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.	Civ. No.: 6:25-cv-01491 Judge: David C. Joseph Mag. Judge: David J. Ayo

MEMORANDUM OF LAW IN SUPPORT OF
DANCO LABORATORIES, LLC'S MOTION TO INTERVENE

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INTRODUCTION

Danco moves to intervene in this case to represent its interest as the sponsor of Mifeprex (mifepristone). The Food and Drug Administration (FDA) approved Mifeprex as safe and effective for its intended use in 2000, attaching certain use restrictions that became a Risk Evaluation and Mitigation Strategy (REMS) in 2008. Consistent with FDA's statutory authority, these REMS been modified multiple times—most recently in 2023, when FDA lifted an in-person dispensing requirement that it had not enforced since April 2021. Through the years, FDA has defended its various actions regarding mifepristone in court and in public. In September 2025, however, FDA announced it was conducting a review of the mifepristone REMS. Just weeks later, Plaintiffs filed this lawsuit, asking for an order that "[h]olds unlawful, stays, sets aside, and vacates the 2023 REMS" and a preliminary injunction directing "Defendants to withdraw or suspend" that REMS. ECF No. 1, Compl. at 50; *see also* ECF No. 20 at 2, Mot. for Prelim. Relief.

This lawsuit directly threatens Danco's interests. Mifeprex is Danco's only product. If Plaintiffs succeed in their request for this Court to enjoin, set aside, or vacate the 2023 REMS, Danco will be unable to continue lawfully distributing its product under that REMS. Although it is not entirely clear what action Danco—or FDA—would have to take for Danco to resume distributing Mifeprex, FDA's past statements indicate Danco would have to submit a new REMS application and obtain FDA approval, which would take an unknown amount of time. Ex. A, Long Decl. ¶¶ 9-17. What is clear, however, is that Danco's business would face substantial, immediate, and nationwide disruption.

Danco's interest is not a surprise to Plaintiffs, who unsuccessfully tried to join an earlier lawsuit in which Danco had spent three years defending FDA's regulation of mifepristone in the Northern District of Texas, in the Fifth Circuit, and in the Supreme Court. *See FDA v. Alliance for Hippocratic Med.*, 602 U.S. 367 (2024) (*Alliance*). Danco is an appropriate party here for the same reasons it was in *Alliance*.

If anything, Danco's interests in intervention now are stronger, given that FDA has initiated a review of the mifepristone REMS on its own initiative. ECF No. 50-1 at 1-2. The Federal

Defendants seek a stay and denial of Plaintiffs' motion for preliminary relief based on FDA's ongoing review and Plaintiffs' lack of ongoing harm or Article III standing. They do not address other substantive bases for denying preliminary relief. Danco believes there is no scientifically valid evidence, before or after the 2023 REMS approval, that warrants any different conclusion regarding (1) the benefit-risk profile of mifepristone when dispensed by a method other than in-person, or (2) how to "minimize the burden on the health care delivery system of complying with the [REMS]." 21 U.S.C. § 355-1(g)(4)(B). And Danco wishes to raise several deficiencies in Plaintiffs' challenge, including in their request for preliminary relief, that FDA has not argued. These divergences all make clear that FDA does *not* adequately represent Danco's interests in this litigation.

Danco thus has a right to intervene in this action under Rule 24(a). *Texas v. United States*, 805 F.3d 653, 657 (5th Cir. 2015) ("Federal courts should allow intervention where no one would be hurt and the greater justice could be attained." (citation omitted)). At the very least—given the economic and proprietary stakes for Danco, which are neither represented nor protected by FDA—the Court should allow permissive intervention, as the district court did in *Alliance*. Such intervention would not prejudice any party and would help ensure a more complete development of the issues presented and allow Danco to protect its interests.

BACKGROUND

A small pharmaceutical company incorporated in Delaware, Danco holds the New Drug Application (NDA) for Mifeprex (mifepristone) Tablets, which is approved for use in a regimen with misoprostol for the medical termination of intrauterine pregnancy through 70 days gestation. Mifeprex is Danco's only product. Long Decl. ¶ 3. FDA first approved Mifeprex in 2000 for use through 49 days of gestation, subject to various use restrictions, including that the drug be dispensed in-person to the patient by the prescriber or someone working under their supervision. *See* ECF No. 1-32. Those use restrictions were deemed a REMS as a result of the 2007 amendments to the Food, Drug, and Cosmetic Act. *See* 73 Fed. Reg. 16,313 (Mar. 27, 2008); 21 U.S.C. § 355-1(a)(1); *see also* ECF Nos. 1-29, 1-30. In 2016, FDA granted Danco's supplemental

NDA (sNDA), extending the drug's approval for use up to 70 days' gestation and modifying the REMS to remove certain restrictions. All of those changes were based on the agency's review of extensive clinical data and its expert judgment that the drug would remain safe and effective for its intended use with these modifications. *See* ECF No. 1-11; 21 U.S.C. § 355-1(g)(4) (authorizing FDA to "modif[y]" or "remove[]" restrictions that are no longer necessary to ensure drug's benefits outweigh risks). The 2016 sNDA approval did not modify the REMS requirement of an in-person visit to receive Mifeprex.

