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.	Civ. No.: 6:25-cv-01491 Judge: David C. Joseph Mag. Judge: David J. Ayo

COMBINED MEMORANDUM OF LAW IN SUPPORT OF DANCO LABORATORIES, LLC'S MOTION TO DISMISS AND IN OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY RELIEF

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INTRODUCTION

Two years ago, the Supreme Court unanimously rejected a group of doctors' efforts to challenge the Food and Drug Administration's (FDA's) regulation of mifepristone. The Court's ruling was unambiguous: doctors who don't prescribe mifepristone are too far removed from FDA's drug approval process to have Article III standing to challenge that process. *FDA v. Alliance for Hippocratic Med.*, 602 U.S. 367, 391-392 (2024) (*Alliance*). But Plaintiffs here offer theories of harm from FDA's actions that are even more attenuated.

Like the *Alliance* doctors, Plaintiffs are not required to "prescribe or use mifepristone" or to "do anything or to refrain from doing anything" as a result of the Risk Evaluation and Mitigation Strategy (REMS) FDA approved in 2023. *Id.* at 385. Instead, Louisiana essentially complains that the mismatch between its policies and that of FDA and those of several other states causes it various injuries. But such divergence is a natural result of the Supreme Court "return[ing]" abortion policy to the states. *Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215, 292 (2022). And states cannot challenge FDA's regulation of mifepristone by asserting an attenuated "downstream" financial or sovereign injury. *Washington v. FDA*, 108 F.4th 1163, 1175-76 (9th Cir. 2024).

Plaintiffs' complaint has other threshold and substantive defects. Both Plaintiffs are outside the relevant statutory zones of interest and failed to exhaust their claims; their Comstock Act claim impermissibly asks the Court to order the Executive to enforce a criminal statute outside the scope of the FDA's REMS authority; and their claims are meritless in any event.

This Court should therefore dismiss Plaintiffs' complaint outright. At the very least, the Court should deny "preliminary" relief. FDA suspended the in-person-dispensing requirement nearly five years ago in April 2020, and it approved the REMS modification over three years ago in January 2023. After waiting years, Plaintiffs demonstrate no need for this Court to resolve their claims in an accelerated and emergency posture. Nor do they seek to preserve the status quo. Just the opposite: one state and one individual seek a novel remedy that FDA previously told the Supreme Court would halt the distribution of FDA-approved mifepristone *nationwide* for an unknown period of time. Ex. B, Long Decl. ¶¶ 8-14. This would gravely harm public health.

The Supreme Court stayed an order that had granted analogous preliminary relief during the *Alliance* litigation, and then held those plaintiffs lacked Article III standing. Plaintiffs here are not entitled to a different result.

FACTUAL BACKGROUND

2000 Mifeprex Approval. Danco, a small pharmaceutical company incorporated in Delaware, holds the NDA for Mifeprex (mifepristone) Tablets for use in a regimen with misoprostol for the medical termination of early intrauterine pregnancy. FDA approved Mifeprex in 2000 for use through 49 days' pregnancy, with certain use restrictions. ECF No. 1-24 (2000 Approval Letter). In 2007, Congress amended the Food, Drug, and Cosmetic Act (FDCA) to give FDA authority to require a REMS if the agency determined that one "is necessary to ensure that the benefits of the drug outweigh the risks of the drug." 21 U.S.C. § 355-1(a)(1). Mifeprex's original use restrictions were deemed a REMS. *See* 73 Fed. Reg. 16,313 (Mar. 27, 2008).[1]

2016 Changes. In 2016, FDA approved a supplemental NDA (sNDA) that modified certain aspects of Mifeprex's label and REMS based on numerous studies and 15 years of data. *See* ECF No. 1-11 (FDA March 29, 2016 Summary Review). "FDA deemed Mifeprex safe to terminate pregnancies up to 10 weeks," "approved a dosing regimen that reduced the number of required in-person visits [to] a single visit to receive Mifeprex," and "changed prescribers' adverse event reporting obligations to require prescribers to report only fatalities." *Alliance*, 602 U.S. at 375-376. In 2019, certain entities (not including Plaintiffs) filed a citizen petition requesting FDA undo the 2016 changes, which FDA denied in 2021. *See id.* at 376; Compl. 35.

2020 Challenge to Enjoin REMS In-Person Dispensation Requirement. In 2020, during the COVID-19 pandemic, the American College of Obstetricians and Gynecologists (ACOG) asked FDA to lift a requirement that mifepristone be dispensed in-person. ECF No. 1-32 at 2. Before FDA responded, ACOG sued to enjoin that requirement. *Am. College of Obstetricians and Gynecologists v. FDA*, 472 F. Supp. 3d 183 (D. Md. 2020) (*ACOG*).

[1] FDA approved a generic version of Mifeprex in 2019 and another in 2025. *See* ECF Nos. 1-25, 1-109. The mifepristone REMS today applies to all three companies' mifepristone products.

Louisiana (and several other states) moved to intervene. The district court denied Louisiana's motion because the State had not demonstrated a "direct and substantial interest" in the litigation. *ACOG*, No. 20-cv-1320, ECF No. 71 at 5-6 (June 15, 2020). Louisiana's laws, the court explained, were not "linked in any way to the enforcement of the FDA's" in-person dispensing requirement, so the "case would not impair those States' ability to enforce their own laws." *Id.* Nor would any judgment "eliminate any state's ability to continue to regulate medication abortion, as they choose, above and beyond the FDA's requirements." *Id.* at 10. The district court ultimately granted the injunction, *see ACOG*, 472 F. Supp. 3d at 233, but the Supreme Court stayed the injunction from taking effect, *FDA v. ACOG*, 141 S. Ct. 578 (2021).

2021 Nonenforcement Decisions and 2023 REMS. In April 2021, FDA responded to ACOG's petition. That response analyzed medical literature, postmarketing adverse-event reporting, and information about deviations or noncompliance events associated with the REMS. ECF No. 1-3. FDA found no indication that adverse events occurred with greater frequency when a patient received the drug by a method other than in-person dispensing. *Id.* FDA's response to ACOG's petition therefore stated the agency would exercise enforcement discretion as to the in-person dispensing requirement during the public health emergency. *Id.*

In December 2021, FDA came to the same conclusion when responding to the 2019 citizen petition seeking to undo the 2016 changes. It explained that "mifepristone may be safely used without in person dispensing," ECF No. 1-10 at 27, and that in-person dispensing was "no longer necessary to ensure" the drug's benefits outweigh the risks, *id.* at 25. FDA relied on safety data from the nonenforcement period, which showed "no indication" that suspending in-person dispensing "contributed to" adverse events. ECF No. 1-51 at 38. FDA pointed to three studies analyzing pharmacy mail dispensing and five studies analyzing clinic mail dispensing, all of which supported finding that mifepristone remains safe and effective without in-person dispensing. *Id.* at 26-28. FDA therefore directed Danco to submit a sNDA proposing removing the in-person dispensing requirement from the REMS. Danco complied, and FDA approved Danco's sNDA in January 2023. *See* ECF No. 1-50 at 3, 5. Plaintiffs did not file a citizen petition.

2025 HHS Letter and Court Remand. Responding to inquiries from State Attorneys General, Secretary Kennedy said on September 19, 2025, that HHS was conducting "a study of the current REMS, in order to determine whether modifications are necessary." ECF No.1-110. A month later, a federal district court held that certain aspects of the 2023 REMS were unlawful under the APA because FDA "fail[ed] to provide a reasoned explanation for its restrictive treatment of the drug" in light of the available evidence that mifepristone was objectively safe—and remanded to FDA without vacatur. *Purcell v. Kennedy*, No. 1:17-cv-00493, 2025 WL 3101785, at *2 (D. Haw. Oct. 30, 2025). Separately, FDA has received "numerous citizen petitions" asking the agency to reconsider aspects of the 2023 REMS. ECF 50-1, FDA Br. at 7 & n.3.

