same time, FDA announced that it would be conducting an additional "study of the safety of the current REMS, in order to determine whether modifications are necessary." Kennedy Letter, *supra*, at 1. Almost three months later, on December 9, 2025, Florida and Texas filed their Complaint here. They challenge the 2000 approval, 2016 changes, 2021 non-enforcement decision, 2023 REMS, and two generic approvals.

ARGUMENT

The Court should dismiss the Complaint for lack of jurisdiction, lack of venue with respect to Florida, or for failure to state a claim.

I. Texas and Florida Fail To Establish Article III Standing.

Like *Alliance*, this case begins and ends with the Plaintiffs' lack of Article III standing. To have standing, the Plaintiff States must show that they "have a 'personal stake' " in FDA's approval decisions for mifepristone. *Alliance*, 602 U.S. at 379 (citation omitted). That is, they must "clearly allege facts demonstrating" that they "(1) suffered an injury in fact, (2) that is fairly traceable to the challenged" FDA actions "and (3) that is likely to be redressed by a favorable judicial decision." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016) (quotation marks and alteration omitted). The Plaintiff States attempt to meet this burden by alleging that FDA's actions make it harder for them to enforce their state-law abortion restrictions, leading to various "economic" and "sovereign" injuries. Compl. ¶¶ 283-304 (describing purported economic injuries), *id.* ¶¶ 305-333 (describing purported sovereign injuries). But none of these theories satisfies Article III's requirements.

Because Texas is the only party that makes venue proper in this district, *see id.* ¶ 29; *Alliance* ECF No. 273 at 19-22, it is Texas that must have standing. Florida cannot show that venue in Texas is proper; Florida is not a resident of the State of Texas and no "substantial part of the events or omissions giving rise to the claim occurred" in Texas. 28 U.S.C. § 1391(e)(1). In any event, Florida does not have different or better arguments for standing than Texas does.

A. *Alliance* Forecloses The Theory That Downstream State Medicaid Payments For Follow-Up Care Create Article III Standing To Challenge FDA's Actions.

Start with the alleged financial injuries. The Plaintiff States assert that FDA's actions around mifepristone will result in their Medicaid systems paying more "for medical expenses incurred to treat women suffering from post-abortion complications." Compl. ¶ 286. This "medical costs" theory is directly foreclosed by *Alliance*—which is why the Ninth Circuit rejected this exact argument when Idaho presented it. *Washington*, 108 F.4th at 1174.

As *Alliance* explained, the causal chain between "FDA's relaxed regulation" of a drug and "downstream economic injuries" for follow-up medical care is too "attenuated" to be a basis for Article III standing. 602 U.S. at 386, 390. Indeed, "the law has never permitted doctors to challenge the government's loosening of general public safety requirements simply because more individuals might then show up at emergency rooms or in doctors' offices with follow-on injuries." *Id.* at 391. Government action that "is so far removed from its distant (even if predictable) ripple effects" cannot satisfy Article III. *Id.* at 383, 391. The Supreme Court was clear: Allowing parties to "challenge general safety regulations as unlawfully lax" based on such distant effects "would be an unprecedented" expansion of Article III jurisdiction and would lack any "principled" endpoint. *Id.* at 391-392.

Florida's and Texas's Complaint does not even cite the *Alliance* decision, much less wrestle with its reasoning. Instead, the Plaintiff States proffer anecdotal stories suggesting that their Medicaid programs may pay doctors for providing follow-up care to a patient in the event such care is needed after a medication abortion. *E.g.*, Compl. ¶¶ 287-288. And Texas and Florida claim, at a high level of generality, that they have been "forced to divert resources to" investigate

mifepristone that has arrived within their borders by mail. *Id.* ¶¶ 302-304. But the causal chain in *Alliance* was already too attenuated—because it flows through too many intermediaries, including patients and doctors—to create Article III standing. That too-attenuated chain in *Alliance* cannot be overcome by adding *more* links in the chain.

The Plaintiff States' monetary theory also runs headlong into another problem. "[I]n our system of dual federal and state sovereignty, federal policies frequently generate indirect effects on state revenues or state spending." *Priorities*, 599 U.S. at 680 n.3. The Supreme Court has thus repeatedly cautioned against granting states standing based on these kinds of downstream effects, explaining that it would erode "bedrock Article III constraints." *Id.*; *see id.* at 674 (rejecting Texas's theory that it was being harmed by expending money on "noncitizens who should be (but are not being) arrested by the Federal Government"); *California v. Texas*, 593 U.S. 659, 675-678 (2021) (expressing skepticism of predictive effects on state budgets). This is especially true "in the FDA drug-approval context," where "virtually all drugs come with complications, risks, and side effects." *Alliance*, 602 U.S. at 392.

