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.	Case No. 2:22-cv-00223-Z

REPLY MEMORANDUM IN SUPPORT OF GENBIOPRO, INC.'S MOTION FOR LEAVE TO INTERVENE

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INTRODUCTION

GenBioPro Inc. has an obvious right to intervene in this case to defend against a direct attack on FDA's approval of its drug, generic mifepristone. GenBioPro's Motion is procedurally proper, and the States' Opposition ("Opp.") (ECF No. 243) ignores in-circuit precedent, distorts GenBioPro's filings, and invites clear error.

The States complain that intervention will delay proceedings in this case. Not true. GenBioPro will not file any further Rule 12 briefing. GenBioPro seeks to join this lawsuit solely to protect its unique interests *to the extent* the case proceeds beyond the pleading stage. GenBioPro's filings provide the notice required by Rule 24, and intervention will cause no delay.

The States' timeliness arguments ignore that the *States* effectively restarted this litigation by filing a transformative Amended Complaint on January 16, 2025. GenBioPro moved to intervene less than two months later. The States' claim that their Amended Complaint is substantively identical to the original Alliance Plaintiffs' Complaint ignores the record. The States' concession that the Amended Complaint does "not challenge the original 2000 approval of mifepristone," Joint Status Report, ECF No. 191 ¶ 6, works a sea change as to GenBioPro. The Alliance Complaint had argued that GenBioPro's drug approval rose and fell with Danco's; but now, the States attack GenBioPro's 2019 approval directly, without challenging Danco's 2000 approval at all. No party shares GenBioPro's interest in defending its flagship product.

GenBioPro's interests likewise are not adequately represented by the existing Defendants. Danco is GenBioPro's *competitor*, and the Federal Defendants are GenBioPro's *regulator*. Neither has the same interest in defending GenBioPro's FDA approval for generic mifepristone.

ARGUMENT

I. GenBioPro Is Entitled to Intervene As of Right

A. GenBioPro's Motion Is Timely

The States' Opposition rests on the flawed premise that their Amended Complaint raises "the *exact same* arguments" as the Alliance Plaintiffs' original complaint. Opp. 2, 6 (emphasis in original). But the States never dispute that GenBioPro's motion is timely and appropriate *if* the Amended Complaint raises unique threats to GenBioPro not present earlier in the case. Opp. 5. The Amended Complaint for the first time presents such threats to GenBioPro's interests, bringing two claims challenging approval of GenBioPro's Abbreviated New Drug Application ("ANDA") on multiple new bases, including that FDA "relied on the unlawful 2016 Major Changes labeling," and sought to "enable the violation of state laws restricting abortion." Am. Compl. ¶¶ 785, 766. GenBioPro timely sought to intervene following the Amended Complaint's fundamental restructuring of this lawsuit. *See* GenBioPro's Mem. in Supp. ("Mem.") at 6-10 (ECF No. 229-1).

First, in arguing that any delay in intervention should be measured from when the Alliance Plaintiffs brought suit, the States ignore that, in the Fifth Circuit, the timeliness of GenBioPro's intervention must be assessed by when GenBioPro "became aware that its interests would no longer *be protected by the original parties*." *Sierra Club v. Espy*, 18 F.3d 1202, 1206 (5th Cir. 1994) (emphasis added); *see Cameron v. EMW Women's Surgical Ctr., P.S.C.*, 595 U.S. 267, 279-80 (2022) (rejecting argument that intervention that "came after years of litigation" was untimely because "the most important circumstance relating to timeliness" is when the intervenor learned its "interests 'would no longer be protected' by the parties in the case" (quoting *United Airlines, Inc. v. McDonald*, 432 U.S. 385, 394 (1977))). The States admit that the Alliance Plaintiffs' Complaint sought to vacate FDA's 2000 approval of Danco's NDA, whereas the States' Amended Complaint does not. Opp. 7; *see* Joint Status Report, ECF No. 191 ¶ 6 (describing the States' then-

