IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

STATE OF MISSOURI, *et al.*,

Intervenor Plaintiffs,

v.

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

Defendants,

and

DANCO LABORATORIES, LLC,

Intervenor Defendant.

2:22-CV-223-Z

MEMORANDUM OPINION AND ORDER

Before the Court is GenBioPro, Inc.'s ("GenBioPro") Motion for Leave to Intervene ("Motion") (ECF No. 229), filed February 25, 2025. Intervenor Plaintiffs responded on March 18, 2025. ECF No. 243. And GenBioPro replied on April 1, 2025. ECF No. 245. The Motion is now ripe. Having reviewed the Motion, briefing, and relevant law, the Court **GRANTS** the Motion.

BACKGROUND

Intervenor Plaintiffs Idaho, Kansas, and Missouri challenge several actions the Food and Drug Administration ("FDA") took after 2016 concerning abortion medications. ECF No. 217. Specifically, they seek the rescission of the FDA's 2019 generic approval of mifepristone, the restoration of the in-person dispensation requirement, and the restoration of the pre-2016 Risk Evaluation and Mitigation Strategy ("REMS") governing mifepristone to necessitate again several safety requirements, including a seven-week gestational limit, post-prescription medical visits, and the reporting of nonfatal adverse events. *Id.* at 197–98.

This Court permitted intervention in this case more than once. First, it granted Danco, the manufacturer of name-brand mifepristone, permissive intervention. ECF No. 33. Danco could intervene because it held an interest in the availability of its product, its interest shared questions of law and fact in common with the underlying case, and it timely filed. *Id.* at 3. Second, it granted Idaho, Kansas, and Missouri intervention by right. ECF No. 175. GenBioPro, the generic manufacturer of mifepristone and misoprostol, now seeks either intervention by right or permissive intervention.

LEGAL STANDARD

Federal Rule of Civil Procedure 24(a) governs intervention by right. It requires a prospective intervenor to either have a statutory right to intervene or meet all four requirements of Rule 24. Those requirements are: (1) the application must be timely; (2) the applicant must have an interest relating to the case's subject; (3) the case's disposition must "impair or impede" the applicant's "ability to protect its interest"; and (4) the case's existing parties must be inadequate to represent the applicant's interest. FED. R. CIV. P. 24(a)(2). *La Union del Pueblo Entero v. Abbott*, 29 F.4th 299, 305 (5th Cir. 2022) (quoting *Texas v. United States*, 805 F.3d 653, 657 (5th Cir. 2015)). The movant bears the burden for all factors. *Brumfield v. Dodd*, 749 F.3d 339, 341 (5th Cir. 2014). Failure to carry that burden for even one factor requires the Court to deny intervention by right. *Haspel & Davis Milling & Planting Co. v. Bd. of Levee Comm'rs*, 493 F.3d 570, 578 (5th Cir. 2007) ("Failure to satisfy any one requirement precludes intervention of right.").

Federal Rule of Civil Procedure 24(b) governs permissive intervention. It allows a court to "permit anyone to intervene who: (A) is given a conditional right to intervene by a federal statute; or (B) 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). Permissive intervention is "wholly

discretionary with the [district] court." *Kneeland v. Nat'l Collegiate Athletic Ass'n*, 806 F.2d 1285, 1289 (5th Cir. 1987) (alteration in original) (quoting *New Orleans Public Serv., Inc. v. United Gas Pipe Line Co.*, 732 F.2d 452, 470–71 (5th Cir. 1984) (en banc)). This is true "even though there is a common question of law or fact, or the requirements of 24(b) are otherwise satisfied." *Id.* When exercising its extensive discretion, a court considers "whether the intervention will unduly delay or prejudice the adjudication of the original parties' rights." FED. R. CIV. P. 24(b)(3). Permissive intervention is appropriate, but not required, when "(1) timely application is made by the intervenor, (2) the intervenor's claim or defense and the main action have a question of law or fact in common, and (3) intervention will not unduly delay or prejudice the adjudication of the rights of the original parties." *Franciscan All., Inc. v. Azar*, 414 F. Supp. 3d 928, 934 (N.D. Tex. 2019) (quoting *Frazier v. Wireline Sols., LLC*, No. C-10-3, 2010 WL 2352058, at *4 (S.D. Tex. June 10, 2010)).