The Plaintiff States' theory would grant states standing to challenge almost any "alleged Executive Branch under-enforcement of . . . drug laws" merely by making statistical assumptions about how many patients could end up encountering a particular product. *Priorities*, 599 U.S. at 681. The Supreme Court has refused to head "down that uncharted path." *Alliance*, 602 U.S. at 392; *see also Summers v. Earth Island Inst.*, 555 U.S. 488, 495, 497 (2009) ("statistical probability that some [plaintiffs] are threatened with concrete injury" insufficient even if coupled with allegations of past harm). Other courts agree. *See, e.g.*, *Maryland v. Dep't of Agric.*, 151 F.4th 197, 210 (4th Cir. 2025) (because "[i]nnumerable federal actions impact state budgets and programs," a state's "alleged decline[] in tax revenue" does not constitute "cognizable injury"); *Arizona v. Biden*, 40 F.4th 375, 386 (6th Cir. 2022) ("peripheral costs on a State" do not satisfy Article III); *Las Ams. Immigrant Advoc. Ctr. v. DHS*, 348 F.R.D. 397, 403 (D.D.C. 2025) (states' indirect financial injuries from federal agency actions are "too attenuated to support Article III standing"); *cf. Vita Nuova, Inc. v. Azar*, 458 F. Supp. 3d 546, 557 (N.D. Tex. 2020) (O'Connor,

J.) (standing doctrine does not "open the floodgates to federal courts so long as a plaintiff could show a not-insignificant loss tied to a subjective fear of unproven harm").

When Idaho made the same standing arguments that Texas and Florida make here, the district court rejected it and the court of appeals agreed. Put directly, Idaho's alleged "economic injury in the form of increased costs to the state's Medicaid system" did not give it standing to challenge FDA's elimination of the in-person dispensing requirement in the 2023 REMS approval. *Washington*, 108 F.4th at 1174. "Allowing Idaho to proceed based on predictions of increased emergency-room visits" or allegations of resource "burden[s] on law enforcement" would be a "boundless conception of Article III's injury requirement." *Id.* at 1176-77. Taken to their logical end, these types of arguments would mean that every state has "standing to challenge virtually every government action that they do not like—an approach to standing that [the Supreme] Court has consistently rejected as flatly inconsistent with Article III." *Alliance*, 602 U.S. at 392. The "lack of historical precedent" for "the States' assertion of standing" is a "telling indication of the severe constitutional problem." *Priorities*, 599 U.S. at 677.

All of these problems are further exacerbated by the Plaintiff States' failure to show that their "[in]direct pocketbook injur[ies]" are "fairly traceable" to *each* of FDA's 2016, 2021, and 2023 actions, as opposed to decisions (like the original 2000 mifepristone approval) that "operate independently." *Haaland v. Brackeen*, 599 U.S. 255, 296 (2023) (citation omitted). "[S]tanding is not dispensed in gross," *TransUnion LLC v. Ramirez*, 594 U.S. 413, 431 (2021), and as a result, the Plaintiff States must show they are "injured in fact *by the action* [they] sought to have reviewed," *Simon v. E. Ky. Welfare Rts. Org.*, 426 U.S. 26, 38-39 (1976) (emphasis added); *see In re Gee*, 941 F.3d 153, 161-162 (5th Cir. 2019) ("To ensure that standing is not dispensed in gross, the district court must analyze Plaintiffs' standing to challenge each provision of law at issue."). Given the contingencies in the causal chain, any alleged "marginal increase in the rate at which pregnant women require additional medical care" stemming from each of FDA's changes since the initial 2000 approval is simply "too attenuated to establish the requisite causal connection." *Washington*, 108 F.4th at 1176.

As a flip side of this same problem, the Plaintiff States also fail to allege a "substantial likelihood that victory" on their challenges to the 2016, 2021, and 2023 actions would redress their alleged Medicaid expenditures. *Simon*, 426 U.S. at 45-46. Those claims seek to return to the pre-2016 mifepristone labeling and REMS, but the 2016 changes reduced the dosage of mifepristone, increased the efficacy of medication abortion, and further reduced adverse events. *Compare* ECF No. 1-6 at App. 717 (92.1% in U.S. trials need no intervention under original labeling), *with id.* at App. 664, 719-720, 727 (97.4% of U.S. women need no intervention following 2016 changes). On the Plaintiff States' own speculative and attenuated logic, the marginally lower efficacy rate under the pre-2016 labeling and REMS would make it more, not less, likely that women prescribed mifepristone may require some follow-up care and that the Plaintiff States' Medicaid programs would be "injured." Both common sense and precedent dictate that a plaintiff lacks standing if it is "uncertain" whether "granting [the plaintiff] the relief it wants would remedy its injuries," *Inclusive Cmtys. Project, Inc. v. Dep't of Treasury*, 946 F.3d 649, 657-658 (5th Cir. 2019), because a plaintiff must show that it will "benefit in a tangible way from the court's intervention," *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 103 n.5 (1998) (citation omitted); *see also Noem v. Haaland*, 41 F.4th 1013, 1018 (8th Cir. 2022) (no standing where "doing away with" the challenged federal provision "will only make it *harder*, not easier, for [the state] to remedy its claimed injury"); *Waterkeeper All., Inc. v. Regan*, 41 F.4th 654, 662 (D.C. Cir. 2022) (no standing where "plaintiffs' requested relief might exacerbate their alleged injuries").