forthcoming Amended Complaint as "*not* challeng[ing] the original 2000 approval of mifepristone, merely the FDA's actions from 2016 to 2023" (emphasis added)). That distinction makes all the difference. In the Alliance Plaintiffs' Complaint, the challenges to GenBioPro's ANDA flowed from the alleged illegality of Danco's Mifeprex approval. *See* Compl. ¶¶ 384-385, ECF No. 1 ("*[I]f* the Court finds that the 2000 Approval was unlawful, as set forth above, then the 2019 ANDA Approval needed independently to satisfy the requirements of the FFDCA and PREA." (emphasis added)); *id.* ¶ 388 (premising a pretext claim on the existence of FDA's "illegal and unreasonable rationales for the 2019 ANDA Approval"—*i.e.*, the 2000 Mifeprex approval). When the Alliance Plaintiffs were challenging the approvals of branded and generic mifepristone *on the exact same basis*, GenBioPro's interests were thus fully aligned with its competitor Danco.

Now that the States have dropped any challenge to the 2000 approval, however, Danco no longer faces a threat to its right to market its drug—only the conditions of its use. Thus, Danco has absolutely no incentive to contest and defend against the States' requested remedies (*e.g.*, the "rescission" or "withdrawal" of an FDA-approved medication, Am. Compl. at 197). Moreover, GenBioPro holds a unique interest in arguing that its ANDA approval *cannot* be vacated based on a challenge to the REMS modifications because its ANDA is inextricably tied to Danco's NDA approval under the Hatch-Waxman Act. *See generally Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 477 (2013). Those arguments (and others) are unique to the States' challenge to the approval of GenBioPro's 2019 ANDA (without any accompanying challenge to the 2000 NDA), and GenBioPro is the only party positioned to assert them.

Second, in any event, the Amended Complaint challenges the 2019 ANDA on new, freestanding grounds, Mem. 7, and it includes new allegations expressly and specifically targeting GenBioPro by name, Mem. 8. While the States seek to minimize their new allegations as a mere

restructuring of the claims, Opp. 7, the reality is that the Amended Complaint is fundamentally different in substance from the Alliance Plaintiffs' Complaint. For instance, none of the five claims in the States' Amended Complaint even mentions the 2000 NDA approval. *See* Am. Compl. ¶¶ 757-788. And the States' Fifth Claim—specifically challenging GenBioPro's ANDA approval—states only that the 2019 ANDA was "unlawfully approved" because FDA "relied on the unlawful *2016 Major Changes* labeling." *Id.* ¶ 785 (emphasis added).[1] The States thus distort their own Amended Complaint by asserting that it "still argue[s] that the 2000 approval was improper and thus FDA is 'unable to rely on an unlawful approval.'" Opp. 7 (quoting Am. Compl. ¶ 786). The cited paragraphs of the States' Amended Complaint *make no such argument*.

Third, the States cannot dispute that GenBioPro would face significant prejudice from being excluded from participation in this lawsuit. The Amended Complaint attacks GenBioPro by name and challenges the approval for the product that constitutes the vast majority of its business. Mem. 10. If the existing defendants do not defend—or inadequately defend—the two claims targeting GenBioPro's ANDA approval, then GenBioPro's rights could be altered in an existential way without any participation from GenBioPro. Rule 24 is intended to prevent precisely such an outcome. *See* Mem. 10; *John Doe No. 1 v. Glickman*, 256 F.3d 371, 379 (5th Cir. 2001) (finding prejudice when denial of intervention would mean that putative intervenor "will not be able to participate in" nor appeal ruling in proceeding that affected its interests); *Espy*, 18 F.3d at 1206-

[1] The States are mistaken in arguing (at 6) that the Alliance Plaintiffs' Complaint raised a freestanding claim challenging GenBioPro's ANDA based solely on allegations concerning the "2016 Major Changes" to mifepristone's REMS. The Alliance Complaint makes no such allegations, *see, e.g.*, Compl. ¶¶ 382-385, ECF No. 1, and it appears that the Alliance Plaintiffs first raised arguments concerning the 2016 Major Changes during the preliminary injunction briefing, *see* ECF No. 7 at 21-23; ECF No. 120 at 23; and even then, they did not argue that the 2016 Major Changes *alone* sufficed to invalidate GenBioPro's 2019 ANDA.

07 (finding prejudice where the "economic interests of the movants are at stake," noting the importance of the "legal rights associated with formal intervention").

