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, *Proposed Intervenor-Defendant*.	No. 7:25-cv-00126-O Chief Judge Reed O'Connor

DANCO LABORATORIES, LLC'S MOTION TO INTERVENE

Pursuant to Federal Rule of Civil Procedure 24, Danco Laboratories, LLC moves to intervene as of right in the above-captioned case, or, in the alternative, for permissive intervention. This motion is supported by the Brief accompanying this motion as well as the Declaration of Abigail Long. Pursuant to Federal Rule of Civil Procedure 24(c), Danco attaches as exhibits hereto its Proposed Motion to Dismiss and accompanying Brief in support. A proposed order granting the Motion to Intervene is also attached.

Counsel for Federal Defendants indicated that the Federal Defendants take no position on Danco's Motion to Intervene. Counsel for Plaintiffs stated that "Florida and Texas take no position on the motion to intervene at this time. The States reserve their right to oppose the motion once they have reviewed it and the accompanying Rule 24(c) pleading."

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Counsel for Danco Laboratories, LLC

Dated: March 13, 2026

CERTIFICATE OF CONFERENCE

I certify that on March 9, 2026, counsel for Danco conferred with counsel for Federal Defendants regarding Danco's Motion to Intervene. Counsel for Federal Defendants stated that Federal Defendants take no position on Danco's Motion. I further certify that counsel for Danco conferred with Plaintiffs' counsel on the Motion on March 9 and 12, 2026. Counsel for Plaintiffs stated that "Florida and Texas take no position on the motion to intervene at this time. The States reserve their right to oppose the motion once they have reviewed it and the accompanying Rule 24(c) pleading."

/s/ Wayne L. Robbins, Jr.
Wayne L. Robbins, Jr.

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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DANCO LABORATORIES, LLC'S BRIEF IN SUPPORT OF ITS MOTION TO INTERVENE

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INTRODUCTION

Danco moves to intervene to represent its interests as the sponsor and holder of the New Drug Application (NDA) for Mifeprex (mifepristone). The Food and Drug Administration (FDA) approved Mifeprex as safe and effective for its intended use in 2000, attaching certain use restrictions. Those restrictions became a Risk Evaluation and Mitigation Strategy (REMS) in 2008 and, consistent with FDA's statutory REMS authority, have been modified multiple times—including in 2016 and most recently in 2023, when FDA lifted an in-person dispensing requirement that it had not enforced since April 2021. Notably, FDA defended its various actions regarding mifepristone in court and in public for a number of years. But FDA announced in September 2025 that it was conducting a review of the mifepristone REMS. Nearly three months later, Plaintiffs Florida and Texas filed this lawsuit, asking for an order that "[d]eclares unlawful and preliminarily and permanently sets aside, rescinds, and vacates" "the 2023 [supplemental NDA] and REMS program." ECF No. 1, Compl. at 119, Prayer for Relief. On top of that, the Plaintiff States seek, among other things, an order that "[d]eclares unlawful and preliminarily and permanently sets aside, rescinds, and vacates" "the 2000 NDA of Mifeprex" and "the 2016 [supplemental NDA] and REMS program." *Id.*

This lawsuit directly threatens Danco's interests. Mifeprex is Danco's only product. If the Plaintiff States succeed in their request for this Court to enjoin, set aside, or vacate FDA's original 2000 approval, Danco will be unable to continue lawfully distributing its product. If the Plaintiff States obtain their requested relief as to the 2016 or 2023 changes to Mifeprex's labeling and REMS, FDA's past statements indicate that Danco would have to submit a new supplemental NDA and obtain FDA approval, which could take an unknown amount of time, before it could continue lawfully distributing its product. Decl. of Abigail Long (Long Decl.) ¶¶ 16-23. Danco's business would face substantial and immediate disruption nationwide. *Id.* ¶ 27.

Danco's interest is not a surprise to the Plaintiff States, which unsuccessfully tried to join an earlier lawsuit in which Danco has spent three years defending FDA's regulation of mifepristone in the Northern District of Texas, in the Fifth Circuit, in the Supreme Court. *See*

FDA v. Alliance for Hippocratic Med., 602 U.S. 367 (2024). Danco is an appropriate party here for the same reasons it was in *Alliance*. If anything, Danco's interests in intervention now are stronger, given that FDA initiated a review of the mifepristone REMS this past fall on the agency's own initiative. Letter from Secretary Robert F. Kennedy, Jr. to State Attorneys General (Sept. 19, 2025), https://perma.cc/UT7C-NXHV (Kennedy Letter). In this litigation and in two other suits brought by states challenging Mifeprex's conditions of use, the Federal Defendants (referred to collectively as FDA) seek a stay based on FDA's ongoing review. FDA has not stated its intent to defend the merits of FDA's regulation of mifepristone. Danco believes there is no scientifically valid evidence that warrants any different conclusion as to the benefit-risk profile of mifepristone when dispensed by a method other than in-person or as to how to "minimize the burden on the health care delivery system of complying with the [REMS]." 21 U.S.C. § 355-1(g)(4)(B). And Danco wishes to raise deficiencies in the Plaintiff States' suit that FDA has not argued at this time. This divergence makes clear that FDA does *not* adequately represent Danco's interests in this litigation.

Danco thus has a right to intervene in this action under Federal Rule of Civil Procedure 24(a). The Western District of Louisiana recently granted Danco's motion to intervene as of right in another challenge to the 2023 REMS. ECF No. 229, *Louisiana v. FDA*, No. 6:25-cv-01491 (W.D. La. Feb. 24, 2026). Danco is likewise entitled to intervene here. At the very least—given the economic and proprietary stakes for Danco, which are neither represented nor protected by FDA—the Court should allow permissive intervention, as the district court did in *Alliance* without addressing intervention as of right. ECF No. 33, *Alliance for Hippocratic Med. v. FDA*, No. 2:22-cv-00223-Z (N.D. Tex. Feb. 6, 2023); *see Texas v. United States*, 805 F.3d 653, 657 (5th Cir. 2015) ("Federal courts should allow intervention where no one would be hurt and the greater justice could be attained.") (citation omitted). No party would be prejudiced by Danco's intervention, and granting intervention would ensure a more complete development of the issues presented and allow Danco to protect its interests.