In short, the Plaintiff States' theory of financial injury flouts the Supreme Court's admonitions in *Alliance* and fails multiple times over. Such allegations are insufficient to establish Article III standing to challenge FDA's actions.

B. The Plaintiff States' Alleged Sovereign Injuries Do Not Create Article III Standing.

Texas and Florida cannot circumvent *Alliance* and other precedents by recasting their asserted injuries as "sovereign." *See* Compl. ¶¶ 305-356. Like their financial-costs theory, none of the supposedly "sovereign" harms they assert are "traditionally recognized as providing a basis for a lawsuit in American courts." *TransUnion*, 594 U.S. at 417.

1. Texas and Florida have not alleged a cognizable sovereign injury.

FDA's regulation of mifepristone does not injure the Plaintiff States' "sovereign interest" because it does not interfere with their "power to create and enforce a legal code." *Alfred L. Snapp & Son, Inc. v. Puerto Rico*, 458 U.S. 592, 601 (1982). "[W]hen speaking about the sovereign's interest in enforcing its laws, the Supreme Court has spoken about the state's interest in the [laws'] *enforceability*." *Harrison v. Jefferson Par. Sch. Bd.*, 78 F.4th 765, 772 (5th Cir. 2023); *see Maine v. Taylor*, 477 U.S. 131, 137 (1986) (constitutional challenge implicates state's "interest in the continued enforceability of its" laws). The federal government infringes that interest when it preempts state law or applies "pressure to change [it] in some substantial way." *Texas v. United States*, 787 F.3d 733, 749 (5th Cir. 2015); *see Texas v. United States*, 809 F.3d 134, 153 (5th Cir. 2015) (holding Texas's sovereign interests were impinged by a federal law precluding states from "establish[ing] their own classifications" for immigration). That is what occurred in *Louisiana v. EEOC*, 705 F. Supp. 3d 643, 652 (W.D. La. 2024) (cited at Compl. ¶ 327), where an agency rule "directly regulated" a state in its capacity as employer, preempted the state's conflicting statutes, and imposed potential penalties for non-compliance. Nothing like that exists here.

Texas and Florida do not claim that any of the challenged FDA actions preempt or otherwise "interfere[] with [their] *authority* to enact or enforce restrictions on medical abortion within [their] boundaries." *Washington*, 108 F.4th at 1177; *see, e.g.*, *Harrison*, 78 F.4th at 770 ("for a sovereign interest" to support standing, the defendant's acts must result "in some tangible interference with [the state's] authority to regulate or to enforce its laws") (citation omitted); *Louisiana v. Biden*, 64 F.4th 674, 683-684 (5th Cir. 2023) (requiring "a direct effect on [state] law or policy" or " 'substantial pressure' for [plaintiff-states] to change their laws") (citation and emphasis omitted). Nor do the Plaintiff States claim that the challenged FDA actions "compel the States to require or prohibit" any conduct. *Printz v. United States*, 521 U.S. 898, 924 (1997). In a case challenging a state law prohibiting abortion in most circumstances as preempted, the Fourth Circuit held that FDA's regulation of mifepristone "aligns with [the agency's] traditional function of ensuring the safety of drugs on the market while leaving the question of access to state

governance." *GenBioPro, Inc. v. Raynes*, 144 F.4th 258, 267, 276 (4th Cir. 2025). Florida and Texas make no claim that FDA has required them (or any other state) to do anything as a matter of state law.

At most, Florida and Texas have articulated a "highly speculative fear," *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 410 (2013), that FDA's actions may "threaten to preempt" their "abortion regulations," Compl. ¶ 328. But it is black-letter law that such "allegations of *possible* future injury are not sufficient" for Article III purposes. *Clapper*, 568 U.S. at 409-410 (brackets and quotation marks omitted); *see also MedX Imaging LLC v. Tex. Dep't of Health and Human Servs.*, No. 4:24-cv-01259-O, 2025 WL 2108005, at *3 (N.D. Tex. July 27, 2025) (O'Connor, J.) (standing cannot be based on "only the possibility of a future injury upon a contingent event") (quotation marks omitted). Florida and Texas identify no state regulation that they say they cannot enforce because it is preempted, leaving them (and this Court) to speculate that a future injury is theoretically possible. And the Fourth Circuit has rejected that FDA's regulation of mifepristone preempts a state law prohibiting abortion in most circumstances. *See GenBioPro*, 144 F.4th at 267.[4]