PROCEDURAL HISTORY

In November 2022, a group of physicians that oppose abortion sued in the Northern District of Texas over various FDA decisions related to mifepristone, including the 2021 non-enforcement decision. *See All. for Hippocratic Med. v. FDA*, Case No. 2:22-cv-00223-MJK. The district court issued a preliminary injunction, which the Supreme Court stayed and reversed, unanimously holding the plaintiffs lacked standing. *Alliance*, 602 U.S. at 374. Over a year later, and more than three years after the *Alliance* suit was filed, Louisiana and Ms. Markezich moved to intervene in the Texas suit. *Alliance* ECF No. 264. Before Danco or FDA responded, the district court denied their intervention motion as moot. *Alliance* ECF No. 273.[2]

A few weeks later, on October 6, 2025, Plaintiffs filed a virtually identical Complaint here, challenging the 2023 REMS. ECF No. 1 (Compl.). More than two months later—on December 17, 2025—Plaintiffs moved for preliminary relief, styled as a "stay" request under 5 U.S.C. § 705 or alternatively a preliminary injunction. ECF No. 20; ECF No. 20-26 (Pls. Br.).

ARGUMENT

The Court should dismiss the complaint for lack of jurisdiction or failure to state a claim,

[2] In the same ruling, the Texas district court transferred a complaint filed by three other states that had intervened far earlier to the Eastern District of Missouri. Because the district court had held, erroneously, that the *Alliance* plaintiffs had standing, it did not analyze whether the three intervenor states had standing. The Missouri court has not yet addressed this issue either.

and it should deny the motion for preliminary relief because Plaintiffs failed to "make a 'clear showing' that" they are "'likely' to establish" jurisdiction or succeed on the merits, and the remaining factors weigh against them. *Murthy v. Missouri*, 603 U.S. 43, 58 (2024) (citation omitted).

I. Plaintiffs Lack Article III Standing.

Like *Alliance*, this case begins and ends with Plaintiffs' lack of Article III standing. Neither Louisiana nor Ms. Markezich can show standing for either claim in their complaint.

A. Louisiana's Asserted Injuries Do Not Establish Standing.

Louisiana claims the 2023 REMS makes it harder for the state to enforce its state-law abortion restrictions, leading to "sovereign," "quasi-sovereign," and financial injuries. Pls. Br. 19-20; Compl. ¶¶ 109, 120, 123. The first two injuries, as alleged, are not "'legally and judicially cognizable.'" *United States v. Texas*, 599 U.S. 670, 676 (2023) (*Priorities* decision) (citation omitted). The 2023 REMS neither requires Louisiana to dispense or use mifepristone nor alters the terms of its state Medicaid plan; nor does it prevent Louisiana from having whatever laws it chooses to enact regarding abortion. And the state's claim that FDA's challenged action has "increase[d] [Louisiana's] Medicaid costs" is even more attenuated than the standing theories rejected in *Alliance*. Pls. Br. 22-23; Compl. ¶¶ 132-134, 148. Indeed, Louisiana's own papers make clear that its asserted injuries flow from independent decisions of providers in other states whose legislatures decided after *Dobbs* to enact "shield laws" for providers in their state.

1. Louisiana has not suffered a sovereign injury.

States have a cognizable interest in "the power to create and enforce a legal code." *Alfred L. Snapp & Son, Inc v. Puerto Rico*, 458 U.S. 592, 601 (1982). But "when speaking about the sovereign's interest in enforcing its laws, the Supreme Court has spoken about the state's interest in the [laws'] *enforceability*." *Harrison v. Jefferson Par. Sch. Bd.*, 78 F.4th 765, 772 (5th Cir. 2023) (emphasis in original); *Maine v. Taylor*, 477 U.S. 131, 137 (1986) (constitutional challenge implicates state's "interest in the continued enforceability of its" laws). The federal government infringes that interest when it preempts state law or applies "pressure to change [it] in some substantial way." *Texas v. United States*, 787 F.3d 733, 749 (5th Cir. 2015); *see Texas v. United*

States, 809 F.3d 134, 153 (5th Cir. 2015) (holding Texas's sovereign interests were impinged by a federal law precluding states from "establish[ing] their own classifications" for immigration).

Nothing like that has occurred here. Louisiana agrees the 2023 REMS does not preempt state laws prohibiting abortion. Pls. Br. 21 n.3; *see GenBioPro, Inc. v. Raynes*, 144 F.4th 258, 267, 276 (4th Cir. 2025) (the REMS "leav[es] the question of access to state governance"). Nothing in the REMS undermines or "interferes with the state's *authority* to enact or enforce restrictions on medical abortion within its boundaries" or renders Louisiana's abortion laws unenforceable. *Washington*, 108 F.4th at 1177; *see, e.g.*, *Harrison*, 78 F.4th at 770 ("for a sovereign interest" to support standing, the defendant's acts must result "in some tangible interference with [state's] authority to regulate or to enforce its laws"). Nor does the REMS "compel the State[] to require or prohibit" any conduct or to change its laws. *Printz v. United States*, 521 U.S. 898, 924 (1997).

For this reason, Louisiana's claims that "the 2023 REMS has *functionally* overridden Louisiana's pro-life laws" amounts to a complaint that the state has to expend state resources to pursue its chosen policies. Pls. Br. 20 (emphasis added) (asserting pursuit of violations "result[s] in monetary harm and depletion of resources"). But using state resources to pursue state policy is entirely normal in our system of dual sovereignty—and it is the *default* for health and safety laws. *See, e.g.*, *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996) (protecting citizens' "health and safety" is "primarily" a "matter of local concern" (citation omitted)); *GenBioPro*, 144 F.4th at 271-272 (same). That does not undermine a law's enforceability. States have no sovereign interest in piggybacking on federal regulation to avoid having to commit resources to pursue their own goals.

Not surprisingly, then, a district court and the Ninth Circuit rejected the exact theory of sovereign injury Louisiana offers. Faced with the same "sovereign authority" argument by Idaho in another case about the mifepristone REMS, the Ninth Circuit explained a state's general "interest in the preservation of sovereign authority" does not confer "standing to challenge federal action that affects state law enforcement indirectly, by making violations of state law more difficult or costly to detect." *Washington*, 108 F.4th at 1176. "[E]ven if the availability of retail and mail-order dispensing does make mifepristone more difficult to police, [courts] have never held that a

logistical burden on law enforcement constitutes a cognizable Article III injury." *Id.* at 1177.

Plaintiffs' invocation of *Louisiana v. EEOC*, 705 F. Supp. 3d 643 (W.D. La. 2024), cuts against them. There, this Court confronted an EEOC rule requiring Louisiana to provide reasonable accommodations for elective abortions in its capacity as an employer. *Id.* at 649-650. The rule "directly regulated" Louisiana, preempted the States's conflicting statutes, and, because Louisiana faced potential penalties for non-compliance, imposed an "intrusion[] … analogous to pressure to change state law." *Id.* at 653 (citation omitted). Nothing like that exists here. To the extent Louisiana believes the 2023 REMS infringes on its sovereignty, it should "take th[ose] concerns to the Executive and Legislative Branches"—not this Court. *Alliance*, 602 U.S. at 393.