BACKGROUND

Danco, a small pharmaceutical company incorporated in Delaware, holds the NDA for Mifeprex (mifepristone) Tablets, which is approved for use in a regimen with another drug, misoprostol, for the medical termination of intrauterine pregnancy through 70 days gestation. Mifeprex is Danco's only product. Long Decl. ¶ 3. FDA first approved Mifeprex in 2000 for use through 49 days gestation, subject to various use restrictions. *See* ECF No. 1-4 at App. 479-490. Those conditions were deemed a REMS as a result of the 2007 amendments to the Food, Drug, and Cosmetic Act. *See* 73 Fed. Reg. 16,313 (Mar. 27, 2008); 21 U.S.C. § 355-1(a)(1); *see also* ECF No. 1-7 at App. 1078-79. In 2016, FDA granted Danco's supplemental NDA, extending the drug's approval for use up to 70 days gestation and modifying the REMS to remove certain restrictions. All of those changes were based on the agency's review of extensive clinical data and its expert judgment that the drug would remain safe and effective for its intended use with these modifications. *See* ECF No. 1-3 at App. 9-36; 21 U.S.C. § 355-1(g)(4) (authorizing FDA to "modif[y]" or "remove[ ]" restrictions that are no longer necessary to ensure drug's benefits outweigh risks). The 2016 supplemental NDA approval did not modify the REMS requirement of an in-person visit to receive Mifeprex.

In April 2021, in response to a request from the American College of Obstetrics and Gynecologists during the COVID-19 pandemic, FDA stated that it would exercise enforcement discretion regarding the in-person dispensing requirement for Mifeprex. *See* ECF No. 1-6 at App. 706-707. After additional analysis, including a review of safety data from the non-enforcement period, FDA directed Danco in December 2021 to submit a supplemental NDA proposing modifications to the REMS to remove the in-person dispensing requirement. Danco did so, and FDA approved Danco's supplemental NDA in January 2023. ECF No. 1-3 at App. 38-211.[1]

In November 2022, individual doctors and organizations to which they belonged brought suit to challenge FDA's regulatory actions in 2000, 2016, 2019, and 2021 relating to mifepristone.

[1] FDA approved generic versions of Mifeprex in 2019 and 2025. ECF No. 1 ¶¶ 153, 199. The Mifeprex REMS also applies to the generics.

Alliance ECF No. 1. Danco promptly filed an unopposed motion to intervene as a defendant, which the court granted. *Alliance* ECF Nos. 19, 33.[2] The *Alliance* court subsequently granted a preliminary injunction, *Alliance* ECF No. 137, but the injunction never took effect because the Supreme Court immediately stayed it. The Supreme Court then granted review of the injunction and reversed it. In a unanimous decision, the Supreme Court held that the *Alliance* Plaintiffs "lack standing to challenge FDA's actions." *Alliance*, 602 U.S. at 374.

Meanwhile, Missouri, Kansas, and Idaho moved to intervene as plaintiffs in the *Alliance* action, which the court granted. *Alliance* ECF Nos. 100, 110, 151. After the Supreme Court's *Alliance* decision, the original *Alliance* Plaintiffs voluntarily dismissed without prejudice "all claims brought in their Complaint as to all defendants." *Alliance* ECF No. 203. Missouri, Kansas, and Idaho amended their complaint-in-intervention, which Danco and FDA moved to dismiss asserting (among other things) that venue was improper in Texas. *Alliance* ECF Nos. 217, 218, 221. While those motions were pending, Plaintiffs here—Texas and Florida—moved to intervene in the Texas suit. *Alliance* ECF No. 255. Both Texas and Florida previously filed amicus briefs in that litigation—first in the district court, *see Alliance* ECF No. 55; then in the Fifth Circuit, *see* ECF Nos. 130, 453, *Alliance*, No. 23-10362 (5th Cir.); and finally in the U.S. Supreme Court, *see* 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).

The *Alliance* court transferred Missouri's, Kansas's, and Idaho's complaint to Missouri and denied Florida's and Texas's motion to intervene as moot. *Alliance* ECF No. 273; *see Missouri v. FDA*, No. 4:25-cv-01580 (E.D. Mo.). 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. According to the announcement, this decision was "informed by the lack of adequate consideration underlying the prior REMS

[2] The *Alliance* court concluded that it "need not consider whether Danco can intervene as of right." *Alliance* ECF No. 33 at 3. The court instead granted "permissive intervention" given "Danco's interest in protecting the continued availability of Mifeprex" and its timely request to intervene. *Id.*

approvals, and by recent studies raising concerns about the safety of mifepristone as currently administered." *Id.* Several months later, Florida and Texas filed this suit seeking virtually identical relief as the original *Alliance* Plaintiffs' suit. Compl. ¶¶ 34-38. Florida and Texas challenge (1) FDA's original 2000 approval of Mifeprex; (2) the 2016 approval of Danco's supplemental NDA (what Plaintiffs call the "2016 Major Changes"); (3) the 2021 and 2023 dispensing changes; and (4) the 2019 and 2025 generic approvals. Compl. ¶¶ 437-487. Florida and Texas argue that each of these actions violated the Administrative Procedure Act and is *ultra vires*. *Id.*

The State of Louisiana and an individual plaintiff also challenged the 2023 REMS, filing their complaint about two months before Texas and Florida, and Danco moved to intervene shortly thereafter. *See Louisiana* ECF Nos. 1, 23, 52. Although the *Louisiana* Plaintiffs initially objected to Danco's intervention, they subsequently withdrew it after FDA sought a stay of the action, and the district court granted Danco intervention as of right. *Louisiana* ECF Nos. 111 at 1 n.1, 229.

ARGUMENT

I. Danco Is Entitled To Intervene As A Matter Of Right.

Rule 24(a) is framed in mandatory terms that favor intervention: "[T]he court must permit" intervention when (1) the application is timely; (2) the applicant has an interest relating to the property or transaction which is the subject of the action; (3) disposition of the action may, as a practical matter, impair or impede the applicant's ability to protect that interest; and (4) the applicant's interest is not adequately represented by the existing parties. Fed. R. Civ. P. 24(a)(2); *see Entergy Gulf States La., LLC v. EPA*, 817 F.3d 198, 203 (5th Cir. 2016). Although "the movant bears the burden" of demonstrating these requirements, the rule is "to be liberally construed" and "courts should allow intervention where no one would be hurt and the greater justice could be attained." *Texas*, 805 F.3d at 656-657 (citations omitted); *see Entergy*, 817 F.3d at 203 ("[D]oubts [are] resolved in favor of the proposed intervenor"). Danco readily satisfies this standard.

Timeliness. Danco's motion to intervene is timely. Danco moved to intervene the same day that FDA's response to the Plaintiff States' Complaint is due. *See* ECF No. 19. The case is

still in its earliest stages, and this Court has not ruled on any substantive motions. Courts regularly find motions to intervene timely in similar circumstances. *See, e.g.*, *Wal-Mart Stores, Inc v. Tex. Alcoholic Beverage Comm'n*, 834 F.3d 562, 565-566 (5th Cir. 2016) (motion to intervene timely when filed three months after defendant filed its answer following denial of motion to dismiss); *NextEra Energy Cap. Holdings, Inc. v. D'Andrea*, No. 20-50168, 2022 WL 17492273, at *3 (5th Cir. Dec. 7, 2022) (per curiam) (motion to intervene timely when filed within two months of plaintiffs bringing suit and before defendants filed responsive pleadings).