That leaves the Plaintiff States to argue that FDA's decisions about mifepristone regulation can lead to states having to invest additional resources to enforce state-law abortion restrictions. Compl. ¶ 353. At its core, this argument is nothing more than a generalized complaint that FDA's actions regarding mifepristone do not advance the policies of Texas and Florida. But the notion that states get to enact and independently enforce their own chosen policies is entirely normal in our system of dual sovereignty—and it is the default for health and safety laws, which is how the

[4] The Plaintiff States' other cited cases are no more helpful to them in showing a non-speculative injury in the form of a Florida or Texas law that they agree is preempted. In *Satanic Temple v. Labrador*, 149 F.4th 1047, 1053 & n.6 (9th Cir. 2025), the court found that the plaintiffs lacked standing to challenge an Idaho abortion ban without deciding whether FDA's REMS preempts the law because the issue was not raised on appeal. And the district court decision in *Bryant v. Stein*, No. 1:23-cv-00077, 2024 WL 1886907, at *15 (M.D.N.C. Apr. 30, 2024), *appeals filed*, Nos. 24-1576, 24-1600, 24-1617 (4th Cir. 2024)), which predates the Fourth Circuit's ruling in *GenBioPro*, is currently on appeal in the Fourth Circuit.

Plaintiff States describe their restrictions. *See, e.g.*, *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996) (protecting citizens' "health and safety" is "primarily" a "matter of local concern") (citation omitted); *GenBioPro,* 144 F.4th at 271-272 (same). The Plaintiff States cannot point to any state law that FDA's challenged actions override. For this reason, as the Ninth Circuit explained when Idaho presented this same exact theory, a state's general "interest in the preservation of sovereign authority" does not confer "standing to challenge federal action that affects state law enforcement indirectly, by making violations of state law more difficult or costly to detect." *Washington*, 108 F.4th at 1176. "Even if the availability of retail and mail-order dispensing does make mifepristone more difficult to police, [courts] have never held that a logistical burden on law enforcement constitutes a cognizable" sovereign injury. *Id.* at 1177.

2. The Plaintiff States' alleged injuries are not traceable to FDA's actions.

The Plaintiff States also face a separate causation problem with asserting Article III standing on the basis that FDA's actions facilitate third parties' violations of state-law restrictions. Simply put, the connection between FDA's actions and supposed downstream violations of state law by third parties is too speculative and too attenuated to be traceable to FDA. *Contra* Compl. ¶ 433; *see supra* pp. 7-10. For example, FDA's challenged actions do not require patients to obtain mifepristone by mail. FDA's challenged actions likewise do not require doctors to prescribe or send mifepristone through the mail. And FDA's challenged actions do not direct states to offer state-law protections to doctors who choose to mail mifepristone to women who seek to request mifepristone by mail.

FDA—by Congressional design—considers only whether a drug is safe and effective for its indicated use, 21 U.S.C. § 355, and whether additional conditions are necessary to "ensure the benefits of the drug outweigh the risks" and to "minimize the burden on the health care delivery system," 21 U.S.C. § 355-1(g)(4)(B). As a result, the Plaintiff States' asserted injuries must filter through several layers of "unfettered choices made by independent" actors—i.e., medical providers who, acting in reliance on shield laws that the Plaintiff States' co-equal sovereign states have enacted, ship mifepristone to women who have requested it in Florida or Texas. *Clapper*,

568 U.S. at 414 n.5 (citation omitted).

The Plaintiff States' allegations repeatedly make clear—over the course of dozens of paragraphs—that their real dispute is with independent actions by out-of-state medical providers, acting under competing out-of-state laws, that the Plaintiff States say make it harder for them to enforce state-law abortion restrictions in Florida and Texas. *E.g.*, Compl. ¶¶ 354-426. The timeline bears this out. FDA has not enforced in-person dispensing since April 2021, which is over a year before the Supreme Court decided *Dobbs* in June 2022. Yet the #WeCount Report on which Florida and Texas rely, *see id.* ¶¶ 427-433, shows that neither of these events precipitated an increase in medication abortion in either State. Instead, the increase started with the enactment of shield laws in 2023. *See* ECF No. 1-9 at App. 1406 (marking increase in telehealth abortions in Q3 2023, when "[p]rovision under US shield laws begins").

