

**UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF LOUISIANA
LAFAYETTE DIVISION**

THE STATE OF LOUISIANA, by and
through its Attorney General, LIZ MURRILL,
and ROSALIE MARKEZICH,

Plaintiffs,

v.

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

Defendants.

Civil Action No. 6:25-cv-01491

Judge: David C. Joseph

Mag. Judge: David J. Ayo

**MEMORANDUM OF LAW IN SUPPORT OF
GENBIOPRO, INC.'S MOTION TO INTERVENE**

TABLE OF CONTENTS

INTRODUCTION 1

BACKGROUND 3

ARGUMENT 6

I. GenBioPro Is Entitled to Intervene As of Right Under Federal Rule 24(a)(2) 6

 A. GenBioPro Has a Protectable Interest in This Action 8

 B. Disposition of This Action May Impair GenBioPro’s Ability to Protect Its Interests 9

 C. GenBioPro’s Interests Are Not Adequately Represented by Defendants..... 9

II. The Court Should Permit GenBioPro to Intervene Under Rule 24(b)..... 14

III. GenBioPro’s Proposed Response to Plaintiffs’ Motion for Preliminary Relief and its Motion to Dismiss Satisfy the Attachment Requirement of Rule 24(c) 15

CONCLUSION..... 16

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>All. for Hippocratic Med. v. FDA</i> , 2023 WL 11840559 (N.D. Tex. Feb. 6, 2023).....	1, 5
<i>Am. Coll. of Obstetricians & Gynecologists v. FDA</i> , 472 F. Supp. 3d 183 (D. Md. 2020).....	4
<i>Apotex Inc. v. FDA</i> , 508 F. Supp. 2d 78 (D.D.C. 2007).....	8
<i>Danco Lab’ys, LLC v. All. for Hippocratic Med.</i> , 143 S. Ct. 1075 (2023).....	5
<i>Eagle Pharms., Inc. v. Price</i> , 322 F.R.D. 48 (D.D.C. 2017).....	8
<i>Edwards v. City of Houston</i> , 78 F.3d 983 (5th Cir. 1996)	7
<i>Entergy Gulf States La., L.L.C. v. EPA</i> , 817 F.3d 198 (5th Cir. 2016)	7
<i>Farina v. Mission Inv. Tr.</i> , 615 F.2d 1068 (5th Cir. 1980)	15
<i>FDA v. All. for Hippocratic Med.</i> , 602 U.S. 367 (2024).....	5
<i>FDA v. Am. Coll. of Obstetricians & Gynecologists</i> , 141 S. Ct. 578 (2021).....	4
<i>United States ex rel. Hernandez v. Team Fin., L.L.C.</i> , 80 F.4th 571 (5th Cir. 2023)	16
<i>John Doe No. 1 v. Glickman</i> , 256 F.3d 371 (5th Cir. 2001)	8
<i>La Union del Pueblo Entero v. Abbott</i> , 29 F.4th 299 (5th Cir. 2022)	9, 13
<i>Liberty Surplus Ins. Co. v. Slick Willies of Am., Inc.</i> , 2007 WL 2330294 (S.D. Tex. Aug. 15, 2007)	15, 16

Louisiana v. Burgum,
132 F.4th 918 (5th Cir. 2025)7, 9, 10, 12, 13

Missouri v. FDA,
2025 WL 1223581 (N.D. Tex. Apr. 28, 2025)1, 3, 5, 7, 9, 12, 13, 14, 15

Missouri v. FDA,
2025 WL 2825980 (N.D. Tex. Sept. 30, 2025).....5

Mova Pharm. Corp. v. Shalala,
140 F.3d 1060 (D.C. Cir. 1998).....8

Newby v. Enron Corp.,
443 F.3d 416 (5th Cir. 2006)14

Rotstain v. Mendez,
986 F.3d 931 (5th Cir. 2021)7

Sierra Club v. Espy,
18 F.3d 1202 (5th Cir. 1994)7, 9

Texas v. United States,
805 F.3d 653 (5th Cir. 2015)8

Trbovich v. United Mine Workers of Am.,
404 U.S. 528 (1972).....9

Wal-Mart Stores, Inc. v. Tex. Alcoholic Beverage Comm’n,
834 F.3d 562 (5th Cir. 2016)7, 8, 9

