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

INTERVENOR-DEFENDANT GENBIOPRO, INC.'S REPLY IN SUPPORT OF MOTION TO DISMISS

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INTRODUCTION

Plaintiffs' opposition confirms that their asserted injuries are not cognizable and, even if they were, rest on the independent actions of third parties, not on anything the FDA requires or authorizes. Their attempt to repackage indirect effects as a "sovereign injury" fails for the same reason similar claims have repeatedly been rejected: If States could challenge any federal policy that allegedly burdened their state-law priorities, Article III would have no meaningful limits. And Plaintiffs' revisionist attempt to avoid these conclusions by claiming Louisiana is somehow the "object" of FDA action—when it is neither a manufacturer nor consumer of mifepristone—is based on nothing more than misleading and irrelevant quotes taken out of context, and a narrative inconsistent with the factual and regulatory history.[1]

Even if Plaintiffs could clear the standing hurdle, their claims would fail. Plaintiffs bypassed FDA's mandatory administrative process, filing suit without first presenting their objections through the citizen-petition mechanism that FDA established for precisely these types of disputes. Their challenge is also premature given FDA's active reconsideration of the mifepristone REMS and they have failed to show that the REMS violates the Comstock Act.[2]

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[1] Far from acquiescing in Plaintiffs' standing as Plaintiffs suggest, FDA has not "sought to dismiss" the case (Opp. at 1) because its responsive pleading is not yet due. *See* ECF 39 (staying Federal Defendants' "deadline to answer or respond to the Complaint … pending the Court's resolution of Plaintiffs' Motion for Preliminary Relief."). FDA has in fact objected to Plaintiffs' standing in opposing Plaintiffs' request for preliminary relief and has moved to dismiss related cases brought by other states on standing grounds. *See* Mem. Supp. Mot. to Stay or Dismiss, *Missouri v. FDA*, No. 4:25-cv-1580 (E.D. Mo. Mar. 6, 2026), ECF 293-1; Mem. Supp. Mot. to Stay or Dismiss, *Florida v. FDA*, No. 7:25-cv-126 (N.D. Tex. Mar. 13, 2026), ECF 20-1.

[2] As GenBioPro explained in opposing Plaintiffs' request for preliminary relief, Plaintiffs cannot establish that the 2023 REMS was arbitrary and capricious. And GenBioPro has moved to dismiss the entire complaint, including Count 1, for lack of standing and other threshold grounds. If Count 1 proceeded despite its threshold defects, GenBioPro would continue to assert—and the administrative record would readily show—that Plaintiffs' arbitrary-and-capricious claim lacks merit.

ARGUMENT

I. Plaintiffs Lack Article III Standing

A. Louisiana Lacks a Cognizable Economic Injury Traceable to the 2023 REMS

Louisiana primarily asserts two forms of "pocketbook injury"—namely, the costs of "enforcing Louisiana law against violations" and "the expenditure of Medicaid dollars to treat adverse events" they claim are "caused by the 2023 REMS." Opp. at 5. Both are foreclosed by controlling precedent. GenBioPro Mem. in Opp. to Mot. for Prelim. Relief ("GBP Mem.") at 11-12, ECF 231.[3]

First, as to Louisiana's enforcement-related costs: Plaintiffs cite cases applying the principle that preventive costs to avoid a "substantial risk" of harm can sometimes constitute a cognizable injury. *See Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 153-55 (2010). But *Monsanto* was a private civil case where alfalfa farmers alleged they would need to take costly, preventive steps to avoid their crops becoming genetically modified. *Id.* That inapt case law does not allow Plaintiffs to avoid controlling Supreme Court authority specifically addressing lawsuits by states based on costs of enforcing state laws like those claimed by Plaintiffs. The Supreme Court has made clear that, in our "system of dual federal and state sovereignty," these sorts of "indirect effects" on "state spending" cannot suffice. *United States v. Texas*, 599 U.S. 670, 680 n.3 (2023). This principle is necessary to ensure that Article III retains meaningful limits. If a State had standing anytime it spent money in response to a federal policy, any state could challenge virtually any policy with which it disagreed.