In response to this gaping causation problem, Florida and Texas insist that FDA "expressly intended" third parties to violate state-law abortion restrictions in approving the 2023 REMS modification. Compl. ¶ 433 (emphasis deleted). This unadorned allegation is both conclusory and legally wrong. The Complaint offers *no* non-conclusory basis for this Court to find that other states' decisions to adopt novel "shield" laws after *Dobbs* was a predictable effect of FDA formalizing a non-enforcement policy that had been in effect for over a year when *Dobbs* issued. There are no facts showing that doctors agreeing to mail mifepristone under the protection of novel and not-yet-enacted shield laws would be a "predictable" outcome of FDA formalizing its 2021 exercise of enforcement discretion. *Alliance*, 602 U.S. at 383 (quotation marks omitted); *see also, e.g.*, *Dep't of Com. v. New York*, 588 U.S. 752, 764-766 (2019) (extensive factual record showed historical basis to conclude that challenged census question would predictably result in significant undercounting of specific populations). Mere speculation does not suffice. *See, e.g.*, *Clapper*, 568 U.S. at 414 (fact that government program made surveillance possible did not mean that plaintiffs were injured by it); *Ariz. Christian Sch. Tuition Org. v. Winn*, 563 U.S. 125 (2011) (taxpayers lacked standing to challenge tax credits benefitting religious schools when private individuals decided how to use credits). And the same principles of state sovereignty that the Plaintiff States

claim to want to vindicate cuts against them. A court cannot blithely assume what legislation will be enacted by co-equal sovereigns to advance their own state policy goals in the wake of an agency's actions.

Thus, like Plaintiff States' alleged monetary harms, their claimed sovereign injuries are also "not fairly traceable" to FDA because "intervening, independent act[s]" of third parties are "a necessary condition." *Texas*, 787 F.3d at 752.

C. The Plaintiff States Have No Cognizable Quasi-Sovereign Interest.

Finally, Florida and Texas cannot establish standing on the basis of a "quasi-sovereign" interest in preventing harms to their citizens' health and safety. *See* Compl. ¶¶ 30, 32, 205-282. It is well established that a "State does not have standing as *parens patriae* to bring an action against the Federal Government" to vindicate its citizens' rights. *Brackeen*, 599 U.S. at 295 (quoting *Snapp*, 458 U.S. at 610, n.16). A state's "quasi-sovereign interest in its citizens' health and well-being" is "wholly derivative of the personal . . . interests of its citizens and therefore not a valid quasi-sovereign interest at all." *Paxton v. Dettelbach*, 105 F.4th 708, 715-716 (5th Cir. 2024); *accord Harrison*, 78 F.4th 765 (rejecting similar quasi-sovereign standing theory). To the extent the Plaintiff States seek to reframe these interests as part of their own "reserved powers to protect their citizens' health and welfare," Compl. ¶ 307, that interest is wholly indistinguishable from their asserted sovereign interests. And it fails for all the same reasons. *See Washington*, 108 F.4th at 1178 (rejecting Idaho's "quasi-sovereign" harm from the 2023 REMS).

* * *

At bottom, the "federal courts are the wrong forum for addressing the [Plaintiff States'] concerns about FDA's actions." *Alliance*, 602 U.S. at 396-397. Florida and Texas may "take th[ose] concerns to the Executive and Legislative Branches"—and may "also express their views about abortion and mifepristone," "including in the political and electoral processes." *Id.* at 393; *see, e.g.*, Citizen Petition from Attorney General of Massachusetts, *et al.* (June 6, 2025), https://tinyurl.com/yc6xaxk5 (citizen petition filed with FDA by Massachusetts and other states asking FDA to eliminate the mifepristone REMS). But this Court lacks Article III jurisdiction

over the Plaintiff States' Complaint.

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

Because the Plaintiff States bring this suit under the APA, they must also show (1) that the interests they assert are "arguably within the zone of interests" of the relevant statutes, *Match-E-Be-Nash-She-Wish Band of Pottawatomi Indians v. Patchak*, 567 U.S. 209, 224 (2012) (citation omitted); (2) that they exhausted the appropriate administrative remedies; and (3) that their suit is timely. The Plaintiff States can make none of these showings.

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

The zone-of-interests test asks "whether Congress intended for a particular class of plaintiffs to be relied upon to challenge agency disregard of the law." *Clarke v. Sec. Indus. Ass'n*, 479 U.S. 388, 399 (1987) (quotation marks and brackets omitted). A court must therefore analyze the relationship between "the injury [the plaintiff] complains of" and the specific "statutory provision whose violation forms the legal basis for [the] complaint." *Bennett v. Spear*, 520 U.S. 154, 176 (1997). The test is not "especially demanding," but it forecloses suit when an unregulated "plaintiff's 'interests are [only] marginally related to or inconsistent with the purposes implicit in the statute.' " *Patchak*, 567 U.S. at 225 (quoting *Clarke*, 479 U.S. at 399). That is the case for all of the Plaintiff States' claims under the Comstock Act, the FDCA, and the Pediatric Research Equity Act (PREA).