ANALYSIS

I. GenBioPro Is Not Entitled to Intervention By Right Because It Fails to Demonstrate Government Defendants' Representation Is Inadequate.

To intervene by right, a movant must satisfy four factors: timeliness, a protectable interest, the potential impairment of that interest, and that the current parties are inadequate to represent that interest. *See La Union del Pueblo Entero*, 29 F.4th at 305. GenBioPro fails to demonstrate one required factor: the inadequacy of current parties. The Court need not address the remaining factors—a movant must satisfy all four factors to prevail.[1]

[1] Intervenor Plaintiffs challenge the procedural propriety of GenBioPro's Motion. ECF No. 243 at 7–8. They argue that its Motion should be denied because GenBioPro did not produce a "pleading," as Rule 24(c) requires. FED. R. CIV. P. 24(c). Intervenor Plaintiffs point to *Second* Circuit caselaw. ECF No. 243 at 7. But the *Fifth* Circuit has already answered the question. It takes a "lenient approach." *Liberty Surplus Ins. Cos. v. Slick Willies of Am., Inc.*, No. H-07-0706, 2007 WL 2330294, at *1 (S.D. Tex. Aug. 15, 2007). The Fifth Circuit has even allowed intervention "in the absence of a motion to intervene." *DeOtte v. Azar*, 332 F.R.D. 173, 182 n.5 (N.D. Tex. 2019) (citing *Farina v. Mission Inv. Tr.*, 615 F.2d

A movant must establish that existing parties inadequately represent its interest. *Texas v. United States*, 805 F.3d at 661; *Edwards*, 78 F.3d at 1005 ("The burden of establishing inadequate representation is on the [movant] for intervention."). The inadequate-representation factor typically "is satisfied if the [movant] shows that the representation of his interest 'may be' inadequate." *Trbovich v. United Mine Workers of Am.*, 404 U.S. 528, 538 n.10 (1972). A movant's burden is usually "minimal." *Edwards*, 78 F.3d at 1005. But it is not minimal when two different presumptions apply "in appropriate cases." *Texas v. United States*, 805 F.3d at 661. If one of the presumptions applies, "'the mere possibility that a party *may* at some future time' diverge in its interest 'cannot alone show inadequate representation.'" *Louisiana v. Burgum*, 132 F.4th 918, 922 (5th Cir. 2025) (emphasis in original) (quoting *Bush v. Viterna*, 740 F.2d 350, 358 (5th Cir. 1984)). Thus, the "requirement [has] some teeth" when a presumption applies. *Veasey v. Perry*, 577 F. App'x 261, 263 (5th Cir. 2014).

The first presumption applies if "the would-be intervenor has the same ultimate objective as a party to the lawsuit." *Edwards*, 78 F.3d at 1005. If this first presumption applies, then the movant "must show adversity of interest, collusion, or nonfeasance on the part of the existing party." *Id.* The movant shows adversity of interest if the movant's interests "diverge from the putative representative's interests in a manner germane to the case." *Guenther v. BP Ret. Accumulation Plan*, 50 F.4th 536, 543 (5th Cir. 2022) (quoting *Texas v. United States*, 805 F.3d at 662). Despite GenBioPro's assertion, a "mere possibility that a party *may* at some future time" diverge from a movant's interest "cannot alone show

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1068, 1075 (5th Cir. 1980)). The Fifth Circuit is lenient on this technical requirement because of Federal Rule of Civil Procedure 8(d)(1) and 8(e), which require courts to abstain from requiring technical forms of pleadings or motions and instead construe them "as to do justice." FED. R. CIV. P. 8(d)(1), (e); *see Farina*, 615 F.2d at 1074 (citing Rule 8's older wording). The Court need not adopt the Second Circuit's "stricter approach" because the Fifth Circuit has laid down its "lenient" one. *Liberty*, 2007 WL 2330294, at *1, 2.

inadequate representation." *Bush v. Viterna*, 740 F.2d 350, 358 (5th Cir. 1984) (emphasis in original); ECF No. 229-1 at 17.

