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

STATE OF FLORIDA, *et al.*, Plaintiffs, v. U.S. FOOD AND DRUG ADMINISTRATION, *et al.*, Defendants.	Case No. 7:25-cv-00126-O

GENBIOPRO, INC.'S MOTION TO INTERVENE

Pursuant to Federal Rule of Civil Procedure 24, GenBioPro, Inc. ("GenBioPro") hereby moves to intervene as a defendant in this action. As detailed in the accompanying Memorandum of Law, GenBioPro has protectable interests in this action that may be impaired by the disposition of the case, and which are not adequately represented by Defendants. GenBioPro therefore is entitled to intervene as of right under Rule 24(a). Alternatively, at a minimum, the Court should grant GenBioPro intervention on a permissive basis under Rule 24(b) because GenBioPro's prospective defenses share common questions of law and fact with the existing action and no party would suffer prejudice from GenBioPro's intervention.

Pursuant to Federal Rule of Civil Procedure 24(c), GenBioPro also attaches hereto a Motion to Dismiss.

GenBioPro has conferred with the existing parties regarding their positions on this motion. Plaintiffs take no position on intervention, but reserve the right to oppose once they have reviewed the motion and accompanying Rule 24(c) pleading. Defendants take no position on intervention.

For the foregoing reasons, and those set forth in the accompanying Memorandum of Law, GenBioPro respectfully requests that the Court grant its motion to intervene as a defendant in this action.

Dated: March 13, 2026

Respectfully submitted,

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CERTIFICATE OF CONFERENCE

I certify that on March 9 and March 12, 2026, counsel for GenBioPro conferred with counsel for Plaintiffs regarding this motion. Plaintiffs' counsel represented that Plaintiffs "take no position on the motion to intervene at this time," but that they "reserve their right to oppose the motion once they have reviewed it and the accompanying Rule 24(c) pleading." I further certify that counsel for GenBioPro conferred with Defendants' counsel on March 9, 2026. Defendants take no position on GenBioPro's motion to intervene.

/s/ Christopher M. Odell
Christopher M. Odell

CERTIFICATE OF SERVICE

I certify that on March 13, 2026, I electronically filed the foregoing Motion for Leave to Intervene using the CM/ECF system. Notice of this filing will be sent by operation of the Court's electronic filing system to all parties of record.

/s/ Christopher M. Odell
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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*.	Civil Action No. 7:25-cv-00126-O

BRIEF IN SUPPORT OF GENBIOPRO, INC.'S MOTION TO INTERVENE

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GenBioPro, Inc. respectfully submits this Memorandum of Law in Support of its Motion for Leave to Intervene pursuant to Rule 24 of the Federal Rules of Civil Procedure.

INTRODUCTION

This is one of three lawsuits filed by states seeking to vacate—on a nationwide basis—regulatory actions by the Food and Drug Administration ("FDA") related to mifepristone. In the other two cases, GenBioPro has already been granted intervention to protect the availability of the generic mifepristone it manufactures—a product that is foundational to its business and critical to healthcare for many Americans. GenBioPro has held an FDA-approved Abbreviated New Drug Application ("ANDA") to market generic mifepristone since 2019, and is one of only two U.S. manufacturers holding that generic approval. Sales of mifepristone represent the majority of the company's revenue.

In this Complaint, like in the other two cases, Plaintiffs Texas and Florida seek an order vacating various FDA actions that control the conditions under which mifepristone can be marketed, sold, prescribed, and distributed to patients, threatening serious harm to GenBioPro and the many Americans it serves. Plaintiffs specifically ask the Court to rescind FDA's 2019 approval of GenBioPro's generic mifepristone as safe and effective for its intended use. GenBioPro's stake in these issues is thus self-evident, as these other two courts—including one in this district—have recognized by granting intervention. *See All. for Hippocratic Med. v. FDA*, 2023 WL 11840559 (N.D. Tex. Feb. 6, 2023); *Missouri v. FDA*, 2025 WL 1223581, at *1 (N.D. Tex. Apr. 28, 2025); *Louisiana v. FDA*, No. 6:25-cv-01491-DCJ-DJA, at 1 (W.D. La. Feb. 24, 2026), ECF No. 229.

Here, GenBioPro meets all of the requirements for intervention as of right under Rule 24(a) in this lawsuit that seeks to void the ANDA that GenBioPro holds. This motion is timely; GenBioPro has a paradigmatic and clear interest in defending the approval of and regulatory regime governing its primary product; GenBioPro's interests would be impaired by Plaintiffs'

requested relief; and the existing parties will suffer no prejudice from intervention. Defendants also do not adequately protect GenBioPro's interests, as their request for a stay (or alternatively for dismissal) in this case amply illustrates. Specifically, in response to Plaintiffs' Complaint, Defendants have moved to stay the litigation based on a recently announced administrative review of what they call the "safety risks of mifepristone." ECF No. 20-1 at 3. In the related litigation, in response to Louisiana's motion to enjoin certain of FDA's actions challenged here, Defendants have declined to defend the merits of these actions at all.

At a minimum, permissive intervention under Rule 24(b) is appropriate. As Judge Kacsmaryk correctly found in one of the two predecessor cases, "GenBioPro's claim [had] a question of law or fact in common with the main action," as "GenBioPro seeks to protect its product's FDA approval" whereas "Plaintiffs challenge GenBioPro's product's FDA approval." *Missouri*, 2025 WL 1223581, at *6. Moreover, "intervention [would] not 'unduly delay or prejudice' [the State Plaintiffs'] rights" because it would "change nothing in the existing case schedule." *Id.* Each of those propositions is equally true in this case, and the Court should grant GenBioPro's motion.[1]

BACKGROUND

Approved by FDA as safe and effective for performing medical abortions up to ten weeks of gestation, mifepristone has been marketed and prescribed under the brand name Mifeprex for more than a quarter of a century, since 2000. Mifepristone's approval is subject to a set of distribution and administration conditions known as a "Risk Evaluation and Mitigation Strategy" or "REMS," which FDA has periodically revised and updated, including most recently in 2023.

[1] GenBioPro has conferred with the existing parties regarding their positions on this motion. Plaintiffs take no position on intervention, but reserve the right to oppose once they have reviewed the motion and accompanying Rule 24(c) pleading. Defendants take no position on intervention.

Compl. ¶ 188. When FDA approved GenBioPro's generic mifepristone ANDA in 2019, FDA subjected generic mifepristone to a single, shared REMS with Mifeprex. *See* 2019 FDA ANDA Approval Letter to GenBioPro (Apr. 11, 2019), ECF No. 1-6 at 694-700.

In November 2022, several individuals and organizations sued FDA and the U.S. Department of Health and Human Services in the Northern District of Texas challenging regulatory actions relating to mifepristone, dating back to the 2000 approval of Mifeprex. *FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 372-77 (2024). Mifeprex's manufacturer Danco intervened in the case without opposition. *See All. for Hippocratic Med.*, 2023 WL 11840559, at *1. Those plaintiffs sought a preliminary injunction or a stay of the effective dates of the challenged FDA actions. The district court entered the requested relief, which the Fifth Circuit largely affirmed, but the Supreme Court barred that order from taking effect. *Danco Lab'ys, LLC v. All. for Hippocratic Med.*, 143 S. Ct. 1075 (2023) (staying case pending resolution of petition for certiorari, and if granted, until judgment of the Court). Ultimately, the Supreme Court unanimously held that the plaintiffs lacked Article III standing. *All. for Hippocratic Med.*, 602 U.S. at 374.