Even if the enforcement costs were cognizable injuries, they are not fairly traceable to the 2023 REMS. Louisiana's theory is that non-parties are knowingly violating Louisiana law by prescribing or mailing mifepristone into the State. But the "unfettered choices made by independent actors not before the courts" break the causal chain required for standing—as the Supreme Court made clear in the challenge that preceded this one. *FDA v. All. for Hippocratic*

[3] As is standard in a motion to dismiss, GenBioPro assumes the truth of the complaint's factual allegations, but reserves the right to "contest th[ose] factual allegations" if this case were to proceed. Opp. at 4 n.3; *e.g.*, *Lee v. Verizon Commc'ns, Inc.*, 837 F.3d 523, 533 (5th Cir. 2016).

Med., 602 U.S. 367, 383 (2024). Louisiana's investigative expenses arise from its efforts to pursue those third parties—not from anything *the REMS* requires or authorizes. Like the plaintiffs in *Clapper*—who claimed that costly "countermeasures" to avoid federally authorized surveillance established standing—Louisiana "ha[s] a similar incentive to engage in many of the[se] countermeasures" *regardless* of the REMS. *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 417 (2013). In other words, if Louisiana has an enforcement priority of stopping all mailing of abortion medications into the State, that goal would necessitate enforcement and monitoring costs *even if* the 2023 REMS did not exist, which demonstrates that the alleged harms cannot be traced to the 2023 REMS.

For similar reasons, Plaintiffs' continued focus on costs attributable to "out-of-state prescribers" in California and New York (Opp. at 6) further confirms that *FDA*'s *actions* are not causing their asserted sovereign injuries. Plaintiffs' disputes are instead with the out-of-state providers who are violating Louisiana law, or the states that have adopted "shield laws."

Second, Louisiana's Medicaid-expenditure theory (Opp. at 7) fails for similar reasons. Louisiana points to "$90,000 for emergency room care and hospitalizations" (*id.*), but still does not attempt—because it cannot—to tie those expenditures to FDA's determination *in the 2023 REMS*, as opposed to the mere use of mifepristone, which would remain a lawful FDA-approved drug even if Louisiana's claim succeeded. GBP Mem. at 11-12. Plaintiffs' desire to avoid these expenditures depends on individuals taking action to ship mifepristone into Louisiana; enjoining the *REMS* would not prevent that from happening.[4] To the extent mifepristone remains on the market, demand for the drug in Louisiana could still be met by third parties willing to break State law to supply it.

[4] Contrary to Plaintiffs' unsupported accusation, GenBioPro has never suggested it would not "follow the law" if the in-person dispensing requirement were restored. Opp. at 16. The issue is that, if independent actors are *already* engaging in "unlawful activity"—as Louisiana claims they are—there is no reason to expect that a change in the REMS reverting to in-person dispensing would solve the problem. Hearing Tr. at 14 (Feb. 24, 2026) (Court observing that "[i]t's already unlawful activity. The doctors that are shipping it already know that they're violating Louisiana law when they do it.").

B. Louisiana Lacks a Cognizable Sovereign Injury Traceable to the 2023 REMS

Louisiana also asserts a theory of "sovereign injury" that courts have squarely rejected. GBP Mem. at 8-11. The Supreme Court has been emphatic that the underenforcement of federal law does not support a sovereign-harm theory of standing, lest courts start "down th[e] uncharted path" of adjudicating "alleged Executive Branch under-enforcement of any similarly worded laws—whether they be drug laws, gun laws, obstruction of justice laws, or the like." *Texas*, 599 U.S. at 681; *see also Washington v. FDA*, 108 F.4th 1163, 1177 (9th Cir. 2024).

Lacking any way to distinguish these cases, Plaintiffs double down on their theory that Louisiana was the "object" of the 2023 REMS because its "whole point" was to override state law—an assertion that, as Defendants have pointed out, does not accord with reality. GBP Mem. at 9-10. For this theory, Louisiana relies heavily on the Supreme Court's recent per curiam order in *Mirabelli v. Bonta*, 146 S. Ct. 797, 803 (2026). But that decision only confirms the weakness of the State's position. The California policies challenged there *prohibited* schools from disclosing a student's gender transition without the student's consent—including *specifically* to "the student's *parents*." Emergency Mot. to Vacate Stay Order, *Mirabelli*, 2026 WL 147443, at *9 (emphasis added) (quoting State FAQs). It is not hard to conceive of parents as the "object" of a restriction on sharing information with parents—just like fuel producers could be the "object" of a state regulation that "explicitly [sought] to restrict the use" of the producers' products. *Diamond Alternative Energy, LLC v. EPA*, 606 U.S. 100, 114-15 (2025). Nothing comparable exists here. The REMS does not regulate States, prevent them from enforcing their laws, or otherwise treat them as regulated parties. Based on scientific review, FDA has established nationwide conditions for prescribing and dispensing an FDA-approved medication. Louisiana identifies no feature of the REMS that singles out States as regulated entities, let alone Louisiana in particular.

