UNITED STATES DISTRICT COURT
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

PLAINTIFFS' BRIEF IN OPPOSITION TO DANCO'S AND GENBIOPRO'S MOTIONS TO DISMISS

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INTRODUCTION

Danco and GenBioPro ask this Court to dismiss Plaintiffs' lawsuit even though FDA does not defend the merits of the 2023 REMS and has not sought to dismiss this case.[1] Dismissal is improper because Plaintiffs have alleged concrete sovereign and economic injuries traceable to the 2023 REMS. Louisiana specifically alleges *ongoing* violations of its pro-life laws, tens of thousands of dollars in *unrecoverable* Medicaid expenditures, and the *daily* nullification of its sovereign enforcement authority. And that's in addition to the expenses Louisiana has incurred attempting to mitigate the harm.

These are classic Article III injuries. And because the harms are easily traceable to FDA's elimination of the in-person dispensing requirement—and would be mitigated by vacatur of the 2023 REMS—Plaintiffs satisfy causation and redressability. The manufacturers' motions to dismiss should be denied.

SUMMARY OF FACTS

FDA long required in-person dispensing of mifepristone. But as pro-life states started to enact limitations on abortion in the late 2010s, abortion activists began "to push harder to make abortion pills available by telemedicine and mail." ECF 111-2 at 93. And "[t]he declaration of a pandemic in March 2020 created new opportunities to make this vision a reality." *Id.* Indeed, abortion activists "used the pandemic as an opportunity to promote telemedicine abortion." *Id.* at 96.

But FDA opposed such opportunistic attempts all the way to the U.S. Supreme Court. FDA affirmed that in-person dispensing was both "minimally burdensome" and "necessary" to preserve

[1] Formally lodged on the Court's docket after the February 24 hearing on Plaintiffs' Motion for Preliminary Relief, Danco and GenBioPro's motions to dismiss are based on the same memoranda filed in opposition to Plaintiffs' motion for preliminary relief. Accordingly, this response largely mirrors Plaintiffs' Reply Memorandum in Support of their Motion for Preliminary Relief (ECF 111). GenBioPro did not move to dismiss Plaintiffs' Count One on the merits. ECF 232. Although it is less clear, it appears that Danco did not either. ECF 230-1 at 17–20. And any argument that dismissal is appropriate would be baseless. Plaintiffs briefed this issue extensively in their filings supporting their Motion for Preliminary Relief and Opposition to Defendants' Motion to Stay. ECF 20-26 at 9; ECF 111 at 15.

the safety of women who take abortion drugs. ECF 1 ¶ 50. The Supreme Court ruled for FDA and restored in-person dispensing in January 2021. *FDA v. Am. Coll. of Obstetricians & Gynecologists*, 141 S. Ct. 578 (2021) (mem.).[2] But everything changed later that month when Joe Biden assumed the U.S. presidency.

In March 2021, the ACLU wrote a letter to President Biden requesting him to direct FDA to review the REMS and "eliminate" these "barriers" to "accessing" abortion particularly in "state[s with] abortion restrictions." Ex. 1, ACLU, *Reproductive Health, Rights, and Justice Groups Letter to Biden Administration on Mifepristone* (March 16, 2021) perma.cc/VP9K-ETUN. Activists even arranged "high-net-worth major donors" to personally meet with President Biden and lobby for him to remove the in-person dispensing requirement. ECF 111-2 at 115. President Biden and his FDA obliged one month later, temporarily suspending the in-person dispensing requirement and expressly authorizing "dispensing of mifepristone through the mail ... or through a mail-order pharmacy." ECF 1 ¶ 51.

After the Supreme Court declined to block a Texas pro-life law in September 2021, President Biden directed HHS and DOJ to "use every lever" available to ensure access to abortion across the country. *Id.* ¶ 55. Two weeks after oral argument in *Dobbs*, when it became apparent that *Roe* was doomed, FDA announced it would permanently allow mail-order abortion. *Id.* ¶ 56. Once *Roe* fell, President Biden promised to do everything in his power to expand access to abortion. *Id.* ¶ 57. He followed through, issuing multiple executive orders mandating access to abortion drugs, including

[2] Danco cites the *ACOG* litigation to highlight how Louisiana (and other states) were denied intervention in that case. ECF 230-1 at 3. But that fact reveals just how diligently Louisiana has opposed mail-order abortion since the first attempts to impose it. And because the district court (incorrectly) concluded that removing the in-person dispensing requirement "would not impair those States' ability to enforce their own laws regulating mifepristone," *Am. Coll. of Obstetricians & Gynecologists v. FDA*, 467 F. Supp. 3d 282, 286 (D. Md. 2020), Louisiana reasonably sought to collect sufficient evidence of its sovereign injuries before bringing this lawsuit. A significant moment came in the summer of 2025, when the Society of Family Planning's #WeCount released state-level abortion data through December 2024. ECF 1 ¶ 5. The updated #WeCount data definitively showed the extent and escalation of Louisiana's injuries from illegally shipped FDA-approved mifepristone under the 2023 REMS. In light of that data, Louisiana engaged in political negotiations and, thereafter, the filing of an intervention motion in Texas followed by this lawsuit.

through the mail. *Id.* ¶¶ 58–61. This culminated in the 2023 REMS, which paved the way for abortion drugs to be mailed into every state, including Louisiana.

The 2023 REMS has been devastatingly effective in allowing access to mifepristone "to the fullest extent possible" regardless of where women live. ECF 1-43 at 6. Despite outlawing nearly all abortions, Louisiana loses nearly 1,000 babies to mail-order abortions every month. ECF 20-26 at 5. And mifepristone doesn't spare women either—its risks are serious: heavy bleeding, cramping, ER visits, surgery rates up to 7%, and a black-box warning for potentially fatal infections. ECF 1 ¶¶ 6, 35. Remote prescribing exacerbates these risks because providers cannot confirm gestational age or detect ectopic pregnancies. *Id.* ¶¶ 36–37. Real-world data show serious complications at least 22 times higher than the label reflects, with nearly 11% of women experiencing sepsis, hemorrhaging, or other major complications. *Id.* ¶ 38. Even FDA admits that it failed to adequately consider the safety risks, and acknowledges "the concerns about removing the in-person dispensing" highlighted by the Fifth Circuit. *Id.* ¶¶ 13, 50; ECF 51 at 1.

The 2023 REMS has caused Louisiana concrete economic harm. Louisiana has spent more than $92,000 in Medicaid funds on emergency care and hospitalization arising from just two unlawful mail-order abortions. ECF 20-26 at 6. Louisiana has also expended significant resources trying to stop the illegal mailing of mifepristone into the State. Across three investigations alone, Louisiana has spent at least $17,604.40, and it continues to incur daily costs to bring criminal prescribers to justice and deter further violations. ECF 111 at 4. These pocketbook injuries satisfy Article III standing.

Louisiana has also suffered sovereign harm by its inability to enforce its pro-life laws. Because the 2023 REMS green-lights illegal mail-order abortions in Louisiana, pro-abortion states like New York and California have seized on this opportunity to make the onslaught of abortions almost impossible to prevent. These States and others have enacted laws specifically designed to evade Louisiana's pro-life laws. ECF 1-90; 20-5. For example, these laws permit prescribers to omit identifying information from pill bottles, allowing abortion drugs to enter Louisiana with no indication of the sender. ECF 20-5.

The 2023 REMS intentionally and effectively breaks the promise of *Dobbs* to return the issue of abortion to the people and their elected representatives. And despite Louisiana law outlawing abortion in most instances, Louisiana's abortion numbers are rising. Because Louisiana's sovereign and pocketbook harms provide it standing to pursue this case, the manufacturers' motions to dismiss should be denied.