While the appeal in that case was pending, the States of Missouri, Kansas, and Idaho intervened in the district court in an effort to bolster standing. On remand following the Supreme Court's ruling, the State plaintiffs amended their complaint; GenBioPro then moved to intervene to defend the challenged FDA actions, which Judge Kacsmaryk permitted under Rule 24(b). *Missouri*, 2025 WL 1223581, at *6.[2] In "a belated attempt to establish venue," Texas and Florida also sought intervention, which the Texas court denied. *Missouri v. FDA*, 2025 WL 2825980, at

[2] Although the *Missouri* court denied mandatory intervention under Rule 24(a)(2), the court ultimately granted GenBioPro permissive intervention under Rule 24(b), *see Missouri*, 2025 WL 1223581, at *4-6; Section II, *infra*.

*11-12 (N.D. Tex. Sept. 30, 2025). The court held that venue was improper and transferred the case to the Eastern District of Missouri. *Id.* at *12-13. Louisiana has also filed a similar challenge to FDA's current REMS framework; on February 24, 2026, the court there granted GenBioPro and Danco leave to intervene. *Louisiana v. FDA*, No. 6:25-cv-01491-DCJ-DJA, at 1 (W.D. La. Feb. 24, 2026), ECF No. 229.

On December 9, 2025, Texas and Florida filed this lawsuit against FDA challenging many of the same regulatory actions at issue in *Missouri*. Among other things, Plaintiffs allege that FDA acted arbitrarily and capriciously by approving Mifeprex in 2000, adopting labeling and regimen changes in 2016, approving GenBioPro's ANDA in 2019, and modifying mifepristone's dispensing and use conditions through the 2023 REMS. Plaintiffs seek declaratory and injunctive relief, asking the Court to permanently set aside, rescind, and vacate the challenged approvals and regulatory actions.

ARGUMENT

I. GenBioPro Is Entitled to Intervene As of Right Under Federal Rule 24(a)(2)

A party must be permitted to intervene in an action if it shows by "timely motion" that (a) "it has a protectable 'interest' in the action," (b) "the 'disposing of the action' could 'impair' its ability to protect that interest," and (c) "existing parties do not 'adequately represent' that interest." *Louisiana v. Burgum*, 132 F.4th 918, 922 (5th Cir. 2025) (quoting Fed. R. Civ. P. 24(a)(2)). Courts "should liberally construe the test for mandatory intervention" and should "allow intervention where no one would be hurt and the greater justice could be attained." *Rotstain v. Mendez*, 986 F.3d 931, 937 (5th Cir. 2021) (cleaned up); *see Entergy Gulf States La., L.L.C. v. EPA*, 817 F.3d 198, 203 (5th Cir. 2016) ("doubts resolved in favor of the proposed intervenor"); *Wal-Mart Stores, Inc. v. Tex. Alcoholic Beverage Comm'n*, 834 F.3d 562, 569 (5th Cir. 2016) (emphasizing "broad policy favoring intervention"). GenBioPro easily meets that standard here.

There is no question that GenBioPro's motion is timely. Plaintiffs filed this suit in December 2025, and the Court thereafter granted Defendants' unopposed motion to extend their response deadline to Plaintiffs' Complaint until March 13, 2026. ECF No. 19. Defendants have not answered the Complaint, the administrative record has not been produced, and no substantive activity has occurred in this case other than the near-contemporaneous filing of Defendants' motion to stay and motion to dismiss.

GenBioPro's filing easily qualifies as timely under the Fifth Circuit's standards. *See Sierra Club v. Espy*, 18 F.3d 1202, 1205-06 (5th Cir. 1994) (intervention was timely even though motion to intervene was filed eight years after suit commenced and two months after preliminary injunction was issued); *see also Edwards v. City of Houston*, 78 F.3d 983, 1001 (5th Cir. 1996) ("[M]ost of our case law rejecting petitions for intervention as untimely concern motions filed after judgment was entered in the litigation."); *Missouri*, 2025 WL 1223581, at *5 (finding GenBioPro's motion to intervene timely because it was filed less than two months after amended complaint implicating GenBioPro's distinct interests).

Having filed a timely motion, GenBioPro meets each of the Rule 24(a)(2) requirements laid out in *Burgum*, as described below.

A. GenBioPro Has a Protectable Interest in This Action

GenBioPro clearly has "direct, substantial, and legally protectable" interests in this action. *John Doe No. 1 v. Glickman*, 256 F.3d 371, 379 (5th Cir. 2001) (cleaned up). Courts routinely recognize that litigation against FDA affecting a drug approval implicates the interests of the holder or potential holder of the approval for Rule 24 purposes. *See, e.g.*, *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1075-76 (D.C. Cir. 1998) (reversing denial of a motion to intervene as of right of New Drug Application ("NDA") holder in litigation concerning FDA's approval of an ANDA); *Eagle Pharms., Inc. v. Price*, 322 F.R.D. 48, 49-50 (D.D.C. 2017) (manufacturer with a

pending ANDA permitted to intervene as of right because plaintiff's requested relief would prevent intervenor "from marketing its generic product"); *Apotex Inc. v. FDA*, 508 F. Supp. 2d 78, 80 n.2 (D.D.C. 2007) (manufacturer permitted to intervene as of right because plaintiff sought to "set aside the FDA's decision as to its approval status" for its generic version of the intervenor's drug).

GenBioPro has a direct interest as "the intended beneficiar[y] of the challenged federal policy," namely FDA's 2019 ANDA approval, *Texas v. United States*, 805 F.3d 653, 660 (5th Cir. 2015), and a "legally protectable interest in the regulatory scheme," *Wal-Mart*, 834 F.3d at 566. The States' Complaint seeks to vacate the 2019 ANDA approval and other agency actions governing the marketing, sale, and distribution of GenBioPro's primary product. Decl. of Evan Masingill ("Masingill Decl.") ¶¶ 4-6. Accordingly, whether GenBioPro "will or will not be" able to market generic mifepristone under the current FDA conditions of use "depend[s] on the outcome of this case." *Texas*, 805 F.3d at 660. GenBioPro thus has a direct stake in the outcome of the litigation that is "sufficiently concrete and specific to support" intervention. *Id.* at 660-61.

It is also "obvious that the economic interests of [GenBioPro] are at stake" in this lawsuit. *See Espy*, 18 F.3d at 1207. "[E]conomic interests can justify intervention when they are directly related to the litigation." *Wal-Mart*, 834 F.3d at 568. GenBioPro is one of just two entities granted ANDA approvals for generic mifepristone in the United States, Compl. ¶ 198, and sales of mifepristone are the company's majority source of revenue, Masingill Decl. ¶ 5. The States' requested relief thus "threatens a 'prospective interference'" with GenBioPro's ability to market its product in the United States, presenting a direct, concrete, and particularized threat to GenBioPro's economic interests that justifies intervention. *Brumfield v. Dodd*, 749 F.3d 339, 343 (5th Cir. 2014); *see Wal-Mart*, 843 F.3d at 567-68 (collecting cases "permitting intervention based on economic interests").

B. Disposition of This Action May Impair GenBioPro's Ability to Protect Its Interests

GenBioPro also easily clears the second Rule 24(a)(2) criterion: There is far more than a mere "possibility that [GenBioPro's] interest could be impaired or impeded" as a result of this litigation. *La Union del Pueblo Entero v. Abbott*, 29 F.4th 299, 307 (5th Cir. 2022). Plaintiffs seek an order that "[d]eclares unlawful and preliminarily and permanently sets aside, rescinds, and vacates" a host of regulatory actions that allow GenBioPro to market and distribute mifepristone—including the original "2000 NDA of Mifeprex" and "the 2019 ANDA and consolidated REMS program." Compl., Prayer for Relief, § A. Granting their requested relief would prevent GenBioPro from marketing generic mifepristone. Masingill Decl. ¶ 6.