2. Louisiana's quasi-sovereign interests are not cognizable.

In its complaint—but not its preliminary injunction papers—Louisiana claims a related "quasi-sovereign" injury to its citizens' health and safety. Compl. ¶¶ 120-123. But a "'State does not have standing as *parens patriae* to bring an action against the Federal Government'" to vindicate its citizens' rights. *Haaland v. Brackeen*, 599 U.S. 255, 295 (2023) (quoting *Snapp*, 458 U.S. at 610, n.16). A state's "quasi-sovereign interests in its citizens' health and well-being" is "wholly derivative of the personal … interests of its citizens and therefore not a valid quasi-sovereign interest at all." *Paxton v. Dettelbach*, 105 F.4th 708, 715-716 (5th Cir. 2024); *accord Harrison*, 78 F.4th 765 (rejecting similar quasi-sovereign standing theory).

Trying to evade that bar, Louisiana claims its "quasi-sovereign theory of harm" is not an impermissible *parens patriae* suit because the state is merely "invoking its *own* sovereign right to regulate for the protection of its citizens." Compl. ¶ 131. If so, this claimed injury is wholly indistinguishable from its asserted "sovereign" interests—which is perhaps why Louisiana does not raise it in its preliminary injunction brief. It fails for all the same reasons. *Washington*, 108 F.4th at 1178 (rejecting Idaho's "quasi-sovereign" harm from 2023 REMS).

3. Louisiana's allegations of economic harms are insufficient.

Louisiana's last claim of injury is that it is "statistically certain" some women who take mifepristone without receiving the drug at an in-person appointment will later seek emergency-

room follow-up care in Louisiana, some of which might be state funded. Pls. Br. 22-23; Compl. ¶¶ 132-134, 148. This "downstream medical costs" theory is an even more attenuated version of the "doctor standing" argument the Supreme Court unanimously rejected in *Alliance*—which is why courts rejected this exact argument when Idaho made it. *Washington*, 108 F.4th at 1174.

As *Alliance* explained, the causal chain between FDA's regulation of mifepristone and downstream medical outcomes is highly "attenuated." 602 U.S. at 390-393. And, "more to the point, the law has never permitted doctors to challenge the government's loosening of general public safety requirements simply because more individuals might then show up at emergency rooms or in doctors' offices with follow-on injuries." *Id.* at 391. Allowing "healthcare providers to challenge general safety regulations as unlawfully lax would [thus] be an unprecedented" expansion of Article III requirements, and would have no "principled" endpoint. *Id.* at 391-392.

Louisiana cannot overcome this bar with anecdotal stories and statistics suggesting that it may ultimately pay for those doctors' services. Pls. Br. 22-23; *e.g.*, Willis Decl., ECF 20-20 ¶¶ 11-13 (asserting that "women who ingest mifepristone may end up in the emergency room" and "[w]hen such women are covered by Medicaid," such care *may* be paid for by the state); New Decl., ECF No. 20-22 at 2-3 (opining on likelihood of Medicaid paying for care). The attenuated causal chain that failed to satisfy Article III in *Alliance* cannot be overcome by adding more links.

Louisiana's monetary theory also runs headlong into another problem. "[I]n our system of dual federal and state sovereignty, federal policies frequently generate indirect effects on state revenues or state spending." *Priorities*, 599 U.S. at 680 n.3. So the Supreme Court has repeatedly cautioned against granting states standing based on these kinds of downstream effects, which would erode "bedrock Article III constraints." *Id.*; *see also California v. Texas*, 593 U.S. 659, 675-678 (2021) (expressing skepticism of predictive effects on state budgets); *Arizona v. Biden*, 40 F.4th 375, 386 (6th Cir. 2022) ("peripheral costs imposed on States" not "cognizable"). This is especially true "in the FDA drug-approval context," where "virtually all drugs come with complications, risks, and side effects." *Alliance*, 602 U.S. at 392. Plaintiffs' theory would grant states standing to challenge a "limitless" array of agency decisions merely by (1) estimating how many

Medicaid-enrolled residents may encounter a particular product—including, for drug products, based on independent actions of health care providers—and thereafter seek medical care, and (2) statistically quantifying how much treating each potential individual could cost. The Supreme Court expressly cautioned against starting "down that uncharted path." *Id.*; *Summers v. Earth Island Inst.*, 555 U.S. 488, 495, 497 (2009) ("statistical probability that some [plaintiffs] are threatened with concrete injury" insufficient even if coupled with allegations of past harm).

Applying these standards, the Ninth Circuit correctly held that alleged "economic injury in the form of increased costs to the state's Medicaid system" does not give states standing to challenge the 2023 REMS. *Washington*, 108 F.4th at 1174. There are simply too many independent and attenuated links in the causal chain. *Id.* Louisiana ignores this decision. Instead, it claims that pro-life states like Louisiana were the "object" of the 2023 REMS in a post-*Dobbs* world. Pls. Br. 18 (quoting *Diamond Alt. Energy, LLC v. EPA*, 606 U.S. 100 (2025)). But the 2023 REMS formalized a non-enforcement policy FDA first put in place in early 2021, and FDA directed Danco to submit a sNDA consistent with that policy that same year—well before the June 2022 *Dobbs* decision or any statements Plaintiffs quote from various federal officials after *Dobbs*. *See, e.g.*, Pls. Br. 4. In any event, the Supreme Court in *Diamond* did not adopt a new, lesser causation standard for entities that are the "object" of a regulation. *Diamond*, 606 U.S. at 115. Rather, it found that plaintiffs there satisfied the *Alliance* standard because their asserted injuries as fuel producers were only one step removed from California's regulations. *Id.* at 117-118. Not so here.

Nor are Louisiana's claimed Medicaid expenditures analogous to standing theories that courts have accepted in the immigration context. Pls. Br. 21 (citing cases). In each of those instances, federal action increased or decreased the overall population that was *eligible* for state benefits—so it did not require conjecture to estimate increased costs to states. *E.g.*, *Texas v. United States*, 126 F.4th 392, 411 n.22 (5th Cir. 2025) ("By conferring lawful presence, DACA makes recipients eligible for a variety of state and federal benefits"); *Texas*, 787 F.3d at 752 (holding the challenged federal "program would have a direct and predictable effect on the state's driver's license regime" by increasing the eligible population); *Dep't of Com. v. New York*, 588 U.S. 752,

767 (2019) (likely undercount of certain households in a census containing a citizenship question would lead states to lose federal funds calculated on the basis of population). Here, however, FDA's action does not increase the overall population of Louisiana residents eligible for Medicaid, which is why Louisiana must engage in a gymnastics routine to estimate how *utilization* of Medicaid may affect costs.[3] That is a categorically different sort of claim because it relies on far more layers of speculation about the actions of independent third parties—and flouts the Supreme Court's admonition in the *Alliance* and *Priorities* decisions.

4. Louisiana's asserted injuries are not traceable to FDA's action.

Louisiana has also not shown that its asserted injuries are traceable to the 2023 REMS for another reason. In Plaintiffs own telling, all of Louisiana's claimed injuries derive from "doctors in states like New York and California" who "prescribe and mail FDA-approved mifepristone into pro-life states" like Louisiana. Pls. Br. 1. But the 2023 REMS does not require those doctors to prescribe mifepristone, nor direct states to shield their identities. FDA—by Congressional design—considers only whether a REMS should be modified to "ensure the benefits of the drug outweigh the risks" and to "minimize the burden on the health care delivery system of complying" with the REMS. 21 U.S.C. § 355-1(g)(4)(B). As a result, Louisiana's asserted injuries are traceable to the "unfettered choices made by independent" actors—i.e., medical providers in other states who ship mifepristone in reliance on shield laws that Louisiana's co-equal states have enacted. *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 414 & n.5 (2013) (quotations omitted).

