No. 26-30203

In the United States Court of Appeals for the Fifth Circuit

STATE OF LOUISIANA, BY AND THROUGH ITS ATTORNEY GENERAL, LIZ MURRILL; ROSALIE MARKEZICH,
Plaintiffs-Appellants/Cross-Appellees,

v.

FOOD & DRUG ADMINISTRATION; MARTY MAKARY, COMMISSIONER, U.S. FOOD & DRUG ADMINISTRATION; RICHARD PAZDUR, IN HIS OFFICIAL CAPACITY AS DIRECTOR, CENTER FOR DRUG EVALUATION & RESEARCH, U.S. FOOD & DRUG ADMINISTRATION; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ROBERT F. KENNEDY, JR., SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,
Defendants-Appellees,

v.

GENBIOPRO, INC.,
Intervenor-Appellee/Cross-Appellant,

v.

DANCO LABORATORIES, L.L.C.,
Intervenor-Appellee/Cross-Appellant.

On Appeal from the United States District Court
for the Western District of Louisiana
No. 25-cv-1491, Hon. David C. Joseph

PLAINTIFFS-APPELLANTS' OPENING BRIEF

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CERTIFICATE OF INTERESTED PERSONS

Louisiana, et al., v. Food and Drug Administration, et al.

The undersigned counsel of record certifies that the following listed persons and entities as described in the fourth sentence of Rule 28.2.1 have an interest in the outcome of this case. These representations are made in order that the judges of this court may evaluate possible disqualification or recusal.

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The State of Louisiana

Rosalie Markezich

Defendants-Appellees:

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GenBioPro, Inc. (GenBioPro represents that its parent company is Xenia Holdco LLC, and there is no publicly held corporation that owns 10% or more of GenBioPro's stock.)

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/s/ J. Benjamin Aguiñaga
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STATEMENT REGARDING ORAL ARGUMENT

Considering the importance of the issues raised herein, Plaintiffs-Appellants respectfully request oral argument, to be held the week of August 31 to September 3, 2026, or on the next available oral argument calendar date.

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INTRODUCTION

This lawsuit challenges the Biden Administration's decision to remove the Food and Drug Administration's (FDA) longstanding in-person dispensing requirement for the abortion drug mifepristone. That decision was part of an avowed "scheme to undermine [the Supreme Court's] decision in *Dobbs v. Jackson Women's Health Organization*, 597 U.S. 215 (2022), which restored the right of each State to decide how to regulate abortions within its borders." *Danco Lab'ys, LLC v. Louisiana*, 146 S. Ct. 1192, 1193 (2026) (Alito, J., dissenting). Where *Dobbs* assured Louisiana that the State's pro-life laws would take full effect, the Biden Administration's removal of the in-person dispensing requirement affirmatively authorized the mailing of mifepristone into Louisiana through the efforts of out-of-state "medical providers, private organizations, and States that abhor laws like Louisiana's and seek to undermine their enforcement." *Id.*

The results are sobering. Although Louisiana prohibits abortion with very narrow exceptions, nearly 1,000[1] Louisiana babies are illegally

[1] The Society of Family Planning recently published a new #WeCount report that reduces its approximation of Louisiana-specific mail-order-abortions to 870 unlawful abortions per month. *See* Society of Family Planning, #WeCount Report April 2022 to December 2025 (June 10, 2026), perma.cc/97KH-6M7N. This brief

aborted via FDA-approved mifepristone every month. Moreover, Louisiana women, like Plaintiff Rosalie Markezich, who find themselves pregnant and in abusive relationships or facing outside pressures are being poisoned with or coerced to take drugs that may be ordered online in minutes. Louisiana women are ending up in emergency rooms; declarations in this case bear that out. FDA's own label states that even using mifepristone as directed will send 1 in 25 women to the emergency room—and that was before in-person dispensing was removed.