Statutes

21 U.S.C. § 355-18

Rules

Fed. R. Civ. P. 24(a)(2).....7

Fed. R. Civ. P. 24(b)(1)(B)14

Fed. R. Civ. P. 24(c)15

LR7.615

GenBioPro, Inc. (“GenBioPro”) 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 case challenges the regulatory terms on which GenBioPro is permitted to distribute its primary product nationwide, and GenBioPro has a right to intervene to defend its interests. Since 2019, GenBioPro has manufactured generic mifepristone in the United States, and sales of mifepristone represent the majority of its revenue. A significant portion of GenBioPro’s revenue derives from the sale of mifepristone prescribed via telehealth services and dispensed via pharmacies in non-party states to non-party patients nationwide. Because this lawsuit seeks to reimpose an obsolete condition, last in effect in early 2021—that mifepristone can be dispensed only in-person in clinics, medical offices, and hospitals (“in-person dispensing requirement,” ECF 1-50 at 8)—it directly and concretely threatens GenBioPro’s interests.

The drug manufacturers’ stake in these issues is self-evident. Indeed, in the predecessor case to this one in Texas, in which various organizations and individuals (and later three intervenor-plaintiff States), sued the U.S. Food and Drug Administration (“FDA”) and others challenging regulatory actions relating to mifepristone, the court granted motions to intervene by both GenBioPro and mifepristone’s branded manufacturer, Danco Laboratories, LLC (“Danco”). *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). Danco’s motion to intervene was not even contested by the plaintiffs, who were represented by the same counsel that represent Plaintiffs here. And the only objection that the State intervenor-plaintiffs raised to permissive intervention by GenBioPro was timeliness, an argument that the court overruled there, and which is plainly inapplicable in this case, which was just filed and remains at the pleadings stage.

Here, GenBioPro meets all of the requirements for intervention as of right under Rule 24(a). This motion is timely; GenBioPro has a paradigmatic and obvious interest in defending the regulatory regime governing its own product; GenBioPro's interest would be impaired by Plaintiffs' requested relief; and the existing parties will suffer no prejudice from intervention.

Defendants do not adequately protect GenBioPro's interests, as their recent combined motion to stay and response to Plaintiffs' motion for preliminary relief (ECF 51, "Defs.' Br.") amply illustrates. Defendants do not defend the merits of the challenged FDA action, even though it was based on a robust body of scientific evidence that the agency detailed at length in its decision. *See generally* ECF 1-50 (FDA 2023 Summary Review). Instead, Defendants rest largely on a recently announced administrative review of what they call the "safety risks of mifepristone." Defs.' Br. 3. Defendants thus echo Plaintiffs' Complaint, which alleges that, in connection with launching this new review, Defendants "admitted that there was a 'lack of adequate consideration' of the safety risks 'underlying the prior REMS approvals,' including the decision to 'remov[e] the in-person dispensing requirement.'" Compl. ¶ 13. GenBioPro emphatically disagrees.

Indeed, comparing Defendants' Brief, on the one hand, with GenBioPro's Conditional Opposition and Conditional Motion to Dismiss (both submitted with this motion), on the other, makes clear that their positions are far from aligned. Defendants' Brief ignores the merits, opposing Plaintiffs' request for preliminary relief solely on standing grounds and because Defendants prefer a stay. *See* Defs.' Br. 9-20. Most glaringly, Defendants stay silent on the reasoned basis for FDA's 2023 modifications to the Risk Evaluation and Mitigation Strategy ("REMS") for mifepristone. In contrast, GenBioPro, if permitted to intervene, would oppose preliminary relief on the grounds that the 2023 REMS was supported by overwhelming scientific

and medical evidence that was the basis of FDA’s action, has been bolstered by subsequent studies, and is still lawful and scientifically sound today.

GenBioPro would also argue that Plaintiffs’ arguments under the Comstock Act are incorrect, that Plaintiffs failed to exhaust administrative remedies, and that their claims are not ripe, all of which render Plaintiffs unlikely to succeed on the merits. Moreover, unlike Defendants, who seek a stay that would permit this litigation to resume later, GenBioPro would seek dismissal now. Those differences in positions are stark, fundamentally distinguishing this case from others where an intervenor-movant was unable to overcome the presumption of adequate representation because its proposed pleading sought the same objective without adding new evidence, claims, or defenses. GenBioPro thus more than satisfies the requirements for intervention under Rule 24(a) and is entitled to intervene in this action.