Louisiana's complaint and brief repeatedly make clear that it is out-of-state medical providers' independent actions under these competing out-of-state laws that frustrate Louisiana's asserted interests in enforcing its abortion restrictions and impose the alleged costs. *E.g.*, Pls. Br. 1, 5, 6, 7; Compl. ¶¶ 4-10, 80-107. FDA has not enforced in-person dispensing since April 2021. *Supra*, p.3. The Supreme Court decided *Dobbs* in June 2022. Yet the #WeCount Report on which Louisiana relies shows that neither of these events precipitated an increase in medication abortion

[3] Unlike in the immigration cases, Louisiana also expressly disclaims reliance on "special solicitude" for its standing analysis. Pls.' Br. at 21 n.4.

in Louisiana; that changed with the enactment of shield laws in 2023. *See* ECF No. 20-2 at 9 (marking increase in telehealth abortions in Q3 2023, when "[p]rovision under US shield laws begins"); Compl. ¶ 85 (same). Louisiana's brief charts this effect in stark form. Pls. Br. 1-2.

Louisiana dismisses these shield laws as a "redressability" issue that would be resolved if this Court enjoined the REMS and thereby eliminated the option of independent actors making independent choices from other states. *Id.* at 25. That approach is backwards: Courts evaluate causation through a forward-facing lens, assessing whether an unregulated plaintiff has demonstrated that independent third-parties would "likely react in predictable ways that in turn will likely injure the plaintiffs." *Alliance*, 602 U.S. at 383 (quotation marks omitted). Just as the Supreme Court rejected a statistical probability argument in *Alliance*, this Court should too where there is an even longer daisy chain of independent actors at play. Indeed, Louisiana offers *no* evidentiary basis for this Court to find that other states' adoption of "shield" laws after *Dobbs* was a predictable effect of FDA formalizing the April 2021 non-enforcement policy.

Further, and just as importantly, the same principles of state sovereignty that Louisiana claims to want to vindicate preclude courts from blithely assuming how co-equal sovereigns will respond to FDA's relaxed regulation. And the Supreme Court has found causation wanting in the absence of that showing—even in cases where an injunction could have arguably remedied the injury. *See, e.g.*, *Clapper*, 568 U.S. at 414 (fact that government program made surveillance possible did not mean that plaintiffs were injured by it); *Ariz. Christian Sch. Tuition Org. v. Winn*, 563 U.S. 125 (2011) (taxpayers lacked standing to challenge tax credits benefitting religious schools when private individuals decided how to use credits).

Simply put, Louisiana's claimed injuries are "not fairly traceable" to FDA because "intervening, independent act[s]" of third parties are "a necessary condition." *Texas*, 787 F.3d at 752.

B. Louisiana Lacks Standing For Count II For Additional Reasons.

Louisiana has an additional redressability problem with its claim that the 2023 REMS contravenes the Comstock Act, 18 U.S.C. § 1461. Pls. Br. 13-14. On its face, this claim seeks to compel FDA to enforce a criminal statute. But requests that the Executive exercise enforcement

in a particular way are not "traditionally thought to be capable of resolution through the judicial process." *Priorities*, 599 U.S. at 676 (quotes and citations omitted). Even when a state seeks to press an APA challenge on the ground that an agency decision does not comport with "statutory [] mandates," *id.*, the claim is unreviewable if it would functionally direct the Executive's "enforcement" of criminal prohibitions. *Id.* at 678-681; *see, e.g.*, *Taylor*, 477 U.S. at 137 ("private parties, and perhaps even separate sovereigns, have no legally cognizable interest in the prosecutorial decisions of the Federal Government"); *Heckler v. Chaney*, 470 U.S. 821, 831 (1985) (recognizing "general unsuitability for judicial review of agency [non-enforcement] decisions").

This principle is all the more true here, where Count II seeks to judicially compel FDA to enforce a criminal statute through the terms of a drug's REMS—which is beyond the factors Congress expressly directed FDA to consider in the REMS provision. *See infra* p. 21. This type of request is not redressable where, as here, the 2023 REMS does not purport to immunize people from any liability flowing from federal or state laws, determine the validity of other laws, or entitle anyone to federal or state benefits. *Priorities*, 599 U.S. at 683 (suggesting standing analysis "could" differ where Executive provides "legal benefits or legal status"); *Texas*, 809 F.3d at 154 ("nonprosecution" is distinct from "nonprosecution and the conferral of benefits"). "If the Court green-lighted this suit," it would be opening the floodgates for Courts to override Congress's express directions regarding REMS, all based on "alleged Executive Branch under-enforcement" of some other law that Congress tasked to a different agency. *Priorities*, 599 U.S. at 681.

C. Ms. Markezich Lacks Standing.

Ms. Markezich likewise lacks standing. She alleges that her ex-boyfriend previously coerced her into taking mifepristone that a California physician prescribed and sent through the mail. ECF Nos. 1 ¶¶ 150-153; 1-92 ¶¶ 9, 11-14. But there is no allegation that she will be coerced to do so in the future, and a claim of "[p]ast wrongs" cannot support standing to seek an injunction. *City of Los Angeles v. Lyons*, 461 U.S. 95, 102 (1983). Rather, to seek "injunctive and declaratory relief," a plaintiff must instead point to some "continuing or threatened future injury" that is "'imminent,'" not speculative or theoretical—and "must also show that there is a substantial risk that

they will suffer" the injury "absent their requested relief." *Stringer v. Whitley*, 942 F.3d 715, 720 (5th Cir. 2019) (quoting *Clapper*, 568 U.S. at 409).

Nothing in the Complaint suggests that Ms. Markezich is likely to be coerced into obtaining an unwanted medication abortion again. She is no longer in a relationship with her ex-boyfriend and does not allege that she intends to become pregnant again with a partner who will pressure her to make a decision she does not want to make. ECF No. 1-92. It is not imminent, concrete, or non-hypothetical that Ms. Markezich will face the same complex series of events and circumstances that she says happened in the past. *See, e.g.*, *Attala Cnty. NAACP v. Evans*, 37 F.4th 1038, 1044-45 (5th Cir. 2022) ("The likelihood of difficulties for the Plaintiffs ... are much less imminent" where they involve multiple steps in a causal chain, some of which are "infrequent[t]"). Put simply, based on Ms. Markezich's declaration, "it is untenable to assert" that the same set of circumstances would play out in the same fashion a second time. *See Lyons*, 461 U.S. at 108.[4]

Without a showing that she faces an "actual or imminent"—as opposed to "speculative"—future injury, Ms. Markezich lacks Article III standing. *Alliance*, 602 U.S. at 383.

II. Plaintiffs Fail To Satisfy Threshold APA Requirements.

Because Plaintiffs sue under the APA, they must also show that the interests they assert are "'arguably within the [FDCA's] zone of interests," *Match-E-Be-Nash-She-Wish Band of Pottawatomi Indians v. Patchak*, 567 U.S. 209, 224 (2012) (citation omitted), and that they exhausted the appropriate administrative remedies. Plaintiffs can make neither showing.