C. GenBioPro's Interests Are Not Adequately Represented by Defendants

The existing Defendants do not adequately represent GenBioPro's interests. "The inadequate-representation factor typically 'is satisfied if the [movant] shows that the representation of his interest may be inadequate.'" *Missouri*, 2025 WL 1223581, at *2 (quoting *Trbovich v. United Mine Workers of Am.*, 404 U.S. 528, 538 n.10 (1972)). That burden is "minimal" unless "one of two presumptions of adequate representation appl[ies]." *Burgum*, 132 F.4th at 922 (quotation marks omitted); *accord Missouri*, 2025 WL 1223581, at *2. The first presumption "arises when the intervenor has the same ultimate objective as a party to the lawsuit." *Burgum*, 132 F.4th at 922 (quotation marks omitted). "The second presumption arises when the existing party is a governmental body or officer charged by law with representing the interests of the movant." *Id.* (quotation marks omitted).

Neither presumption applies here. The first is inapplicable because the existing Defendants do not have "the same ultimate objective" as GenBioPro. *See Burgum*, 132 F.4th at 922. GenBioPro's ultimate objective is to defend the challenged FDA actions—including on the merits,

as necessary—to ensure that both GenBioPro's ANDA and the existing REMS remain in effect. Defendants are instead undertaking what they call a "study" of the safety of the current REMS, in order to "determine whether modifications are necessary." ECF No. 20-1 at 7-8 (quoting Letter from Secretary Robert F. Kennedy, Jr. to State Attorneys Generals describing FDA's mifepristone study). Whereas GenBioPro intends to robustly defend FDA's actions on the merits, Defendants in related litigation have declined to do so, instead seeking primarily to *stay* the litigation out of deference to its ongoing review. Defs.' Mem. Supp. Mot. to Stay at 3, Louisiana v. FDA, No. 6:25-cv-1491-DCJ-DJA (Jan. 27, 2026), ECF No. 50-1. Defendants have even invoked "concerns" raised by the Fifth Circuit regarding mifepristone's safety record—the same concerns identified in Plaintiffs' Complaint. *See* ECF No. 20-1 at 1; Compl. ¶ 141. GenBioPro's goal of defending FDA's regulation of mifepristone on the merits—while Defendants fail to do so—is dispositive on this element.

Even if the "ultimate objective" presumption of adequate representation somehow applied (it does not), Defendants' failure to affirmatively defend their prior actions concerning mifepristone on the merits, coupled with their repetition of statements cited in the Complaint, would be sufficient to overcome it. *See Burgum*, 132 F.4th at 922 (first presumption can be overcome "by showing adversity of interest, collusion, or nonfeasance on the part of the existing party") (quotation marks omitted). Defendants' litigation positions and public statements discussed above are textbook examples of "specific conduct showing that the party at issue inadequately represent[s] [the proposed intervenor's] interests, notwithstanding that it share[s] an ultimate objective." *Id.* at 923; *see La Union del Pueblo Entero*, 29 F.4th at 308-09 (finding inadequate representation prong satisfied because, even assuming presumptions applied, state

officials "prefer[red] to not resolve th[e] case on the merits at all" and moved for dismissal only on standing and sovereign immunity grounds).

The second presumption of adequate representation—arising when "the existing party is a governmental body or officer charged by law with representing the interests of the movant," *Burgum*, 132 F.4th at 922 (quotation marks omitted)—does not apply here either. FDA of course is not charged by law with representing the interests of the drug companies it regulates. *See Missouri*, 2025 WL 1223581, at *3 ("The second presumption does not apply."). Indeed, Defendants' express statement that they are investigating a change in the REMS, shows that they are *not* bound to represent GenBioPro's interests in maintaining the status quo.

Since neither presumption applies, GenBioPro's burden of showing inadequate representation is "minimal," and GenBioPro need only show that FDA's representation "may" be inadequate. *Missouri*, 2025 WL 1223581, at *2. GenBioPro easily clears that low threshold. As discussed above, given FDA's and GenBioPro's divergent responses to the Complaint, there can be no question that FDA's representation *is* inadequate to protect GenBioPro's interests.

II. The Court Should Permit GenBioPro to Intervene Under Rule 24(b)

The Court should, at a minimum, permit GenBioPro to intervene under Rule 24(b), as Judge Kacsmaryk did in the other case in this district. "Permissive intervention may be granted if the movant 'has a claim or defense that shares with the main action a common question of law or fact.'" *Missouri*, 2025 WL 1223581, at *4 (quoting Fed. R. Civ. P. 24(b)(1)(B)). The motion must be timely, and intervention must not "unduly delay or prejudice the adjudication of the original parties' rights." *Id.*; *see also Newby v. Enron Corp.*, 443 F.3d 416, 424 (5th Cir. 2006).

Here, as in the recent *Missouri* decision by Judge Kacsmaryk granting permissive intervention, GenBioPro's defenses—including that FDA's approval of the ANDA for generic mifepristone was reasonable, that the agency's modification of the REMS was both reasonable

and reasonably explained, and that all of the challenged agency actions are lawful and should be upheld—clearly share common questions of law and fact with the main action. *See Missouri*, 2025 WL 1223581, at *4-6. Plaintiffs' claims against FDA center on those very same questions. *See id.* at *6 (finding common questions for Rule 24(b) purposes where "GenBioPro seeks to protect its product's FDA approval" whereas "Plaintiffs challenge GenBioPro's product's FDA approval").

GenBioPro thus satisfies all requirements for permissive intervention. As discussed above, this motion is plainly timely, *supra* p. 5, and there is no conceivable way in which GenBioPro's participation could delay or prejudice adjudication of FDA's or Plaintiffs' rights. As in *Missouri*, GenBioPro's intervention "will change nothing in the case schedule." *Missouri*, 2025 WL 1223581, at *6 (quotation marks omitted). "No deadlines will need to be moved, no additional discovery will be necessary, and no delay will occur, and, therefore, the parties will not be prejudiced." *Id.* (quotation marks omitted). The Court should permit GenBioPro to intervene.

III. GenBioPro's Motion to Dismiss Satisfies Rule 24(c)

Rule 24(c) requires that an intervention motion be "accompanied by a pleading that sets out the claim or defense for which intervention is sought." Fed. R. Civ. P. 24(c). The Fifth Circuit "takes a 'lenient approach'" to Rule 24(c), *Missouri*, 2025 WL 1223581, at *2 n.1 (quoting *Liberty Surplus Ins. Co. v. Slick Willies of Am., Inc.*, 2007 WL 2330294, at *1 (S.D. Tex. Aug. 15, 2007)); *see Farina v. Mission Inv. Tr.*, 615 F.2d 1068, 1074 (5th Cir. 1980) (rejecting "excessively technical" interpretation of Rule 24(c) as contrary to Rule 8's policy of flexibility in pleadings).

GenBioPro has attached to this motion a motion to dismiss, which, together with this motion, apprise the Court and all parties of the defenses GenBioPro intends to raise if the motion is granted, serving Rule 24(c)'s purpose to "put the parties on notice of [GenBioPro's] grounds for intervention." *Liberty Surplus*, 2007 WL 2330294, at *2; *see United States ex rel. Hernandez v.*

Team Fin., LLC, 80 F.4th 571, 575 n.1 (5th Cir. 2023) ("proposed motion to unseal, and supporting declaration" submitted with motion to intervene satisfied attachment requirement).

CONCLUSION

For the foregoing reasons, the Court should grant GenBioPro's Motion for Leave to Intervene and accept GenBioPro's Motion to Dismiss for filing on the docket in this action.

Dated: March 13, 2026

Respectfully submitted,

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**Application for admission to the bar of the District Court for the Northern District of Texas pending

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*.	Civil Action No. 7:25-cv-00126-O

DECLARATION OF EVAN MASINGILL

I, Evan Masingill, declare as follows:

1. I am the President and Chief Executive Officer of GenBioPro Inc. I make this declaration in support of GenBioPro's Motion to Intervene. If called to testify, I would testify competently to all of the statements in this Declaration.