Finally, any delay (and again, GenBioPro did not delay) would be, at most, just one factor in the mix, rather than automatically precluding intervention. "A motion to intervene may still be timely even if all the factors do not weigh in favor of a finding of timeliness." *John Doe No. 1*, 256 F.3d at 376. And "[t]he requirement of timeliness is not a tool of retribution to punish the tardy would-be intervener, but rather a guard against prejudicing the original parties by the failure to apply sooner." *Espy*, 18 F.3d at 1205.

Here, the States' only claims of harm from intervention rest on a mistaken argument that GenBioPro's intervention would require the existing parties to "redo" motion-to-dismiss briefing. Opp. 4, 8. But in making that argument, the States rely on the *exact same* inapposite personal jurisdiction cases that they cited when arguing "waiver" in opposition to Danco's motion to dismiss. *Compare* Opp. 4, *with* ECF No. 228 at 6. Accordingly, as a practical matter, any waiver argument as to GenBioPro will rise or fall with Defendants' existing venue arguments: GenBioPro has adopted, incorporated by reference, and will continue to rely upon the motion-to-dismiss arguments from the existing defendants. Its intervention thus would change nothing in the existing case schedule. *See NBIS Constr. & Transp. Ins. Servs. v. Kirby Smith Mach., Inc.*, 2021 WL 4227787, at *1 (N.D. Tex. Apr. 8, 2021) ("[T]he second factor weighs in favor of timeliness because 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 by . . . intervention.").

B. GenBioPro Has Met Its Minimal Burden to Demonstrate Inadequate Representation By the Existing Defendants

GenBioPro has made the required "minimal" showing that "representation" of its interests by the existing parties "'*may* be' inadequate." *Edwards v. City of Houston*, 78 F.3d 983, 1005 (5th

Cir. 1996) (emphasis added) (quoting *Trbovich v. United Mine Workers of Am*., 404 U.S. 528, 538 n.10 (1972)); *see* Mem. 11-12. The States misconstrue that lenient standard and fail to refute that no existing defendant "adequately represent[s] GenBioPro's interests." Mem. 11.

The States incorrectly assume GenBioPro's interests are aligned with those of the existing Defendants merely because all interested parties *except* the States agree that the States' claims should be dismissed now for procedural and jurisdictional reasons. Opp. 10-11. But temporary alignment of interests does not undermine intervention; in the Fifth Circuit, it suffices that the existing parties' interests and the intervenors' interests "*may* diverge in the future, even though, at this moment, they appear to share common ground." *Heaton v. Monogram Credit Card Bank of Ga.*, 297 F.3d 416, 425 (5th Cir. 2002) (emphasis added). The States do not contest that inadequate representation can arise based on the mere *possibility* that the parties' interests may at some point cease to align. Mem. 11; *see La Union del Pueblo Entero v. Abbott*, 29 F.4th 299, 309 (5th Cir. 2022) ("Though we 'cannot say for sure that the state's more extensive interests will *in fact* result in inadequate representation,' we can say that 'surely they might, which is all that [Rule 24(a)(2)] requires.'" (quoting *Brumfield v. Dodd*, 749 F.3d 339, 346 (5th Cir. 2014)).

Despite the States' protests, Opp. 11, Danco and GenBioPro do not have the type of identical objective that would give rise to a presumption of adequate representation. Danco's ultimate objective is to defend FDA's post-approval regulatory decisions addressing the distribution *conditions* for Mifeprex; its right to market Mifeprex *at all* is not threatened. *See* Am. Compl. ¶ 788 (noting that Danco can "simply revert to a previously approved label" if the States' relief is granted); Joint Status Report, ECF No. 191 ¶ 6. GenBioPro, in contrast, must defend FDA's 2019 grant of approval to market its generic mifepristone at all, a right that the States challenge directly. Put simply, GenBioPro's defense of its ability to market and sell its generic

drug at all and Danco's defense of the *conditions of use* for its drug, are materially different. Consequently, GenBioPro and Danco do not have the same "ultimate objective," and there is no presumption of adequate representation. *See Edwards*, 78 F.3d at 1006.[2]