That is why Louisiana and Rosalie filed this lawsuit seeking vacatur of the Biden FDA's action—the 2023 Risk Evaluation and Mitigation Strategy (REMS)—under the Administrative Procedure Act (APA). In the proceedings below, the district court declined to enter a preliminary stay of the REMS under 5 U.S.C. § 705, and Plaintiffs appealed.

This appeal is narrow because it covers a well-traveled path. The district court below and three separate panels of this Court—including a stay panel (Southwick, Duncan, Engelhardt, JJ.) in this very case—have

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reflects the estimates already included in the record from prior reports. Even if the number is closer to 900 than 1,000, the loss of each life is still intolerable for Louisiana.

already concluded that Plaintiffs are likely to succeed on the merits of this APA challenge. *See All. for Hippocratic Med. v. FDA* (*Alliance I*), 2023 WL 2913725 (5th Cir. Apr. 12, 2023); *All. for Hippocratic Med. v. FDA* (*Alliance II*), 78 F.4th 210 (5th Cir. 2023); ECF.119-1. To its credit, the current FDA has refused to defend the 2023 REMS.

The only real question, pressed heavily by the intervenor drug Manufacturers (Danco and GenBioPro) in the Supreme Court during stay proceedings, is whether Louisiana has standing to sue. It does. As both the district court and the stay panel agreed, the 2023 REMS has directly caused economic injuries to Louisiana in the form of actual and undisputed Medicaid costs and enforcement costs. The 2023 REMS also has directly caused sovereign injuries in the form of close to 1,000 violations of Louisiana abortion laws every month and Louisiana's inability to enforce those laws. In that way, this case is structurally different than the challenge that the Supreme Court considered, and rejected on standing grounds, in *FDA v. Alliance for Hippocratic Medicine*, 602 U.S. 367 (2024). And the district court and the stay panel correctly agreed on that point in finding both standing and irreparable harm to Louisiana absent a stay of the 2023 REMS.

Given the district court's agreement with Plaintiffs on standing, the merits, and irreparable harm, one fairly might ask why Plaintiffs have appealed. That is because the district court believed the public interest was not in favor of giving Louisiana relief from undisputed irreparable harm. The stay panel directly addressed the district court's reasons for so concluding, and correctly rejected them. Among others, the stay panel addressed the district court's concern that FDA says it is studying the 2023 REMS. In response, the stay panel observed that "[g]ranting a stay would do nothing to prevent FDA from completing its review of mifepristone's safety protocols." ECF.119-1 at 17. Indeed, "[a]s Louisiana points out, it 'makes no sense to deny preliminary relief on the grounds that agency action is so unlawful that the agency openly concedes a review is necessary.'" *Id.*

Following the stay panel's decision to grant Plaintiffs relief, the Manufacturers rushed to the Supreme Court to secure, by an unreasoned order, a reversal of that ruling "pending disposition of the appeal in the United States Court of Appeals for the Fifth Circuit and disposition of a petition for a writ of certiorari, if such a writ is timely sought." *Danco Lab'ys, LLC*, 146 S. Ct. at 1192. FDA, notably, declined to file responsive

briefing at the Supreme Court. Because time continues to be of the essence for Louisiana, Louisiana files this brief ahead of its opening-brief deadline and contemporaneously with a motion to expedite oral argument.

Plaintiffs respectfully request that the merits panel follow the stay panel in entering a § 705 stay of the 2023 REMS. In light of the Supreme Court's stay order, Plaintiffs understand that this Court's entry of a stay in favor of Plaintiffs would be stayed pending appeal to the Supreme Court.

JURISDICTIONAL STATEMENT

The district court has jurisdiction over the denial of Plaintiffs' motion for preliminary relief under 5 U.S.C. § 705 and under 28 U.S.C. § 1292(a)(1). The district court entered the Memorandum Ruling at issue in this appeal on April 7, 2026. ROA.9084-9120. The State filed a notice of appeal the following day, on April 8, 2026. ROA.9121-9123.

ISSUE PRESENTED

Whether the district court erred by denying Plaintiffs preliminary relief and instead staying the litigation in FDA's favor after finding that Plaintiffs are likely to succeed on the merits and are suffering irreparable harm as a result of the agency's action.