A. Plaintiffs Are Outside The Statutory Zones Of Interest.

The zone-of-interests test asks "whether Congress 'intended for a particular class of plaintiffs to be relied upon to challenge agency disregard of the law.'" *Clarke v. Sec. Indus. Ass'n*, 479 U.S. 388, 399 (1987) (citation modified). Thus, a court must analyze the relationship between "the

[4] To the extent the "mental-health effects from the trauma [Ms. Markezich] experienced" are a continuing injury, Compl. ¶ 154, it is not redressable by an injunction here. *See Lyons*, 461 U.S. at 107 n.8 ("The emotional consequences of a prior act simply are not a sufficient basis for an injunction absent a real and immediate threat of future injury[.]"); *Steel Co v. Citizens for a Better Env't*, 523 U.S. 83, 103 n.5 (1998) (similar).

injury [the plaintiff] complains of" and the specific "statutory provision whose violation forms the legal basis for [the] complaint." *Bennett v. Spear*, 520 U.S. 154, 176 (1997). The test is not "especially demanding," but it forecloses suit when an unregulated "plaintiff's 'interests are [only] marginally related to or inconsistent with the purposes implicit in the statute.'" *Patchak*, 567 U.S. at 225 (quoting *Clarke*, 479 U.S. at 399).

Neither Plaintiff falls within the Comstock Act's zone of interests. The Act is a federal criminal statute, which is not being enforced against Plaintiffs—and Plaintiffs do not have an interest in having it enforced against others. *See, e.g.*, *Priorities*, 599 U.S. at 677 ("a party 'lacks a judicially cognizable interest in the prosecution ... of another.'" (citation omitted)); *see also Town of Castle Rock v. Gonzales*, 545 U.S. 748, 768 (2005). Further, unlike other contexts, such as immigration—where Congress "has explicitly allowed states to" limit their costs by refusing "benefits to illegal aliens"—Comstock envisions no role or participation by states. *Texas*, 809 F.3d at 163. Indeed, whatever the parties' disputes about the Act's meaning and applicability, *see infra* p. 21-22, Plaintiffs do not allege it was designed to protect states' sovereign, quasi-sovereign, or economic interests. *See* Pls. Br. 13-14; Compl. ¶¶ 14, 30, 172-175. And permitting state or private parties to seek enforcement of a federal criminal law is far "more likely to frustrate ... statutory objectives" by interfering with the Executive's enforcement discretion and fracturing a uniform federal regime. *Scheduled Airlines Traffic Off. v. DOD*, 87 F.3d 1356, 1359 (D.C. Cir. 1996).

Similarly, Louisiana does not fall within the zone of interests of the FDCA's REMS provision, 21 U.S.C. § 355-1. That provision authorizes FDA to impose use restrictions when the agency finds such restrictions are necessary to "ensure the benefits of the drug outweigh the risks," 21 U.S.C. § 355-1(a)(1); requires periodic assessments of any imposed use restrictions, *id.* § 355-1(c), (g)(2)-(3); and directs FDA to modify use restrictions based on the benefit-risk balance and to "minimize the burden on the health care delivery system of complying with the [REMS]," *id.* § 355-1(g)(4)(B). This framework was designed to safeguard and advance public health by protecting consumers taking drugs that are found to have specific risks. Noticeably absent is an intent to protect states that want to restrict access to FDA approved drugs. Nor does the REMS statute

attempt to regulate Medicaid expenditures. *See Ass'n of Am. Physicians and Surgeons, Inc. v. FDA*, 539 F. Supp. 2d 4, 18 (D.D.C. 2008) (rejecting plaintiffs' standing argument because "alleged competitive and economic injuries do not fall within the [FDCA's] zone of interests").

At best, then, Louisiana's asserted interests have nothing to do with the FDCA's purposes. *See, e.g.*, Compl. ¶¶ 80, 84, 94 (asking for "change in federal regulation" to protect "state pro-life laws"). More realistically, allowing the state to pursue its interests in enforcing abortion restrictions via this suit would "'severely disrupt" the FDCA's "complex and delicate administrative scheme.'" *Clarke*, 479 U.S. at 399 (citation omitted).

B. Plaintiffs Failed To Exhaust Administrative Remedies.

An "aggrieved party" must also "exhaust[ ] all administrative remedies expressly prescribed" before seeking APA review. *Darby v. Cisneros*, 509 U.S. 137, 146, 153 (1993). FDA's regulations mandate that any request for FDA to "take or refrain from taking any form of administrative action must first be the subject of a final administrative decision based on a [citizen] petition" before suit is filed. 21 C.F.R. § 10.45(b); *see id.* § 10.25(a). Plaintiffs never filed a citizen petition regarding either the 2023 REMS or the 2021 non-enforcement decision on the same topic. Courts routinely dismiss suits in such circumstances. *See, e.g., Ctr. for Food Safety v. Hamburg*, 696 F. App'x 302, 303 (9th Cir. 2017); *Cody Lab'ys, Inc. v. Sebelius*, 446 F. App'x 964, 969 (10th Cir. 2011); *Ass'n of Am. Physicians & Surgeons v. FDA*, 358 F. App'x 179, 180-181 (D.C. Cir. 2009). This Court should do the same.

The Fifth Circuit previously concluded that exhausting a challenge to the 2021 non-enforcement decision would have been futile because FDA (1) rejected a similar argument in response to a 2019 citizen petition challenging the 2016 changes and (2) "formalized" the non-enforcement policy in the 2023 REMS. *All. for Hippocratic Med. v. FDA*, 78 F.4th 210, 255 (5th Cir. 2023) (citing *Tesoro Refin. & Mktg. Co. v. FERC*, 552 F.3d 868, 874 (D.C. Cir. 2009)), *rev'd*, 602 U.S. 367 (2024). But the futility "exception is quite restricted," and should be applied only in the "exceptional" case when there is "a *certainty* of an adverse decision"; that "an unfavorable decision [is] highly likely" does not suffice. *Tesoro*, 552 F.3d at 874 (quotations omitted). The

2019 petition did not raise the core issues that Plaintiffs say infect FDA's 2023 REMS: the alleged conflict with the adverse event data, supposed concerns about the underlying studies on which FDA relied, or the claimed Comstock Act problem. *See* Pls. Br. 10-14. Plaintiffs cannot know how FDA would respond to arguments it never considered.[5] So exhaustion would not be futile.

III. This Dispute Is Not Ripe.

Beyond these threshold defects, FDA's recent "decision to review the REMS for mifepristone" also renders Plaintiffs' claims unripe. ECF No. 50-1 at 1. "A case becomes ripe when it 'would not benefit from any further factual development and when the court would be in no better position to adjudicate the issues in the future than it is now.'" *DM Arbor Ct., Ltd. v. City of Houston*, 988 F.3d 215, 218 (5th Cir. 2021) (citation omitted). Yet further factual development is exactly what FDA is seeking: its motion to stay asserts that, given the recent litigation and "numerous citizen petitions," it wishes "to reconsider the restrictions on mifepristone based on all the evidence before the agency." ECF No. 50-1 at 2-3. In FDA's own words, this "review may eliminate any need for the Court's" intervention—presumably because the agency could decide to reimpose the kinds of restrictions Plaintiffs are seeking or to analyze the underlying data in a way that satisfies Plaintiffs. *Id.* at 10. This alone justifies "withholding court consideration." *Choice Inc. of Tex. v. Greenstein*, 691 F.3d 710, 715 (5th Cir. 2012) (citation omitted).