In April 2021, in response to a request from the American College of Obstetrics and Gynecologists during the COVID-19 pandemic, FDA said it would exercise enforcement discretion regarding the in-person dispensing requirement for Mifeprex. *See* ECF No. 1-3. After additional analysis, including of safety data from the non-enforcement period, FDA in December 2021 directed Danco to submit a sNDA proposing modifications to the REMS to remove the in-person dispensing requirement. Danco did so, and FDA approved Danco's sNDA in January 2023. ECF No. 1-50.[1]

In November 2022, a group of plaintiffs challenged FDA's 2000, 2016, 2019, and 2021 decisions in the U.S. District Court for the Northern District of Texas. *Alliance* ECF No. 1. Danco promptly filed an unopposed motion to intervene in support of the Federal Defendants, which the court granted. *Alliance* ECF Nos. 19, 33.[2] The *Alliance* district court "in effect enjoined" those decisions, but the Supreme Court stayed that injunction before it took effect and unanimously held that the *Alliance* plaintiffs "lack[ed] standing to challenge FDA's actions," *Alliance*, 602 U.S. at 374, 377.

[1] FDA approved generic versions of Mifeprex in 2019 and 2025. ECF No. 1 ¶ 43 n.32, 1-109. The Mifeprex REMS also applies to the generics.

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

Meanwhile, Missouri, Kansas, and Idaho moved to intervene as plaintiffs in the *Alliance* action, which the court granted. *Alliance* ECF No. 151. And after the Supreme Court's *Alliance* decision, Missouri, Kansas, and Idaho amended their complaint-in-intervention, which Danco and FDA moved to dismiss, asserting (among other things) that venue was improper in Texas. *Alliance*, ECF Nos. *Alliance* ECF Nos. 203, 217, 218, 221. While those motions were pending, Louisiana and Rosalie Markezich moved to intervene in the Texas suit. *Alliance* ECF No. 264. The court transferred Missouri, Kansas, and Idaho's complaint to Missouri and denied Louisiana and Ms. Markezich's motion to intervene as moot. *Alliance* ECF No. 273.

A few weeks later, and after FDA had announced it was initiating a review of the mifepristone REMS, Louisiana and Ms. Markezich refiled their complaint in this Court. ECF No. 1, Compl. (Oct. 6, 2025). The suit asserts that the 2023 REMS, which removes the in-person dispensing requirement, is arbitrary and capricious and an abuse of discretion (Count 1) and contrary to law (Count 2). More than two months later, Plaintiffs sought a preliminary injunction. ECF No. 20.

ARGUMENT

I. Danco Is Entitled To Intervene As A Matter Of Right Under Rule 24(a).

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

203 ("[D]oubts [are] resolved in favor of the proposed intervenor"). Danco readily satisfies this standard.

Timeliness. Danco's motion to intervene is timely. Danco noticed its intent to intervene just two days after Plaintiffs moved for a preliminary injunction, and before Defendants had responded to Plaintiffs' complaint. *See* ECF No. 23. The case is still in its early stages, and this Court has not ruled on any substantive motions. Courts regularly find motions to intervene timely in similar circumstances. *See, e.g.*, *Wal-Mart Stores, Inc v. Texas Alcoholic Beverage Comm'n*, 834 F.3d 562, 565-566 (5th Cir. 2016) (motion to intervene timely when filed three months after defendant filed its answer following denial of motion to dismiss); *NextEra Energy Cap. Holdings, Inc. v. D'Andrea*, No. 20-50168, 2022 WL 17492273, at *3 (5th Cir. Dec. 7, 2022) (per curiam) (motion to intervene timely when filed within two months of plaintiffs bringing suit and before defendants filed responsive pleadings); *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1076 (D.C. Cir. 1998) (seeking "to intervene a few weeks after [plaintiff] initiated its action, and before the district court ruled on the preliminary injunction . . . cannot be regarded as untimely").