The Comstock Act is a federal criminal statute that the government is not seeking to enforce against the Plaintiff States. Nor do the Plaintiff States have a judicially cognizable interest in seeing the law enforced against others. *See, e.g.*, *Priorities*, 599 U.S. at 677 ("a party lacks a judicially cognizable interest in the prosecution of another") (citation, quotation marks, and ellipses omitted); *Town of Castle Rock v. Gonzales*, 545 U.S. 748, 768 (2005). Unlike in other contexts, such as immigration—where Congress "has explicitly allowed states to" limit their costs by refusing "benefits to illegal aliens"—the Comstock Act envisions no role or participation by states. *Texas*, 809 F.3d at 163. Indeed, the Plaintiff States do not allege the Act was designed to

protect states' sovereign, quasi-sovereign, or economic interests. *See, e.g.*, Compl. ¶¶ 75-76. Nor could they. Requests that the Executive enforce criminal statutes through the APA are not "traditionally thought to be capable of resolution through the judicial process" at all. *Priorities*, 599 U.S. at 676, 678-681 (citations and quotation marks omitted); *see also, e.g.*, *Taylor*, 477 U.S. at 137 ("private parties, and perhaps even separate sovereigns, have no legally cognizable interest in the prosecutorial decisions of the Federal Government"); *Heckler v. Chaney*, 470 U.S. 821, 831 (1985) (recognizing "general unsuitability for judicial review of agency [non-enforcement] decisions"). Permitting state or private parties to seek enforcement of a federal criminal statute is far "more likely to frustrate . . . statutory objectives" by interfering with the Executive's enforcement discretion and fracturing a uniform federal regime. *Scheduled Airlines Traffic Off. v. DOD*, 87 F.3d 1356, 1359 (D.C. Cir. 1996) (quotation marks omitted).

For similar reasons, the Plaintiff States do not fall within the zone of interests of the FDCA, including the REMS provisions. Those provisions authorize FDA to approve safe and effective drugs, 21 U.S.C. § 355; to impose use restrictions when the agency finds such restrictions are necessary to "ensure that the benefits of the drug outweigh the risks," *id.* § 355-1(a)(1); to periodically assess imposed use restrictions, *id.* § 355-1(c), (g)(2)-(3); and to modify use restrictions based on the benefit-risk balance and to "minimize the burden on the health care delivery system of complying with the [REMS]," *id.* § 355-1(g)(4)(B). This overall framework was designed to safeguard and advance public health by protecting consumers taking drugs that are found to have specific risks. Noticeably absent is an intent to protect states that want to impose additional access restrictions on FDA-approved drugs or to regulate Medicaid expenditures. *See Ass'n of Am. Physicians and Surgeons, Inc. v. FDA*, 539 F. Supp. 2d 4, 18 (D.D.C. 2008) (rejecting plaintiffs' standing argument because "alleged competitive and economic injuries do not fall within the [FDCA's] zone of interests"), *aff'd*, 358 F. App'x 179 (D.C. Cir. 2009).

The same goes for the PREA, which generally requires pediatric-specific assessments before FDA can approve a new drug for pediatric populations, although FDA can waive the assessment for a variety of reasons. *See* 21 U.S.C. § 355c. Children—not states—are the class

that PREA was intended to protect.

At best, the Plaintiff States' asserted interests have nothing to do with the statutory purposes. *See, e.g.*, Compl. ¶¶ 283, 327. More realistically, allowing the Plaintiff States to pursue their interests in enforcing abortion restrictions via this suit would "severely disrupt" the FDCA's and PREA's "complex and delicate administrative scheme." *Clarke*, 479 U.S. at 399 (citation omitted).

B. The Plaintiff States Failed To Exhaust Administrative Remedies.

The Plaintiff States' suit should also be dismissed because they have not "proceeded through each step of the [agency's] administrative review scheme and received a 'final decision' before seeking judicial review" as to each FDA decision they challenge. *Carr v. Saul*, 593 U.S. 83, 88 n.2 (2021); *see Darby v. Cisneros*, 509 U.S. 137, 146, 153 (1993) (APA requires an "aggrieved party" to "exhaust[ ] all administrative remedies").

FDA regulations clearly mandate that any request for FDA to "take or refrain from taking any form of administrative action must first be the subject of a final administrative decision based on a [citizen] petition . . . before any legal action is filed in a court." 21 C.F.R. § 10.45(b); *see id.* §§ 10.25(a), 10.30. Unlike other states and many other interested parties,[5] neither Florida nor Texas filed a citizen petition challenging any of the FDA decisions at issue. Courts routinely dismiss suits in such circumstances. *See, e.g.*, *Ctr. for Food Safety v. Hamburg*, 696 F. App'x 302, 303 (9th Cir. 2017); *Cody Lab'ys, Inc. v. Sebelius*, 446 F. App'x 964, 969 (10th Cir. 2011); *Ass'n of Am. Physicians*, 358 F. App'x at 180-181.