The States cannot avoid the commercial reality that GenBioPro's generic mifepristone competes against Danco's Mifeprex, making Danco's interests adverse as an economic competitor. *See Edwards*, 78 F.3d at 1005-06 (finding that existing parties were "competitors" for jobs with intervenors and thus could not be presumed to adequately represent the intervenors' interests); *VanDerStok v. Garland*, 2022 WL 19023858, at *4 (N.D. Tex. Dec. 19, 2022) (finding inadequacy of representation for "a competitor" of existing party). Should this Court "vacate" or "stay" GenBioPro's 2019 ANDA but keep other FDA regulatory decisions in place, Danco would not have the same incentive to continue litigating to protect GenBioPro's generic approval.[3]

Nor do the Federal Defendants adequately represent GenBioPro's interests. The States fail to address the extensive Fifth Circuit case law finding government agency interests not aligned with those of regulated parties. *Compare* Mem. 12-13, *with* Opp. 9-10.[4] And in any event, the States' citation to *Entergy Arkansas, LLC v. Thomas*, 76 F.4th 1069 (8th Cir. 2023), supports

[2] Because GenBioPro's interests are not aligned with Danco's, the States' suggestion that the Court require consolidated briefing at future stages of the case, Opp. 8, is not only wildly premature, but also ignores the fundamental purpose of intervention. GenBioPro will coordinate with Defendants, as possible, to avoid duplicating arguments, but its purpose in intervening is to protect its own *unique* interests in the litigation, which its competitor Danco may not share.

[3] The States' fanciful speculation that Danco might seek approval to market a generic version of its drug, Opp. 11, is groundless. Danco has no generic mifepristone approval, and the States have offered no reason to believe that Danco intends to seek such approval to market a generic version of its own branded product.

[4] The States' suggestion that a "narrower" interest displaces the presumption of adequate representation only in "real property" cases, Opp. 10, is based on an incomplete picture of out-of-circuit authority. For present purposes, it suffices to note that there is no such limitation in the Fifth Circuit. *See, e.g.*, *Wal-Mart Stores, Inc. v. Tex. Alcoholic Beverage Comm'n*, 834 F.3d 562, 569 (5th Cir. 2016); *Heaton*, 297 F.3d at 425.

GenBioPro, confirming that a presumption of adequate representation by the government applies *only* when the "intervenor's asserted interest is one that a governmental entity who is a party to the case *is charged with protecting*." *Id.* at 1071 (emphasis added). Here, of course, FDA, as a regulator of the drug industry, is not "charged with protecting" the interests of the companies it regulates. GenBioPro's economic interests in protecting the regulatory approval of its product are far "narrower than the [Federal Defendants'] broad public mission," which includes FDA's institutional interest, implementing the agenda of a new administration, and, most importantly, *regulating* GenBioPro. *See Wal-Mart Stores, Inc. v. Tex. Alcoholic Beverage Comm'n*, 834 F.3d 562, 569 (5th Cir. 2016).

In any event, even the mere possibility of adverse interests is enough to demonstrate inadequate representation in the Fifth Circuit. *See id.* And under that standard, the *actual* divergence of interests between GenBioPro and the Federal Defendants more than suffices. *See id.*; *see also La Union del Pueblo Entero*, 29 F.4th at 309 (finding inadequacy of representation when the "State and its officials have many interests that the [intervenors] do not"); *Heaton*, 297 F.3d at 425 ("Government agencies . . . must represent the public interest, not just the economic interests of one industry."); *John Doe No. 1*, 256 F.3d at 381 ("Given the [intervenor's] minimal burden and [the federal agency's] duty to represent the broad public interest, not just the [intervenors' interests], we conclude that . . . representation of the [intervenor] *may* be inadequate." (emphasis added)). The States offer no argument to the contrary. They instead claim that GenBioPro is adequately represented because GenBioPro does not stand to lose in this litigation any differently than the public at large. Opp. 10. That argument fails on its face. This litigation threatens GenBioPro's ability to sell its key product in its current form, risking harm that is specific and particularized to GenBioPro.

Because all of the Rule 24(a)(2) factors support GenBioPro's intervention, GenBioPro should be allowed to intervene in this action as of right.