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

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

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

Second, and relatedly, Danco has "economic interests" that "are directly related to the litigation," which independently "justify intervention." *Wal-Mart*, 834 F.3d at 568; *Black Fire Fighters Ass'n of Dallas v. City of Dallas*, 19 F.3d 992, 994 (5th Cir. 1994) (litigation's "prospective interference with [economic] opportunities can justify intervention") (citation omitted). Plaintiffs' suit asks this Court to stay, vacate, or enjoin FDA's 2023 REMS. FDA's prior statements, and its recently filed brief, suggest that any such order against the 2023 REMS would leave Danco unable to distribute Mifeprex until Danco submits, and FDA approves, a new REMS. Long Decl. ¶¶ 10-15 (citing Declaration of FDA Principal Deputy Commissioner Janet Woodcock, M.D., in support of Emergency Stay Application, *FDA v. Alliance for Hippocratic Medicine*, Supreme Court No. 22A902, at Appendix 113a-116a); FDA Br. 11. Even if FDA were to approve a new REMS quickly, Danco would then still have to revise product labels, packaging, and promotional materials, and to amend its supplier and distributor contracts and policies (among other things). Long Decl. ¶¶ 7, 17. Absent a remand without vacatur, exercise of enforcement discretion by FDA, or other action similarly permitting continued distribution in the interim, Plaintiffs' requested relief would thus likely halt Danco's distribution of Mifeprex nationwide, for an unknown and unknowable period of time. *Id.* ¶ 17. It would also impose significant compliance

costs on Danco. *Id.* Because Mifeprex is Danco's only drug, Plaintiffs' requested relief could impose existential harm on Danco. *Id.* ¶ 20.

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

Impairment of Interest. Danco "need only show that if [it] cannot intervene, there is a possibility that [those] interest[s] could be impaired or impeded." *La Union del Pueblo Entero v. Abbott*, 29 F.4th 299, 307 (5th Cir. 2022) (citing *Brumfield v. Dodd*, 749 F.3d 339, 344-345 (5th Cir. 2014)). Danco satisfies this "liberal[]" and "generous" standard. *See Edwards v. City of Houston*, 78 F.3d 983, 1004-05 (5th Cir. 1996). Plaintiffs seek to impose a significant change to the conditions under which Mifeprex is currently approved for distribution. FDA's prior statements in the *Alliance* litigation indicate that, if that were to occur, Danco would be precluded from labeling and marketing its product for at least some period of time. *See* Long Decl. ¶¶ 10-15. Further, excluding Danco from this litigation would create a situation in which Danco "would be prevented from ever being heard in a lawsuit that has the potential to [up]end" its product's regulatory-approval status. *John Doe No. 1 v. Glickman*, 256 F.3d 371, 380 (5th Cir. 2001); *see also NextEra*, 2022 WL 17492273, at *4 ("a party's interest in a regulatory scheme 'is impaired by the *stare decisis* effect of the district court's judgment' as to the scheme's validity") (quoting *Espy*, 18 F.3d at 1207).

Inadequate Representation. Finally, Danco satisfies the "minimal" burden of showing "that representation of [its] interest" by the current parties "'may be' inadequate." *Entergy*, 817 F.3d at 203 (citation omitted). The Fifth Circuit presumes adequate representation only when an "existing party 'is a governmental body or officer charged by law with representing the interests' of the movant" or "when the intervenor 'has the same ultimate objective as a party to the lawsuit.'" *Louisiana v. Burgum*, 132 F.4th 918, 922 (5th Cir. 2025) (citation omitted); *see also Texas*, 805 F.3d at 661-662. FDA is certainly not charged with generally protecting drug manufacturers' interests or specifically protecting Danco's interests. In opposing Plaintiffs' request for

preliminary relief and seeking a stay instead, FDA's "interests diverge" from Danco's in several material ways that are "germane to the case." *Burgum*, 132 F.4th at 922 (quotation marks omitted).

As explained above, Danco has a distinct commercial interest in the 2023 REMS pursuant to which it has sold its product for over three years. Danco would face significant economic losses if those conditions were enjoined or vacated, even for a short period. Danco's understanding is that the company cannot act unilaterally to put new or revised conditions of approval in place, or even revert to ones that pre-existed the 2023 REMS. *See* Long Decl. ¶¶ 10-15. For this reason, Danco is committed to defending the 2023 REMS on all available grounds. FDA—which announced it would undertake a review of the mifepristone REMS in September 2025 and has described to this Court the competing demands the agency faces across multiple litigations and citizen petitions—does not share Danco's financial or practical interests in the 2023 REMS. *See* ECF No. 50-1 at 1-2. Instead, FDA seeks to exercise its regulatory discretion while "bear[ing] in mind broader public-policy implications" of its decisions. *Berger v. North Carolina State Conf. of the NAACP*, 597 U.S. 179, 196 (2022); *see also Espy*, 18 F.3d at 1208 (noting disunity of interests where "government must represent the broad public interest, not just the economic concerns of" regulated entities).