2. GenBioPro is a privately held pharmaceutical company founded in 2011.

3. Between 2011 and 2019, GenBioPro invested several million dollars in working to bring to market a generic version of the drug mifepristone. That investment was necessary to satisfy requirements set by the U.S. Food and Drug Administration (FDA) for approval of an Abbreviated New Drug Application (ANDA) to sell a generic drug.

4. FDA approved GenBioPro's ANDA for generic mifepristone on April 11, 2019, and GenBioPro continues to hold that ANDA.

5. Sales of mifepristone account for the majority of GenBioPro's revenue.

6. Enjoining or vacating GenBioPro's ANDA approval, or the 2000 NDA approval that serves as the predicate for that ANDA approval, would have immediate and irreparable consequences for GenBioPro's business by cutting off the majority of GenBioPro's revenue.

7. GenBioPro also currently manufactures and distributes mifepristone according to FDA's Risk Evaluation and Mitigation Strategy ("REMS"). FDA updated mifepristone's REMS in 2023 to formally remove a requirement that the drug be dispensed only in-person in clinics, medical offices, and hospitals—a requirement that prevented pharmacies from dispensing the drug. Currently, a significant portion of GenBioPro's total sales are to pharmacies. As such, vacating or enjoining the 2023 REMS and reimposing the in-person dispensing requirement would have an immediate effect of cutting off sales to pharmacies, and therefore cutting off a substantial portion of GenBioPro's revenue.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct to the best of my knowledge, information, and belief.

Dated: 12-Mar-26

Signed by Evan Masingill
Evan Masingill
I approve this document
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Evan Masingill

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

STATE OF FLORIDA, *et al.*,
Plaintiffs,

v.

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

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

PROPOSED INTERVENOR-DEFENDANT GENBIOPRO, INC.'S MOTION TO DISMISS

Proposed Intervenor-Defendant GenBioPro, Inc. ("GenBioPro") hereby moves to dismiss this action pursuant to Federal Rules of Civil Procedure 12(b)(1), 12(b)(3), and 12(b)(6). GenBioPro submits that Plaintiffs lack Article III standing; venue is improper because Texas is collaterally estopped from relitigating standing and Florida has no basis for venue in the Northern District of Texas; Plaintiffs have not exhausted their claims, which are not ripe for judicial review; and certain of Plaintiffs' claims are time-barred, as described in GenBioPro's Brief in Support of this Motion to Dismiss, filed herewith.

Dated: March 13, 2026

Respectfully submitted,

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**Application for admission to the bar of the District Court for the Northern District Texas pending

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

STATE OF FLORIDA and STATE OF TEXAS, Plaintiffs, v. U.S. FOOD AND DRUG ADMINISTRATION, *et al.*, Defendants.	Case No. 7:25-cv-00126-O

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

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INTRODUCTION

For years, the Food and Drug Administration (FDA) has recognized that mifepristone is safe and effective. FDA's regulatory actions regarding mifepristone have been grounded in a substantial body of scientific evidence and expert analysis accumulated over decades. Congress entrusted FDA—not the courts—with responsibility for evaluating that evidence and using it to make scientific judgments about safety and access. Yet Texas and Florida now ask this Court to displace FDA's expert scientific judgment and to invalidate the entire array of FDA's regulatory actions relating to mifepristone, over the last two-and-a-half decades, ranging from its initial 2000 approval of the drug to the drug's governing Risk Evaluation and Mitigation Strategy, known as the "REMS."

This Court should reject that effort at the threshold. The Supreme Court has already held that federal courts are not the proper forum for generalized objections to FDA's alleged under-regulation of a drug—particularly where the asserted injuries depend on attenuated chains of events involving the choices of independent third parties. *FDA v. All. for Hippocratic Medicine*, 602 U.S. 367, 380-83 (2024) (*Alliance*). That unanimous holding forecloses Plaintiffs' similar effort here. FDA's regulatory decisions impose no obligations on Texas or Florida—just as they imposed none on the doctors who challenged these same FDA actions in *Alliance*. Nor do those decisions prevent the States from enforcing their own laws. Plaintiffs' theories instead depend on attenuated theories about how potential choices by third parties might indirectly affect state expenditures or enforcement efforts. If those downstream effects were sufficient to establish standing, there would be no meaningful limit on states' ability to challenge federal policy.

The Complaint suffers from additional threshold defects as well. Texas is precluded from relitigating theories of standing that it has already advanced—and lost—in prior litigation challenging FDA's regulation of mifepristone. And with Texas unable to establish standing, this

case does not belong in this venue even if Florida could establish standing (which it cannot). Florida asserts no basis, and would have no basis, for suing in the Northern District of Texas.

Both States, moreover, seek to bypass mandatory administrative procedures that permit FDA to assess scientific questions and regulatory policy in the first instance. FDA regulations require parties to present such challenges to the agency in the first instance through the citizen-petition process, allowing the agency to bring its expertise to bear on the issues and to evaluate the relevant evidence. Plaintiffs never did so here, even as FDA continues actively to review the mifepristone REMS and consider multiple pending petitions addressing the drug's regulation. And much of the Complaint is untimely: Plaintiffs attempt to challenge agency actions taken in 2000, 2016, and 2019—years or decades before this suit was filed and well outside the six-year statute of limitations governing suits against the federal government.

GenBioPro, Inc. holds an FDA-approved abbreviated new drug application authorizing it to market generic mifepristone—a product that is foundational to its business and an important component of healthcare nationwide. GenBioPro intervened in this action to protect those interests and now asks the Court to dismiss the Complaint.[1]

[1] Because this Court lacks Article III jurisdiction over this case and the States' claims are unexhausted, unripe, and untimely, the proper remedy is dismissal. But to the extent the Court declines to dismiss the case at this time, GenBioPro would not oppose the FDA's request for a stay of these proceedings pending its ongoing review.

BACKGROUND

I. Factual and Regulatory Background

A. FDA's Science-Based Regulation of Mifepristone for 25 Years

2000 Approval and Initial REMS. In 2000, FDA approved mifepristone under the brand name Mifeprex as a safe and effective medication for terminating early pregnancies up to 49 days' of pregnancy. *See* 21 U.S.C. § 355; *Alliance*, 602 U.S. at 375. That approval was accompanied by certain conditions to assure safe use—which, by virtue of the Food and Drug Administration Amendments Act of 2007 (FDAAA), became part of mifepristone's "risk evaluation and mitigation strategy" (or "REMS").

Specifically, in the FDAAA, Congress charged FDA with determining whether a REMS is "necessary to ensure that the benefits of the drug outweigh the risks of the drug." 21 U.S.C. § 355-1(a)(1). Congress further directed that each REMS must be designed in a manner that "assur[es] access and minimiz[es] burden" on "the health care delivery system." *Id.* § 355-1(f)(2)(D). Drugs "approved before the effective date of [the] Act," like mifepristone, were "deemed to have in effect an approved risk evaluation and mitigation strategy" if they were subject to existing "elements to assure safe use" under certain FDA regulations. Pub. L. No. 110-85, § 909(b)(1), 121 Stat. 951 (2007); *see* 73 Fed. Reg. 16,313, 16,314 (Mar. 27, 2008). The "elements" for mifepristone at the time included, among other things, requirements that the drug be dispensed in person, under the supervision of a physician with certain qualifications, and that the patient return in person for two follow-up appointments. Compl. ¶ 12; Ex. 18. Mifepristone was initially indicated for pregnancies up to 49 days' gestation. *Id.*

2016 Changes. In 2016, FDA approved several changes to mifepristone's REMS and product label based on a review of more than a decade of safety data and peer-reviewed studies. ECF No. 1-4 at 14-35. The revisions allowed licensed non-physician healthcare providers to

become certified prescribers, and changed the labeling to extend the approved gestational age from 49 to 70 days, and to eliminate two previously required in-person follow-up visits, among other changes. *Id.* at 11, 14; Compl. ¶ 132.