ARGUMENT

I. Plaintiffs Have Standing.

To establish standing, "a plaintiff must demonstrate (i) that she has suffered or likely will suffer an injury in fact, (ii) that the injury likely was caused or will be caused by the defendant, and (iii) that the injury likely would be redressed by the requested judicial relief." *FDA v. All. for Hippocratic Med. (Alliance)*, 602 U.S. 367, 380 (2024). At the pleading stage, a plaintiff need only allege facts that, taken as true, plausibly establish injury in fact, traceability, and redressability. When a defendant raises a facial Rule 12(b)(1) challenge, the Court accepts those well-pleaded allegations as true.[3] *See Cranor v. 5 Star Nutrition, L.L.C.*, 998 F.3d 686, 689–90 (5th Cir. 2021); *Data Mktg. P'ship, LP v. U.S. Dep't of Labor*, 45 F.4th 846, 851 (5th Cir. 2022).

Louisiana has suffered pocketbook and sovereign harms from the 2023 REMS—harms that tragically led to bodily harm to Plaintiff Rosalie and her unborn child. Those injuries are traceable to FDA's removal of the in-person dispensing requirement. And those injuries are redressable by a decision vacating the 2023 REMS.[4]

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[3] Neither Danco nor GenBioPro contest the factual allegations, and it's therefore presumed that their motions are facial challenges.

[4] Danco contends that, even if Plaintiffs "could establish standing, they have failed to make the 'clear showing' of irreparable harm required" for preliminary relief because they sued two years after the 2023 REMS was approved. ECF 230-1 at 23. But that argument fails. By definition, the injuries that Louisiana has established are inherently irreparable and ongoing. Louisiana's sovereign interest in protecting unborn children from harm is an undeniably irreparable injury. *Abbott v. Perez*, 585 U.S. 579, 602 n.17 (2018). And unrecoverable economic losses are also irreparable injuries. *All. for Hippocratic Med. v. FDA (Alliance II)*, 78 F.4th 210, 248 (5th Cir. 2023) (citing *Wages & White Lion Invs., L.L.C. v. FDA*, 16 F.4th 1130, 1142 (5th Cir. 2021)).

A. Louisiana Has Suffered Injuries in Fact.

1. Louisiana suffers classic pocketbook injuries.

"Pocketbook harm is a traditional Article III injury." *Bost v. Illinois State Bd. of Elections*, 146 S. Ct. 513, 524 (2026*)* (Barrett, J., concurring) (citation omitted). After all, "an economic injury is the quintessential injury upon which to base standing." *Young Conservatives of Tex. Found. v. Smatresk*, 73 F.4th 304, 309 (5th Cir. 2023) (citation modified). Indeed, "[f]or standing purposes, a loss of even a small amount of money is ordinarily an 'injury.'" *Czyzewski v. Jevic Holding Corp.*, 580 U.S. 451, 464 (2017); *United States v. Texas*, 599 U.S. 670, 687–88 (2023) (Gorsuch, J., concurring). These well-recognized economic injuries can often take the form of the "effect on the states' fiscs." *Texas v. United States (DAPA)*, 809 F.3d 134, 152 (5th Cir. 2015); *see also, e.g.*, *Biden v. Nebraska*, 600 U.S. 477, 490 (2023) (Missouri's "financial harm is an injury in fact"). Here, Louisiana has suffered two types of classic pocketbook injuries, either or both of which assure the Court's jurisdiction: (a) economic harms incurred while enforcing Louisiana law against violations caused by the 2023 REMS; and (b) the expenditure of Medicaid dollars to treat adverse events caused by the 2023 REMS.

a. Consider the first type. Pocketbook harm occurs when a plaintiff "reasonably incur[s] costs to mitigate or avoid" the "substantial risk" of a harm caused by government action. *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 414, n. 5 (2013) (collecting cases). In *Monsanto Co. v. Geertson Seed Farms*, 561 U. S. 139, 153–154 (2010), for example, the question was whether alfalfa farmers could seek judicial relief against agency action permitting the planting of genetically modified alfalfa. The farmers "established a reasonable probability that their organic and conventional alfalfa crops [would] be infected with [an] engineered gene" through cross-contamination. *Id.* at 153 (citation modified). And because the farmers took costly preventative measures to "minimize the likelihood of potential contamination," they suffered an Article III injury. *Id.* at 154.

Justices Barrett and Kagan recently reprised that reasoning to confirm a congressman's standing to challenge a state election law: "Like the farmers in *Monsanto*," they said, the congressman "will 'reasonably incur costs to mitigate or avoid' the 'substantial risk' of harm caused by the challenged statute." *Bost*, 146 S. Ct. at 524 (Barrett, J., concurring) (quoting *Clapper*, 568 U.S. at 414 n.5). They

noted that the congressman's campaign "has spent, and will spend, money, time, and resources" to avoid alleged harms from the challenged law. *Id.* Because those "expenditures mitigate a substantial risk of harm, [the congressman] has pleaded Article III injury." *Id.*

So too here. Like the alfalfa farmers and the congressman, Louisiana has expended substantial money, time, and resources attempting to mitigate the avowedly intended harm caused by the 2023 REMS. Louisiana has indicted two out-of-state prescribers who violated Louisiana law by sending FDA-approved mifepristone into the State. Louisiana has also issued warrants for their arrest. And Governor Landry has completed the necessary paperwork and formally asked the governors of California and New York to extradite these fugitive prescribers. When Louisiana asked Governor Newsom to extradite the California doctor who unlawfully shipped the FDA-approved drugs used to kill Rosalie's child, Governor Newsom provided an unequivocal answer:

[5]

To quantify the costs: In just *three* distinct investigations into the unlawful mailing of mifepristone into Louisiana, the State has spent at least $17,604.40. ECF 111-1 ¶ 4–6. *Cf. Texas*, 599

[5] Governor Gavin Newsom (@GavinNewsom), X (Feb. 5, 2026, 8:43 PM), perma.cc/46CV-HMZ9; Governor Hochul also refused extradition. ECF 1 ¶¶ 100–02.

U.S. at 687–88 (Gorsuch, J., concurring) (discussing States' standing to "challenge [] Executive Branch policies that indirectly caused them monetary harms" where "the States have spent, and continue to spend, more money on law enforcement, incarceration, and social services"). These undisputed expenditures to mitigate harm "plead[] an Article III injury." *Bost*, 146 S. Ct. at 524 (Barrett, J., concurring) (quoting *Clapper*, 568 U.S. at 414 n.5).

b. If that were not enough, Louisiana's Medicaid pocketbook harms would be. Federal law allocates significant financial costs to state Medicaid programs when Medicaid-covered women suffer complications from mifepristone. The manufacturers do not dispute these economic harms.

Louisiana has already spent over $90,000 for emergency room care and hospitalizations directly traceable to just *two* FDA-approved mifepristone-induced abortions. ECF 20-26 at 6, 23. And the total amount spent is likely much higher, considering that high numbers of abortions are occurring and that prescribers are counseling women to conceal that they took mifepristone. There is at least a "substantial risk" these costs will continue to occur. *Clapper*, 568 U.S. at 414 n.5.

These continued costs are obvious given mifepristone's documented complication rate. When FDA removed the in-person dispensing requirement, the agency anticipated that the roughly 1 in 25 women who go to the emergency room after taking mifepristone as directed (per the prior label) would increase. ECF 1-10 at 35. There is at least a "reasonable probability" and "substantial risk" that Medicaid-covered women will seek care, especially in Louisiana where half a million women are on Medicaid. *See Monsanto*, 561 U.S. at 153–54; ECF 20-26 at 23. At day's end, there is at least a "substantial risk" that Louisiana will continue to pay Medicaid costs, an indisputable economic harm.