The second presumption applies if "the putative representative is a governmental body or officer charged by law with representing the interests of the [putative intervenor]." *Bush*, 740 F.2d at 358. If this second presumption applies, then the movant must show "that its interest is in fact different from that of the [governmental entity] and that the interest will not be represented by [it]." *Id.* (alterations in original) (internal quotations omitted). A movant may overcome this presumption "by showing that the intervenor's 'interest is in fact different from that of the' governmental party 'and that the interest will not be represented by' the existing governmental party." *Burgum*, 132 F.4th at 922 (quoting *La Union*, 29 F.4th at 308).

GenBioPro claims Danco and the federal Defendants inadequately represent its interests. ECF No. 229-1 at 15–17. It argues that neither presumption applies. It claims the first presumption does not apply because neither Danco nor the federal Defendants have the same "ultimate objective" as GenBioPro. *Edwards*, 78 F.3d at 1005. Concerning Danco, GenBioPro claims that because Danco is GenBioPro's direct competitor, it is only interested in protecting its name-brand approval and not GenBioPro's generic approval. ECF No. 229-1 at 16. And concerning the federal Defendants, GenBioPro claims they do not have the same ultimate objective because government agencies represent the public interest and not "just the economic interests of one" manufacturer. *Id.* at 17 (quoting *Heaton v. Monogram Credit Card Bank of Ga.*, 297 F.3d 416, 425 (5th Cir. 2002)). It claims the second presumption does not apply because none of the current Defendants are its "legal representative." *Id.* at 16 (quoting *Brumfield*, 749 F.3d at 345).

The second presumption does not apply. But the first does. And GenBioPro does not overcome it. To overcome the first presumption, GenBioPro must show an "adversity of interest" with a current party that has the same ultimate objective. It does not.

GenBioPro correctly argues that Danco does not have the same ultimate objective. Danco intends to "maintain its regulatory approval and ability to continue providing Mifeprex that can be dispensed to patients." ECF No. 20 at 8. That is not GenBioPro's ultimate objective. Its ultimate objective is to protect "GenBioPro's 2019 regulatory approval for *generic* mifepristone"—not Danco's name-brand Mifeprex. ECF No. 229-1 at 16. Thus, Danco and GenBioPro's interests do "not align precisely." *Brumfield*, 749 F.3d at 345. Intervenor Plaintiffs attempt to construe Danco and GenBioPro's ultimate objective as "the boost in sales that comes when a pill can be distributed with fewer safeguards." ECF No. 243 at 15. But that badly misunderstands how the ultimate objective analysis works. It does not evaluate the tertiary consequences of litigation. It evaluates the parties' intended outcome of the litigation and the relief they seek. And in any event, Intervenor Plaintiffs cite nothing to support their assertion.

However, the federal Defendants and GenBioPro do have the same ultimate objective: to "uphold" the challenged FDA actions. *See Burgum*, 132 F.4th at 922 (defining ultimate objective at the same level of generality). GenBioPro infers that there is an "adversity of interest" between it and the federal Defendants because a government agency protects public interests, but not necessarily private, economic ones. ECF No. 229-1 at 17 ("FDA also has objectives in protecting the independence and flexibility of the regulatory process that are broader than GenBioPro's unique interest in protecting the regulatory approval of its product."); *Edwards*, 78 F.3d at 1005.

That argument is the same one the Fifth Circuit recently rejected. In *Louisiana v. Burgum*, an oil industry group sought intervention to defend a Bureau of Ocean Energy

Management ("BOEM") administrative rule. *Burgum*, 132 F.4th at 920–21. The group argued that BOEM inadequately represented its interest because it "represents the *public* interests of a federal government agency, but not the *specific, private* interests of [the group] and its members. *Id.* at 922 (emphasis added). But the Fifth Circuit held that the group failed to overcome the first presumption because it "did not discuss any action taken by BOEM that is adverse to its own interest." *Id.* at 923. All it demonstrated was "'the mere possibility that [BOEM] *may* at some future time' diverge, [so] it [did] not rebut the first presumption of adequate representation." *Id.* (first alteration in original) (emphasis in original) (quoting *Bush*, 740 F.2d at 358).