Further, Danco's intervention at this early stage does not prejudice any party. *See Sierra Club v. Espy*, 18 F.3d 1202, 1205 (5th Cir. 1994) ("absolute measures of timeliness should be ignored" in favor of "contextual" factors, including prejudice to parties and the would-be intervenor); *Ford v. City of Huntsville*, 242 F.3d 235, 240 (5th Cir. 2001) (per curiam) ("[T]he relevant prejudice is that created by the intervenor's delay in seeking to intervene . . . not prejudice to existing parties if intervention is allowed."); *Wal-Mart*, 834 F.3d at 565-566 (intervention timely where party sought to join case "before discovery progressed"). Danco will observe all case deadlines. And, as discussed below, Danco would be severely prejudiced if it were precluded from participating in a suit seeking to invalidate or otherwise alter the conditions of the FDA approval for Danco's sole product.

Protectable Interest. "The touchstone of the [interest] inquiry" under Rule 24(a)(2) "is whether the interest alleged is 'legally protectable.' " *Wal-Mart*, 834 F.3d at 566. Danco has a legally protectable interest in Mifeprex, its labeling, and the mifepristone REMS, which govern the terms on which Danco is authorized under federal law to distribute its sole product.

First, as the holder of the Mifeprex NDA, Danco is an "intended beneficiary of [the] government regulatory system" that governs approval and distribution of prescription drug products. *Id.* at 567 (quoting *Texas*, 805 F.3d at 660). Under Fifth Circuit precedent, Danco "has an interest in protecting its legally prescribed market" for its product, including any restrictions the FDA imposes on where and how its product is available. *Id.*; *accord NextEra*, 2022 WL 17492273, at *3. This interest, which is "neither undifferentiated nor generalized," is itself

sufficient to support intervention. *Texas*, 805 F.3d at 660 (quotation marks omitted).

Second, and relatedly, Danco has "economic interests" that "are directly related to the litigation," which independently "justify intervention." *Wal-Mart*, 834 F.3d at 568; *Black Fire Fighters Ass'n of Dallas v. City of Dallas*, 19 F.3d 992, 994 (5th Cir. 1994) (litigation's "prospective interference with [economic] opportunities can justify intervention") (citation omitted). The Plaintiff States ask this Court to vacate or enjoin FDA's 2000 approval, 2016 changes, and the 2023 REMS. Invalidating Mifeprex's approval would plainly and directly affect Danco's economic interests. And based on FDA's prior statements, any judicial order altering the approved use restrictions for mifepristone would leave Danco unable to distribute Mifeprex until Danco submits, and FDA approves, a new supplemental NDA. Long Decl. ¶¶ 16-22 (citing Declaration of FDA Principal Deputy Commissioner Janet Woodcock, M.D., in support of Emergency Stay Application, *FDA v. Alliance for Hippocratic Med.*, Supreme Court No. 22A902, at Appendix 113a-116a); *see also Louisiana* ECF No. 50-1 at 10 ("if the Court vacates or stays the 2023 REMS Modification before FDA's review is complete, it could prompt the sponsors of mifepristone to file supplemental applications seeking modifications to the REMS"). Even if FDA were to approve a new supplemental NDA and REMS quickly, Danco would then still have to revise product labels, packaging, and promotional materials, as well as amend its supplier- and distributor-contracts and policies (among other things). Long Decl. ¶¶ 14, 23-24. Absent a remand without vacatur, exercise of enforcement discretion by FDA, or other action similarly permitting continued distribution in the interim, the Plaintiff States' requested relief would thus likely halt Danco's distribution of Mifeprex nationwide, for an unknown and unknowable period of time. *Id.* ¶ 27. It would also impose significant compliance costs on Danco. *Id.* ¶¶ 23-24, 27. Because Mifeprex is Danco's only drug, the Plaintiff States' requested relief could impose existential harm on Danco. *Id.* ¶¶ 6-8.

In short, this suit directly implicates Danco's "concrete, personalized" and specific "property interest," which is "the most elementary type of right that Rule 24(a) is designed to protect." *Texas*, 805 F.3d at 658 (citation omitted).

Impairment of Interest. Danco "need only show that if [it] cannot intervene, there is a possibility that [those] interest[s] could be impaired or impeded." *La Union del Pueblo Entero v. Abbott*, 29 F.4th 299, 307 (5th Cir. 2022) (citing *Brumfield v. Dodd*, 749 F.3d 339, 344-345 (5th Cir. 2014)). Danco satisfies that "liberal[]" and "generous" standard. *See Edwards v. City of Houston*, 78 F.3d 983, 1004-05 (5th Cir. 1996). The Plaintiff States seek to remove Mifeprex from the market entirely or impose significant changes to Mifeprex's current regulatory approval. Excluding Danco from this litigation would create a situation in which Danco "would be prevented from ever being heard in a lawsuit that has the potential to end" or upend its product's regulatory-approval status. *John Doe No. 1 v. Glickman*, 256 F.3d 371, 380 (5th Cir. 2001); *see also NextEra*, 2022 WL 17492273, at *4 ("a party's interest in a regulatory scheme 'is impaired by the *stare decisis* effect of the district court's judgment' as to the scheme's validity") (quoting *Espy*, 18 F.3d at 1207).

Inadequate Representation. Finally, Danco satisfies the "minimal" burden of showing "that representation of [its] interest" by the current parties " 'may be' inadequate." *Entergy*, 817 F.3d at 203 (citation omitted). The Fifth Circuit presumes adequate representation only when an "existing party 'is a governmental body or officer charged by law with representing the interests' of the movant" or "when the intervenor 'has the same ultimate objective as a party to the lawsuit.' " *Louisiana v. Burgum*, 132 F.4th 918, 922 (5th Cir. 2025) (citation omitted); *see also Texas*, 805 F.3d at 661-662. FDA is certainly not charged with generally protecting drug manufacturers' interests or specifically protecting Danco's interests. And FDA's filings here and in the two other related lawsuits make clear that FDA's "interests diverge" from Danco's in several material ways that are "germane to the case." *Burgum*, 132 F.4th at 922 (quotation marks omitted); *see Louisiana* ECF No. 51; *Missouri* ECF No. 293-1.

As explained above, Danco has a distinct commercial interest in FDA's approval decisions pursuant to which Danco has sold its product for years. Danco would face significant economic losses if Mifeprex's original approval or its use conditions were enjoined or vacated, even for a short period. Danco's understanding is that the company cannot act unilaterally to put new or

revised conditions of approval in place, or even revert to those that pre-existed the 2023 REMS. *See* Long Decl. ¶¶ 17-22. Danco is committed to defending the 2000 approval, 2016 changes, and 2023 REMS on all available grounds. FDA, which initiated a review of the mifepristone REMS in September 2025 and has described to this Court the competing demands the agency faces across multiple litigations and citizen petitions, *see* ECF No. 20-1 at 8, 10, does not share Danco's financial or practical interests in the 2000 approval, 2016 changes, or the 2023 REMS. Instead, FDA seeks to exercise its regulatory discretion while "bear[ing] in mind broader public-policy implications" of its decisions. *Berger v. N.C. State Conf. of the NAACP*, 597 U.S. 179, 196 (2022); *see also Espy*, 18 F.3d at 1208 (noting disunity of interests where "government must represent the broad public interest, not just the economic concerns of" regulated entities).