2. Louisiana suffers classic sovereign harms.

On top of its pocketbook harm, Louisiana has established injury to its sovereign interests in enforcing its pro-life laws. *See Texas v. United States*, 787 F.3d 733, 752 n.38 (5th Cir. 2015); *cf. Abbott v. Perez*, 585 U.S. 579, 602 n.17 (2018) ("[T]he inability to enforce its duly enacted plans clearly inflicts irreparable harm on the State[.]"). States have standing to vindicate their sovereign interests. *Alfred L. Snapp & Son, Inc. v. Puerto Rico, ex rel., Barez*, 458 U.S. 592, 601–02 (1982). They also have standing based on "federal interference with the enforcement of state law." *DAPA*, 809 F.3d at 153. Those

basic rules carry the day here: "Because the principles of federalism afford the states a sovereign interest in creating and enforcing their own laws and public policy," Louisiana "clearly ha[s] Article III standing to challenge" the 2023 REMS. *Louisiana v. EEOC*, 705 F. Supp. 3d 643, 654 (W.D. La. 2024).

Louisiana's argument on this point is very simple: (a) it is undisputed that Louisiana law bars the dispensing of mifepristone within Louisiana to cause an unlawful abortion; (b) it is undisputed that some 1,000 such abortions are occurring every month in violation of Louisiana law; and (c) it is undisputed that it is nearly impossible for Louisiana to prosecute those violations. Those undisputed—and unremedied—violations of Louisiana law are quintessential sovereign harms. And while the manufacturers quibble with *who* bears responsibility for violating state law, that is a *causation* question rather than a question about whether Louisiana is suffering sovereign injuries.

The closest Danco comes to disputing Louisiana's sovereign injuries is to say that the 2023 REMS does nothing to render "Louisiana's abortion laws unenforceable." ECF 230-1 at 6. But that, too, goes to whether the 2023 REMS is legally at fault versus whether Louisiana actually is suffering sovereign harms. And on that latter point, it is telling that the manufacturers could not identify a single instance in which Louisiana has been able to enforce its criminal code to stop the onslaught of illegal abortions. The manufacturers' arguments rest on a false premise: that so long as a State can find some other way to stop a violation of its laws, the State lacks Article III standing to sue the federal government for causing the violation in the first place. That is emphatically wrong. Just as "federal interference with the *enforcement* of state law" is a sound basis for Article III standing, *DAPA*, 809 F.3d at 153 (emphasis added), so too is the federal government's "encourage[ment]" that "doctors [] *violate* [Louisiana's] abortion laws," *Texas v. Becerra*, 623 F. Supp. 3d 696, 714 (N.D. Tex. 2022) (emphasis added). Or, to put in this Court's words, a State plainly may defend its "sovereign interest in creating ... [its] own laws and public policy" against the federal government's interference. *Louisiana*, 705 F. Supp. 3d at 654. FDA's action "interferes with adherence to—and, therefore, enforcement of—[Louisiana's] laws." *Texas*, 623 F. Supp. 3d at 714.

The 2023 REMS has also inflicted sovereign and quasi-sovereign harms on Louisiana by overriding the State's interest in respecting and preserving prenatal life at all stages of development. ECF 1 ¶¶ 129–30. And by facilitating the deaths of thousands of unborn Louisiana children each year, the 2023 REMS directly infringes Louisiana's sovereign prerogatives, thereby causing direct and irreparable harm. *See, e.g.*, *Kansas v. United States*, 249 F.3d 1213, 1227 (10th Cir. 2001) (recognizing irreparable harm where a federal agency action "places [a State's] sovereign interests and public policies at stake"). This theory is not one of *parens patriae*, because Louisiana is not asserting the rights of its citizens. *Cf. Murthy v. Missouri*, 603 U.S. 43, 76 (2024). Instead, Louisiana invokes its own sovereign authority to protect its citizens—a sovereign interest directly harmed by the 2023 REMS.

This assault on state sovereignty constitutes a concrete injury.

B. Louisiana's Harms Are Traceable to the 2023 REMS.

Given the concrete sovereign and economic harms Louisiana is suffering, the only real Article III issue is traceability. That is a straightforward issue best answered as a practical matter and as a historical matter—and the other side has no answer.

1. Practicality first. The best way to determine whether Louisiana's harms are traceable to the 2023 REMS is to ask whether those harms would be mitigated or eliminated if the 2023 REMS were vacated. *Cf. Alliance*, 602 U.S. at 380 ("The second and third standing requirements—causation and redressability—are often 'flip sides of the same coin.'" (citation omitted)). The answer is yes. On this score, common sense leads the way: Why do FDA's *amici* care so much about retaining the 2023 REMS? Because the in-person dispensing requirement (or absence thereof) dictates whether some 1,000 abortions a month may continue in Louisiana. And that pattern repeats throughout the country. In States where abortion is legal, mail-order abortion constitutes a minority of total abortions. ECF 20-1 at 8. For instance, mail-order abortions account for just 10% of all abortions in New York and 11% in California. *Id.* By contrast, in States that have banned abortion, mail-order abortion accounts for virtually all abortions. *Id.* at 10. Among the twelve States with abortion bans, mail-order abortions

account for 100% of all abortions in nine of those States, and the lowest percentage among them is 96%. *Id.*[6]

This reality defeats the manufacturers' attempts to shift the blame elsewhere. They claim that third-party providers and the anonymous people who order the drugs online (rather than the 2023 REMS) are responsible for the violations of Louisiana's law. And they emphasize that "shield" laws are to blame for Louisiana's difficulty in enforcing its pro-life laws. But that is not how causation works: Article III does not require that an action be the sole cause of harm. ECF 20-26 at 20–22. Quite the reverse. "Article III requires no more than *de facto* causality." *Dep't of Com. v. New York*, 588 U.S. 752, 768 (2019) (citation omitted). Otherwise, the farmers in *Monsanto* could never have sued. *Department of Commerce* makes clear that the predictable actions of third parties do not defeat standing. *Id.*

Here, there is no question that Louisiana's injuries are traceable to the 2023 REMS. The third-party providers—*certified* by the very manufacturers making this argument—could not legally mail mifepristone into Louisiana without the 2023 REMS' removal of the in-person dispensing requirement. Likewise, "shield" laws would be meaningless without the 2023 REMS because providers in "shield" law States could not mail mifepristone without risking their prescriber certifications.

To buttress its claim that shield laws are to blame, Danco says that the #WeCount data (cited at ECF 20-26 at 1) show that the rise of mail-order abortions in Louisiana in 2023 "coincided with shield laws being enacted by other States, not with *Dobbs* and not with the 2023 REMS." Hearing Tr. at 41:10–25, Feb. 24, 2026. That's just wrong. New York enacted its shield law on June 13, 2022 (after

[6] Danco claims that it would "face significant economic losses" if the 2023 REMS were vacated, ECF 52-1 at 8, and GenBioPro says its "business model relies directly on the 2023 REMS," ECF 54-1 at 8. But companies cannot claim lost profits or justifiable reliance when those profits largely stem from violating state law and from an agency action the Fifth Circuit has twice found likely unlawful within months of its issuance.

the *Dobbs* decision was leaked) and five other States and D.C. had shield laws *before* the 2023 REMS.[7] An additional nine States' shield laws became effective between April and June 2023.[8]

So what explains the rise in mail-order abortions in July of 2023? That's when the Society of Family Planning "*began to count* abortions provided under shield laws." ECF 20-1 at 19 (emphasis added). Indeed, the proliferation of state shield laws *pre-dated* the 2023 REMS, baking those laws into the regulatory background against which the agency made its decision to remove in-person dispensing.

In short, the 2023 REMS is the indispensable ingredient in the 1,000 abortions occurring in Louisiana every month. For the practical reasons explained above, Louisiana easily satisfies the Article III causation standard.