Specifically, Secretary Kennedy instructed FDA to "conduct a study of the safety of the current REMS, in order to determine whether modifications are necessary." ECF No. 1-110 at 2; Compl. ¶ 13. This announcement questioned the consideration and scientific evidence supporting the 2023 REMS approval, asserting that HHS's reconsideration "is informed by the lack of adequate consideration underlying the prior REMS approvals, and by recent studies raising concerns about the safety of mifepristone as currently administered." ECF No. 1-110 at 2. Danco strongly disagrees with these statements, which come as FDA is currently under a court order to reconsider some aspects of the 2023 REMS that another court found *overly* restrictive. *See Purcell v. Kennedy*, No. 17-cv-00493, 2025 WL 3101785, at *1-2 (D. Haw. Oct. 30, 2025). But regardless, FDA's "reevaluation" constitutes exactly the kind of "conduct showing that the [FDA] inadequately represent[s]" Danco's interests in the 2023 REMS. *Burgum*, 132 F.4th at 923

(discussing *Trbovich v. United Mine Workers of Am.*, 404 U.S. 528, 536-537 (1972), and *Epsy*, 18 F.3d at 1208).

FDA's request for a stay and opposition to Plaintiffs' preliminary injunction motion lays bare the difference in parties' legal positions. As FDA observes, it has "concluded that the best path forward is for the agency to reconsider the restrictions on mifepristone based on all the evidence before the agency." ECF No. 50-1 at 3. Thus, it offers no basis to deny Plaintiffs' preliminary-injunction request claims on the merits. *Id.* at 9-20. Instead, it requests the court pause proceedings and explains that a stay is not prejudicial to Plaintiffs given their lack of ongoing or irreparable harm and their lack of Article III standing. *Id.* Danco's arguments against preliminary relief are significantly broader. Danco raises zone-of-interest, exhaustion, ripeness, and merits defenses that are not part of the Federal Defendants' filing. *See* Ex. D (proposed motion to dismiss and opposition to motion for preliminary relief). And, unlike FDA, Danco has also moved to dismiss the complaint at this time—which would obviate any need for a stay. These differences clearly rebut any presumption of adequate representation. *See Miller v. Vilsack*, No. 21-11271, 2022 WL 851782, at *3 (5th Cir. Mar. 22, 2022) (per curiam); *La Union del Pueblo Entero*, 29 F.4th at 308; *see also Burgum*, 132 F.4th at 923 (noting representation is inadequate where intervenor "wishe[s] to introduce" distinct evidence, seek distinct "remedies," and make distinct "legal arguments").

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

its exclusivity period that is not . . . shared by the public"). Danco is entitled to intervene in this case as of right under Rule 24(a).

II. Alternatively, The Court Should Permit Danco To Intervene Under Rule 24(b).

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

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

Danco's participation will also materially aid the development of key legal issues. Among other things, Danco's opposition will address this Court's subject-matter jurisdiction; the standards imposed on FDA by the APA; and the factual record that informed FDA's decision to approve the 2023 REMS. These issues are core to resolving Plaintiffs' challenge. And unlike FDA—which must consider broader institutional interests and triangulate its defense between the expressed policy concerns of HHS and FDA's obligation under the *Purcell* remand order—Danco will be unencumbered in raising all available arguments, both on threshold grounds and on the merits. It also will be uniquely positioned to present arguments about economic harm and its supply chain disruptions. Danco's interest is just as germane to this litigation as it was in the *Alliance* case,

where Danco participated in briefing and oral argument at every stage, from the district court's proceedings through the Supreme Court.

Like in *Alliance*, the preliminary injunction Plaintiffs seek here underscores the need for Danco's intervention. As noted above, Danco has a financial interest in its continued ability to market its product and in the pharmacy dispensing model it has developed the three years since FDA approved the 2023 REMS. Danco would be significantly and immediately harmed if the injunction that Plaintiffs seek were granted. FDA will not suffer this same type of harm if an injunction issues, since it is Danco (not the government) that is charged with complying with REMS conditions. And, unlike Danco, FDA has not currently offered a thorough defense of its actions to forestall that harm.

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

CONCLUSION

For these reasons, this Court should grant Danco's motion and permit it to intervene in this action.

Dated: February 3, 2026

Respectfully submitted,

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