Before the Plaintiff States filed this case, FDA announced that it would undertake a review of the mifepristone REMS. *See generally* Kennedy Letter. Secretary Kennedy instructed FDA to "conduct a study of the safety of the current REMS, in order to determine whether modifications are necessary." *Id.* at 1. This announcement questioned the consideration and scientific evidence supporting the 2023 REMS approval, asserting that reconsideration by the Department of Health and Human Services (HHS) "is informed by the lack of adequate consideration underlying the prior REMS approvals, and by recent studies raising concerns about the safety of mifepristone as currently administered." *Id*. at 1-2. Danco strongly disagrees with these statements, which come as FDA is currently under a court order to reconsider some aspects of the 2023 REMS that another court found *overly* restrictive. *See Purcell v. Kennedy*, No. 1:17-cv-00493, 2025 WL 3101785, at *1-2 (D. Haw. Oct. 30, 2025). Regardless, FDA's "reevaluation" constitutes exactly the kind of "conduct showing that the [FDA] inadequately represent[s]" Danco's interests. *Burgum*, 132 F.4th at 923 (discussing *Trbovich v. United Mine Workers of Am.*, 404 U.S. 528, 536-537 (1972), and *Epsy*, 18 F.3d at 1208).

FDA's requests for a stay in this and two other cases involving mifepristone lay bare the difference in the parties' legal positions. As FDA observes, it has "concluded that the best path forward is for the agency to undertake a new review based on the evidence before the agency."

ECF No. 20-1 at 3; *see also Louisiana* ECF No. 51 at 3; *Missouri* ECF No. 293-1 at 7. FDA's filings to date in Louisiana have not defended FDA's actions related to mifepristone on the merits. *Louisiana* ECF No. 50-1 at 9-20. Danco, in contrast, raised zone-of-interest, exhaustion, ripeness, and merits defenses that are not part of FDA's filing. *See Louisiana* ECF No. 230-1 at 13-20. These differences clearly rebut any presumption of adequate representation. *See La Union del Pueblo Entero*, 29 F.4th at 308-309; *Burgum*, 132 F.4th at 923 (noting representation is inadequate where intervenor "wishe[s] to introduce" distinct evidence, seek distinct "remedies," and make distinct "legal arguments"); *Miller v. Vilsack*, No. 21-11271, 2022 WL 851782, at *3-4 & n.4 (5th Cir. Mar. 22, 2022) (per curiam). Indeed, the *Louisiana* Plaintiffs withdrew their objection to Danco's intervention motion "in light of" FDA's "refusal to defend" the 2023 REMS on the merits, *Louisiana* ECF No. 111 at 1 n.1, and the district court granted Danco intervention as of right, *Louisiana* ECF No. 229; *accord Franciscan All., Inc. v. Azar*, 414 F. Supp. 3d 928, 935 (N.D. Tex. 2019) (O'Connor, J.) (holding that government's position that rule is "unlawful under the APA" "demonstrat[es] they will not adequately represent Putative Intervenors' interests").

Courts regularly find that drug manufacturer interests are not adequately represented by FDA in far less dramatic circumstances. *See, e.g.*, *Apotex, Inc. v. Daiichi Sankyo, Inc.*, 781 F.3d 1356, 1361 (Fed. Cir. 2015) (manufacturer has a "right to be a party in th[e] case because of its obvious stake in" a dispute contesting market exclusivity period); *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1076 (D.C. Cir. 1998) (manufacturer of brand-name drug "was entitled to intervene as of right" into case challenging FDA's approval of a generic); *Apotex Inc. v. FDA*, 508 F. Supp. 2d 78, 80 n.2 (D.D.C. 2007) (drug manufacturer permitted to intervene as of right "because the plaintiff seeks to set aside the FDA's decision as to its approval status" and the manufacturer "has a financial interest in [maintaining] its exclusivity period that is not . . . shared by the public"). Danco is entitled to intervene in this case as of right under Rule 24(a).

II. Alternatively, This Court Should Grant Permissive Intervention.

A court may also "permit anyone to intervene who" files a "timely motion" and "has a claim or defense that shares with the main action a common question of law or fact." Fed. R. Civ.

P. 24(b)(1)(B). In acting on the request, the court "may consider" some of the same criteria found in Rule 24(a), such as "whether the intervenors' interests are adequately represented by other parties," whether intervention will "unduly delay the proceedings or prejudice" the parties, and whether intervention may aid the case's development. *Kneeland v. Nat'l Collegiate Athletic Ass'n*, 806 F.2d 1285, 1289 (5th Cir. 1987); *see New Orleans Pub. Serv., Inc. v. United Gas Pipe Line Co.*, 732 F.2d 452, 472 (5th Cir. 1984) (courts consider whether intervenors "will significantly contribute to full development of the underlying factual issues") (quotation marks omitted).

Danco meets these requirements. It has timely moved for leave to intervene such that granting this motion would not prejudice the original parties or delay this case. Further, Danco's interest in protecting the continued availability of Mifeprex, under the current REMS, unquestionably shares both questions of law and fact in common with this case. Indeed, the *Alliance* court concluded the same when it permitted Danco to intervene in that litigation. *See Alliance* ECF No. 33 at 3.

Danco's participation will also materially aid the development of key legal issues. Among other things, Danco's briefing will address this Court's subject-matter jurisdiction; the standards imposed on FDA by the APA; and the factual record that informed FDA's decisions to approve Mifeprex in 2000, the 2016 changes, and the 2023 REMS. These issues are core to resolving the Plaintiff States' challenges. And unlike FDA—which must consider broader institutional interests and triangulate its defense between HHS's expressed policy concerns and FDA's obligation under the *Purcell* remand order—Danco is unencumbered in raising all available arguments, both on threshold grounds and on the merits. Danco also is uniquely positioned to present arguments about economic harm and its supply chain disruptions.

Danco's interest is just as germane to this litigation as it was in the *Alliance* case—where Danco participated in briefing and oral argument at every stage, from the district court's proceedings through the Supreme Court. Danco's role as an intervenor continues in the *Missouri* States action that was transferred to Missouri, and the court in the *Louisiana* litigation granted Danco intervention as of right. Like in *Alliance*, *Missouri*, and *Louisiana*, the expansive relief the

Plaintiff States seek here—forcing a product off the market or altering its FDA-approved conditions—underscores the need for Danco's intervention. As noted above, Danco has a financial interest in its continued ability to market its product and in the pharmacy dispensing model it has relied on for years. Danco would be significantly and immediately harmed if the relief that the Plaintiff States seek were granted. FDA will not suffer this same type of harm, since it is Danco (not the government) that is charged with complying with drug approval and REMS conditions. And, unlike Danco, FDA has not currently offered a thorough defense of its actions to forestall that harm.