STATEMENT OF THE CASE

A. FDA Removes Protections for Women by Modifying the 2023 REMS.

When *Dobbs* returned the issue of abortion to the states, laws protecting life awoke in states like Louisiana. The State's policy on life and abortion is unequivocal. By statute, the State's policy is "that every unborn child is a human being from the moment of conception"—and accordingly, the Legislature has "declare[d] that the longstanding policy of this state [is] to protect the right to life of every unborn child from conception." La. R.S. 40:1061.1(A)(1)-(2).

To that end, Louisiana law prohibits all abortions, except medical procedures to separate mother and child if deemed medically necessary to prevent the death or substantial risk of death of the mother. *See* La. R.S. 40:1061, 14:87.7, 14:87.8.1. Relevant here, Louisiana law also criminalizes, with exceptions, the dispensing, distribution, or delivery of abortion drugs to a pregnant woman. La. R.S. 40:1061(C); La. R.S. 14:87.9(A). And, if a narrow exception applies, Louisiana law also requires abortion drugs to be administered, dispensed, or provided in-person by the prescribing physician. La. R.S. 40:1061.11(A).

Notwithstanding Louisiana's policy and laws, nearly 1,000 abortions occur every month in Louisiana. That is the predictable consequence of a drug war enabled by President Biden's FDA. Mere days after oral argument in *Dobbs*, the Biden FDA concluded that the abortion-drug REMS "must be modified to remove the in-person dispensing requirement." ROA.970. The same day the Supreme Court decided *Dobbs*, President Biden announced a whole-of-government attack on pro-life states who choose to ban or otherwise restrict abortion.

In particular, he identified "threats from state officials saying they will try to ban or severely restrict access to medication for reproductive health care." ROA.956. He followed that up with Executive Order 14,076 of July 8, 2022, Protecting Access to Reproductive Health Care Services, 87 Fed. Reg. 42053 (July 13, 2022), which promised "abortion care, including medication abortion"—"especially for those who live in States that are banning or severely restricting abortion care." ROA.943; *see* ROA.946-949 (Executive Order No. 14,079 of Aug. 3, 2022, Securing Access to Reproductive and Other Healthcare Services, 87 Fed. Reg. 49505 (Aug. 11, 2022), challenging "the continued advancement of

restrictive abortion laws in States across the country" and announcing a policy to protect "medication abortions").

Abortion "medication" is code for the FDA-approved abortion drug mifepristone. President Biden "directed the Secretary of Health and Human Services" (and thus FDA) "to identify all ways to ensure that mifepristone is as widely accessible as possible ... *including when prescribed through telehealth and sent by mail*." ROA.956 (emphasis added); ROA.1230-1231 (President Biden's fact sheet claiming that "states may not ban mifepristone" and promising "to allow mifepristone to continue to be prescribed by telehealth and sent by mail"). That directive was significant because, until the COVID-19 pandemic, FDA regulations had long required mifepristone to be dispensed in-person; in 2021, the Biden FDA cited its enforcement discretion to *temporarily* "not enforce the in-person dispensing requirement" and thereby facilitate "the dispensing of mifepristone through the mail" (the 2021 Non-Enforcement Decision). *See Alliance II*, 78 F.4th at 222, 226 (citation modified).

In the wake of *Dobbs*, that temporary position gave way to the Biden Administration's vow that it would "ensure every American has access to ... medication abortion." ROA.958. "[W]e will double down,"

then-Secretary Becerra said, "and use every lever we have to protect access to abortion care." *Id.*; *see also* ROA.960 (then-Secretary Becerra claiming that the *Dobbs* decision was "despicable" but also "predictable," and that "HHS has been preparing for this for some time"); ROA.962; ROA.1235; ROA.1238; ROA.1239; *accord* ROA.1226 ("Since *Dobbs*, HHS has worked to protect and expand access to reproductive care amidst unprecedented efforts by Republican officials at the national and state level to restrict access to abortion[.]"). Fulfilling that promise, the Biden FDA issued the 2023 REMS in January 2023, ROA.965-1053, which permanently "formalize[d] the removal of the in-person dispensing requirement," "allow[ing] mifepristone to be prescribed remotely and sent via mail." *Alliance II*, 78 F.4th at 226; *accord Alliance I*, 2023 WL 2913725, at *2; ROA.353; ROA.970; ROA.973; ROA.980.