2. History confirms as much because, if anything is clear from the record, it is that these injuries to pro-life States like Louisiana were not just the "predictable effect" of the 2023 REMS, *Dep't of Com.*, 588 U.S. at 768—they were the "whole point," *Tex. Corn Producers v. EPA*, 141 F.4th 687, 700 (5th Cir. 2025) (emphasis omitted).

a. This story begins at least as far back as 1994, when the former Director of FDA's Office of Women's Health stated that mifepristone "was going to be very important especially in states where surgical abortions are not permitted. And if [the Court] overturn[s] *Roe v. Wade*, it's going to be really important." ECF 1 ¶ 54.[9] As abortion activists grew increasingly worried about *Roe*'s future in the 2010s, they began "to push harder to make abortion pills available by telemedicine and mail." ECF 111-2 at 93. In March 2021, the ACLU wrote a letter to President Biden demanding that he direct

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[7] N.Y. Crim. Proc. Law § 570.17; 11 Del. Code § 2506; Conn. Gen. Stat. § 54-162; N.J. Stat. § 2A:160-14.1; Mass. Gen. Laws ch. 276, § 13; Cal. Penal Code § 819; D.C. Code § 2-1461.01.

[8] Colo. Rev. Stat. §§ 16-19-107(2); Minn. Stat. §§ 629.02; Wash. Rev. Code § 7.115.020(2); Vt. Stat. tit. 12, § 7306; Nev. Rev. Stat. § 179.540; Md. Code Crim. Proc. § 9-106; N.M. Stat. § 31-4-6; Or. Rev. Stat. § 24.500(3); R.I. Gen. Laws § 12-9-36.

[9] The end goal of abortion drugs was universally known. *See, e.g.*, *Evangelium Vitae*, Pope John Paul II (March 25, 1995), at perma.cc/XK4E-HDK7 ("In order to facilitate the spread of abortion, enormous sums of money have been invested and continue to be invested in the production of pharmaceutical products which make it possible to kill the fetus in the mother's womb without recourse to medical assistance. . . . and which at the same time are capable of removing abortion from any kind of control. . . .").

FDA to review the REMS and "eliminate" these "barriers" to "accessing" abortion, particularly in "state[s with] abortion restrictions." Ex. 1, ACLU, *Reproductive Health, Rights, and Justice Groups Letter to Biden Administration on Mifepristone* (March 16, 2021) at PDF 3. Activists even arranged for "high-net-worth major donors" to personally meet with President Biden and lobby for him to remove the in-person dispensing requirement. President Biden obliged one month later.

And by May 2022, abortion activists knew *Roe* would fall and thus argued that mifepristone would be necessary to ensure people could obtain abortions even where restricted.[10] President Biden was listening, and on the day the Supreme Court issued *Dobbs*, he explicitly directed the Secretary of HHS to ensure access to "medication abortion" and identify all ways to make mifepristone as widely accessible as possible, including by "mail." ECF 1 ¶ 59. And he later 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." *Id.* ¶ 57. This culminated in the 2023 REMS. *Id.* ¶ 62. Evidence that undermining *Dobbs* was the avowed purpose for the 2023 REMS does not get much stronger.

b. This history brings this case squarely in line with precedents like *Texas Corn Producers* and *Diamond Alt. Energy, LLC v. EPA*, 606 U.S. 100 (2025)—precedents that say "the object" of a regulation obviously has standing to challenge it. In the face of these cases, the manufacturers suggest that Louisiana is not "the object" of the 2023 REMS. ECF 230-1 at 19; 231 at 9. But that is wrong on the law and the facts.

The Supreme Court recently explained that an entity can be "the object" of a regulatory regime even if other parties are "the directly regulated parties." *Diamond*, 606 U.S. at 115. That's because officials often "seek to indirectly target" people "through a conduit." *Id.* at 116. Whether an entity "is in fact an object of a regulation is a flexible inquiry rooted in common sense." *Contender Farms, L.L.P. v. U.S. Dep't of Agric.*, 779 F.3d 258, 265 (5th Cir. 2015). So private schools can be the object of a law barring parents from sending children to private schools, and sugar producers can be the target of FDA actions making it "harder for soda manufacturers to use sugar." *Energy Future Coal. v. EPA*, 793

[10] Abigail Abrams and Jamie Ducharm, *Inside the Effort to Promote Abortion Pills For a Post-Roe America*, Time (May 31, 2022) perma.cc/H6SD-BMGD.

F.3d 141, 144 (D.C. Cir. 2015) (Kavanaugh, J.); *Diamond*, 606 U.S. at 115. What matters is who the government "targets." *Diamond*, 606 U.S. at 115–16 (citing *Energy Future Coal.*, 793 F.3d at 144–145). If the government seeks to "impede" an entity by regulating intermediaries, the targeted entity is one of the "objects of the government action." *Id.* at 115.

In *Diamond*, for example, the Supreme Court said that fuel producers "might be considered an object" of California restrictions on automakers' use of gasoline in cars. *Id.* at 114–15. The "entire purpose of California's fleet-wide emissions standards and electric-vehicle mandate" was to reduce gas-powered cars. *Id.* at 112. Even though the fuel producers were not directly regulated, they were "the targets of government regulations" and had standing to challenge California's "regulations that threaten" their interests. *Id.* at 120.

The Supreme Court reaffirmed this principle just days ago. In *Mirabelli v. Bonta*, the district court permanently enjoined California's policies that "prevent schools from telling [parents] about their children's efforts to engage in gender transitioning at school unless the children consent to parental notification." No. 25A810, 2026 WL 575049, at *1 (Mar. 2, 2026) (per curiam). After the Ninth Circuit stayed that injunction, the Supreme Court vacated the stay and held that the parents had standing as "objects" of the challenged policies—even though they were not directly regulated and suffered no economic injury. *Id.* at *3. Standing existed because the State's policies excluded them from critical decisions regarding their children and thus prevented them from exercising parental authority.

So too here. FDA "target[ed]" pro-life states—through the "conduit" of abortion-drug prescribers—seeking to "impede[]" state pro-life laws. *Diamond*, 606 U.S. at 115–116. "Indeed, that is the whole point of the regulations." *Id.* at 114. Because the 2023 REMS likewise effectively prevents Louisiana from exercising its sovereign authority to enforce its pro-life laws, Louisiana too is an "object" of FDA's action.

Danco and GenBioPro argue that *Diamond* doesn't apply here because Louisiana isn't in the "link" or "chain." ECF 231 at 9; ECF 230-1 at 19. Nonsense. Louisiana is in the chain just as much as the fuel producers in *Diamond* and the parents in *Mirabelli*. Indeed, *Mirabelli* confirms that

object-status extends beyond entities in the same commercial "supply chain," *contra* ECF 231 at 9, to those whose rights or duties are impaired by government action, *see Alliance*, 602 U.S. at 385 ("[T]o establish causation, the plaintiff must show a predictable chain *of events* leading from the government action to the asserted injury[.]" (emphasis added)). Though not a "directly regulated part[y]," *Diamond*, 606 U.S. at 115, Louisiana was the intended target of FDA's regulatory regime. ECF 20-26 at 23–26. The "whole point" was to keep mifepristone flowing, particularly in pro-life states. *Tex. Corn Producers*, 141 F.4th at 700 (emphasis omitted). So Louisiana has established both injury-in-fact and traceability.

3. Because Louisiana's standing is plain, the opposing parties offer a litany of distractions—none availing.

First, GenBioPro tries to rewrite history altogether. It claims, for example, that the story above is "pure fiction," ECF 232-4 at 9, and it revises the historical record to claim that the 2023 REMS was just an innocuous extension of the pandemic-era 2021 enforcement decision suspending the in-person dispensing requirement. *See* ECF 1 ¶ 51. This lawsuit, of course, does not challenge that temporary suspension, which no longer exists. But, more importantly, the Fifth Circuit already has determined that "FDA simply did not tether its [2023] action" in permanently removing the in-person dispensing requirement "to the continued existence of the public health emergency" that prompted the 2021 decision. *All. for Hippocratic Med. v. FDA (Alliance II)*, 78 F.4th 210, 248 (5th Cir. 2023).

GenBioPro also tries to cover the Court's eyes to the fact that President Biden openly directed this assault into pro-life States. These were all just statements from "public officials," GenBioPro says—and besides, President Biden is not even an FDA official. ECF 232-4 at 17. With all due respect, the idea that the Court should disregard the President's avowed purpose to abridge pro-life States' laws is unserious. *See Dep't of Com.*, 588 U.S. at 782–84.