FDA views the current uncertainty about its ultimate decision as favoring a stay of proceedings. ECF No. 50-1 at 9-12. Such a stay was appropriate in the cases FDA cites, where an agency took some action after litigation commenced. *Id.* (citing *Purcell*, 2025 WL 3101785). Here, however, Plaintiffs waited years and filed this suit *after* FDA already announced that it was reviewing the 2023 REMS. *See* ECF No. 50-1 at 7-8 (FDA review announced on September 19, 2025). This delay makes abundantly clear that the "key considerations" of ripeness—"the fitness

[5] Numerous high-quality studies post-dating FDA's decision confirm its wisdom, which FDA could have considered had Plaintiffs raised these issues. *See, e.g.*, ACOG, Citizen Pet. 7-9 (Jan. 31, 2025), https://tinyurl.com/4e2483w7 (collecting studies). That FDA is currently considering these arguments in response to citizen petitions, the *Purcell* remand, and Secretary Kennedy's own initiative, underscores that Plaintiffs do not know what FDA would have done had they exhausted their claims. *See* FDA Br. 7 & n.3.

of the issues for judicial decision and the hardship to the parties of withholding court consideration"—favor dismissal. *Greenstein*, 691 F.3d at 715 (citation modified).

IV. Plaintiffs' Claims Fail On The Merits.

A. Plaintiffs' Arbitrary And Capricious Claims Fail.

Arbitrary-and-capricious review is narrow and "deferential." *FCC v. Prometheus Radio Project*, 592 U.S. 414, 426 (2021). "[A] court may not substitute its own policy judgment for that of the agency"; its role is "simply" to determine whether the agency "acted within a zone of reasonableness." *Id.* at 423. That is doubly true on issues that "require[] a high level of technical expertise," *Kleppe v. Sierra Club*, 427 U.S. 390, 412 (1976), where "a reviewing court must generally be at its most deferential," *Balt. Gas & Elec. Co. v. NRDC, Inc.*, 462 U.S. 87, 103 (1983). FDA's 2023 REMS modification clears this low bar.

To begin, the Court cannot properly evaluate this claim absent the administrative record. *See, e.g., Vt. Yankee Nuclear Power Corp. v. NRDC*, 435 U.S. 519, 549, 553 (1978) (under arbitrary-and-capricious review, agency's decision "stand[s] or fall[s] ... on the administrative record'"). Judicial review of whether the agency properly considered the evidence before it must be "based on the full administrative record" before the agency at the time of its decision. *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 420 (1971), *abrogated on other grounds*, *Califano v. Sanders*, 430 U.S. 99 (1977). Granting a preliminary injunction on arbitrary-and-capricious grounds inherently relies on "speculat[ion]" about the "basis" for "the agency action the plaintiff seeks to enjoin." *Am. Bioscience, Inc. v. Thompson*, 243 F.3d 579, 580-582 (D.C. Cir. 2001).

For similar reasons, Plaintiffs are also wrong to suggest the Fifth Circuit already "decided" that FDA acted arbitrarily. Pls. Br. 9. Like this Court, the Fifth Circuit lacked the underlying administrative record, so it could not have come to a definitive conclusion. Further, the Supreme Court reversed the Fifth Circuit's decision for lack of standing, meaning the Fifth Circuit never had jurisdiction to reach the merits. *See, e.g., Ctr. for Biological Diversity v. EPA*, 937 F.3d 533, 545 (5th Cir. 2019). And the fact that some judges previously expressed their views on the merits does not mean they were correct. *See, e.g.*, *Alliance*, 602 U.S. at 380-396.

The record, such as it is here, reveals why.[6] In December 2021, FDA reviewed the then-existing post-marketing and study data to analyze whether mifepristone could safely be used without in-person dispensing and whether in-person dispensing was "unduly burdensome on patient access." *See* 21 U.S.C. § 355-1(f)(1), (f)(2)(C), (g)(4)(B). FDA compared adverse reports in the period when in-person dispensing was enforced against data from eleven months when it was not—and found no difference. ECF No. 1-50 at 62-65. FDA also conducted a "comprehensive review of the published literature," *id.* at 45, including three studies permitting pharmacy dispensing through mail, one of which showed a mere 0.9% of women experienced an adverse event after taking mifepristone, *id.* at 67-69. These studies supported finding "that the efficacy of medical abortion is maintained with mail order pharmacy dispensing." *Id.* at 69. In addition, FDA examined five studies allowing clinic dispensing by mail, which further "support that dispensing by mail is safe and effective." *Id.* at 69-75. Exercising its expert judgment, FDA determined this evidence collectively showed the "benefits of" lifting the in-person dispensing requirement "outweigh[ed] the risks." *Id.* at 11.

Plaintiffs urge this Court to ignore the "particular judicial deference" owed to agencies on scientific matters and second-guess FDA's judgment. *Atchafalaya Basinkeeper v. U.S. Army Corps of Eng'rs*, 894 F.3d 692, 701 (5th Cir. 2018). *First*, they contend that FDA could not rely on the lack of adverse events reported in FDA's database because FDA "'eliminat[ed]'" mandatory reporting in 2016 for non-fatal adverse events, leaving in place only "voluntary" reporting. Pls. Br. 10-11 (quoting *All. for Hippocratic Med. v. FDA*, No. 23-10362, 2023 WL 2913725, at *17 (5th Cir. 2023)). This misunderstands the adverse-event-reporting system that FDA uses for virtually all drugs. Anyone can still report any adverse events to FDA or to Danco, and Danco must pass those reports on to FDA.[7] In this sense, Mifeprex adverse-event reporting is the same as for

[6] No record as to the 2023 REMS was before the Fifth Circuit, nor is it before this Court.

[7] From 2000 to 2016, Mifeprex prescribers had to report all serious adverse events. In 2016, consistent with 15 years of data demonstrating Mifeprex's proven track record across more than 2.5 million patients, FDA concluded that mandatory reporting was necessary only for fatalities. ECF No. 1-11 at 12. FDA relied on data and literature showing that serious adverse events were very rare, generally far below 1% for any individual event. *Id.* at 12-13. Notably, only seven of

virtually all FDA approved drugs: Danco is affirmatively required to report every adverse event that it learns of from any source to FDA. *See* Long Decl. ¶ 18-19; 21 C.F.R. §§ 314.80, 314.81.

As with all drugs, FDA looks at the voluntary adverse event reporting data as one of the mechanisms for the agency to identify trends suggesting safety issues it should investigate. It also looks to scientific literature and, where there is a REMS, to the required REMS "assessments" that the drug's sponsor must provide to FDA at regular intervals, 21 U.S.C. § 355-1(d), (g)(2)(B)-(C). That adverse event reporting does not capture every single adverse event is well known. Indeed, it "is not unusual" for agencies to act without "perfect empirical or statistical data." *Prometheus*, 592 U.S. at 427. And FDA routinely relies on adverse event data (or the lack thereof) that is voluntarily reported to relax or discontinue a REMS over time. *E.g.*, FDA, Lotronex sNDA Approval 2 (Sept. 8, 2023), https://tinyurl.com/bdh82ftc. If voluntary reporting were insufficient for FDA to make REMS-related decisions, virtually every REMS modification would be unlawful. FDA Scholars Br. 24-25, *All. for Hippocratic Med. v. FDA*, No. 23-235, 2024 WL 400099 (5th Cir. Jan. 30, 2024). Plaintiffs do not justify such a radical standard.