Nor would exhaustion of administrative remedies be futile. In its vacated *Alliance* decision, the Fifth Circuit held that a futility exception to exhaustion applied to the *Alliance* plaintiffs because FDA had rejected an argument about in-person dispensing in a properly filed

[5] *See, e.g.*, Citizen Petition from Students for Life of America (Oct. 17, 2025), https://tinyurl.com/5x9br66h; Citizen Petition from Attorney General of Washington, *et al.* (Aug. 26, 2025), https://tinyurl.com/2nz6bh9j; Citizen Petition from Attorney General of Massachusetts, *supra*; Citizen Petition from American College of Obstetricians and Gynecologists, *et al.* (Jan. 31, 2025), https://tinyurl.com/4e2483w7 (ACOG Citizen Petition).

citizen petition, and FDA approved removing in-person dispensing from the REMS in 2023. *Alliance for Hippocratic Med. v. FDA*, 78 F.4th 210, 255 (5th Cir. 2023) (citing *Tesoro Refin. & Mktg. Co. v. FERC*, 552 F.3d 868, 874 (D.C. Cir. 2009)), *rev'd*, 602 U.S. 367 (2024); *see also id.* (suggesting that FDA's denial of the 2002 citizen petition "further aids" the conclusion that FDA would have denied any request for an administrative stay of the 2021 non-enforcement decision). Despite relying on *Tesoro*, the panel did not reconcile its ruling with *Tesoro*'s holding that the futility "exception is quite restricted" and applies only in the "exceptional" case when there is "a *certainty* of an adverse decision" rather than a claim that "an unfavorable decision [is] highly likely." *Tesoro*, 552 F.3d at 874 (quotations omitted).

That certainty is missing here. Start with the 2002 citizen petition, which requested that FDA stay and ultimately revoke its approval of Mifeprex. ECF No. 1-4 at App. 375. The petitioners argued that (1) Subpart H was inapplicable; (2) the clinical trials upon which FDA relied were deficient; (3) the medication abortion regimen could not include misoprostol, which was not independently approved for use as an abortifacient; (4) Mifeprex was not safe and effective under the approved regimen; (5) physicians did not comply with the use restrictions; (6) the safeguards in the U.S. clinical trial were not captured in the regimen FDA approved; (7) FDA's decision to waive pediatric studies was unreasoned; and (8) FDA did not require Danco to conduct sufficiently broad clinical studies. ECF No. 1-4 at App. 378-390. In challenging the 2000 approval, Florida and Texas argue that (1) Subpart H was inapplicable (Compl. ¶¶ 438-443); (2) the clinical trials upon which FDA relied were deficient (Compl. ¶¶ 444-452); (3) FDA's decision to waive pediatric studies was unreasoned (Compl. ¶¶ 453-462); (4) the 2000 approval violated the Comstock Act (Compl. ¶¶ 463-464); and (5) FDA's stated reasons for approving the NDA in 2000 were pretextual (Compl. ¶ 465). Granted, some of the Plaintiff States' arguments overlap with those FDA rejected. But without complete overlap, Florida and Texas—and the Court—cannot be "certain" that FDA would have rejected their arguments, too.

The same goes for the 2019 citizen petition, which did not raise the core issues that the Plaintiff States say taint FDA's 2021 and 2023 decisions: that the non-enforcement decisions are

facially invalid because they relied on the original 2000 approval, which was itself invalid under Subpart H; that the decisions violate the Comstock Act; and that FDA's reasoning was pretextual. *See* Compl. ¶¶ 477-483; ECF No. 1-6 at App. 668-693. The Plaintiff States have not pointed to other citizen petitions raising the arguments they make now against any of the actions they challenge in this suit. They cannot know how FDA would respond to arguments it never considered, especially when FDA has made clear that it is studying several issues relating to mifepristone regulation in response to citizen petitions that others *did* submit.[6]

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

Finally, Counts I and II of the Complaint—which challenge FDA's original approval of Mifeprex and 2016 changes—are time barred. *See Taylor v. Bailey Tool Mfg. Co.*, 744 F.3d 944, 946 (5th Cir. 2014) ("A motion to dismiss may be granted on a statute of limitations defense where it is evident from the pleadings that the action is time-barred, and the pleadings fail to raise some basis for tolling."). APA challenges must be brought "within six years after the right of action first accrues." 28 U.S.C. § 2401(a). That limitations period begins running when the plaintiff is injured by the final agency action. *Ortega v. Off. of the Comptroller of the Currency*, 155 F.4th 394, 410 (5th Cir. 2025) (citing *Corner Post, Inc. v. Bd. of Govs. Fed. Res. Sys.*, 603 U.S. 799, 808-809 (2024)). FDA approved the initial NDA for Mifeprex in September 2000, and approved Danco's 2015 supplemental NDA—what the Plaintiff States call the "2016 Major Changes"—in March 2016. Compl. ¶¶ 107, 132. But the Plaintiff States did not file their Complaint until December 2025, which is over twenty-five years after the first action and nearly ten years after the second one. *See generally id.*

Notably, the Plaintiff States themselves claim that both the 2000 approval and the 2016 changes immediately "frustrate[d]" and "exacerbate[d] Plaintiffs' inability to regulate abortion