Because nothing in the 2023 REMS itself regulates States, Plaintiffs attempt to manufacture a "targeting" theory by pointing to statements by other Executive Branch actors. Opp. at 11-14. But judicial review of agency action turns on the agency's decision and record—not "extrinsic statements" by officials who were not the decisionmakers. *Trump v. Hawaii*, 585 U.S.

667, 702-04 (2018) (declining to "probe the sincerity of the stated justifications for the [facially neutral] policy by reference to extrinsic statements"); *see also FDA v. Wages & White Lion Invs.*, 604 U.S. 542, 576-77 (2025) (rejecting allegations of "surreptitious[]" agency action).

Contrary to Plaintiffs' suggestion (at 14), this case is nothing like *Department of Commerce v. New York*—an "unusual" case where there was both direct evidence that the agency "contrived" a pretextual rationale, and the agency's decision "c[ould] not be adequately explained" by the stated rationale. 588 U.S. 752, 780-85 (2019). FDA, by contrast, adopted the 2023 REMS after a scientific review of mifepristone's safety and effectiveness and formalized a policy the agency had already implemented before *Dobbs*—and therefore could not have "targeted" states that would later ban abortions after *Dobbs*. GBP Mem. at 4, 9-10.

Even if these extrinsic statements were relevant, Plaintiffs' "targeting" narrative depends on misleading, selective quotations and unsupportable characterizations of the historical record. For example, Plaintiffs claim that President Biden "recommitted to doing everything in his power to expand access to abortion, noting that some States are trying to 'ban or severely restrict access to these medications.'" Opp. at 12. But that snippet comes from the end of a White House fact sheet announcing a range of reproductive-health measures the Administration was taking in light of *Dobbs*. *See* ECF 1-47. The statement does not direct FDA to override state law, nor does it suggest that the REMS should be modified to circumvent state abortion restrictions. To the contrary, the fact sheet acknowledged that the only way to restore nationwide abortion rights would be "for *Congress* to restore the protections of *Roe* as federal law." *Id.* (emphasis added). Plaintiffs likewise quote a few words from a pre-*Dobbs* advocacy letter from several organizations to President Biden. Opp. at 2, 11-12. Plaintiffs offer no explanation for how an organizational advocacy letter to the President could have any bearing on whether States were the object of *FDA*'s ultimate decision. Regardless, the letter simply asked the Administration to suspend the in-person dispensing requirement during the COVID-19 emergency and to conduct "a comprehensive … FDA review of the full set of restrictions on mifepristone" so that access would reflect "the latest science and medical evidence." ECF 253-1. Louisiana's "object" theory rests not on the content of

the REMS itself, but on speculation about the motivations of federal officials and the downstream conduct of private actors. Article III does not permit standing for States on that basis.

Finally, Louisiana hardly defends its "quasi-sovereign" standing theory. Opp. at 9; *see* GBP Mem. at 10-11. Louisiana does not dispute that the Supreme Court has repeatedly rejected *parens patriae* actions as impermissible against the Federal Government, and it fails to distinguish a recent appellate court decision rejecting this same theory as a "thinly veiled attempt to circumvent the limits on *parens patriae* standing." GBP Mem. at 10-11 (citing *Washington*, 108 F.4th at 1178). Louisiana also fails to demonstrate any causal chain between the challenged FDA actions and this asserted injury, or assert that the 2023 REMS affects a "substantial segment" of Louisiana's population, as these types of claims require. *Arizona v. Garland*, 730 F. Supp. 3d 258, 276 (W.D. La. 2024). Rather, Louisiana's sole argument is that this is not a true *parens patriae* action because "Louisiana is not asserting the rights of its citizens," but rather invokes Louisiana's "authority to protect its citizens." Opp. at 9. That is a distinction without a difference: The *parens patriae* theory rejected in *Brackeen*, for instance (asserting "equal protection claims on behalf of its citizens") could readily have been described in Louisiana's terms (asserting a sovereign right to protect its citizens from unconstitutional discrimination). *Haaland v. Brackeen*, 599 U.S. 255, 294 (2023). Louisiana's asserted injury ultimately rests on the alleged harms to individuals within the State and thus remains precisely the type of *parens patriae* claim the Supreme Court has repeatedly held States cannot bring "against the Federal Government." *Id.* (citation omitted).

