

UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

STATE OF MISSOURI, *et al.*,
Intervenor Plaintiffs,

v.

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

Case No. 4:25-cv-01580-CMS

**INTERVENOR-DEFENDANT GENBIOPRO, INC.’S RESPONSE TO PLAINTIFFS’
SECOND NOTICE OF SUPPLEMENTAL AUTHORITY**

Intervenor-Defendant GenBioPro, Inc. (“GenBioPro”) responds to Plaintiffs’ Second Notice of Supplemental Authority (Doc. 326), which attached the decision of a Fifth Circuit motions panel in *Louisiana v. FDA*, 2026 WL 1194924 (5th Cir. May 1, 2026). The Fifth Circuit’s decision, which is not binding precedent in this Court, does not alter the fact that this case must be dismissed for lack of standing and exhaustion under controlling Supreme Court and Eighth Circuit precedent.

GenBioPro respectfully disagrees with the May 1 Fifth Circuit decision, which is subject to further appellate review.¹ The panel’s reasoning as to standing runs directly counter to the Supreme Court’s recent decisions in this case, *FDA v. Alliance for Hippocratic Medicine*, 602 U.S. 367 (2024), and in *United States v. Texas*, 599 U.S. 670 (2023), as well as the Ninth Circuit’s decision in *Washington v. FDA*, 108 F.4th 1163 (9th Cir. 2024), which directly binds Idaho via collateral estoppel.

¹ As reflected in the States’ Notice, GenBioPro filed an emergency application with the Supreme Court for a stay of the Fifth Circuit’s order and Justice Alito granted an administrative stay, which has now been extended through May 14, 2026.

Even under the May 1 Fifth Circuit decision’s reasoning, however, this case should still be dismissed because the panel’s reasons for finding Louisiana had standing do not apply to Plaintiff States here. The holding that Louisiana had a sovereign injury sufficient to give it standing to challenge FDA’s 2023 mifepristone Risk Evaluation and Mitigation Strategy (“REMS”) hinged on the premise that “Louisiana law bans administering, prescribing, procuring, or selling a drug like mifepristone to end the life of an unborn human being.” 2026 WL 1194924, at *4. The panel reasoned (albeit wrongly) that the 2023 REMS was designed to, and did, “cause[] federal interference with the enforcement of [that] law, which gives Louisiana standing to challenge it.” *Id.* at *5. Here, in contrast, Missouri and Kansas stand on very different footing, as their constitutions recognize the “fundamental right to reproductive freedom” and “abortion care,” Mo. Const. art. I, § 36(2), and “protect[] ... a pregnant person’s right to terminate a pregnancy,” *Hodes & Nauser, MDs, P.A. v. Kobach*, 551 P.3d 37, 46 (Kan. 2024).

Moreover, Louisiana challenged only the 2023 REMS, while Plaintiffs here challenge FDA’s 2016, 2019, and 2021 actions as well. Prior to the Supreme Court’s 2022 decision in *Dobbs*, the right to abortion was protected by the federal Constitution, and no state could enforce laws prohibiting or substantially burdening that right. Thus, the 2016, 2019, and 2021 FDA actions that Plaintiffs challenge could not possibly have been motivated by any purpose of interfering with any abortion laws of Missouri, Kansas, or Idaho at the time.

The holding that Louisiana had financial injury sufficient for standing is also inapplicable here. The Fifth Circuit based that holding on what it called “hard evidence” of Louisiana’s purported injury: \$92,000 “paid in Medicaid costs from two women who needed emergency care in 2025 from complications caused by out-of-state mifepristone.” 2026 WL 1194924, at *5. Here, in contrast, only one of the three Plaintiff States (Missouri) submitted such declarations, and even

those declarations fail to connect Missouri's Medicaid spending to any of the particular FDA actions Missouri challenges.

Moreover, Louisiana's lawsuit does not present the unique jurisdictional problem created in this case by the fact that "the Original Plaintiffs never had a jurisdictionally valid case" in which the Plaintiff States could validly intervene. Doc. 273 at 12; *see also Mattice v. Meyer*, 353 F.2d 316, 319 (8th Cir. 1965) (absent the "pendency of any action, there was no basis for intervention"). That inherent flaw would require dismissal even if the Plaintiff States themselves had standing.

The Fifth Circuit's view that Louisiana was not required to exhaust administrative remedies before suing to challenge the 2023 REMS runs counter to the law in this Circuit, where the futility exception requires Plaintiffs to show that an agency "*certainly* would have denied [their] claim." *Brown v. J.B. Hunt Transp. Servs., Inc.*, 586 F.3d 1079, 1085 (8th Cir. 2009) (emphasis added). Plaintiffs cannot meet that high bar here given FDA's ongoing review of the mifepristone REMS. Doc. 293-1 at 1. Finally, as Louisiana only challenged a single FDA action taken in 2023, the Fifth Circuit panel had no occasion to consider statute-of-limitations issues, which doom Plaintiffs' challenge to FDA's 2016 action in this case.

For these reasons, the May 1 Fifth Circuit decision does not save Plaintiffs' claims, and the amended and supplemental complaints should be dismissed.

Dated: May 12, 2026

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Respectfully submitted,

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* Deemed admitted pro hac vice per Local Rule
12.01 and the Court's Case Opening
Notification dated October 23, 2025

** Pro hac vice application forthcoming