2019 ANDA Approval. In 2019, FDA approved GenBioPro's abbreviated new drug application ("ANDA") to market a generic version of mifepristone. In doing so, FDA determined that generic mifepristone is "bioequivalent" to the reference drug Mifeprex and is therefore safe and effective. 21 U.S.C. § 355(j). The generic product is subject to a single, shared REMS with Mifeprex, sold by Danco Laboratories, LLC. Compl. ¶ 153.

2021 Non-Enforcement Decision. Early in the COVID-19 pandemic, FDA suspended the in-person dispensing requirements for most drugs, but maintained it for mifepristone. *See Am. Coll. of Obstetricians & Gynecologists v. FDA*, 472 F. Supp. 3d 183, 191-97 (D. Md. 2020). In July 2020, a court required FDA to temporarily suspend the in-person dispensing requirement in response to a lawsuit filed by mifepristone providers, allowing the drug to be mailed to patients. *Id.* at 233. That suspension was in effect for six months, from July 2020 until January 2021, when the Supreme Court stayed the injunction. *See FDA v. Am. Coll. of Obstetricians & Gynecologists*, 141 S. Ct. 578 (2021).

Based in part on the information gained from the non-enforcement period, in April 2021, FDA exercised its discretion to suspend enforcement of the in-person dispensing requirement during the COVID-19 pandemic. Compl. ¶ 165. FDA also initiated a full review of the mifepristone REMS program. ECF No. 1-3 at 128. After this robust review, FDA in December 2021 announced its determination that the in-person dispensing requirement was not necessary to assure mifepristone's safe use. *Id*. at 165. FDA explained that its decision was based on "a thorough scientific review by [agency] experts," who evaluated data from FDA's assessment

report for the mifepristone REMS, postmarketing safety information, and published scientific studies evaluating different methods for dispensing mifepristone. ECF No. 1-6 at 715.

2023 REMS Modification. In January 2023, FDA issued a new REMS that formally removed the in-person dispensing requirement for mifepristone, confirming that mifepristone, like most drugs, can be used safely when dispensed by mail or at pharmacies. ECF No. 1-3 at 104-06. The 2023 REMS changed some requirements for prescribers, *id.*, and also added a pharmacy certification requirement to, among other things, "ensure[] that pharmacies are aware of and agree to follow applicable REMS requirements." *Id.* at 98. Particularly with those additional certification requirements, FDA determined that the REMS will "continue to ensure that the benefits of mifepristone for medical abortion outweigh the risks." *Id.*

2025 Evita Approval. In September 2025, FDA approved an abbreviated new drug application submitted by Evita Solutions, LLC to market and manufacture generic mifepristone. Compl. ¶¶ 198-99.

B. Plaintiff States' Laws

More than a year after FDA suspended enforcement of the in-person dispensing requirement, the Supreme Court held in *Dobbs v. Jackson Women's Health Organization*, 597 U.S. 215 (2022), that there is no federal constitutional right to abortion. *Dobbs* allowed Texas laws that generally prohibit abortions to take effect. *See* Texas Rev. Civ. Stat. Art. 4512.1–4512.6; Tex. Health & Safety Code § 170A. After *Dobbs*, Florida statutes went into effect that prohibit abortions in many cases—but permit them up to a gestational age of six weeks. *See* Fla. Stat. § 390.0111(1). Both Texas's and Florida's abortion laws include additional exceptions, including to save the life of the patient. Compl. ¶¶ 318, 322-23. Both states exclude miscarriage care from the definition of abortion. *See* Tex. Health & Safety Code § 245.002(1)(B); Fla. Stat. § 390.011(1). Mifepristone

thus may be used lawfully for abortions that Texas and Florida laws permit and for non-abortion purposes, including miscarriage management.

C. Ongoing FDA Consideration of Mifepristone

The FDAAA directs FDA to periodically reassess its REMS. *See* 21 U.S.C. § 355-1(d), (g). FDA by regulation has also established a process whereby any interested person can request that the agency "take or refrain from taking any other form of administrative action," 21 C.F.R. § 10.25(a), including actions related to a REMS. The filing of such a "citizen petition" is a prerequisite to judicial review of FDA action. *Id.* § 10.45(b).

FDA is currently evaluating the mifepristone REMS. It has eight mifepristone-related citizen petitions pending before it, including one from GenBioPro that includes comprehensive and up-to-date data demonstrating the safety of mifepristone. *See, e.g.*, GenBioPro, Citizen Petition, FDA-2025-P-2162 (July 7, 2025), https://tinyurl.com/mr3vaj4e. The FDA Commissioner in September also announced that the agency will be conducting further safety studies of the 2023 REMS to "determine whether modifications are necessary." ECF No. 20-1 at 7-8. FDA has recently confirmed its ongoing evaluation in responding to similar litigation challenging FDA's actions, stating that it is undertaking "a new review based on the evidence before the agency," including "FDA's own study." *Id.* at 3. "Once FDA has analyzed the study data (as well as all other evidence before the agency), it will decide whether 'substantive changes to the REMS' are warranted." *Id.*

II. Procedural History

In November 2022, several doctors and associations challenged virtually every FDA action taken regarding mifepristone, including FDA's initial 2000 approval of the drug, its 2016 changes to the REMS and label, its 2019 approval of GenBioPro's generic mifepristone, and its 2021 non-enforcement of the in-person dispensing requirement. *All. for Hippocratic Med. v. FDA*, 668 F.

Supp. 3d 507, 522-23 (N.D. Tex. 2023). Although the district court granted the requested relief and the Fifth Circuit largely affirmed, those orders were stayed pending appellate review and never took effect. *Danco Lab'ys, LLC v. All. for Hippocratic Med.*, 143 S. Ct. 1075 (2023) (stay order). Ultimately, the Supreme Court unanimously held that the plaintiffs lacked Article III standing. *Alliance*, 602 U.S. at 374. On remand, Texas and Florida unsuccessfully sought to intervene; the district court held that venue was improper and transferred the case to the Eastern District of Missouri. *Missouri v. FDA*, 2025 WL 2825980, at *12-13 (N.D. Tex. Sept. 30, 2025).

Plaintiffs then filed the Complaint in this case on December 9, 2025. ECF No. 1. FDA filed an unopposed motion for an extension of time to respond to the Complaint on January 30, 2026. ECF No. 18. This Court granted FDA's motion on February 2, 2026, permitting FDA until March 13, 2026, to file their response to the Complaint. ECF No. 19.

LEGAL STANDARD

Under Rule 12(b)(1), dismissal is required if the court lacks subject matter jurisdiction over the action. *Reule v. Jackson*, 114 F.4th 360, 365 (5th Cir. 2024). Plaintiffs have the burden of demonstrating that the court has subject matter jurisdiction, including that the Plaintiffs have standing. *Id*. at 365-67. Under Rule 12(b)(3), once a party moves to dismiss based on improper venue, the plaintiff must "come forward with evidence showing venue is proper." *Perez v. Pan Am. Life Ins. Co.*, 70 F.3d 1268 (5th Cir. 1995) (per curiam). Under Rule 12(b)(6), "where it is evident from the plaintiff's pleadings that the action is [time] barred" dismissal of that claim is proper. *Jones v. Alcoa, Inc.*, 339 F.3d 359, 366 (5th Cir. 2003). The Court must also dismiss any claim which fails to state a claim as a matter of law. *Boudreaux v. Louisiana State Bar Ass'n*, 3 F.4th 748, 753 (5th Cir. 2021).

ARGUMENT

The Complaint fails for multiple independent reasons: Plaintiffs lack standing; their claims are unexhausted and unripe; and their challenges to earlier FDA actions are barred by the statute of limitations.