B. The 2023 REMS Floods Louisiana with Illegal Mifepristone.

This assault on pro-life states has worked as intended. While in-person abortions have virtually vanished from Louisiana after *Dobbs*, illegal mifepristone-induced abortions—facilitated by out-of-state doctors mailing FDA-approved mifepristone into Louisiana—have skyrocketed. Said one mifepristone mailer to spite pro-life states' laws: "We really

don't change things unless we're legally required to." ROA.2172. "We're confident people in ... every state ... will still be able to get abortion pills by mail," said another. ROA.2173.

To carry out this attack, organizations like AidAccess.org have blanketed the Internet with order forms for FDA-approved mifepristone, *e.g.*, ROA.1303-1307, extolling the ease with which New York and California doctors may distribute pills into locales across Louisiana—and emphasizing that "[t]he FDA has approved abortion pills by mail":

Get Abortion Pill Online in Louisiana · Order Here

You can buy an abortion pill online and get it by mail in Louisiana. The FDA has approved abortion pills by mail. Aid Acces works with U.S. based abortion providers in so called shield law states (this means that the states will protect the providers against legal action). Therefor Aid Access can provide abortion services to all 50 U.S. states including Louisiana.

Aid Access will help you order abortion pills and have them delivered to your home in New Orleans, Baton Rouge, Shreveport, Metairie, Lafayette, or anywhere else in Louisiana.

Louisiana abortion pill online orders:

- Louisiana abortion pill online orders costs $150 USD
- Reliable abortion pill shipping to Louisiana in 1-5 days
- Tracking numbers provided when the pills are mailed
- Help desk support available in 16 languages

ROA.1304.

When Louisiana filed this suit, the available data showed a monthly abortion rate that fluctuated between 300 and 600, with an apparent high watermark of just over 800 abortions in December 2024 alone. ROA.225. Just days before Louisiana filed its request for

preliminary relief in the district court, however, new data revealed that 800 mifepristone-induced abortions per month was *the minimum* in Louisiana in 2025; more frequently, that number was approximately 900, and nearly 1,000 in March 2025 alone. ROA.2358; ROA.2541-2542.

There are real women and real-world harms behind those numbers. *See, e.g.*, ROA.2560-2564, ¶¶ 8–13, 15–16, 18–20; ROA.2509-2512, ¶¶ 8–12; ROA.2513-2516, ¶¶ 2–9; ROA.2565-2567, ¶¶ 2–8 (testifying to dozens of women who took or received mifepristone from out-of-state prescribers). Just take Plaintiff Rosalie Markezich, who did not want an abortion. ROA.1487-1502, ¶ 16. She told her then-boyfriend that she wanted to raise their unborn baby. ROA.1499, ¶ 5; ROA.1500, ¶ 11. Yet he went online in late 2023, filled out a form with her information, gave her money to pay a California doctor through Venmo, and had the drug mailed to her Louisiana home. ROA.1499-1500, ¶¶ 7, 8, 9. She pleaded with him, "Don't make me do this." ROA.1500, ¶ 11. But he grew angry and erratic, his behavior escalating so much that she—a domestic abuse survivor—was terrified and took the drugs in front of him as a means to escape. ROA.1500, ¶ 12. She ended up on a bathroom floor for an hour, then in a garage, as she began bleeding out—an unspeakable experience

that continued "for about a week" and "still haunts [her]." ROA.1501, ¶¶ 14, 15, 17, 18.