Second, the manufacturers run through a number of precedents—none of which helps them. For example, Danco and GenBioPro assert that *United States v. Texas* precludes any state standing based on indirect effects of federal agency actions. 599 U.S. 670 (2023). But that "extraordinarily unusual lawsuit" involved Texas's challenge to federal prosecutorial discretion—a core executive power. *Id.* at 686. It addressed "only the narrow Article III standing question of whether the Federal

Judiciary may in effect order the Executive Branch to take enforcement actions against violators of federal law," *id.* at 684–85—a question that is worlds away from the issues presented here. *See id.* at 686 ("The Court's standing decision today is narrow and simply maintains the longstanding jurisprudential status quo."). But, more fundamentally, insofar as *Texas* gestured at "federal policies [that] frequently generate indirect effects on state revenues or state spending," *id.* at 680 n.3, the 2023 REMS is nothing of the sort. By design, the 2023 REMS was intended to authorize a *direct* attack on pro-life States, and that attack, in turn, has caused sovereign and economic harms. There is nothing "indirect" about it.

The manufacturers also rely on the Ninth Circuit's nonbinding decision on Idaho's motion to intervene in *Washington v. FDA*, 108 F.4th 1163 (9th Cir. 2024). *Washington* deemed "highly speculative" a State's Medicaid costs incurred under the 2023 REMS, and it dismissed as based "heavily on speculation" the State's argument that the 2023 REMS would make it more difficult to enforce Idaho's pro-life laws. *Id.* at 1174, 1177. *Washington* is self-distinguishing because Louisiana need not speculate: It has the Medicaid receipts to prove that the 2023 REMS has caused tens of thousands of dollars in unrecoverable financial harm. And subsequent to *Washington*, pro-abortion groups published rounds of data most recently showing that, although Louisiana has significantly restricted abortion, there are nearly 1,000 abortions occurring in the State every month—all through FDA-facilitated mail-order abortions. ECF 20-26 at 5. The *Washington* court had none of this evidence and did not purport to issue a decision on facts like these. It is also why Louisiana took the time necessary to build the evidentiary record of its irreparable injuries.

Finally, the manufacturers unpersuasively try to shoehorn Louisiana into the *Alliance* decision where the Supreme Court found that plaintiff doctors did not have standing. The doctors' problem there was that they did not show "they could be forced to participate in an abortion or provide abortion-related medical treatment over their conscience objections." *Alliance*, 602 U.S. at 387. Here, by contrast, the State has demonstrated not only that it "could be" forced to pay for the medical costs attributable to FDA-approved mifepristone but also that it has been so forced—to the tune of tens of thousands of dollars. That is precisely the direct line of causation that the *Alliance* Court said was

lacking. And that is in addition to the sovereign harms that flow from the 2023 REMS permitting doctors to mail mifepristone in violation of Louisiana law.

C. Plaintiffs' Injuries Are Redressable.

The redressability inquiry is open-and-shut—and indeed, no one contests this point: A judicial decision staying the 2023 REMS would leave prescribers no choice but to only dispense mifepristone in-person. Put otherwise, prescribers could not continue mailing mifepristone into Louisiana. Just listen to the ACLU: "If the court grants Louisiana's motion, [requesters] will no longer be able to fill their mifepristone prescription by mail[.]"[11] That is the very definition of redressability.[12]

Without that flood of mifepristone, 1,000 illegal abortions each month in Louisiana cannot occur. And without these 1,000 illegal abortions (and attendant emergency costs), Louisiana's sovereignty and fisc are restored. Now, to be sure, that restoration may not be complete if some prescribers opt to violate the (newly reinstated) federal in-person dispensing requirement. GenBioPro appears to make this argument. But in so doing, GenBioPro suggests it will not follow the law, for it has an affirmative duty to audit prescribers to ensure REMS are followed. ECF 20-16 at 4; 21 U.S.C. § 355-1. And prescribers ignore the in-person dispensing requirement at their own peril, jeopardizing their certification and even medical licenses. In any event, redressability requires only a substantial likelihood that the injury will be partially redressed. *See Larson v. Valente*, 456 U.S. 228, 243 n.15 (1982). That is undoubtedly the case here. Plaintiffs satisfy all three elements of Article III standing.

D. Rosalie Has Standing.

Rosalie has standing because FDA turned a blind eye to women like her. Rosalie did not want an abortion. ECF 1 ¶ 153. Had FDA retained its in-person dispensing requirement, her boyfriend would not have been able to order the drugs and coerce her to take them. *Id.* ¶ 156. Now, she faces

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[11] Press Release, *Louisiana Lawsuit Seeks Immediate Nationwide Restrictions on Medication Abortion*, ACLU (Dec. 17, 2025), perma.cc/MB39-DSAV.

[12] *See, e.g.*, Carrie Baker, *Mifepristone Manufacturers Move to Block GOP Lawsuit Seeking Nationwide Telehealth Abortion Ban*, Ms. Magazine, perma.cc/5P43-CBEJ ("Telehealth abortion from out of states is a critical avenue of access for women living in states that restrict abortion providers located inside the states from providing abortion services.")

prolonged emotional trauma and mourns the loss of her child. *Id.* She endured physical pain and heavy bleeding. *Id.* ¶ 154. And she continues to suffer mental-health effects from the trauma she experienced. *Id.* She is also at risk for future injury if she is placed in the same position for future pregnancies. *Id.* ¶ 155. Her bodily injury, pain and suffering, mental anguish are cognizable injuries, *Rideau v. Keller Indep. Sch. Dist.*, 819 F.3d 155, 163 (5th Cir. 2016)—as is her lost child.

Those injuries are traceable to—and would be redressed by staying—the 2023 REMS. If FDA had required an in-person visit, Rosalie's boyfriend would not have been able to access the abortion drugs and compel Rosalie to take them. ECF 1 ¶ 156. And if he tried to obtain the drugs from an abortion facility, a medical professional would have screened Rosalie for coercion and abuse. Should this Court grant Rosalie's requested relief, she will not be subject to the same coercion and bodily injury in the future. And a favorable ruling "would mitigate the ongoing pain and suffering that she experiences as she attempts to heal." ECF 1 ¶ 158.

E. Plaintiffs Fall Within the Relevant Zones of Interest.

Among other efforts to get around Plaintiffs' standing, the manufacturers argue Plaintiffs are not within the zone of interests of the FDCA and the Comstock Act. ECF 230-1 at 13–15; ECF 231 at 12 n.2. They are wrong. The prudential zone-of-interests test "is not meant to be especially demanding and is applied in keeping with Congress's evident intent when enacting the APA to make agency action presumptively reviewable." *DAPA*, 809 F.3d at 162 (citation modified). This test "looks to the law's substantive provisions to determine what interests (and hence which plaintiffs) are protected." *Simmons v. UBS Fin. Servs., Inc.*, 972 F.3d 664, 669 (5th Cir. 2020). That "lenient approach" is necessary to preserve a federal court's "virtually unflagging" obligation to hear cases within its jurisdiction. *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 126, 130 (2014) (citation modified). "The test forecloses suit only when a plaintiff's interests are so marginally related to or inconsistent with the purposes implicit in the statute that it cannot reasonably be assumed that Congress intended to permit the suit." *DAPA*, 809 F.3d at 162 (citation modified). In other words, "[t]here is no presumption against judicial review and in favor of administrative absolutism unless that

purpose is fairly discernible in the statutory scheme." *Ass'n of Data Processing Serv. Orgs., Inc. v. Camp*, 397 U.S. 150, 157 (1970) (internal citation omitted).