II. GenBioPro's Motion to Intervene is Procedurally Proper

The States' interpretation of Rule 24(c) cites *no precedent* from within the Fifth Circuit, and their procedural argument poses no obstacle to intervention. Opp. 3-4. Under the Fifth Circuit's "permissive" approach to intervention, GenBioPro's filings sufficiently "put the parties on notice of [its] grounds for intervention." *Liberty Surplus Ins. Cos. v. Slick Willies of Am., Inc.*, 2007 WL 2330294, at *2 (S.D. Tex. Aug. 15, 2007) (citing *Farina v. Mission Inv. Trust*, 615 F.2d 1068, 1074 (5th Cir. 1980)); *Ross Neely Sys., Inc. v. Navistar, Inc.*, 2015 WL 12916405, at *5, *10 (N.D. Tex. June 3, 2015). GenBioPro's submissions make clear it agrees with the existing Defendants that this case should be dismissed or transferred: As the Motion states, GenBioPro "seeks intervention to ensure that its rights are fully and adequately represented *in the event this case proceeds any further in this Court*." Mem. 1 (emphasis added).[5]

Tellingly, the States fail to articulate what pleading they believe GenBioPro *should have* filed with its motion under Rule 24(c). It cannot be right, as the States seem to suggest, Opp. 3, that GenBioPro should have filed an answer. *No defendant* (including Intervenor-Defendant Danco) has filed an answer in this case, and submitting a proposed answer-in-intervention would make no sense at this stage, where the existing defendants (and GenBioPro) urge dismissal or transfer of the case, and the motions to dismiss will not be fully briefed for weeks. As discussed

[5] Even a complete failure to comply with Rule 24(c), on its own, is not grounds for denying intervention when the parties are on notice of the intervenor's interests. *See Liberty Surplus*, 2007 WL 2330294, at *2; *see In re Royal Alice Props., LLC*, 2021 WL 150397, at *2 (Bankr. E.D. La. Jan. 15, 2021); *DeOtte v. Azar*, 332 F.R.D. 173, 182 n.5 (N.D. Tex. 2019); *see also Providence Baptist Church v. Hillandale Comm., Ltd.*, 425 F.3d 309, 314-15 (6th Cir. 2005) (finding district court abused its discretion in denying motion to intervene based on mere failure to attach a pleading).

above, the States' additional argument that GenBioPro's intervention requires additional briefing on venue, Opp. 3-4, 8, is simply incorrect. GenBioPro's proposed joinder and motion to dismiss expressly incorporate Danco's and the Federal Defendants' arguments by reference, Mem. 1, and GenBioPro does not intend to file any separate motion to dismiss on venue or any other issue.[6]

Finally, the courts in the States' out-of-circuit cases, Opp. 3-4, denied intervention in distinguishable contexts, and for reasons not applicable here. *See Abramson v. Pennwood Inv. Corp.*, 392 F.2d 759, 762 (2d Cir. 1968) (affirming denial of intervention where proposed intervenor had litigated and lost the same issues in state court and was bound by that ruling); *Brown v. Colegio de Abogados de Puerto Rico*, 277 F.R.D. 73, 76 (D.P.R. 2011) (denying intervention where proposed intervenors "surprisingly failed to comply with" court order prescribing specific requirements for intervention in class action suit).

III. GenBioPro Should Be Allowed To Intervene Permissively Under Rule 24(b)

The States' only challenge to GenBioPro's intervention on Rule 24(b) grounds is that GenBioPro's motion is not timely under Rule 24(a). Opp. 12. For the reasons stated above, GenBioPro's intervention is timely under either standard, so permissive intervention should be granted even if GenBioPro cannot intervene as of right.

CONCLUSION

The Court should grant GenBioPro's Motion for Leave to Intervene.

[6] The States' footnote argument that GenBioPro should have filed a "brief" in support of dismissal, Opp. 4 n.1, invites the exact kind of disruptive and unnecessary briefing that GenBioPro has *avoided* with its Motion. The States' footnote also ignores the established practice of courts in this district allowing joinders to avoid duplicative arguments. *See, e.g.*, *Patel v. Brighthouse Life Ins. Co.*, 2022 WL 2718553, at *2-*3 (N.D. Tex. Jan. 25, 2022), *report & recommendation adopted as modified*, 2022 WL 2718217 (N.D. Tex. Feb. 9, 2022); *Golden Spread Coop., Inc. v. Emerson Process Mgmt. Power & Water Sols., Inc.*, 360 F. Supp. 3d 494, 501 n.2 (N.D. Tex. 2019).

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on April 1, 2025, I electronically filed the foregoing Reply Memorandum 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.

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