In the same way, GenBioPro did not discuss "*specific conduct* showing that the party at issue inadequately represented its interests." *Burgum*, 132 F.4th at 923 (emphasis added). Instead, it repeatedly notes that "even the mere possibility of adverse interests is enough to demonstrate inadequate representation in the Fifth Circuit." ECF No. 245 at 12. Not so—if a presumption applies. *Burgum*, 132 F.4th at 922 n.6. It may be true that the federal Defendants have broader interests to defend than GenBioPro does. But if they have the same ultimate objective, which they do, then GenBioPro must provide more. *Burgum* requires that for a movant to overcome the same-ultimate-objective presumption, it must point to "specific conduct" or "action taken" that would show the existing party is acting "adverse to [movant's] interest." *Burgum*, 132 F.4th at 923. For example, in *Trbovich v. United Mine Workers of America*, the movant highlighted specific conduct showing an adversity of interest because it cited "distinct evidence it wished to introduce, remedies it sought, and legal arguments it intended to make." 404 U.S. 528; *Burgum*, 132 F.4th at 923 (citing *Trbovich*, 404 U.S. at 536–37). GenBioPro shows nothing similar. So for that reason, it does not overcome the

same-ultimate-objective presumption and thus does not demonstrate that the federal Defendants are inadequate. Accordingly, intervention by right must be denied.

II. The Court Grants Proposed Intervenors Permissive Intervention

If the Court denies intervention by right, GenBioPro requests permissive intervention. ECF No. 229-1 at 18. 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." FED. R. CIV. P. 24(b)(1)(B); *Bush*, 740 F.3d at 359 ("Permissive intervention is wholly discretionary with the district court even though there is a common question of law or fact, or the requirements of Rule 24(b) are otherwise satisfied.") But that is not the only question. The Court must also "consider whether the intervention will unduly delay or prejudice the adjudication of the original parties' rights." FED. R. CIV. P. 24(b)(3). In sum, permissive intervention is appropriate when "(1) timely application is made by the intervenor, (2) the intervenor's claim or defense and the main action have a question of law or fact in common, and (3) intervention will not unduly delay or prejudice the adjudication of the rights of the original parties." *Franciscan All., Inc. v. Azar*, 414 F. Supp. 3d 928, 934 (N.D. Tex. 2019) (quoting *Frazier v. Wireline Sols., LLC*, No. C-10-3, 2010 WL 2352058, at *4 (S.D. Tex. June 10, 2010)).

GenBioPro claims its interest in defending mifepristone's availability implicates common questions of law and fact. And it argues its motion is timely and will not unduly delay the litigation or prejudice the rights of any existing party. ECF No. 229-1 at 18. Intervenor Plaintiffs challenge little of that. They only contend that GenBioPro's motion is untimely for the same reasons they argued it was untimely for mandatory intervention. ECF No. 243 at 16.

First, GenBioPro's Motion is timely. GenBioPro argues that it sought intervention soon after it became "'aware that its interests would no longer be protected by the original'

Defendants." ECF No. 229-1 at 10 (quoting *Sierra Club v. Espy*, 18 F.3d 1202, 1206 (5th Cir. 1994)). They note that the original Plaintiffs' complaint directly challenged Danco's 2000 name-brand approval—but only challenged the 2019 general approval to the extent it relied on the 2000 approval. *See* ECF No. 1 at 106–07 ("Because the FDA relied on the unlawful 2000 Approval of Mifeprex as a means to approve GenBioPro's generic drug . . . *if* the Court finds that the 2000 Approval was unlawful . . . *then* the 2019 ANDA Approval . . . was [unlawful]." (emphasis added)).