Second, Plaintiffs fault FDA for supposedly ignoring the scientific literature, claiming that FDA "conceded that 'the studies neither confirmed nor rejected'" lifting the in-person dispensing requirement, Pls. Br. 13 (quoting *Alliance*, 78 F.4th at 250). This is wrong. FDA explicitly said its conclusion was "supported by [its] review of the published literature." ECF No. 1-10 at 26. The Fifth Circuit's decision critiquing this analysis rests on the flawed premise that agencies cannot act absent perfect data. But even an agency decision that relies on the *absence* of data can be upheld, if the agency makes a "reasonable predictive judgment." *Prometheus*, 592 U.S. at 427. That is what happened here. FDA reviewed the data and—based on the lack of real-world adverse events and several supporting studies—reasonably predicted that the in-person dispensing requirement could be "modified … without compromising patient safety." ECF No. 1-10 at 23. Echoing the Fifth Circuit, Plaintiffs criticize FDA for relying on these studies despite "recogniz[ing]" their

71 REMS programs mandate adverse-event reporting of deaths. *See* FDA, Approved Risk Evaluation and Mitigation Strategies (REMS), https://tinyurl.com/yx34edph (last visited Feb. 3, 2026).

limitations. Pls. Br. 13 n.2 (quoting *Alliance*, 78 F.4th at 250). But an agency *should* candidly acknowledge the "limitations" of its data and "carefully explain[] why its limited reliance on [that data] was justified"—far from being arbitrary and capricious, that is what the APA demands. *In re Polar Bear ESA Listing & Section 4(d) Rule Litig.*, 709 F.3d 1, 14 (D.C. Cir. 2013).

Plaintiffs also wrongly suggest that FDA erred on the science itself. Pls. Br. 13 n.2; *see also Cytori Therapeutics, Inc. v. FDA*, 715 F.3d 922, 927 (D.C. Cir. 2013) (Kavanaugh, J.) (courts are "ill-equipped to second-guess" FDA's "scientific judgment"). Plaintiffs protest that some studies involving clinic dispensing by mail showed there could be "more frequent ED/urgent care visits" without in-person dispensing, and that "FDA's only response … was a nonanswer." Pls. Br. 13 n.2; *see* ECF Nos. 1-10 at 35, 1-50 at 75.[8] In fact, FDA provided four explanations: (1) the Mifeprex label reports only emergency department (ED) visits, and the increased frequency could result from "reporting of combined ED and urgent care visits"; (2) "a substantial proportion of participants lived significant distances from their providers," potentially leading to "higher use of ED[s]"; (3) "half of the ED/urgent care visits did not entail any medical treatment"; and (4) there were no increases in other serious adverse events. ECF No. 1-50 at 70, 73, 75. No study involving pharmacy dispensing by mail showed ER visits above the labeled frequency. *Id.* at 67-69. In other words, FDA "examined the relevant data," "extrapolate[d] from" it to draw "a reasonable inference," and "articulated a satisfactory explanation" for why the higher combined rate of ED/urgent care visits did not justify requiring burdensome and otherwise unnecessary in-person dispensing. *FDA v. Wages & White Lion Invs., L.L.C.*, 604 U.S. 542, 567, 586 (2025) (brackets and citation omitted). No more is required.

B. Plaintiffs' Comstock Arguments Also Fail.

Plaintiffs' claim that the 2023 REMS violates the Comstock Act fails twice over. *First*, like any agency, FDA has only the authority Congress granted it. *FDA v. Brown & Williamson*

[8] Plaintiffs cite (at 13 n.2) a study showing 1 in 8 women had "unplanned clinical encounters," meaning "in-person medical care" that was not pre-planned, ECF No. 1-50 at 72. Comparing that to *ER visits* is like comparing apples and oranges, hence why FDA did not do so.

Tobacco Corp., 529 U.S. 120, 126, 161 (2000). When regulating drugs, FDA's responsibility is to "protect the public health by ensuring that … [the drug is] safe and effective" under the proposed conditions of use. 21 U.S.C. § 393(b)(2); *see id.* § 355(b)(1)(A)(i), (d); *Merck Sharp & Dohme Corp. v. Albrecht*, 587 U.S. 299, 302 (2019). This requires FDA to, among other things, evaluate scientific evidence and real-world data. *See, e.g.*, 21 C.F.R. § 314; FDA, *How Drugs are Developed and Approved*, https://tinyurl.com/3va9946s (last updated Oct. 24, 2022). The REMS framework is similarly focused on safety and efficacy, allowing FDA to attach such conditions only if "necessary to ensure that the benefits of the drug outweigh the risks." 21 U.S.C. § 355-1(a)(1).

Nothing in this framework indicates that Congress intended or authorized FDA to consider whether a drug's distribution might be restricted under other laws administered by another entity. *Id.* § 355(d). Nor has FDA interpreted the FDCA to permit that. 21 C.F.R. §314.125(b) (reasons to deny applications). FDA routinely and validly approves drugs that are subject to restrictions under other statutes or regulations that FDA does not administer, like fentanyl, methadone, and alprazolam, all of which are subject to the Controlled Substances Act. 21 U.S.C. § 812; *see id.* §§ 811(a), 841(a)(1), 844(a). Whatever the scope of the Comstock Act's prohibitions, Congress assigned it no role within the FDCA or REMS framework. Imposing a REMS based on Comstock would amount to relying on "factors which Congress has not intended [FDA] to consider," rendering its decision invalid. *Motor Vehicle Mfrs. v. State Farm Mut. Auto. Ins.*, 463 U.S. 29, 43 (1983).

Plaintiffs take out of context the Supreme Court's statement in *FCC v. NextWave Personal Communications Inc.* that the APA requires agencies to follow "*any* law and not merely those laws that the agency itself is charged with administering." 537 U.S. 293, 300 (2003). The Court's point was that an agency could not violate law applicable *to that agency*—there, a provision of the Bankruptcy Code prohibiting any "governmental unit[s]" from taking the very action the FCC had taken. *See id.* at 300-301; 11 U.S.C. §525(a). Here, no law requires or permits FDA to formulate a REMS around Comstock.

Second, courts have long recognized that the Comstock Act prohibits only the distribution of items intended to produce *unlawful* abortions. *See Bours v. United States*, 229 F. 960, 964-965

(7th Cir. 1915); *Youngs Rubber Corp. v. C.I. Lee & Co.*, 45 F.2d 103, 107-108 (2d Cir. 1930); *Davis v. United States*, 62 F.2d 473, 474-475 (6th Cir. 1933); *United States v. One Package*, 86 F.2d 737, 738-739 (2d Cir. 1936); *United States v. Nicholas*, 97 F.2d 510, 512 (2d Cir. 1938); *Consumers Union of United States v. Walker*, 145 F.2d 33, 33, 35 (D.C. Cir. 1944); *see Poe v. Ullman*, 367 U.S. 497, 546 n.12 (1961) (Harlan, J., dissenting) (noting "judicial interpretation" that Comstock's "absolute prohibitions … exclude professional medical use"). Congress ratified that established construction by repeatedly amending the Act without material change after that construction had been called to Congress's attention in a 1948 Historical and Revision Note. *See* Off. of Legal Counsel, *Application of the Comstock Act*, 46 Op. O.L.C.__, slip op. at 12-15 (Dec. 23, 2022), https://perma.cc/TZ98-5T46; 18 U.S.C. § 1461 note; *see also Ex parte Collett*, 337 U.S. 55, 71 (1949) ("flatly reject[ing]" argument that "Congress did not appreciate what it was enacting" in light of similar note).

Congress also repeatedly amended the FDCA without limiting FDA's authority to approve the types of drugs enumerated in the Comstock Act—including, most recently, in 2007, when Congress "deemed" drugs like mifepristone to have an enforceable REMS. FDAAA § 909(b), 121 Stat. 823, 950-951 (2007). Congress was well aware that by doing so, it was authorizing mifepristone's distribution system to continue. *See, e.g.*, 153 Cong. Rec. S5765 (daily ed. May 9, 2007) (Sen. Coburn recognizing that mifepristone "is deemed to have a REMS and is subject to periodic review"). The "plain import" of this decision is that the Comstock Act does not bar those same activities. *See Dorsey v. United States*, 567 U.S. 260, 274-275 (2012).