I. Plaintiffs Lack Article III Standing

Plaintiffs lack Article III standing, which deprives this Court of subject matter jurisdiction. Plaintiffs have not alleged a cognizable injury-in-fact traceable to any of FDA's challenged actions and redressable through the relief sought. Those deficiencies require dismissal of the case. Article III standing is an "essential" and "core component" of the Court's subject matter jurisdiction. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992). "Without jurisdiction the court cannot proceed at all in any cause," and "the only function remaining to the court is that of announcing the fact and dismissing the cause." *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 94 (1998) (quoting *Ex parte McCardle*, 7 Wall. 506, 514 (1868)); *see also Alliance*, 602 U.S. at 396-97 (directing dismissal of challenge to mifepristone regulations for lack of standing).

A. Texas Is Precluded From Relitigating Theories Of Standing It Has Argued And Lost In Prior Litigation Against FDA

As a threshold matter, Texas is precluded from relitigating its standing to challenge FDA's regulation of mifepristone based on alleged increases in Medicaid spending, purported interference with the State's enforcement of its laws, or asserted harms to women and fetal life. And because Texas lacks standing, there is no basis for venue in this district. *See, e.g.*, *Associated Gen. Contractors of Am., Inc. v. Fed. Acquisition Regul. Council*, 720 F. Supp. 3d 461, 472 (W.D. La. 2024) (when some plaintiffs are "dismissed from the lawsuit for lack of standing, the Court must determine whether venue is proper in this district in their absence").

The doctrine of issue preclusion prohibits "relitigation by a party to a previous action of issues that were actually litigated and decided in that previous action." *Hogue v. Royse City*, 939 F.2d 1249, 1252 n.2 (5th Cir. 1991); *see also, e.g.*, *Robin Singh Educ. Sers. Inc. v. Excel Test Prep Inc.*, 274 F. App'x 399, 404-05 (5th Cir. 2008). The doctrine applies with equal force to jurisdictional holdings: A party may not relitigate "the same jurisdictional issue decided [against it] in a prior case." *Bank of La. v. FDIC*, 33 F.4th 836, 838 (5th Cir. 2022) (emphasis omitted).

That doctrine forecloses Texas from establishing standing here. In *Washington v. FDA*, Texas sought to intervene to defend certain of FDA's restrictions on mifepristone. 108 F.4th 1163, 1174 & n.3 (9th Cir. 2024). In doing so, Texas advanced—and the Ninth Circuit rejected—the same theories of standing the States assert in this case. Specifically, as here, Texas claimed standing to challenge FDA's elimination of the in-person dispensing requirement because the agency's elimination of that requirement would cause Texas "economic injury in the form of increased costs to the state's Medicaid system." *Compare id.* at 1174, *with* Compl. ¶¶ 283-298 (alleging that Texas's "Medicaid reimbursements" for emergency treatment relating to "chemical abortion complications" has "diverted resources from [Texas's] general budget[]"). The Ninth Circuit disagreed, holding that the "causal chain between FDA's regulation of mifepristone" and Texas's theory of economic injury was "too attenuated to establish" standing, and, moreover, that Texas's "alleged uptick in Medicaid costs is exactly the kind of 'indirect effect on state spending' that the Supreme Court has rejected as a basis for standing" in prior cases. *Washington*, 108 F.4th at 1175-76 (quoting *United States v. Texas*, 599 U.S. 670, 680 n.3 (2023)).

The Ninth Circuit similarly rejected Texas's theory—also asserted here—that it had standing because FDA's relaxed regulation of mifepristone interfered with the State's "sovereign interest" in "enact[ing]" and "enforc[ing]" its "own laws regulating chemical abortion." *Compare*

Washington, 108 F.4th at 1176 ("[Texas] alleges an injury to its sovereign interest in enforcing state abortion laws, which make mifepristone illegal to use under most circumstances."), *with* Compl. ¶¶ 305-09, 321-33 (alleging interference with Texas's "sovereign power to enact and enforce regulations on abortion"). And the Ninth Circuit rejected Texas's third theory of standing—its "'quasi-sovereign interest' in maternal health and fetal life"—recognizing that this was just a "thinly veiled attempt to circumvent the limits on *parens patriae* standing." *Compare Washington*, 108 F.4th at 1177-78 (quoting *Murthy v. Missouri*, 603 U.S. 43, 76 (2024)), *with* Compl. ¶¶ 21, 205-82 (alleging that "[a]bortion drugs harm women and girls" and claiming standing to "protect [its] residents"). Because each of Texas's asserted theories of standing was previously litigated and decided against it in *Washington*, the State's attempt to relitigate those exact same issues here must fail.

Without Texas as a proper plaintiff in this action, only Florida remains—meaning that venue is unavailable in this district. *See Associated Gen. Contractors*, 720 F. Supp. 3d at 472; *see Missouri*, 2025 WL 2825980, at *11 (Missouri, Idaho, and Kansas could not establish venue in this district for a similar challenge to FDA's mifepristone-related actions). Plaintiffs' Complaint acknowledges this: their sole asserted basis for venue is that "the State of Texas resides in this judicial district." Compl. ¶ 29. Collateral estoppel is thus reason enough to dismiss this case.

B. Plaintiffs Lack a Cognizable Sovereign Injury Traceable to Any Challenged FDA Action

Texas and Florida cannot establish Article III standing in any event. They assert standing based on a theory of sovereign injury, arguing that the challenged actions "interfere with Plaintiffs' 'sovereign interests in "the power to create and enforce a legal code"' by enabling state-law criminal and civil violations by third parties." Compl. ¶ 327 (quoting *Texas Office of Public Utility*

Counsel v. FCC, 183 F.3d 393, 449 (5th Cir. 1999)). But this "sovereign injury" theory is foreclosed on multiple grounds.

First, precedent forecloses states from using their generalized interests in law enforcement as a means to challenge federal policy. In *United States v. Texas*, 599 U.S. 670, 680 n.3 (2023), the Supreme Court held that Louisiana's and Texas's alleged "sovereign" and economic injuries did not give them standing to challenge a federal policy that they claimed violated federal law. The Court reaffirmed that the underenforcement of federal law does not support a sovereign-harm theory of standing, declining to "start the Federal Judiciary down th[e] uncharted path" of adjudicating "alleged Executive Branch under-enforcement of any similarly worded laws—whether they be drug laws, gun laws, obstruction of justice laws, or the like." *Id.* at 681. And as discussed above, *see supra* pp. 9-10, the Ninth Circuit—applying *United States v. Texas*—rejected a sovereign injury theory materially identical to the one Plaintiffs assert here regarding the mifepristone REMS, holding that "[courts] have never held that a logistical burden on law enforcement constitutes a cognizable Article III injury." *Washington*, 108 F.4th at 1177.

Plaintiffs invoke *Louisiana v. EEOC*, 784 F. Supp. 3d 886 (W.D. La. 2025), as supporting their theory of sovereign injury. Compl. ¶ 327. But in that case, the Court found that the federal action "force[d]" state action "that directly conflict[ed] with the States' own laws and policies" in the State's capacity as an employer. *Louisiana*, 784 F. Supp. 3d at 901. Here, in contrast, the challenged FDA actions do not require Plaintiffs "to do or refrain from doing anything." *Alliance*, 602 U.S. at 374. And as noted, both States permit the use of mifepristone in some circumstances—especially Florida, which permits abortion up to six weeks' gestation. Fla. Stat. § 390.0111(1); *see also supra* p. 5 (describing other exceptions). Given these state-law exceptions, Plaintiffs lack cognizable sovereign interests in banning use of mifepristone within their borders.