Danco and GenBioPro complain that Plaintiffs identify no particular provision of the FDCA protecting their interests. But "no explicit statutory provision [is] necessary[.]" *Id.* at 155. Moreover, Plaintiffs' interests are far more than "marginally related" to the FDCA's purposes. *DAPA*, 809 F.3d at 162. The FDCA prohibits the introduction and delivery of adulterated or misbranded drugs into interstate commerce. 21 U.S.C. § 331. The FDCA's mandates include "protect[ing] the public health," Public Law No. 87-781, 76 Stat. 780, "assur[ing] the safety, effectiveness, and reliability" of FDA-approved drugs, *id.*, and considering the "seriousness of any known or potential adverse events that may be related to the drug." 21 U.S.C. § 355-1(a)(1). Certainly, Louisiana has an interest in protecting public health and safety and in keeping adulterated or misbranded drugs from entering its borders.[13]

Likewise, Louisiana is within the zone of interests of the Comstock Act. This statute "indicates a national policy of discountenancing abortion as inimical to the national life." *Bours v. United States*, 229 F. 960, 964 (7th Cir. 1915); *see also Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 70 n.19 (1983) (the "thrust" of the Act was "to prevent the mails from being used to corrupt the public morals"). Louisiana is well within this zone of interest because it has a "longstanding policy" protecting the "right to life of every unborn child from conception" and declaring abortion "impermissible." La. R.S. § 40:1061.1. It also has an interest in protecting the public health and well-being of its citizens, promoting public morals, and protecting its self-governing authority. *Sierra Club v. City of San Antonio*, 115 F.3d 311, 315 (5th Cir. 1997). As to both statutes, there is no evidence that Congress "sought to preclude judicial review of administrative rulings" by FDA "as to the legitimate scope of activities available" concerning chemical abortion drugs. *Camp*, 397 U.S. at 157. Accordingly, the manufacturers' zone-of-interests argument is meritless.

[13] And "[t]he threatened injury to a State's enforcement of its safety laws is within the zone of interests of the Administrative Procedure Act[.]" *State of Ohio ex rel. Celebrezze v. U.S. Dep't of Transp.*, 766 F.2d 228, 233 (6th Cir. 1985).

II. The 2023 REMS Violates the Comstock Act.

GenBioPro seeks dismissal of Plaintiffs' claim that the 2023 REMS violates the Comstock Act. Danco similarly includes a few paragraphs on Comstock in its opposition brief. But those arguments provide no basis for dismissal. As Judge Ho concluded, the 2023 REMS directly conflicts with the Comstock Act. Indeed, "using the mails for the mailing of a drug for producing abortion is *precisely* what the Comstock Act prohibits." *Alliance II*, 78 F.4th at 267–68 (Ho, J., concurring) (citation modified and emphasis added).

Danco's responses are difficult to follow. It claims that administrative agencies may disregard federal law outside of their enabling statutes—a claim directly refuted by (a) the APA's mandate to set aside actions that are "otherwise not in accordance with law" and (b) the Supreme Court's unqualified statement in *FCC v. NextWave Pers. Commc'ns Inc.*, 537 U.S. 293 (2003), that "otherwise not in accordance with law" means "any law." *Id.* at 300; *contra* ECF 230-1 at 21–22. Moreover, Danco's argument would mean that federal agencies need not concern themselves with the Religious Freedom Restoration Act or a multitude of environmental statutes. That is not the law.

Danco also notes that FDA routinely approves drugs that are subject to other statutes, like the Controlled Substances Act ("CSA"). ECF 230-1 at 21. But FDA approval does not authorize conduct prohibited by the CSA. Here, in contrast, the 2023 REMS authorizes using the mails to distribute an abortion-producing drug—conduct that the Comstock Act expressly forbids.

Finally, both Danco and GenBioPro would rewrite the Comstock Act to prohibit only "illegal abortions" based on post-enactment history. ECF 231 at 20–21; ECF 230-1 at 21–22. But the text contains no such limitation, and Congress in 1978 considered—and rejected—an amendment limiting the law to "illegal abortions." H.R. 13959, 95th Cong. §§ 6701(a)(2), 6702(1)(C)(i) (1978); *accord* Rep. of the Subcomm. on Crim. Just. on Recodification of Fed. Crim. L., H.R. Rep. No. 95-29, pt. 3, at 42 (1978) (explaining the amendment would "change[ ] current law by requiring proof … to produce an illegal abortion"); *see also* ECF 101 at 5; ECF 103-1 at 9. As a result, the post-enactment history of the Comstock Act "only reinforces the natural reading of the text." *Alliance II*, 78 F.4th at 270 (Ho, J., concurring). And to the extent the manufacturers cling to a smattering of old dicta from some circuit

courts, the prior-construction canon modifies a statute's text only when the pre-enactment meaning is settled by "a uniform interpretation by inferior courts"—a standard plainly not satisfied here. *Tex. Dep't of Hous. & Cmty. Affs. v. The Inclusive Communities Project, Inc.*, 576 U.S. 519, 536 (2015) (citation omitted).

III. The Manufacturers' Exhaustion Argument Is Meritless.

In the same desperate vein, the manufacturers assert that Plaintiffs failed to exhaust administrative remedies. That is doubly wrong.

First, the APA requires exhaustion only when required by statute or a rule "provides that the [agency] action … is inoperative" during appeal. 5 U.S.C. § 704; *accord Darby v. Cisneros*, 509 U.S. 137, 154 (1993) (exhaustion required "*only* when expressly required by statute or when an agency rule requires appeal before review and the administrative action is made inoperative pending that review"). No such statute or rule exists here. Krupka, *Exasperated But Not Exhausted: Unlocking the Trap Set by the Exhaustion Doctrine on the FDA's REMS Petitioners*, 77 Vand. L. Rev. 937, 977–78, 980 (2024), perma.cc/3BHM-WRQE. Because FDA does not hold its REMS "inoperative" upon receiving a petition, exhaustion does not apply. *MCR Oil Tools, L.L.C. v. U.S. Dep't of Transp.*, 110 F.4th 677, 691 (5th Cir. 2024).

Second, courts do not require exhaustion where one of the "traditionally recognized exceptions" applies. *Wash. Ass'n for Television & Children v. FCC*, 712 F.2d 677, 682 (D.C. Cir. 1983). At least three are relevant here.

Start with administrative abuse of process. It is "well-established that where an agency fails to follow its own regulations, exhaustion may not be required." *All. For Hippocratic Med. v. FDA (Alliance I)*, No. 23-10362, 2023 WL 2913725, at *16 (5th Cir. 2023); *see also Way of Life Television Network, Inc. v. FCC*, 593 F.2d 1356, 1359–60 (D.C. Cir. 1979). FDA's own regulations require it to respond to citizen petitions within 180 days. *See* 21 C.F.R. § 10.30(e)(2). Yet the average REMS petition languishes for 937.6 days. *See supra* Krupka at 957–63. Worse, in *Alliance I*, FDA subjected plaintiffs to "sixteen years of delay, dawdle, and dithering," before eventually rejecting their petitions. *All. For Hippocratic Med. v. FDA*, 668 F. Supp. 3d 507, 538 (N.D. Tex. 2023). Plaintiffs here can expect no better. Based on

"FDA's repeated failure to follow its own regulations," this Court should waive exhaustion (if such a requirement existed). *Alliance I*, 2023 WL 2913725, at *16.

Next take futility. "[T]he record shows that FDA would have denied any request for an administrative stay." *Alliance II*, 78 F.4th at 255. Indeed, FDA opposes Plaintiffs' motion for preliminary relief. There is no reason to believe that the agency would respond differently to an administrative request seeking a stay. FDA also previously "expressly reaffirmed its commitment to mail-order abortion drugs" in a 2021 petition denial—the day FDA decided to permanently remove in-person dispensing and direct the abortion-drug companies to submit a proposed REMS without that requirement. *Alliance I*, 2023 WL 2913725, at *15. And FDA doubled down on its mail-order scheme by denying a similar petition on January 3, 2023—the day FDA formally approved the 2023 REMS. ECF 1-34. That is why the *Alliance II* Court concluded that it would have been clearly useless to raise the same challenge again. 78 F.4th at 255. In fact, another court found that a coalition of States need not file a petition that others had already filed and FDA had rejected because the agency could not "credibly argue that its decision on the Mifepristone REMS Program would change upon another citizen petition." Order Granting in part Pls.' Mot. Prelim. Inj., *State of Washington v. FDA*, No. 1:23-cv-03026 (E.D. Wash. Apr. 7, 2023), ECF 80, at 17. The same is true here.