At a minimum, permissive intervention under Rule 24(b) is appropriate. In the predecessor case in Texas, the court correctly found that “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.

BACKGROUND

In April 2019, FDA approved GenBioPro’s Abbreviated New Drug Application (“ANDA”) for Mifepristone Tablets, 200mg, a generic version of mifepristone. Approved by FDA as safe and effective for performing medical abortions at 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. *See, e.g.*, ECF 1-50 at 6-8.

Until 2020, as part of the REMS, FDA required that mifepristone be dispensed only in-person at clinics, medical offices, and hospitals. A court enjoined that requirement during the COVID-19 pandemic. *See Am. Coll. of Obstetricians & Gynecologists v. FDA*, 472 F. Supp. 3d 183 (D. Md. 2020). Although the Supreme Court later stayed that injunction, *see FDA v. Am. Coll. of Obstetricians & Gynecologists*, 141 S. Ct. 578 (2021), FDA suspended enforcement of the in-person dispensing requirement in April 2021, ECF 1-50 at 48-49. Then, in December 2021, based on a “comprehensive review” of the published literature and postmarketing safety data, including real-world evidence from when the in-person dispensing requirement was not being enforced, FDA concluded that this requirement was unnecessary from a safety perspective. *See id.* at 45, 77.

On January 3, 2023, FDA published a new, shared REMS for Mifeprex and generic mifepristone. The 2023 REMS formally withdrew the in-person dispensing requirement for mifepristone. FDA’s decision was based on a robust administrative record that included its review of safety data, the distribution model in use while the in-person dispensing requirement was not being enforced, and other REMS assessment data and published literature. *Id.* at 80-83. Having evaluated that evidence, FDA concluded that “the REMS program, with the removal of the in-person dispensing requirement and the addition of a requirement for pharmacy certification, will continue to ensure the benefits of mifepristone for medical abortion outweigh the risks while minimizing the burden imposed by the REMS on healthcare providers and patients.” *Id.* at 82. Without the in-person dispensing requirement, prescribers and pharmacies can now dispense mifepristone by mail or in-person, making it available and accessible to many more patients.

In the meantime, in November 2022, several individuals and organizations (represented by counsel who also represent Plaintiffs in this case) sued FDA, the U.S. Department of Health and Human Services, and various federal officials in the Northern District of Texas challenging regulatory actions relating to mifepristone, including the 2021 policy of non-enforcement of the in-person dispensing requirement. *FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 372-77 (2024). Those plaintiffs sought a preliminary injunction or a stay of the effective dates of the challenged FDA actions.

Mifeprex's manufacturer Danco intervened in the case without opposition. *See All. for Hippocratic Med.*, 2023 WL 11840559, at *1. The district court and the Fifth Circuit then granted the plaintiffs different forms of partial relief, but the Supreme Court barred those orders 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 defuse defendants' standing-based challenges to the original plaintiffs' lawsuit. The States also sought to intervene in the Supreme Court, but their motion was denied. 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 the court permitted under Rule 24(b). *Missouri*, 2025 WL 1223581, at *6. The Texas district court subsequently 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).

On October 6, 2025, after unsuccessfully attempting to intervene in the *Missouri* case, *see id.*, Louisiana and Rosalie Markezich filed this lawsuit against FDA challenging the 2023 REMS. Plaintiffs allege that the 2023 REMS is arbitrary and capricious and contrary to law and ask the Court to stay, set aside, and vacate FDA’s approval of the REMS.

More than two months later, on December 17, 2025, Plaintiffs filed a Motion for Preliminary Relief under 5 U.S.C. § 705, seeking to stay the effective date of the 2023 REMS, which has now been in effect for three years. ECF 20. The Court ordered the Government to respond to Plaintiffs’ motion by January 27, 2026, and further ordered prospective intervenors Danco and GenBioPro to file their motions and conditional responses to Plaintiffs’ motion by January 30, ECF 28, later extended to February 3, ECF 39. The Court also stayed FDA’s deadline to respond to the Complaint. ECF 39.

On January 27, Defendants filed a motion to stay the proceedings, ECF 50, and a memorandum in support of the motion to stay and in opposition to Plaintiff’s motion for preliminary relief, ECF 50-1, 51. In their submissions, Defendants ask the Court to “stay this litigation pending the outcome of FDA’s review of the mifepristone REMS,” Defs.’ Br. 4, 9-13, and argue that Plaintiffs lack Article III standing, *id.* at 14-20. Defendants offer no other arguments in opposition to Plaintiffs’ motion for preliminary relief.