C. Ms. Markezich Lacks Standing

Ms. Markezich lacks Article III standing. *See* GBP Mem. at 12. Plaintiffs' opposition, like the complaint, focuses on the abuse by a non-party she alleges she experienced in the past (Opp. at 16-17), which cannot support *prospective* relief. A generalized fear that she "*could* be placed in the same position for future pregnancies," Compl. ¶ 155 (emphasis added), depends on a speculative chain of contingencies—at least one of which is the independent criminal conduct of a third party—and falls far short of Article III's requirement that future injury be "*certainly* impending." *Clapper*, 568 U.S. at 409 (citation omitted). Neither Ms. Markezich nor the States

can rely on this tragic incident as a basis for standing to invalidate an FDA action that had nothing to do with an individual's criminal actions.

II. Plaintiffs' Challenge Is Unexhausted and Not Ripe for Judicial Review

A. Plaintiffs' Challenge Is Unexhausted

Plaintiffs' efforts to circumvent the procedural requirements for seeking judicial review of FDA actions fail. GBP Mem. at 13-14. Plaintiffs dispute neither that FDA's regulations require parties to file citizen petitions with FDA "before any legal action is filed in a court complaining of the action or failure to act," 21 C.F.R. § 10.45(b), nor that they have filed no citizen petition. They also make no effort to distinguish the multiple decisions applying these regulations to foreclose judicial review. *See* GBP Mem. at 13-14. Plaintiffs rely principally on a 2024 law review article that advocates for a change in the law, which the article acknowledges is *not* on Plaintiffs' side: "courts across the country have dismissed plaintiffs' claims for failure to exhaust administrative remedies when they failed to file citizen petitions with the FDA or failed to wait until the Agency responded to the petition before suing." Krupka, *Exasperated But Not Exhausted: Unlocking the Trap Set by the Exhaustion Doctrine on the FDA's REMS Petitioners*, 77 Vand. L. Rev. 937, 956 (2024), perma.cc/3BHM-WRQE. A straightforward application of FDA's rules requires dismissal.

Nor do any of Plaintiffs' asserted exceptions to exhaustion apply. Plaintiffs invoke "administrative abuse" (in the form of delay), "futility," and "irreparable harm," Opp. at 20-21, but none is supported here. Plaintiffs cite the Fifth Circuit's *Alliance* decision to support their theory that they need not exhaust because FDA generally takes too long to respond to citizen petitions. *Id.* But that decision was overturned unanimously by the Supreme Court, and in any event, the case is distinguishable because plaintiffs there had filed their *own* petition. *All. for Hippocratic Med. v. FDA*, 78 F.4th 210, 225-26 (5th Cir. 2023). Plaintiffs' complaints here about alleged delay in FDA's handling of *other* petitions do not excuse their failure to file one themselves. Nor have Plaintiffs shown futility. They concede that FDA is currently reviewing the mifepristone REMS and considering multiple citizen petitions addressing the same issues Plaintiffs raise here, underscoring that the agency remains actively engaged with the subject.

Finally, Plaintiffs cannot credibly claim that following the exhaustion rules many others have followed would impose irreparable harm—particularly when Plaintiffs waited *years* after the relevant regulatory changes before bringing this suit. GBP Mem. at 22-23. And regardless, FDA—not this Court—is the forum Congress has chosen to protect against any such harm that might arise during FDA's ongoing review. As FDA explained in responding to this Court's request, the agency has several statutory authorities to address exigent public health concerns that may arise with respect to an FDA-approved drug. *See* ECF 250. Plaintiffs' bare speculation that FDA might not invoke these authorities even if warranted (Opp. at 21 n.14) is not license to ignore a mandatory exhaustion rule. Plaintiffs made no attempt to comply with FDA's mandatory citizen-petition process and have not demonstrated that any recognized exception applies; their claims remain unexhausted and must be dismissed.