Last, an exception exists "where irreparable injury would result unless immediate judicial review is permitted." *Randolph-Sheppard Vendors of Am. v. Weinberger*, 795 F.2d 90, 107 (D.C. Cir. 1986) (collecting cases). That exception plainly applies here given the irreparable harms articulated above.

IV. Plaintiffs' Challenge to the 2023 REMS Is Ripe.

Article III ripeness is no obstacle here. The same reasons that show Louisiana has standing likewise demonstrate that its claims are ripe.[14] *Braidwood Mgmt., Inc. v. EEOC*, 70 F.4th 914, 930 (5th

[14] FDA claims it could invoke its 355(e) authority to suspend mifepristone's approval if the HHS Secretary finds it presents "an imminent hazard to the public health." ECF 250 at 2. Plaintiffs are aware of only *one* instance in FDA's 120-year history where it exercised this authority—nearly 50 years ago—for a drug estimated to have had as many as 60 deaths/month. *See Forsham v. Califano*, 442 F. Supp. 203, 209 (D.D.C. 1977). And even if FDA were to invoke this once-used statutory provision, abortion activists will likely challenge this action under the APA and seek immediate, interim relief

Cir. 2023); *supra* Section I. Louisiana's injuries are not "contingent future events that may not occur as anticipated, or indeed may not occur at all." *Contra* ECF 230-1 at 16–17 (quoting *Texas v. United States*, 523 U.S. 296, 300 (1998)). That Louisiana has established an Article III injury should end the inquiry.[15]

Instead, the drug manufacturers fall back on prudential considerations. ECF 230-1 at 16–17; ECF 231 at 15. But the Supreme Court cautions that the prudential ripeness doctrine is inconsistent with federal courts' "virtually unflagging obligation ... to exercise the jurisdiction given them." *Colo. River Water Conservation Dist. v. United States*, 424 U.S. 800, 817 (1976); *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 167 (2014) (calling into question "the continuing vitality of the prudential ripeness doctrine"). Nevertheless, the doctrine's factors do not support dismissal here. For one, the "fitness and hardship factors are easily satisfied[.]" *SBA List*, 573 U.S. at 167 (citation modified). "[D]enying prompt judicial review would impose a substantial hardship on [Louisiana]," *id.* at 167–68, which experiences ongoing, irreparable harm to its sovereignty and fiscs each day the concededly unlawful REMS remains in effect. *Supra* Section I.A. And Louisiana's claims are "purely legal, and will not be clarified by further factual development." *SBA List*, 573 U.S. at 167 (citation omitted). Nor could they be: The lawfulness of an agency action is assessed on the basis articulated by the agency at the time of the decision.[16] *See Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins.*, 463 U.S. 29, 41 (1983).

(which Danco impliedly admits). ECF 230-1 at 23 n.10. Besides its suspension authority, there are "no '*interim* orders' FDA could issue" to address immediate public health concerns: Plaintiffs are relegated to agency actions that are "influenced by factors outside FDA's control, most notably the degree of cooperation of the drug's sponsor." ECF 250 at 2–3.

[15] Ripeness—even prudential ripeness—asks only whether there is an injury in fact or hardship, not whether that hardship is irreparable. Danco's attempt to insert "delay" into the inquiry should thus be squarely rejected.

[16] Danco's speculation that FDA *might* someday reinstate in-person dispensing based on its safety review confuses ripeness with mootness; the case is ripe because Plaintiffs suffer an ongoing, concrete injury from the current, unlawful regulation. *Purcell* is likewise irrelevant to Danco's Motion; the court granted an unopposed stay only once plaintiffs had secured relief from their alleged injuries. *Chelius v. Becerra*, No. CV 17-00493 JAO-RT, 2023 WL 5041616, at *2–3 (D. Haw. 2023).

CONCLUSION

The Court should deny Danco and GenBioPro's Motions to Dismiss.

Dated: March 10, 2026

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on March 10, 2026, pursuant to Federal Rule of Civil Procedure 5(b)(2)(C), a true and correct copy of the foregoing memorandum, and all attachments thereto, was served by CM/ECF.

/s/ *Caitlin Huettemann*
Caitlin Huettemann

EXHIBIT 1

ACLU, *Reproductive Health, Rights, and Justice Groups Letter to Biden Administration on Mifepristone*
(March 16, 2021)

March 18, 2021

The Honorable Joseph R. Biden, Jr.
President of the United States
The White House
1600 Pennsylvania Ave.
Washington, DC 20500

Dear Mr. President:

The undersigned organizations write to urge your administration to immediately reverse a dangerous policy that is subjecting abortion and miscarriage patients to needless COVID-19 risk, and to prioritize the elimination of unnecessary barriers to medication abortion care. Specifically, we call for an immediate suspension of the in-person requirement for mifepristone, a safe and effective medication used for early abortion, during the COVID-19 public health emergency, as well as a comprehensive Food and Drug Administration (FDA) review of the full set of restrictions on mifepristone to bring patient access in line with the latest science and medical evidence.

Consistent with your important commitment to follow the science in responding to COVID-19, as well as your critical promise to tackle issues of systemic equity across the government, it is imperative that your administration prioritize safe access to medication abortion. Burdensome restrictions on medication abortion, which are not based in medical evidence, deepen the health inequities already experienced by those who are struggling to make ends meet, particularly people of color, who comprise a majority of medication abortion patients and are now being hit hardest by the COVID-19 pandemic.

Mifepristone is a prescription medication that patients have relied on for 20 years to safely and effectively end early pregnancies and, more recently, to treat early miscarriages.[1] Despite its excellent, extensive safety record,[2] FDA continues to subject mifepristone to a set of outdated and medically unnecessary restrictions, known as a Risk Evaluation and Mitigation Strategy (REMS). Leading medical authorities have long called to permanently lift the mifepristone REMS,[3] which unjustifiably obstructs patients' access to time-sensitive, essential health care, most severely in rural and low-income communities. These restrictions uniquely burden abortion patients: out of more than 20,000 drugs that FDA regulates, mifepristone, when used for abortion or miscarriage care, is the *only* one that FDA requires to be dispensed in a clinical setting, despite permitting patients to self-administer it at home.[4]

During the pandemic, that in-person requirement is also particularly dangerous. Patients must travel to a hospital, clinic, or medical office for the sole purpose of picking up the pill and signing a form, forcing them to risk needless COVID-19 exposure in order to access care.[5] Not only is this entirely medically unnecessary, its enforcement is also a glaring departure from the government's policy of minimizing in-person health care visits during the pandemic. As COVID-19 first surged across the nation last March, the Department of Health and Human Services (HHS) and FDA quickly suspended enforcement of other in-person requirements -- including for far *less* safe medications like opioids-- and encouraged the use of telehealth

wherever possible, consistent with the public health consensus that unnecessary in-person medical visits must be avoided to mitigate viral spread.[6] Leading medical authorities repeatedly called on FDA to do the same for mifepristone,[7] so that eligible patients could safely receive their prescriptions by mail, just as they would any other prescription. Instead, the Trump administration did everything in its power to continue subjecting abortion and miscarriage patients to this unique and dangerous requirement—fighting medical and reproductive justice organizations all the way up to the Supreme Court to reinstate the policy after it was blocked by a federal court.