Plaintiffs do not wrestle with any of this. Instead, they cite to the Fifth Circuit's stay decision in *Alliance* suggesting a different interpretation, and Judge Ho's separate opinion. Pls. Br. 13-14. But these opinions lack precedential value following the Supreme Court's holding that plaintiffs lacked standing. And, respectfully, they are not persuasive. Making it a federal crime to mail drugs for lawful medical purposes contravenes nearly a century of precedent and all indicia of Congressional intent. It would also significantly interfere with states' traditional power to enact their own "health and welfare laws." *Dobbs*, 597 U.S. at 301; *see Medtronic*, 518 U.S. at 485

(because of "federalism concerns and the historic primacy of state regulation of matters of health and safety," courts "start with the assumption" that Congress does not intrude on states' "historic police powers" (citation modified)). Any such interpretation should be rejected.

V. The Remaining Equitable Factors Weigh Decisively Against Plaintiffs

Plaintiffs also come up short on the remaining equitable factors. They claim to seek a § 705 "stay," but they plainly ask for a preliminary injunction. *See, e.g.*, Pls. Br. 8.[9] The "limited purpose" of such relief "is merely to preserve the relative positions of the parties until a trial on the merits can be held." *Univ. of Tex. v. Camenisch*, 451 U.S. 390, 395 (1981). Yet Plaintiffs are asking the Court to upend the status quo that has been in place for nearly five years. Plaintiffs do not come close to justifying that extraordinarily disruptive result.

As a threshold matter, even if the harm that Plaintiffs assert could establish standing, they have failed to make the "clear showing" of irreparable harm required for this "extraordinary and drastic remedy." *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997) (citation modified); *see Tate v. Am. Tugs, Inc.*, 634 F.2d 869, 870 (5th Cir. 1981) (irreparable injury is "indispensable prerequisite" to preliminary injunction). Their own litigation conduct confirms it. "[A] party requesting a preliminary injunction must generally show reasonable diligence." *Benisek v. Lamone*, 585 U.S. 155, 159 (2018) (per curiam). But Plaintiffs waited *two years* after the 2023 REMS was approved—and nearly *five years* after FDA first implemented the relevant policy—to bring suit. And they waited two more months before seeking a preliminary injunction.[10] Courts regularly deny relief after delays measured in months, let alone years. *See, e.g.*, *W. Surety Co. v. PASI of LA, Inc.*, 334 F. Supp. 3d 764, 800-801 (M.D. La. 2018) (246 days); *BeatStars, Inc., v. Space Ape Ltd.*, 624 F. Supp. 3d 681, 688-689 (W.D. Tex. 2022) (nine months, and collecting cases); *Atchafalaya Basinkeeper v. U.S. Army Corps of Eng'rs*, No. 18-cv-23, 2019 WL 491312, at *2 (M.D. La. Feb.

[9] Indeed, it makes little sense to "postpone the effective date of an agency action" that has been in effect for more than two years. 5 U.S.C. § 705; *see* FDA Br. 11.

[10] Plaintiffs claim that relief is needed now because FDA has not yet completed its mifepristone review. Pls. Br. 8. But FDA's internal deliberations cannot excuse Plaintiffs' tactical decisions. That review, when completed, will stand or fall based on the merit of its reasoning—not its timing.

7, 2019) (ten months); *AMID, Inc., v. Medic Alert Found. U.S.*, 241 F. Supp. 3d 788 (S.D. Tex. 2017) ("Courts are hesitant to manufacture a sense of urgency that is not supported by plaintiff's own conduct." (quotation omitted)); *Crossover Mkt. LLC v. Newell*, No. 21-cv-640, 2022 WL 1797359 (W.D. Tex. Jan. 12, 2022) (five months). If nothing else, Plaintiffs' delay "militates against the issuance of a preliminary injunction by demonstrating that there is no apparent urgency to the[ir] request." *Symetra Life Ins. Co. v. Rapid Settlements Ltd.*, 612 F. Supp. 2d 759, 774 (S.D. Tex. 2007); *Pastel Cartel, LLC v. FDA*, No. 23-cv-1010, 2023 WL 9503484, at *4 (W.D. Tex. Dec. 14, 2023) (irreparable harm absent where plaintiff waited six weeks after filing "to request a preliminary injunction").

On the other hand, the harm to the public and Danco from a stay or an injunction would be grave and immediate. *See Nken v. Holder*, 556 U.S. 418, 435 (2009) (harm to defendants and public interest "merge" when relief is sought against the government). FDA disagrees with Plaintiffs' assurances about the impact of an injunction or stay of the 2023 REMS; FDA officials told the Supreme Court that such an order would preclude Danco from distributing Mifeprex *unless and until* Danco submits, and FDA approves, a new REMS. Long Decl. ¶¶ 8-14; Gov. Opening Br. 46-47, *Alliance* (U.S. Jan. 23, 2024). That costly and time-consuming process would be made even more complicated by the fact that Danco would, in effect, be asking FDA to add a burden to the health care delivery system, contrary to the statutory directive for FDA to minimize such burdens. As a practical matter, the vacatur or injunction would prevent Danco, a single-product company, from distributing Mifeprex for months, if not longer. Long Decl. ¶¶ 16-17, 20.

These harms would be felt across the country. Many States permit first-trimester abortions and public hospitals, clinics, and patients alike have come to rely on brick-and-mortar and mail-order pharmacy distribution of mifepristone, including for residents in rural areas, or those for whom transportation, child care, or occupational constraints make it more difficult to get to a provider's office for an in-person consultation. Because the FDCA neither envisions nor permits different drug approvals or REMS in different states, Plaintiffs' requested relief would disrupt this care, harm patients, and make it more difficult for doctors to provide care nationwide—at the

request of a single state and single individual.

For many patients outside Louisiana, mifepristone is the best method to lawfully terminate a pregnancy. They may choose mifepristone over surgical abortion for reasons such as medical necessity or past trauma. A stay of the 2023 REMS would—at the very best—significantly limit those patients' ability to obtain mifepristone. Such a deprivation of "necessary medical care" imposes irreparable harm. *Jones v. Texas Dep't of Crim. Just.*, 880 F.3d 756, 759-760 (5th Cir. 2018) (per curiam). And even if FDA could quickly make the required changes, the more restrictive conditions of use that Plaintiffs seek would unnecessarily impair current access to mifepristone for many women. *See* Long Decl. ¶ 17 (noting the reduced "options for in-person clinic appointments given the increase in telemedicine" in recent years).

Presented with these same harms, the Supreme Court in *Alliance* stayed an analogous order disrupting mifepristone distribution. 143 S. Ct. 1075. That order necessarily reflects the Court's judgment that the equities weighed in favor of the Federal Defendants and Danco. *See Nken*, 556 U.S. at 434. Plaintiffs blithely assert that there is no legitimate public interest in enforcing a REMS if the Court finds it unlawful. Pls. Br. 14. But that collapses the different preliminary injunction factors. *See, e.g.*, *Benisek*, 585 U.S. at 158 ("[A] preliminary injunction does not follow as a matter of course from … a likelihood of success on the merits."). Plaintiffs' request should be denied.

CONCLUSION

For these reasons, the Court should dismiss the complaint and deny Plaintiffs' motion for preliminary relief.

Dated: February 3, 2026

Respectfully submitted,

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