Accordingly, even if the Court were not inclined to grant Danco's motion to intervene as of right, it should grant Danco's request for permissive intervention so Danco can adequately defend its interests in this case.

CONCLUSION

For these reasons, Danco respectfully requests that this Court grant its Motion to Intervene.

Respectfully submitted,

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Counsel for Danco Laboratories, LLC

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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Wayne L. Robbins, Jr.

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*.	Civ. No.: 7:25-cv-00126-O Chief Judge Reed O'Connor

DECLARATION OF ABIGAIL LONG

I, Abigail Long, declare under penalty of perjury as follows:

1. I am over the age of 18, am competent to testify as to the matters herein, and make this declaration based on my personal knowledge.

2. I am an employee of Danco Laboratories, LLC. Based on my position as Vice President of Marketing and Operations at Danco, I have personal knowledge of the matters herein.

3. Danco is a small, privately held pharmaceutical company that holds the New Drug Application (NDA) for Mifeprex. As the sponsor of the NDA for Mifeprex, Danco has the right under the Federal Food, Drug, and Cosmetic Act to market and distribute Mifeprex. Danco holds no other NDAs and does not do any other business other than marketing and distributing Mifeprex.

4. Danco has held the NDA and been responsible for the distribution of Mifeprex in the United States for over 25 years.

5. Plaintiffs in this case challenge many of the same FDA decisions as the plaintiffs challenged in *FDA v. Alliance for Hippocratic Medicine*. As I explained in my declarations filed

in the Fifth Circuit and U.S. Supreme Court in that case, *see* Exs. 1-2, the relief Plaintiffs seek here would impose numerous harms on Danco.

6. If this Court issues an order withdrawing FDA's 2000 approval of Mifeprex, Danco would no longer be able to distribute Mifeprex.

7. From the time Danco acquired the rights to distribute and market Mifeprex, Danco has relied on the fact that Congress expressly granted pharmaceutical companies due process rights that generally apply before a pharmaceutical product can be withdrawn from the market. Danco, like other pharmaceutical companies, relies on the fact that FDA cannot simply change its mind about a previous approval; it must invoke specific procedures to revoke a previously granted approval.

8. Because Danco has only a single pharmaceutical product, any action that prevents Danco from distributing its product would result in the effective closure of our business. Danco would no longer have the ability to market its sole product and would no longer be generating any revenue.

9. If the 2000 approval of Mifeprex were withdrawn, the suppliers, manufacturers, distributors and pharmacies associated with Mifeprex will also be negatively affected by the loss of business.

10. Other court ordered changes regarding Mifeprex would also negatively affect Danco. The approval of Mifeprex was subject to a number of restrictions and requirements about how the drug is distributed, which have been incorporated into a Risk Evaluation and Mitigation Strategy (REMS) since 2008. The specific provisions of the REMS have been subject to revisions over the years, including in 2016 and 2023.

11. The 2016 changes to the conditions of use and REMS for Mifeprex were extensive. They include:

a. Approving the drug for use up to 70 days' gestation, from the initially approved 49 days.

b. Changing the approved dose of Mifeprex from 600 mg to 200 mg.

c. Changing the approved dose of misoprostol from 400 mcg to 800 mcg, and the route of administration from oral to buccal.

d. Changing the time interval between dosing Mifeprex and misoprostol from 48 hours to 24-48 hours.

e. Removing the requirement that the patient take the drugs at the medical facility.

f. Decreasing the number of required office visits from three to one.

g. Permitting non-physicians with state-authorized prescribing authority to be certified prescribers.

h. Requiring the REMS-specific safety reporting (as opposed to the generally applicable adverse event reporting required by FDA regulation, which also apply) to include only patient deaths.

12. The 2023 revisions primarily removed a requirement that the drug be dispensed in-person by the prescribing healthcare provider or someone under their supervision, allowing the drug to be dispensed by certified pharmacies in response to a prescription from a certified prescriber, either through retail locations or by mail or courier service (such as Federal Express).

13. Since the 2023 REMS took effect, Danco has certified retail pharmacies, both pharmacy chains and independent pharmacies, to dispense Mifeprex in accordance with the terms of the REMS.

14. The new conditions of use in the 2023 REMS required changes to multiple, related materials, including:

a. Prescribing Information

b. Medication Guide

c. Patient education materials

d. Patient Agreement

e. REMS document and supporting document

f. Prescriber Agreement

g. Danco website

h. Promotional materials

i. Contracts with suppliers and distributors.

15. To my knowledge, no court-ordered stay or injunction of a REMS for any product has ever taken effect. As a result, there is substantial uncertainty about what that would mean for a sponsor, for FDA, for a health care provider, and for patients.

16. In endeavoring to understand what FDA would expect of Danco if the court were to order the requested stay or injunction of the 2016 or 2023 changes or REMS, I have reviewed the declaration that FDA submitted to the Supreme Court of the United States in connection with seeking emergency relief in the Alliance litigation

17. That declaration provided FDA's response to the Fifth Circuit's "assum[ption] that the conditions of use for Mifeprex, including the REMS, could simply snap back to what they were prior to" any stayed approvals of labeling changes or REMS modifications. Declaration of Janet Woodcock ¶ 10, Emergency Stay Application, Appendix 113a, *FDA v. Alliance for Hippocratic Medicine*, Supreme Court No. 23A902 ("Stay Appendix").[1] The declaration stated that "[t]he reality is far more disruptive" than simply reverting to a previously approved REMS. *Id.*

18. The FDA declaration stated that, if the court were to invalidate certain revisions to the REMS, "the sponsor would be required to submit a supplement to revise" all of the documents stating the approved conditions of use "and obtain FDA approval in order to distribute a product whose labeling conforms" with earlier iterations of the FDA's "conditions of approval (including the REMS)" and the court orders. *Id.* ¶ 13, Stay Appendix 114a.

[1] This declaration is available on the Supreme Court's docket at https://www.supremecourt.gov/DocketPDF/22/22A902/263491/20230414103258942_Alliance%20for%20Hippocratic%20Med%20%20application.pdf.

19. The FDA declaration further stated that "[t]he combination of the District Court's and Fifth Circuit's orders thus arguably requires all current prescribers to be re-certified." *Id.* ¶ 14, Stay Appendix 114a.

20. The FDA declaration stated that absent a stay of the lower court orders from the Supreme Court, "the sponsors' drug products immediately would become misbranded and thus unlawful to introduce in interstate commerce." *Id.* ¶ 15, Stay Appendix 115a.