Aside from these recent filings, no motion practice has occurred in this case; Defendants have not responded to the Complaint; and the administrative record has not been produced.

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 just October 2025 and moved for preliminary relief in December 2025. The day after Plaintiffs filed their motion, GenBioPro notified the Court of its intent to file a motion to intervene. ECF 26. The Court ordered that all proposed intervenors file intervention motions by January 30, 2026, ECF 28, which was later extended to February 3, 2026. ECF 39. 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 filing of the motion for preliminary relief, which GenBioPro seeks to oppose, and Defendants’ motion to stay in response to Plaintiffs’ motion. This Court’s briefing schedule avoids any prejudice to Plaintiffs by giving them a reasonable time after GenBioPro’s Conditional Opposition to file their reply in support of preliminary relief. *See id.*

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.”); cf. *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).

Here, GenBioPro has a direct and substantial interest in this litigation as a party directly regulated by the 2023 REMS, *Texas v. United States*, 805 F.3d 653, 660 (5th Cir. 2015), with a concrete and “legally protectable interest in the regulatory scheme” under which its product is distributed, *Wal-Mart*, 834 F.3d at 566. At FDA’s request, GenBioPro proposed the REMS modifications at issue here, ECF 1-50 at 5, and those FDA-approved distribution conditions control GenBioPro’s ability to lawfully market its product nationwide, *see generally* 21 U.S.C. § 355-1. As GenBioPro’s CEO explains in the declaration submitted with this motion, GenBioPro’s business model relies directly on the 2023 REMS that Plaintiffs seek to stay or vacate. *See Decl.*

of Evan Masingill ¶¶ 7-10. On these facts, “it is obvious that the economic interests of [GenBioPro] are at stake” in this lawsuit. *See Espy*, 18 F.3d at 1207; *see also Wal-Mart*, 834 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. If Plaintiffs’ claims succeed and the challenged 2023 REMS is vacated, GenBioPro would face severe operational distress. *See Masingill Decl.* ¶¶ 7, 11-15. A “stay” of the 2023 REMS and a return to the in-person dispensing requirement would immediately disrupt GenBioPro’s national distribution model and network, causing financial, reputational, and operational harm. *Id.* ¶¶ 11-14. If GenBioPro is not able to present its evidence and arguments explaining those harms in this litigation, there is far more than a mere “possibility that [GenBioPro’s] interest could be impaired or impeded” as a practical matter. *See La Union del Pueblo Entero v. Abbott*, 29 F.4th 299, 307 (5th Cir. 2022). That harm is a virtual certainty if Plaintiffs are awarded any relief. *See Masingill Decl.* ¶¶ 7, 10-15.

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 2023 REMS on the merits and ensure that the REMS remains in effect, whereas Defendants are in the midst of what they call “a study of the safety of the current REMS, in order to determine whether modifications are necessary.” ECF 1-110 at 1; *see* Defs.’ Br. 3 (stating FDA is conducting a “review and study of the safety risks of mifepristone”). On its own, GenBioPro’s goal of defending the REMS on the merits—while Defendants fail to do so—is dispositive on this element.

The gap between GenBioPro’s and Defendants’ objectives is vividly illustrated by comparing Defendants’ response to Plaintiffs’ motion for preliminary relief to the Conditional Opposition that GenBioPro would file if permitted to intervene. Defendants oppose Plaintiffs’ motion for preliminary relief on two grounds: (1) Defendants would prefer a stay pending FDA’s review of the safety of the current REMS, Defs.’ Br. 9-13; and, (2) Plaintiffs lack standing, *id.* at 14-20. Defendants do not address, much less defend against, the merits of Plaintiffs’ claims. They do not defend the 2023 REMS as supported by the medical and scientific evidence before the agency, do not engage on any legal issues relating to the Comstock Act, do not invoke FDA’s strict exhaustion requirement or the “ripeness” doctrine, and do not address the concrete harms that a suspension of the 2023 REMS would inflict on GenBioPro and public health across the country. Nor do Defendants actively seek dismissal of this case.