Second, even if Plaintiffs had cognizable sovereign injuries, they could not draw the requisite causal link between FDA's actions and those injuries. While Plaintiffs assert that FDA's actions make mifepristone easier to access in their States, both of their laws *permit* using mifepristone in a variety of situations—including, in Florida, up to six weeks without caveats—meaning that any "sovereign injury" depends on independent individuals making "unfettered choices" to violate state law. *Alliance*, 602 U.S. at 383 (citation omitted). For the same reasons, Plaintiffs cannot establish redressability: Even if the challenged FDA actions were vacated, nothing would prevent third parties from continuing to prescribe, distribute, or obtain mifepristone in other jurisdictions or through other lawful channels. And though Plaintiffs challenge the 2000 NDA approval (thereby seeking to remove mifepristone from the market altogether), that particular claim is plainly untimely and thus cannot serve as the basis for Article III jurisdiction. *See infra* pp. 20.

Third, Plaintiffs' related contention that the "purpose" of the 2023 REMS and other challenged actions was to "undermine state abortion laws," *see* Compl. ¶ 89, 328, 352-53, is pure fiction. Of course, none of the challenged FDA actions before *Dobbs*—the 2000 approval, 2016 changes, and 2019 approval—could possibly have been designed to undermine Texas' or Florida's abortion laws. *Contra* Compl. ¶¶ 89, 328. During the nearly two decades during which these actions occurred, abortion was legal in every state under *Roe v. Wade*, 410 U.S. 113 (1973), and *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833, 874 (1992), including in Texas and Florida. So too for the removal of the in-person dispensing requirement, which was first effected by court injunction in 2020 (two years before *Dobbs*) and then by FDA in 2021 (more than a year before *Dobbs*). *See supra* pp. 3-5. As FDA's website says expressly, the "Mifepristone REMS Program" was *not* "modified in 2023 in response to" *Dobbs* or any state abortion law. FDA,

Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation, Question Nos. 33, 34 (Feb. 2, 2026), https://tinyurl.com/38m6ea9f; *see* ECF No. 1-3 at 129 (FDA's REMS evaluation was initiated "[i]n connection with *Chelius v. Becerra*, [No. 17-cv-00493, (D. Haw.)]"). Since abortion remained legal nationwide in 2021, FDA could not possibly have been motivated by a desire to undermine state abortion laws.

To argue otherwise, Plaintiffs rely on assorted statements by various public officials supporting the goal of ensuring lawful abortion access. None of the statements comes from an FDA official actually responsible for making REMS determinations or approving drug applications. *See* Compl. ¶¶ 8-9, 13, 16, 84, 88-90, 160-163, 177-82. Judicial review of agency action is based on the administrative record generated by the actual decision-makers, not "extrinsic statements" by other Executive Branch actors—particularly statements postdating the relevant decisions. *Trump v. Hawaii*, 585 U.S. 667, 702-04 (2018); *see also, e.g.*, *FDA v. Wages & White Lion Invs., L.L.C.*, 604 U.S. 542, 576-77 (2025) (rejecting allegations of "surreptitious[]" agency action). In any event, none of these statements actually signals an intent to override state law. Plaintiffs' selective quotations are extremely misleading, omitting significant language that undermines their narrative.

For example, quoting a few words from the White House announcement of a 2023 presidential memorandum on reproductive healthcare—which *postdated* the key FDA actions challenged here, including the 2023 REMS—Plaintiffs assert that "President Biden specifically directed HHS Secretary Xavier Becerra to ensure women have 'access' to abortion drugs 'no matter where they live.'" Compl. ¶ 178 (quoting *White House,* Fact Sheet: President Biden to Sign Presidential Memorandum on Ensuring Safe Access to Medication Abortion (Jan. 22, 2023), https://perma.cc/S6R9-AT7W). But far from a binding directive to "ensure [that] women have

'access,'" as Plaintiffs suggest, the Presidential Memorandum merely directed HHS to "*consider* new *guidance*" on mifepristone. Fact Sheet, *supra* (emphasis added). And far from promoting access in instances where it would contravene state law, as Plaintiffs suggest, the guidance the President was calling for would "support patients, providers, and pharmacies who wish to *legally* access, prescribe, or provide mifepristone—no matter where they live." *Id.* (emphasis added); *see* Presidential Mem., *Further Efforts to Protect Access to Reproductive Healthcare Services*, 88 Fed. Reg. 4895, 4896 (Jan. 22, 2023) (directing HHS to "consider … issuing guidance for patients seeking *legal access to mifepristone*, as well as for providers and entities, including pharmacies, that provide reproductive healthcare and seek to *legally prescribe and provide mifepristone* (emphasis added)). Plaintiffs tellingly identify no ensuing HHS "guidance," let alone one imposing the sort of universal mifepristone-"access" mandate they suggest.[2]

Finally, Plaintiffs assert a "quasi-sovereign" theory based on the notion that the challenged actions interfere with the States' rights to regulate and protect their own citizens. Compl. ¶¶ 30, 32, 205-282. This "quasi-sovereign" theory is equally without merit: "States do not have 'standing as *parens patriae* to bring an action against the Federal Government.'" *Murthy v. Missouri*, 603 U.S. 43, 76 (2024) (quoting *Haaland v. Brackeen*, 599 U.S. 255, 295 (2023)); *see Washington*, 108 F.4th at 1178 (rejecting "thinly veiled attempt to circumvent the limits on *parens patriae* standing" based on similar allegations). Plaintiffs also fail to allege traceability or that the challenged actions affect a "substantial segment" of Texas's and Florida's populations. *See Alfred*

[2] Indeed, it appears that the only relevant guidance issued in the wake of this memorandum was a "remind[er]" to retail pharmacies that, "as recipients of federal financial assistance, [they] are prohibited under law from discriminating on the basis of race, color, national origin, sex, age, and disability in their programs and activities." *Fact Sheet: Biden-Harris Administration Highlights Commitment to Defending Reproductive Rights and Actions to Protect Access to Reproductive Health Care One Year After Overturning of Roe v. Wade* (June 23, 2023),https://tinyurl.com/4e85m8xm.

L. Snapp & Son, Inc. v. Puerto Rico, 458 U.S. 592, 607 (1982). And this theory, just like Plaintiffs' others, was also considered and rejected by the Ninth Circuit in *Washington v. FDA*, *see supra* p. 10.

C. Plaintiffs Lack a Cognizable Economic Injury Traceable to Any Challenged FDA Action

Plaintiffs' theory that FDA's challenged actions "have inflicted concrete economic injury on [Plaintiffs] as the payers and insurers of residents' medical expenses" and the 2021 non-enforcement decision and 2023 REMS modification have caused Plaintiffs "to divert resources to address the explosion of abortion drugs mailed to their residents," Compl. ¶¶ 283, 302, is equally flawed. The Court in *United States v. Texas* rejected the notion that a federal policy's "indirect effects" on "state spending" establishes standing. 599 U.S. at 680 n.3. As the Court explained, "in our system of dual federal and state sovereignty, federal policies frequently generate indirect effects on state revenues or state spending." *Id.* But those "indirect effects" were not adequate to demonstrate standing in *United States v. Texas*, *id.*, and any indirect effect of the challenged actions on Plaintiffs' law enforcement or Medicaid spending is even "far[ther] removed from" the "distant … ripple effects" that the Court found too attenuated in *Alliance*, 602 U.S. at 383.

Indeed, the Ninth Circuit specifically rejected Texas's standing theory based on "downstream medical costs … borne by the state" that purportedly result from the "elimination of the in-person dispensing requirement." *Washington*, 108 F.4th at 1175-76. Allowing such allegations to establish standing "would greatly expand state standing to challenge any federal action that allegedly increases crime or disorder, or imposes indirect compliance costs for state law enforcement." *Id.* at 1177.