21. Speaking specifically to Mifeprex, the FDA declaration said "as a result of the courts' orders, Mifeprex … will be misbranded until the sponsor submits a supplemental application proposing changes to the conditions of use consistent with the courts' orders, FDA reviews and approves that supplement, and the sponsor incorporates those changes into the labeling and packaging for the product. The sponsor would also need to post and disseminate new Prescriber and Patient Agreement Forms and, as noted above, most prescribers would need to become recertified." *Id.*

22. The FDA declaration addressed the impact of enjoining several FDA decisions, including the 2016 changes and 2021 non-enforcement decisions. *Id.* ¶ 10. I do not know for sure whether FDA's view of the need to submit a supplemental application, obtain FDA approval, and incorporate those changes into the labeling and packaging would apply in the context of Plaintiffs' challenges to several other decisions, including the 2023 REMS, or whether providers would have to be recertified. Based on the FDA declaration, however, the company's current understanding is that these steps must be taken in response to any stay or injunction of the 2023 REMS.

23. Consistent with FDA's view as stated in its Supreme Court declaration and Danco's understanding of the applicable statutory provisions on which FDA's view is presumably based, Danco would be required to revise all of the materials listed in paragraph 14 above, and we expect it would require prescribers to be re-certified and policies and procedures in place with distributors to be substantially revised. Under the statements in FDA's declaration, it is Danco's current understanding that Danco would not be legally authorized to distribute

Mifeprex unless and until all of those steps have been completed, which would take time to accomplish.

24. Danco would also be required to notify all Certified Pharmacies that they are effectively de-certified and no longer able to order Mifeprex or to fill or dispense Mifeprex to patients. Danco would need to undertake an administrative and logistical process for Certified Pharmacies to return any product to Danco's distributors. Danco's understanding is that there are fewer options for in-person clinic appointments given the increase in telemedicine and pharmacy availability over the past several years. As a result, Danco's understanding is that the removal of pharmacies from the distribution chain would have severe impacts on women seeking care, given the reduced number of clinics, and leading to women being underserved.

25. Like all other NDA holders, Danco is (and has always been) required to report to FDA all adverse drug experiences from any source at least annually and all adverse drug experiences that are both serious and unexpected within 15 days of receipt. Anyone can report an adverse drug experience to Danco or directly to FDA, and the approved Mifeprex labeling includes Danco's telephone number and email and FDA's telephone number and website for reporting such events.

26. In addition, under the current REMS, Mifeprex prescribers have an additional reporting requirement. They are required to report to Danco—and Danco then is required to report to FDA within 15 days—any patient deaths. This additional reporting requirement has been included in each iteration of the REMS applicable to Mifeprex. I understand that this additional reporting requirement is highly atypical, even for products subject to a REMS.

27. Because Danco has only a single pharmaceutical product, any action that prevents dispensing of Danco's product or affects the terms of distribution would significantly and negatively affect Danco. If, as a result of changes to the approved conditions of distribution and/or the process for adopting such changes, Danco is prevented from distributing our product, we will not be generating revenue. The failure to generate revenue for anything longer than a de minimis period of time would cause grave concerns and could result in the effective closure of

our business. The impacts to patient care in states that have taken a different approach than Florida and Texas would also be immediate and substantial.

I declare under the penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: March 10, 2026

Abigail Long

Exhibit 1

Declaration of Abigail Long in support of Danco Laboratories, LLC's motion to stay in *Alliance for Hippocratic Medicine v. FDA*, No. 23-10362 (5th Cir. Apr. 10, 2023), ECF No. 29

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

Alliance for Hippocratic Medicine, *et al.*, *Plaintiffs-Appellees,* v. U.S. Food and Drug Administration, *et al.*, *Defendants-Appellants,* and Danco Laboratories, LLC, *Intervenor-Appellant.*	No. 23-10362

DECLARATION OF ABIGAIL LONG

I, Abigail Long, declare under penalty of perjury as follows:

1. I am over the age of 18, am competent to testify as to the matters herein, and make this declaration based on my personal knowledge.

2. I am an employee of Danco Laboratories, LLC. Based on my position as Director of Marketing and Public Affairs at Danco, I have personal knowledge of the matters herein.

3. Danco is a small, privately held pharmaceutical company that holds the New Drug Application (NDA) for Mifeprex. As the sponsor of the NDA for Mifeprex, Danco has the right under the Federal Food, Drug, and Cosmetic Act to

market and distribute Mifeprex. Danco holds no other NDAs and does not do any other business other than marketing and distributing Mifeprex.

4. Danco has held the NDA and been responsible for the distribution of Mifeprex in the United States for over 20 years.

5. The District Court's ruling states that it is "staying" FDA's approval of Mifeprex under Section 705 of the APA. I am not aware of any circumstance in which a court has ever "stayed" FDA's approval of a pharmaceutical product. There is no statutory or regulatory guidance for us about what a judicial "stay" of FDA's approval means or what obligations it imposes on us or FDA. For example, there is no guidance about whether Mifeprex will remain in FDA's Orange Book as an approved drug.

6. The District Court's ruling also states that if the appeals court disagrees with the "stay" analysis, the District Court would have alternatively ordered Defendants to suspend Mifeprex's approval and all subsequent FDA actions that the Plaintiffs challenge until reaching a decision on the merits. I am not aware of any circumstance in which a court has ever suspended an FDA approval of a pharmaceutical product, and the District Court cited no authority for this alternative remedy. There is no statutory or regulatory guidance for us about what a judicial "suspension" of FDA's approval means or what obligations it imposes on us or FDA.

7. From the time Danco acquired the rights to distribute and market Mifeprex, Danco has relied on the fact that Congress expressly granted pharmaceutical companies due process rights that generally apply before a pharmaceutical product can be withdrawn from the market. Danco, like other pharmaceutical companies, relies on the fact that FDA cannot simply change its mind about a previous approval; it must invoke specific procedures to revoke a previously granted approval. *See* 21 U.S.C. § 355(e); 21 C.F.R. § 314.150.

8. The District Court's order appears designed to preclude the distribution of mifepristone for the indeterminate amount of time between now and a final judgment on the merits. My understanding is that both the "stay" and alternative "suspension" remedies give the Plaintiffs a greater remedy than would be available at the time of a judgment on the merits, even if that judgment were in Plaintiffs' favor, because the ordinary rules of administrative law require remand without vacatur.

9. Innovation and investment in the pharmaceutical industry will be negatively impacted if courts can second-guess FDA's scientific judgment and negate long-existing approvals without first returning any identified issues to FDA for its consideration and without regard for companies' statutory rights.

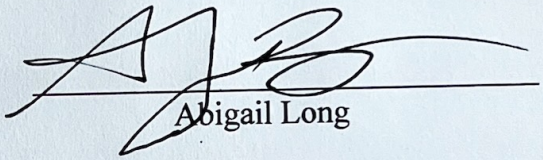
10. My understanding is that FDA's approval of Mifeprex as safe and effective is, and has been, under FDA's REMS authority since 2008.