GenBioPro departs from Defendants on all of those issues. GenBioPro’s Conditional Opposition offers overwhelming scientific and medical evidence—relied on by FDA—that

supports the 2023 REMS, which independently undercuts Plaintiffs’ likelihood of success on the merits of their claims. GenBioPro’s Conditional Opp. § III.A. GenBioPro also attaches voluminous exhibits supporting FDA’s 2023 actions and rebutting Plaintiffs’ incorrect claims that subsequent events refute the reasonableness of lifting the in-person dispensing requirement. *See id.*; Ex. B (GenBioPro’s Citizen Petition to FDA); Exs. B-1–B-9 (appendix in support of GenBioPro’s Citizen Petition). GenBioPro’s Conditional Opposition also opposes Plaintiffs’ novel Comstock Act argument, which Defendants do not address. GenBioPro’s Conditional Opp. § III.B.¹ And GenBioPro seeks outright dismissal of this case due to its jurisdictional flaws, whereas Defendants seek a stay. *See* GenBioPro’s Conditional Mot. to Dismiss.

Defendants further illustrate that they do not share GenBioPro’s objective of defending and preserving the 2023 REMS when they repeat Plaintiffs’ claim that Defendants “admitted that there was a ‘lack of adequate consideration’ of the safety risks ‘underlying the prior REMS approvals,’ including the decision to ‘remov[e] the in-person dispensing requirement.’” Compl. ¶ 13 (quoting ECF 1-110 at 1); *see* Defs.’ Br. 1 (quoting same). Similarly, Defendant Kennedy has pledged to “review all the evidence ... on the safety of [mifepristone],” claiming that “[r]ecent studies already point to serious risks when mifepristone is used without proper medical oversight.” ECF 1-108. Defendants have explained that their review of the mifepristone REMS was prompted by the same publication by the Ethics and Public Policy Center (EPPC)—an anti-abortion advocacy group—

¹ The government’s change in position from the *Alliance for Hippocratic Medicine* litigation further demonstrates that Defendants do not adequately represent GenBioPro’s interest. For instance, in their opposition to the plaintiffs’ motion for a preliminary injunction in the *Alliance* case, Defendants rebutted plaintiffs’ Comstock Act arguments as untimely, unexhausted, and legally incorrect and explained why in-person dispensing is unnecessary based on the scientific and medical evidence. Defs.’ Opp. to Mot. for Prelim. Inj. at 23, 28-30, *All. for Hippocratic Med. v. FDA*, No. 2:22-cv-00223 (N.D. Tex. Jan. 13, 2023), ECF 28. In Defendants’ response in this case, they make none of those arguments.

that features prominently in Plaintiffs' Complaint. *See* ECF 1-110 at 2 (Defendants Kennedy and Makary citing to the EPPC report, "The Abortion Pill Harms Women," when announcing their "study of the safety of the current REMS"); ECF 1-13 (copy of "The Abortion Pill Harms Women"); Compl. ¶ 38 & nn.18-19 (referencing same). While Defendants' Brief does not address the EPPC study, as GenBioPro's conditional opposition explains, the EPPC report is a self-published (non-peer reviewed) report posted by an advocacy organization and not grounded in any reliable scientific methodology. *See* GenBioPro's Conditional Opp. § III.A; *see* Ex. B at 16-20 (discussing critical methodological problems with EPPC report).

The sharp contrast between GenBioPro's and Defendants' objectives makes this case far different from *Burgum*, where the first presumption of adequate representation applied because would-be intervenor American Petroleum Institute (API) "ha[d] the same ultimate objective as [defendant] BOEM [(the Bureau of Ocean Energy Management)]: to uphold the Rule." *Burgum*, 132 F.4th at 922; *see id.* at 921 (noting API's "proposed answer was materially identical to BOEM's, stating no new claims or defenses"). The same conclusion simply does not apply here.

The divergence in objectives also distinguishes this case from *Missouri*, in which the Texas court determined that GenBioPro's interests were adequately protected by FDA for purposes of mandatory intervention.² At that point in the *Missouri* case, no motion for injunctive relief was pending; the only issue presented was whether the States' amended complaint should be dismissed for lack of standing, exhaustion, and venue. On those issues, GenBioPro presented the same arguments as FDA (and Danco, which had already been allowed to intervene). *See Missouri*, 2025

² Although the *Missouri* court found that the representation presumption precluded *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, which is also warranted in the alternative here, *see* Section II, *infra*.

