

**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

**PROPOSED INTERVENOR-DEFENDANT GENBIOPRO, INC.’S
CONDITIONAL MOTION TO DISMISS**

Proposed Intervenor-Defendant GenBioPro, Inc. (“GenBioPro”) hereby conditionally moves to dismiss this action pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6). In its position as a proposed Intervenor-Defendant (pending adjudication of its Motion to Intervene), GenBioPro respectfully submits that Plaintiffs lack Article III standing; that they have not exhausted their claims; and that Count Two of the Complaint fails as a matter of law, as described below and detailed in GenBioPro’s Conditional Memorandum in Opposition to Plaintiffs’ Motion for Preliminary Relief (“GenBioPro’s Opposition”) filed herewith.

First, Plaintiffs’ Complaint should be dismissed under Rule 12(b)(1) because Plaintiffs lack Article III standing, depriving the Court of subject matter jurisdiction. As explained in Section I of GenBioPro’s Opposition, neither Plaintiff has alleged a cognizable injury-in-fact traceable to FDA’s 2023 REMS and redressable through the relief sought. Those deficiencies not only preclude the preliminary relief plaintiffs seek, but also require dismissal of the case. Article III standing is an “essential” and “core component” of the Court’s subject matter jurisdiction. *Lujan v. Defs. of*

Wildlife, 504 U.S. 555, 560 (1992). “Without jurisdiction the court cannot proceed at all in any cause,” and “the only function remaining to the court is that of announcing the fact and dismissing the cause.” *Steel Co. v. Citizens for a Better Env’t*, 523 U.S. 83, 94 (1998) (quoting *Ex parte McCardle*, 7 Wall. 506, 514 (1868)); *see also* *FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 380 (2024) (directing dismissal of challenge to mifepristone regulations for lack of standing).

Second, since Plaintiffs failed to exhaust their claims, they breached a binding FDA requirement for filing suit. *See* 21 C.F.R. § 10.45(b). When an “agency rule” requires a party to first pursue administrative remedies as a “prerequisite to judicial review,” as FDA regulations do, the party’s failure to exhaust those remedies bars the claim from proceeding. *Darby v. Cisneros*, 509 U.S. 137, 153 (1993). As detailed in Section II of GenBioPro’s Opposition, Plaintiffs failed to present their claims to the FDA before bringing suit and they offer no legally sufficient basis to excuse their lack of exhaustion. Accordingly, their claims should be dismissed under Rule 12(b)(6) for failure to exhaust, *see Bunker v. Dow Chem. Co.*, 111 F.4th 683 (5th Cir. 2024), or alternatively as unripe in light of FDA’s ongoing reconsideration of the challenged actions, *see, e.g., Huawei Techs. USA, Inc. v. FCC*, 2 F.4th 421, 434 (5th Cir. 2021) (“The ripeness doctrine prevents the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies.” (cleaned up)).

Third, Count Two of the Complaint fails to state a claim upon which relief may be granted because Plaintiffs have not plausibly pleaded that FDA’s adoption of the 2023 REMS violated the Comstock Act. As detailed in Section III.B of GenBioPro’s Opposition, Plaintiffs have not plausibly pleaded that the FDA engaged in conduct proscribed by the Comstock Act and nor have they plausibly pleaded that the FDA’s determination in the 2023 REMS—that in-person dispensing of mifepristone is unnecessary for safety—compelled or permitted anyone else to

violate the Comstock Act. Because the issues raised by Plaintiffs in Count Two are purely legal, the administrative record is unnecessary for resolution of this claim.

For the foregoing reasons, and those set forth in GenBioPro's Opposition, the Court should dismiss Plaintiffs' Complaint under Rules 12(b)(1) and 12(b)(6).

Dated: February 3, 2026

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Respectfully submitted,

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