[6] Numerous high-quality studies post-dating FDA's decision confirm the reasonableness of its decision, which FDA could have considered had the Plaintiff States raised these issues in a citizen petition. *See, e.g.*, ACOG Citizen Petition, *supra*, at 7-9 (collecting studies). That FDA is currently considering the mifepristone REMS in response to citizen petitions, the *Purcell* remand, and Secretary Kennedy's own initiative, underscores that the Plaintiff States do not know what FDA would have done had they exhausted their claims.

within their borders." *Id.* ¶¶ 342-344; *see also id.* ¶ 341 (2000 approval caused abortions to "take place and be completed in Florida or Texas"); *id.* ¶¶ 311-313, 322 (describing how Florida has had laws restricting abortion since 1868, and Texas has since 1925), *id.* ¶ 350 ("Plaintiffs' sovereign injuries would exist under the 2000 or 2016 REMS"). Same with Texas's and Florida's purported fiscal injuries. *See id.* ¶¶ 283-304. Accordingly, the Plaintiff States' claims first accrued as soon as FDA issued each challenged decision. 28 U.S.C. § 2401(a) (limitations period starts "after the right of action *first accrues*") (emphasis added). Indeed, the States admit as much. *See, e.g.*, Compl. ¶¶ 341-343 (alleging that the 2000 approval caused abortions to take place in Florida and Texas that are otherwise banned by state law); *id.* ¶¶ 348-349 (alleging that the 2016 changes caused more abortions in each state, "further undermin[ing] Plaintiffs' ability to enforce their abortion regulations").

Nothing stopped the Plaintiff States from bringing their claims sooner. Florida and Texas are sophisticated repeat litigants who had sufficient notice, time, and resources to sue. Indeed, both Texas and Florida filed five amicus briefs over the last three years in the *Alliance* litigation raising the same issues. *See Alliance* ECF No. 55; ECF Nos. 130, 453, *Alliance*, No. 23-10362 (5th Cir.); Brief for Mississippi and 21 Other States, *Alliance*, Nos. 22A901, 22A902 (U.S. Apr. 18, 2023); Brief for Mississippi and 21 Other States, *Alliance*, Nos. 23-235, 23-236 (U.S. Feb. 29, 2024). Because Florida and Texas have not established that any circumstances prevented timely filing, they are not entitled to equitable tolling, which applies only in "rare and exceptional circumstances." *Teemac v. Henderson*, 298 F.3d 452, 457 (5th Cir. 2002) (citation omitted); *see also Menominee Indian Tribe of Wis. v. United States*, 577 U.S. 250, 255-256 (2016). The statute of limitations for the Plaintiff States' claims about FDA's 2000 and 2016 actions ran years ago.

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

Finally, this suit is not ripe because it was filed after FDA announced its "decision to review the REMS for mifepristone." ECF No. 20-1 at 1. A challenge to an agency action is only "ripe when it would not benefit from any further factual development and when the court would be in no better position to adjudicate the issues in the future than it is now." *DM Arbor Ct., Ltd. v. City*

of Houston, 988 F.3d 215, 218 (5th Cir. 2021) (citation omitted). Yet FDA is in the midst of undertaking further factual development right now. As FDA has made clear in seeking to stay or dismiss litigation brought by other states and here, the agency is in the process of "undertak[ing] a new review based on the evidence before the agency." ECF No. 20-1 at 3; *see also Louisiana* ECF No. 50-1 at 2-3 (FDA Motion to Stay) (similar); *Missouri* ECF No. 293-1 at 1-4 (FDA Motion to Stay and Alternatively to Dismiss) (similar). That review includes "investigating the circumstances under which mifepristone can be safely dispensed," Kennedy Letter, *supra*, at 2, demonstrating that FDA may revisit some or all of the actions challenged in the Plaintiff States' Complaint. The ongoing review justifies "withholding court consideration" of an agency decision that is under reconsideration. *Choice Inc. of Tex. v. Greenstein*, 691 F.3d 710, 715 (5th Cir. 2012) (citation omitted).

FDA views the current uncertainty about its ultimate decision as favoring a stay of proceedings. ECF No. 20-1 at 4-5; *see also Louisiana* ECF No. 50-1 at 9-12; *Missouri* ECF No. 293-1 at 8-9. Such a stay was appropriate in the cases FDA cites, where an agency took some action after litigation commenced. ECF No. 20-1 at 10 (citing *Purcell*, 2025 WL 3101785). Here, however, the Plaintiff States filed their suit months *after* FDA announced that it was reviewing its mifepristone decisions. *See* Kennedy Letter, *supra*; Compl. (dated Dec. 9, 2025). This timing makes abundantly clear that the "key considerations" of ripeness—"the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration"—favor dismissal. *Greenstein*, 691 F.3d at 715 (cleaned up).

CONCLUSION

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

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on March 13, 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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