In January, after six months of an injunction that allowed patients to safely obtain their mifepristone prescription by mail, the Court allowed the Trump administration to reinstate this dangerous travel mandate on its way out the door, in spite of soaring COVID-19 rates nationwide.[8] Since that disastrous decision, patients and their families are once again at risk every day. Despite a recent decline in new cases, there is still a very long road ahead in this unprecedented public health crisis: the U.S. recently marked half a million COVID-19 deaths, and new variants are spreading while vaccine plans are still being implemented. Your administration must reverse this dangerous approach and respond to the medical experts that the previous administration ignored. Continuing to impose the in-person requirement during this public health emergency is at odds with both science and common sense. No one should have to risk needless exposure to a life-threatening virus to access essential health care, including people who need abortion care.

It is important to note that the existing restrictions also harm patients who experience miscarriage—as an average of more than a million do each year—and seek medical care to complete it. While not yet an FDA-approved indication, there is robust clinical trial data to show that pre-treating patients with mifepristone before using the standard medical treatment of misoprostol results in a higher likelihood of successful management of first-trimester pregnancy loss than treatment with misoprostol alone. Given that the other alternatives are to wait out the miscarriage at home (which can take days if not weeks), or travel to a hospital emergency department or other health center for a procedure to evacuate the uterus, the REMS unduly limits miscarriage patients' access to a safe medical option and forces them to incur unnecessary viral exposure risks.

In addition, we call for a comprehensive FDA review of the full REMS on mifepristone. For far too long, these unwarranted restrictions have pushed care out of reach for people who already face significant barriers when it comes to accessing health care. Particularly as state abortion restrictions force people in many parts of the country to travel further and further to reach providers, the government must eliminate medically unnecessary obstacles that prevent people from accessing safe care. In light of this, an evidence-based review of the REMS is not only long overdue, but urgent.

Such a review is consistent with the law and adheres to the process authorized by Congress as part of the Federal Food, Drug and Cosmetic Act (FFDCA). Specifically, the statute allows for the Secretary, in consultation with the FDA, to modify a REMS 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 restrictions.[9] Moreover, Congress required that any REMS "element to assure safe use" not be "unduly burdensome on patient access," with particular consideration of the impact on

those in rural or medically underserved areas, or who otherwise have difficulty accessing care.[10] A reevaluation of the mifepristone REMS is all the more pressing given its outsized impact on those populations. It must be a priority to ensure that patients' access to abortion and miscarriage care, like all other health care, is based on the latest science and medical evidence.

We urge your administration to act quickly to ensure that people can safely access the time-sensitive, essential care they need not only during the pandemic, but also after it ends. The past four years brought relentless attacks on access to safe, affordable reproductive health care from an administration that based its policy on false and inflammatory rhetoric rather than medical evidence. We welcome the opportunity to now work with your administration to reverse that course and ensure that science, not politics, guides access to reproductive health care, including abortion.

Sincerely,

American Civil Liberties Union
EMAA Project
Advocates for Youth
All* Above All
American Medical Student Association
American Society for Reproductive Medicine (ASRM)
Catholics for Choice
Center for Reproductive Rights
CHANGE (Center for Health and Gender Equity)
Community Catalyst
Hey Jane
Ibis Reproductive Health
If/When/How: Lawyering for Reproductive Justice
In Our Own Voice: National Black Women's Reproductive Justice Agenda
International Women's Health Coalition
Ipas
Jacobs Institute of Women's Health
Jewish Women International
Just The Pill
Lawyering Project
Medical Students for Choice
MomsRising
NARAL Pro-Choice America
NASTAD
National Abortion Federation
National Asian Pacific American Women's Forum (NAPAWF)
National Center for Lesbian Rights
National Council of Jewish Women
National Family Planning & Reproductive Health Association
National Health Law Program
National Institute for Reproductive Health
National Latina Institute for Reproductive Justice

National Network of Abortion Funds
National Organization for Women
National Partnership for Women & Families
National Women's Health Network
National Women's Law Center
Not Without Black Women
Our Justice
PAI
Physicians for Reproductive Health
Planned Parenthood Federation of America
Population Connection Action Fund
Population Institute
Power to Decide
Raising Women's Voices
SIECUS: Sex Ed for Social Change
Society for Maternal-Fetal Medicine
UCSF Bixby Center for Global Reproductive Health
Union for Reform Judaism
UnRestrict Minnesota
URGE: Unite for Reproductive & Gender Equity
VA NOW, Inc
We Testify
Women of Reform Judaism

Cc: Acting HHS Secretary Norris Cochran
Acting FDA Commissioner Janet Woodcock

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[1] Mifepristone is FDA-approved for use in combination with another drug, misoprostol, to end early pregnancies. While misoprostol alone has long been used to medically manage early pregnancy loss (i.e., miscarriage), it is now widely recognized that the superior miscarriage treatment regimen includes mifepristone. *See, e.g.*, Am. College of Obstetricians & Gynecologists, Practice Bulletin 200: Early Pregnancy Loss, https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2018/11/early-pregnancy-loss.

[2] In the FDA's words, mifepristone "has been increasingly used as its efficacy and safety have become well-established by both research and experience, and serious complications have proven rare." U.S. Food and Drug Admin., Ctr. for Drug Evaluation & Res., *Medical Review of Mifeprex* 12 (Mar. 29, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf.

[3] *See, e.g.* American Medical Association, *Ending the Risk Evaluation and Mitigation Strategy (REMS) policy on mifepristone (Mifeprex)*, Policy H-100.948 (2018), https://www.ama-assn.org/sites/default/files/mediabrowser/public/hod/a18-resolutions.pdf; American Academy of Family Physicians, *FPs Tackle Primary Care Spending, Other Weighty Topics* (Oct. 12, 2018), https://www.aafp.org/news/2018-congress-fmx/20181012codadvocacy.html; American Congress of Obstetricians and Gynecologists, *ACOG Statement on Medication Abortion* (Mar. 30, 2016), https://www.acog.org/About-ACOG/News-Room/Statements/2016/ACOG-Statementon-Medication-Abortion?IsMobileSet=false.

[4] When mifepristone is used for purposes other than treating abortion or miscarriage, FDA allows the identical compound to be mailed in higher doses and vast quantities for chronic use.

[5] The REMS requires patients seeking abortion and miscarraige care to pick up the pill in person, even when they have already been evaluated by a clinician, will not receive in-person medical services at the time, and will swallow the pill later at home.

[6] *See, e.g.,* U.S. Food & Drug Admin., *Policy for Certain REMS Requirements During the COVID-19 Public Health Emergency* 7 (2020), https://www.fda.gov/media/136317/download; *OCR Announces Notification of Enforcement Discretion for Telehealth Remote Communications During the COVID-19 Nationwide Public Health Emergency*, Health & Human Servs. (Mar. 17, 2020), https://www.hhs.gov/about/news/2020/03/17/ocr-announces-notification-of-enforcement-discretion-for-telehealth-remote-communications-during-the-covid-19.html; *COVID-19 Information Page, Telemedicine*, U.S. Drug Enf't Admin., https://www.deadiversion.usdoj.gov/coronavirus.html#TELE (last visited May 25, 2020).

[7] *See, e.g.*, Letter from John S. Cullen, Board Chair, Am. Acad. of Family Physicians, to Stephen M. Hahn, Comm'r, U.S. Food and Drug Admin. (Mar. 25, 2020); Letter from Maureen G. Phipps, Chief Exec. Officer, Am. Coll. of Obstetricians and Gynecologists; Judette Louis, President, Soc'y for Maternal-Fetal Med.; and Matt J. Granato, Chief Exec. Officer, Soc'y for Maternal-Fetal Med., to Stephen M. Hahn, Comm'r, U.S. Food and Drug Admin. (Apr. 20, 2020); Letter from Public Health Experts and Advocates to Janet Woodcock, M.D., U.S. Food & Drug Admin. (Apr. 28, 2020).

[8] *FDA v. Am. Coll. of Obstetricians & Gynecologists*, 141 S. Ct. 578 (2021).

[9] 21 U.S.C. § 355-1(g)(4)(b).

[10] 21 U.S.C. § 355-1 (f)(2)(C)(ii).