But now the Intervenor-Plaintiffs' amended complaint directly challenges the generic approval. *See* ECF No. 217 at 192–97 (challenging the generic approval for lacking legal authority, being arbitrary and capricious, and improperly relying on the mifepristone regimen's 2016 changes). And it does not challenge the 2000 approval anymore. Consequently, GenBioPro now has an independent reason to intervene. Under the original complaint, Danco could defend the 2000 approval, and if it succeeded, the 2019 generic approval would likely remain. That is no longer the case. Now, the 2019 generic approval may fall or stand independently of other regulatory changes that Danco seeks to defend. *See* ECF No. 229-1 at 11 ("Danco lacks any commercial incentive to oppose the States' new challenges to GenBioPro's 2019 ANDA approval."). GenBioPro moved to intervene a few weeks after the amended complaint was filed. *See* ECF No. 217 (filed January 16, 2025); ECF No. 229 (filed February 25, 2025). "[T]he speed with which the would-be intervenor acted when it became aware that its interests would no longer be protected by the original parties" reveals whether an intervention motion is timely or not. *Espy*, 18 F.3d at 1206. GenBioPro acted promptly after the amended complaint changed the suit's nature.

Intervenor Plaintiffs claim they raise "the *exact same* arguments" against the 2019 generic approval as the original Plaintiffs did. ECF No. 243 at 10 (emphasis in original).

Thus, the Motion is untimely because GenBioPro would have known about its interest potentially being threatened for "two and a half years." *Id.* at 9. Intervenor Plaintiffs assert that even though they are not challenging the 2000 approval anymore, their challenge to the 2019 approval still depends on the 2000 approval being unlawful. *Id.* at 11 ("With respect to the generic approval, the States are asserting the *exact same* arguments the original Plaintiffs did." (emphasis in original)).

That is incorrect. The original complaint asserted that "*if* the Court finds that the 2000 Approval was *unlawful*," the 2019 approval must also fall. ECF No. 1 at 106 (emphasis added). And Intervenor Plaintiffs' amended complaint facially does not depend on the validity of the 2000 approval to challenge the 2019 approval. In fact, it even neglects to mention the 2000 approval in its claims against the 2019 approval. *See* ECF No. 217 at 191–97. Even more, *nowhere* in the 199-page amended complaint do the Intervenor Plaintiffs directly challenge the lawfulness of the 2000 approval. Thus, their claim "the States still argue that the 2000 approval was improper" appears false. ECF No. 243 at 11. All they do is cite one line that argues the 2019 approval was unlawful because the FDA was "[u]nable to rely on an unlawful approval." ECF No. 217 at 196. That only hints that the 2000 approval was unlawful—at best. But it does not argue it. Intervenor Plaintiffs' attempt to characterize their amended complaint as a mirror challenge to the original complaint ignores the reality of how they fashioned their challenge.

Thus, GenBioPro moved to intervene less than two months after Intervenor Plaintiffs directly challenged its product's approval and dropped the challenge to Danco's product's approval. ECF No. 245 at 7 ("Danco no longer faces a threat to its right to market its drug—only the conditions of its use."). GenBioPro now faces the possible rescission of approval for its product and Danco does not. This is a "unique threat . . . not present earlier in this case." ECF No. 245 at 6. Thus, GenBioPro "became aware that its interests would no longer be

protected by the original parties" when Intervenor Plaintiffs filed the amended complaint. *Espy*, 18 F.3d at 1206. Accordingly, GenBioPro's Motion is timely.

Intervenor Plaintiffs challenge none of the other factors governing permissive intervention. *See* ECF No. 243 at 16. The Court will briefly address each anyway. GenBioPro's claim has a question of law or fact in common with the main action. *See Franciscan*, 414 F. Supp. 3d at 934. GenBioPro seeks to protect its product's FDA approval. Intervenor Plaintiffs challenge GenBioPro's product's FDA approval. Each argues a different side of whether the 2019 approval was lawful. Finally, intervention will not "unduly delay or prejudice" Intervenor Plaintiffs' rights. *Id.* "Its intervention [will] change nothing in the existing case schedule." ECF No. 245 at 9 (citing *NBIS Constr. & Transp. Ins. Servs. v. Kirby Smith Mach., Inc.*, No. 5:20-CV-182, 2021 WL 4227787, at *1 (N.D. Tex. Apr. 8, 2021) ("[N]o 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 . . . .")).

Accordingly, in its wide discretion, the Court **GRANTS** GenBioPro permissive intervention. *Kneeland*, 806 F.2d at 1289.

SO ORDERED.

April 28, 2025

MATTHEW J. KACSMARYK
UNITED STATES DISTRICT JUDGE