WL 1223581, at *4. The court held in those circumstances that GenBioPro did “not overcome the same-ultimate-objective presumption” because it showed no “distinct evidence it wished to introduce, remedies it sought, [or] legal arguments it intended to make.” *Id.* (quotation marks omitted). The present situation—where GenBioPro seeks to mount a much more expansive opposition to Plaintiffs’ motion for preliminary relief than the standing and stay arguments offered by Defendants, and seeks dismissal of the case—is dramatically different. GenBioPro’s conditional opposition leaves no doubt that it would introduce distinct evidence, seek additional remedies (*i.e.*, dismissal), and make different legal arguments than FDA.

Even if the “ultimate objective” presumption of adequate representation somehow applied (it does not), Defendants’ failure to defend the 2023 REMS on the merits or to seek dismissal, as well as 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 position and public statements 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, Defs.’ Br. 3; ECF 1-110, shows that they are *not* bound to represent GenBioPro’s interest 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 objectives and positions, there can be no question that FDA’s representation *is* inadequate to protect GenBioPro’s interests.³

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). “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). Although the *Missouri* court found that the presumption of adequate representation meant GenBioPro could not intervene *as of right* under Rule 24(a)(2), it granted GenBioPro’s motion for *permissive* intervention under Rule 24(b) (for which inadequate representation by existing parties is not a requirement). *Missouri*, 2025 WL 1223581, at *4-6.

³ As explained in GenBioPro’s Conditional Opposition to Plaintiffs’ motion for preliminary relief, Plaintiffs lack standing, and this Court therefore lacks jurisdiction over this case. GenBioPro’s Conditional Opp. § I. Plaintiffs’ failure to exhaust administrative remedies and FDA’s ongoing review of the mifepristone REMS similarly support dismissal. *Id.* § II. For those reasons, denial of Plaintiffs’ request for preliminary relief and dismissal of the Complaint are the appropriate remedies. To the extent the Court declines to dismiss the case at this time, GenBioPro would not oppose Defendants’ request for a stay of these proceedings pending the ongoing FDA review.

Here, as in *Missouri*, GenBioPro’s defense that the 2023 REMS was reasonable, reasonably explained, and should be upheld clearly shares common questions of law and fact with the main action. *See* GenBioPro’s Conditional Opp. § III.A. Louisiana’s claims against FDA center on those very same questions. *See Missouri*, 2025 WL 1223581, 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, *see supra* at 6-8, 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 Proposed Response to Plaintiffs’ Motion for Preliminary Relief and its Motion to Dismiss Satisfy the Attachment Requirement of 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); *see* LR7.6 (requiring proposed pleading to be filed with motion to intervene). 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 both its Conditional Memorandum in Opposition to Plaintiffs’ Motion for Preliminary Relief and its Conditional Motion to Dismiss. Those

submissions, together with the instant 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., L.L.C.*, 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 (1) Conditional Memorandum in Opposition to the Motion for Preliminary Relief and (2) Conditional Motion to Dismiss for filing on the docket in this action.

Dated: February 3, 2026

Skye L. Perryman
WDLA Temp. Bar No. 918774
Carrie Y. Flaxman
WDLA Temp. Bar No. 918135
Lisa Newman
WDLA Temp. Bar No. 918773
DEMOCRACY FORWARD
FOUNDATION
P.O. Box 34553,
Washington, DC 20043
Tel: (202) 448-9090
sperryman@democracyforward.org
cflaxman@democracyforward.org
lnewman@democracyforward.org

Respectfully submitted,

/s/ Robert J. Katerberg

Robert J. Katerberg
WDLA Temp. Bar No. 918627
Daphne O'Connor
WDLA Temp. Bar No. 918772
ARNOLD & PORTER
KAYE SCHOLER LLP
601 Massachusetts Avenue, N.W.
Washington, D.C. 20001
Tel: (202) 942-5000
daphne.oconnor@arnoldporter.com
robert.katerberg@arnoldporter.com

John Adcock
ADCOCK LAW LLC
Louisiana Bar No. 30372
8131 Oak Street, Ste 100
New Orleans, LA 70118
Tel: (504) 233-3125
Fax: (504) 308-1266
jnadcock@gmail.com

*Counsel for Proposed Intervenor-Defendant
GenBioPro, Inc.*