Plaintiffs also assert that they suffer economic injury from the "expense of investigating, prosecuting, and enforcing" alleged violations of state abortion laws, including costs associated

with investigating out-of-state prescribers and responding to the mailing of abortion drugs. Compl. ¶¶ 299–304. That theory fails for the same reasons as Plaintiffs' Medicaid-cost theory. The investigative and enforcement costs Plaintiffs identify arise only if "independent actors" choose to prescribe, distribute, or use mifepristone in ways that allegedly violate state law—conduct that is neither required nor authorized by FDA's actions. *Alliance*, 602 U.S. at 383. And even if these actions were not independent, recognizing standing on this theory would permit states to challenge any federal policy that even arguably prompts violations of state law or increases the costs of enforcing it. Article III is not so limitless. *See United States v. Texas*, 599 U.S. at 680 n.3; *Alliance*, 602 U.S. at 383, 390-93.

D. Plaintiffs Fall Outside the FDCA's Zone of Interests

Finally, even if Plaintiffs had standing, their claims fail because they do not "fall[] within the 'zone of interests' sought to be protected by the statutory provision whose violation forms the legal basis for [their] complaint." *Louisiana v. United States*, 948 F.3d 317, 321 (5th Cir. 2020) (quotation marks omitted). The FDCA is designed to protect patients by ensuring that drugs are safe and effective—not to protect state interests in regulating abortion or limiting Medicaid expenditures. Because Plaintiffs seek to use the FDCA to vindicate interests unrelated to the statute's purposes, their claims cannot proceed.

II. Plaintiffs' Challenges Are Unexhausted and Not Ripe for Judicial Review

When an "agency rule" requires a party to pursue remedies within the agency as a "prerequisite to judicial review," the party's failure to exhaust those remedies generally requires dismissal. *Darby v. Cisneros*, 509 U.S. 137, 153 (1993). This requirement ensures that agencies have an opportunity to bring their expertise to bear on issues before courts intervene, and prevents the circumvention of agency procedures for resolution of those issues. *Gulf Restoration Network v. Salazar*, 683 F.3d 158, 175 (5th Cir. 2012).

Exhaustion is particularly critical in the context of FDA's regulatory decisions, which, as courts recognize, depend on the agency's "background, competence, and expertise to assess public health." *S. Bay United Pentecostal Church v. Newsom*, 590 U.S. 965, 967 (2020) (Roberts, C.J. concurring). FDA's evaluation of safety and efficacy draws from an array of complex medical evidence—including expert interpretation of clinical-trial data, adverse event reports, and real-world postmarketing studies. And the FDAAA's direction that FDA account for the need to "assur[e] access and minimiz[e] burden" on "the health care delivery system," 21 U.S.C. § 355-1(f)(2)(d), further underscores the delicate balancing that informs FDA's REMS decisions.

FDA's exhaustion requirements preclude judicial review here. Under FDA's regulations, a party typically must file a citizen petition with FDA "before any legal action is filed in a court complaining of the action or failure to act." 21 C.F.R. § 10.45(b); *see id.* § 10.25(a) (citizen petition procedures). FDA regulations also include "an explicit issue-exhaustion requirement," giving the agency "primary jurisdiction to make the initial determination on issues within its statutory mandate." *Indep. Turtle Farmers of La., Inc., v. United States*, 703 F. Supp. 2d 604, 616 (W.D. La. 2010) (quoting 21 C.F.R. § 10.25(b)). Courts have applied these provisions strictly, requiring the filing of a citizen petition and FDA's resolution of that petition as a precondition to judicial review. *See, e.g.*, *Ass'n of Am. Physicians v. FDA*, 358 F. App'x 179, 180-81 (D.C. Cir. 2009) (affirming dismissal where plaintiffs failed to file a "citizen petition with FDA contesting the SNDA approval of Plan B and [ ] proffered no legally viable excuse for this failure"); *Cody Lab'ys., Inc. v. Sebelius*, 446 F. App'x 964, 969 (10th Cir. 2011) ("Courts have often dismissed suits against the FDA for failure to utilize the citizen petition procedure."); *Indep. Turtle Farmers,* 703 F. Supp. 2d at 616 (noting the "science has progressed since" FDA's action, but declining to

consider unexhausted issues because "without presentation of arguments to FDA on these issues, [the court is] foreclosed from evaluating them in any substantive capacity").

Under these exhaustion rules, this case cannot proceed. Plaintiffs never filed a citizen petition raising any of the challenged actions, and so FDA could not have reached a "final administrative decision based on" that petition, as FDA's regulations require. 21 C.F.R. § 10.45(b). Indeed, Plaintiffs rely heavily on evidence *postdating* those FDA decisions, *see, e.g.*, Compl. ¶¶ 89, 194 n.136—evidence the agency *could not* have considered it in making those decisions. *See Sierra Club v. FERC*, 827 F.3d 59, 69-70 (D.C. Cir. 2016) (no exhaustion where agency "did not have the opportunity to consider [new objection] in the first instance"). Meanwhile, other parties (including GenBioPro) have played by the rules, submitting a host of petitions seeking a variety of actions from FDA related to mifepristone. *See, e.g.*, GenBioPro, Citizen Petition, FDA-2025-P-2162 (July 7, 2025), https://tinyurl.com/mr3vaj4e. Those petitions allow FDA to do its job of collecting data, assessing stakeholders' interests, and evaluating scientific literature. *See Troy Corp. v. Browner*, 120 F.3d 277, 283 (D.C. Cir. 1997).

While courts have recognized exceptions to the exhaustion requirement if the agency is "powerless to grant the relief requested." *Carr v. Saul*, 593 U.S. 83, 93 (2021), or the agency's decision would "certain[ly]" be adverse, *Tesoro Ref. & Mktg. Co. v. FERC*, 552 F.3d 868, 874 (D.C. Cir. 2009), neither exception applies here. To the contrary, FDA is undertaking a review of mifepristone, and current HHS and FDA leadership have signaled the potential for changes in the drug's status and REMS. *See* Defs.' Mem. Supp. Mot. to Stay at 3, *Louisiana v. FDA*, No. 6:25-cv-1491-DCJ-DJA (Jan. 27, 2026), ECF No. 50-1. For similar reasons, the States' claims challenging the REMS that the agency is currently reconsidering are not ripe; those claims "rest[ ] upon 'contingent future events that may not occur as anticipated, or indeed may not occur at all.'"

Texas v. United States, 523 U.S. 296, 300 (1998); *see Miss. State Democratic Party v. Barbour*, 529 F.3d 538, 547 (5th Cir. 2008) (claims unripe when "[f]urther factual development" would "enhance th[e] case's fitness for judicial review").

III. The Statute of Limitations Bars The States' Challenges to FDA's 2000 and 2019 Approvals and 2016 Changes

The States' claims challenging the 2000 approval, the 2016 changes, and the 2019 ANDA approval must be dismissed because they are time barred. The applicable statute of limitations for suits against the federal government requires a plaintiff to file a complaint "within six years after the right of action first accrue[d]," 28 U.S.C. § 2401(a), *i.e.*, when the "plaintiff is injured by final agency action" and "has a complete and present cause of action," *Corner Post, Inc. v. Board of Governors of Fed. Reserve Sys.*, 603 U.S. 799, 820, 825 (2024). That analysis bars Plaintiffs' challenges here. Specifically, the States' causes of action accrued to challenge FDA's 2000 approval, 2016 changes, and 2019 approval—and the statute of limitations began running—when the challenged action occurred, on September 28, 2000; March 29, 2016; and April 11, 2019, respectively. Therefore, for these claims to be timely, Plaintiffs must have filed complaints challenging these actions by September 28, 2006; March 29, 2022; and April 11, 2025, respectively. Yet Plaintiffs did not file their Complaint challenging each of these actions until December 9, 2025. These claims are time-barred and must be dismissed under Rule 12(b)(6). *Jones*, 339 F.3d at 366.

CONCLUSION

The Court should dismiss the Complaint under Rules 12(b)(1), 12(b)(3), and 12(b)(6).

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Respectfully submitted,

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**Application for admission to the bar of the District Court for the Northern District of Texas pending