11. Because Danco has only a single pharmaceutical product, if Danco is prevented from distributing its product, that will result in the effective closure of our business because Danco would no longer be generating any revenue.

12. If the approval of Mifeprex remains "stayed" or "suspended" pending appeal, the suppliers, manufacturers, distributors, and pharmacies associated with Mifeprex will also lack clarity on their obligations and responsibilities, given the unprecedented nature of the District Court's remedies. These suppliers, manufacturers, distributors, and pharmacies will be negatively impacted by the loss of business.

I declare under the penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

April 9, 2023



Abigail Long

Exhibit 2

Declaration of Abigail Long in support of Danco Laboratories, LLC's application for stay in *Danco Laboratories, LLC v. Alliance for Hippocratic Medicine*, No. 22A901 (U.S. Apr. 14, 2023)

IN THE SUPREME COURT OF THE UNITED STATES

Danco Laboratories, LLC, *Applicant,* v. Alliance for Hippocratic Medicine, *et al.*, *Respondents*	No. 22A___

DECLARATION OF ABIGAIL LONG

I, Abigail Long, declare under penalty of perjury as follows:

1. I am over the age of 18, am competent to testify as to the matters herein, and make this declaration based on my personal knowledge.

2. I am an employee of Danco Laboratories, LLC. Based on my position as Director of Marketing and Public Affairs at Danco, I have personal knowledge of the matters herein.

3. Danco is a small, privately held pharmaceutical company that holds the New Drug Application (NDA) for Mifeprex. As the sponsor of the NDA for Mifeprex, Danco has the right under the Federal Food, Drug, and Cosmetic Act to market and distribute Mifeprex. Danco holds no other NDAs and has no business other than marketing and distributing Mifeprex.

4. Danco has held the NDA and been responsible for the distribution of Mifeprex in the United States for over 20 years.

5. The Fifth Circuit's ruling upholds the District Court's "stay" of the 2016 changes to the Mifeprex approval, the 2019 approval of generic mifepristone, and the 2021 decision to exercise enforcement discretion with respect to the in-person dispensing requirement.

6. The ruling also implies that the court "stays" the 2023 REMS modifications, which officially removed the in-person dispensing requirement and made other changes to the REMS. The District Court's ruling stated that Plaintiffs sought "a preliminary injunction ordering Defendants to withdraw or suspend: (1) FDA's 2000 Approval and 2019 Approval of mifepristone tablets, 200 mg, thereby removing both from the list of Approved Drugs; (2) FDA's 2016 Changes and 2019 Generic Approval; and (3) FDA's April 12, 2021, Letter and December 16, 2021, Response to the 2019 Petition concerning the in-person dispensing requirement for mifepristone." District Court Preliminary Injunction Order at 5. There was no express challenge by Plaintiffs during the preliminary injunction proceedings to the 2023 REMS modification. The District Court does not refer to or cite the 2023 REMS modification in its ruling.

7. I do not understand what legal basis the Fifth Circuit has to expand the "stay" issued by the District Court to include the 2023 REMS modifications when the only question before the Fifth Circuit was whether to leave the District Court's ruling in effect during the appeal. I also do not understand the effect of the Fifth Circuit's order in this regard.

8. I am not aware of any circumstance in which a court has ever "stayed" changes to an FDA approval of a pharmaceutical product. There is no statutory or regulatory guidance for us about how to revert to a prior NDA or prior version of the REMS, whether in whole or in part.

Effect of the Fifth Circuit's Order:

9. The 2016 changes to the conditions of use for Mifeprex were extensive and did much more than amend certain REMS requirements. They include:

a. Approving the drug for use up to 70 days' gestation, from the initially approved 49 days.

b. Changing the approved dose of Mifeprex from 600 mg to 200 mg.

c. Changing the approved dose of misoprostol from 400 mcg to 800 mcg, and the route of administration from oral to buccal.

d. Changing the time interval between dosing Mifeprex and misoprostol from 48 hours to 24-48 hours.

e. Removing the requirement that the patient take the drugs at the medical facility.

f. Decreasing the number of required office visits from three to one.

g. Permitting non-physicians with state-authorized prescribing authority to be certified prescribers.

h. Requiring the REMS-specific safety reporting (as opposed to the generally applicable adverse event reporting required by FDA regulation, which also apply) to include only patient deaths.

10. The 2023 REMS revisions primarily removed the in-person dispensing requirement and provided for dispensing by certified pharmacies.

11. These new conditions of use required changes to multiple, related materials, including:

a. Prescribing Information

b. Medication Guide

c. Package Insert

d. Product packaging

e. Patient education materials

f. REMS document

g. Prescriber Agreement

h. Patient Agreement

i. Danco website

j. Promotional materials

k. Contracts with suppliers and distributors.

12. Complying with the Fifth Circuit's order would require revisions to all of these materials, and we expect would require prescribers to be re-certified and the policies and procedures in place with distributors to be substantially revised. Much of this would require FDA approval before it could be implemented. All of this would be time-consuming, and conceivably would leave Mifeprex misbranded – and its distribution in interstate commerce therefore prohibited – for an extended period of time.

13. Moreover, the order of the Federal District Court for the Eastern District of Washington (Judge Rice) expressly *prohibits* FDA from approving any changes with regard to how Mifeprex is labeled, distributed, prescribed, dispensed and used in the 17 states and District of Columbia that are parties in that suit. This creates serious uncertainty, at best, as to whether FDA can approve the revisions necessary to comply with the Fifth Circuit's order.

14. If FDA cannot approve those changes, Danco will be forced into a completely untenable position: it will have to either discontinue distribution of Mifeprex in the 33 states not covered by the Washington federal court injunction, or distribute Mifeprex there that is not accompanied by FDA-approved revisions to the materials that must be revised under the Fifth Circuit's order.

15. The Fifth Circuit's ruling provided Danco no guidance on how it can comply with the competing court rulings in terms of how Mifeprex is labeled, packaged, promoted, distributed, prescribed and dispensed, among other things. This will certainly affect whether (or how) Mifeprex is available to patients, and whether Danco remains in compliance with its own obligations under the REMS, the terms of FDA's approval of Mifeprex, and applicable laws and regulations more generally. Danco is well aware that failing to meet these obligations, requirements and responsibilities can have statutory, regulatory, and administrative repercussions, including criminal prosecution, administrative fines, and product seizures.

16. As listed above, the 2016 changes included revising the dosing regimen to 200 mg of mifepristone orally followed by 800 mcg of misoprostol buccally, 24-48 hours later. Previously, the dosing regimen was 600 mg of mifepristone orally followed by 400 mcg misoprostol orally, 48 hours later. The Fifth Circuit's stay puts Danco in the position of affirmatively telling providers to prescribe *three times* the amount of Mifeprex that is needed for a safe and effective medication abortion.