B. Plaintiffs' Challenge Is Not Ripe

Nor is Plaintiffs' challenge ripe for judicial review. While there are many prudential factors counseling against judicial intervention here, ripeness is not a mere "prudential" inquiry, as Plaintiffs suggest. Opp. at 22. Rather, the question is whether Plaintiffs "demonstrate sufficient ripeness *to establish a concrete case or controversy*"—which they cannot when their claims depend on "contingent future events that may not occur as anticipated, or indeed may not occur at all." *Thomas v. Union Carbide Agric. Prods. Co.*, 473 U.S. 568, 579-81 (1985) (emphasis added) (citation omitted). Here, FDA is currently reconsidering the mifepristone REMS, evaluating the very issues Plaintiffs ask this Court to resolve, and has tools at its disposal to redress any harm that could arise in the meantime. *See* ECF 250.

III. Plaintiffs' Comstock Act Claim Fails

Plaintiffs' Comstock Act claim fails for two independent reasons. *First*, the Comstock Act has no bearing on FDA's REMS determination under the FDCA and FDAAA. Plaintiffs contend that the Administrative Procedure Act requires courts to invalidate agency action that is inconsistent with "any law," relying on *FCC v. NextWave Personal Communications*. Opp. at 19. But Plaintiffs do not dispute that *NextWave* involved a statute that directly regulated the agency's

conduct—a Bankruptcy Code provision that prohibited the FCC from revoking licenses under specified conditions. 537 U.S. 293, 300-01 (2003). Plaintiffs identify no way in which the Comstock Act performs that function for FDA's REMS decisions. And the REMS itself in no way compels or authorizes FDA or anyone else to violate the Comstock Act. GBP Mem. at 21.

Rather, FDA's REMS determination arises under the FDCA and FDAAA which, together, instruct the agency to determine whether a drug is safe and effective and whether particular conditions are necessary to ensure that its benefits outweigh its risks. 21 U.S.C. §§ 355, 355-1. These statutes specify the grounds on which FDA may approve or reject a drug and the factors it must consider in imposing a REMS. None of those factors requires FDA to interpret or enforce federal criminal statutes that Plaintiffs argue govern downstream distribution. *See Motor Vehicle Mfrs. Ass'n v. State Farm*, 463 U.S. 29, 43 (1983) (explaining that agency decisions must be evaluated based on the factors Congress actually assigned to the agency—not extraneous factors litigants would prefer the agency consider).

Second, even if the Comstock Act were relevant here, Plaintiffs' interpretation is wrong. GBP Mem. at 20-22; Br. for Former U.S. Dep't Of Justice Officials as Amici Curiae at 6-18, ECF 220. Plaintiffs rely principally on a concurring opinion in a Fifth Circuit decision that was vacated on jurisdictional grounds and has no precedential value. GBP Mem. at 21 & n.6 (citing *All. for Hippocratic Med.*, 78 F.4th at 267-69 (Ho., J., concurring in part)). But Plaintiffs cannot deny that every court of appeals decision to address the issue, dating back over a century, has rejected Plaintiffs' theory and confirmed that the Comstock Act only prohibits distribution of items intended to produce *unlawful* abortions. *See Bours v. United States*, 229 F. 960, 964-65 (7th Cir. 1915); *Youngs Rubber Corp. v. C.I. Lee & Co.*, 45 F.2d 103, 107-08 (2d Cir. 1930); *Consumers Union of U.S., Inc. v. Walker*, 145 F.2d 33, 34-35 (D.C. Cir. 1944). Congress then reenacted the Comstock provisions in 1948 without altering the operative language, against the backdrop of those uniform appellate decisions, and the Executive Branch has consistently rejected Plaintiffs' view as well. GBP Mem. at 21. Moreover, in 2007, when Congress enacted legislation that "carr[ied] forward" an enforceable REMS for mifepristone, it did so "consistent with the

understanding" that the Comstock Act does *not*, as Plaintiffs claim, "invariably prohibit the conveyance by mail or common carrier of drugs intended to induce abortions." *Application of the Comstock Act to the Mailing of Prescription Drugs that Can Be Used for Abortions*, 46 Op. O.L.C. __ at 14 & n.18 (Dec. 23, 2022), https://www.justice.gov/olc/opinion/file/1560596/dl. Adopting Plaintiffs' theory would upend over a century of law that has been settled by all three branches of government.

CONCLUSION

The Court should dismiss Plaintiffs' complaint.

Dated: March 17, 2026

Respectfully submitted,

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