17. The 2023 REMS materials, including the prescriber and pharmacy certification process, are based on the 2023 REMS modifications. There are currently 13 pharmacies that are certified to dispense Mifeprex, consistent with the 2023 REMS. Absent a stay, Danco will be unable or chilled from selling Mifeprex to those pharmacies because it does not know whether it may do so, as the 2023 REMS and the Washington federal court order contemplates, or whether it may not do so, as the Fifth Circuit's order mandates.

18. Danco's current distribution model is also premised on the 2023 REMS. Danco cannot run its business without knowing what precise changes the company must make in its distribution model in order to be in compliance with the portion of the District Court's injunction that remains in effect during the Fifth Circuit appeal of the preliminary injunction ruling.

19. Danco cannot determine how the decision from the Eastern District of Washington relates to this litigation, and whether Danco is able to comply with both court orders, and/or whether Danco will be required to operate under two

potentially conflicting sets of REMS and accordingly establish two sets of supply and distribution, two sets of literature, and the like.

20. Danco is receiving multiple inquiries from certified prescribers and healthcare settings seeking advice and direction on whether Mifeprex will continue to be available to them, so they can prepare to treat patients with the necessary timeliness. Danco is at a loss of how to respond. By way of example, Danco does not know how it should interact with and advise certified providers who practice in a state covered by the Washington federal court's decision, let alone those who practice both in such a state and also a state not in that litigation. During the Fifth Circuit appeal proceedings, must Danco re-certify that provider using the pre-2016 Provider Certification process, as the Fifth Circuit order would contemplate, or is the current certification sufficient, as the Washington ruling suggests? Should Danco advise providers in that situation that they are governed by different obligations depending on the geographic location of the clinic or facility where they see each patient? What version of the Medication Guide should Danco tell providers to give to patients? This is an untenable situation that threatens Danco's ability to conduct its business in a manner that complies with applicable law and that is commercially feasible.

The Significant Uncertainty Regarding the Fifth Circuit's Order Threatens and Will Chill Danco's Continued Operation

21. As a direct result of the Fifth Circuit's order and the confusion it has engendered, it is unclear to me that Danco will be willing and able to continue distributing Mifeprex. By intention, FDA regulation of pharmaceuticals is national

in scope. It is inimical to federal regulation of pharmaceuticals for there to be anything other than a single set of conditions under which an FDA-approved prescription drug is approved and made available. Danco is simply not set up to market and distribute Mifeprex simultaneously under two separate REMS programs or, more broadly, conditions of use.

22. Because Mifeprex is Danco's only product, if we are prevented from distributing our product, we will not be generating revenue. The failure to generate revenue will result in the effective closure of our business.

23. Even if Danco is able to continue operating, reverting to the pre-2016 conditions of use for Mifeprex will substantially disrupt Danco's business because it cannot make those adjustments before the District Court's stay of its ruling expires later today, Friday, April 14.

24. Because of the confusion engendered by the Northern District of Texas and Fifth Circuit's orders, as well as the conflicting order from the Eastern District of Washington, it is unclear to me how Danco should handle the following situations:

a. Must Danco make significant changes to the manufacturing and packaging of the product to supply three tablets in each box? If so, what would those changes include?

b. If labeling changes are being made, will Danco be able to distribute finished product with the currently approved labeling that is sitting

with a distributor or third-party logistics provider? Is the answer different in different states?

c. Danco has thousands of certified prescribers across the country, many of whom are contacting the company to ask whether they will be able to continue obtaining Mifeprex, whether they will be permitted to continue prescribing and dispensing it, and under what conditions (*e.g.*, what dose is approved, what Medication Guide should be provided to patients). The dueling court rulings give no guidance on how Danco can remain in compliance with the law when responding.

d. Will Danco face enforcement action – which can include criminal liability, civil fines, product seizures and injunctions – for distributing its product in interstate commerce if the company's certified providers, or at least certified providers in certain states, have signed only the current REMS Prescriber Agreement.

e. To what extent must Danco revise its website to revert to pre-2106 conditions of use, and will we be required to maintain separate websites by state?

f. Will Danco be required to submit a supplemental new drug application (sNDA) to amend the Prescribing Information, Medication Guide, REMS documentation, among other things, to revert to the pre-2016 conditions of use? Should that sNDA ask for different rules for different states, which is something FDA has never before approved?

g. What can Danco do in the likely months (or more) before FDA approves any such supplement, assuming it can do so given the Eastern District of Washington's order? (The 2023 REMS revisions, which were more limited in scope than what would be required by the Fifth Circuit's order, took more than a year to be approved.)

h. How will Danco renegotiate with its vendors and contractors, including its contract manufacturers, distributors, and pharmacies, to implement these changes, especially if we have different conditions in two different sets of states?

i. How will Danco certify new providers while the appeal is pending? (Danco has certified 72 new providers to date in 2023 in various states around the country using the certification process in the 2023 REMS.)

25. Although the potentially conflicting decision from the Eastern District of Washington exacerbates many of these issues, the Fifth Circuit's order purporting to instruct Danco to return to a pre-2016 state of affairs independently will cause Danco significant confusion and irreparable harm. These injuries are distinct from any that flowed from the District Court's ruling.

26. The Fifth Circuit's order will require Danco to make material changes to how Mifeprex is packaged, labeled, distributed and the product's conditions of use. These changes will need to be accomplished primarily by revisions to the REMS, which will require preparation and submission of an sNDA and FDA review of the same. The process of sNDA review and approval typically requires back and

forth between the company and the agency, and can be expected to take months, at the very least. Danco might very well be forced to halt operations until the sNDA is approved.

27. Further, this "stay" could be rendered ineffective or otherwise amended during the course of the litigation, which would create additional disruption and require further changes to the approval. Switching back and forth between the 2023 REMS, pre-2016 changes, and another potential option based on the appeal of the "stay" would be particularly burdensome, generating confusion for Danco, its vendors and contractors, healthcare providers, and patients.

28. The Northern District of Texas ruling, as partially affirmed by the Fifth Circuit, completely upends the status quo, and in a way that is not supported by the facts or the law, and that would be hugely disruptive to all concerned.

29. My declaration submitted to the Fifth Circuit focused on the ruling being appealed, which stayed the 2000 approval. Given the drastic nature of the district court's injunction, there was no reason to address the harms and complexities that would result from a stay of only the 2016 and forward FDA decisions.

30. A full stay of the order of the Northern District of Texas pending appeal would allow Danco time to consult with FDA and determine how best to implement the ruling of the District Court and/or the Fifth Circuit, if either were to stand following further appellate review. It would also allow Danco time to

determine how best to accommodate the two apparently conflicting court orders regarding the 2023 REMS.

I declare under the penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: April 14, 2023

Abigail Long

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.

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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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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

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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