Rosalie is not alone. Consider the story of Margaret Carpenter, a New York doctor who mailed FDA-approved mifepristone to a Louisiana woman who forced the drug on her pregnant teenage daughter. ROA.261-263; ROA.1440-1450; ROA.1451-1456. The teen faced a medical emergency alone at home, called 911, and was rushed to the hospital in an ambulance. ROA.1457-1460. Or consider data from the Louisiana Department of Health showing that over $92,000 in Medicaid dollars were paid for emergency room care and hospitalization resulting from just *two* mifepristone-induced abortions in 2025—ordered from and mailed by out-of-state prescribers through Aid Access, which trafficks FDA-approved mifepristone. ROA.2520-2521, ¶¶ 11–12. And these instances are just two examples of many women believed to have suffered similar adverse events requiring emergency medical care at Louisiana hospitals, paid for by Louisiana Medicaid. ROA.2521, ¶¶ 13–14.

These stories are not just disturbing but entirely predictable. That is because, as this Court has observed, the federal government's "own documents" show that "emergency room care is statistically certain" in

mifepristone cases. *Alliance I*, 2023 WL 2913725, at *10. For example, FDA's own mifepristone label states that roughly 1 in 25 (or 4% of) women who take mifepristone *as directed* will end up in the emergency room. ROA.334-335; ROA.2529-2530, ¶¶ 30–31. And this statistic was calculated *before* the Biden Administration removed the requirement for an initial in-person visit—the only opportunity to screen for dangerous conditions like ectopic pregnancy, to accurately assess gestational age, to screen for coercion and trafficking, and to ensure informed consent. ROA.2527-2529, ¶¶ 21, 22–28; ROA.2533-2534, ¶ 41; ROA.2536, ¶ 49. The label also features a Black Box warning that mifepristone can cause "[s]erious and sometimes fatal infections and bleeding" and that mifepristone can cause other problems warranting emergency attention. ROA.328-329; ROA.2529-2532, ¶¶ 31–37, ROA.2532-2533, ¶ 38; ROA.2534-2536, ¶¶ 42–48. What's more, there is good reason to believe that the emergency-room-visit rate is at least as high as 11%, ROA.2531, ¶ 34; ROA.426-427—and the industry's own data demonstrates that dispensing mifepristone by mail exacerbates that rate. *See* ROA.1030-1031 (FDA stating the Hyland study showed higher-than-labeled hospitalizations by mail after an ultrasound); ROA.1037 ("Study reports

of Raymond, Chong, and Kerestes all suggest there may be an increase in ED/urgent care visits with telemedicine visits and dispensing by mail without increases in other adverse events."); ROA.1037 (suggesting "a pre-abortion examination may decrease the occurrence of procedural intervention and decrease the number of unplanned visits for postabortion care"); ROA.2395-2396; *see also* ROA.2523-2538, ¶¶ 23-25, 32, 41. It is thus unsurprising that the flood of mifepristone into Louisiana under the 2023 REMS is directly resulting in life-threatening harm to Louisiana's women and babies, as well as identifiable sovereign and monetary harms to Louisiana itself.

C. Louisiana Spends Significant Time and Resources to Prevent the Illegal Mailing of Mifepristone.

Because of the seriousness of this issue, Louisiana has expended substantial time and resources attempting to stop the mailing of mifepristone into the State. That includes over $17,000 in investigatory costs related to just three investigations. ROA.5731, ¶ 6. That also includes outstanding arrest warrants for Dr. Carpenter and the California doctor Rosalie's ex-boyfriend engaged, Dr. Remy Coeytaux. ROA.1440-1450; ROA.261-263; ROA.110-127, ¶¶ 100–102, 115, 159. But, predictably, governors in states like New York and California have

pursued every avenue available to thwart pro-life states from stopping the mifepristone flood. New York Governor Kathy Hochul, for example, refused to extradite Dr. Carpenter: "Let me be clear: we will never comply with Louisiana's extradition request. Not now, not ever." ROA.1477-1478; *see also* Governor Gavin Newsom (@GavinNewsom), X (Feb. 5, 2026, 8:43 PM), perma.cc/46CV-HMZ9. Acting upon the 2023 REMS's removal of the in-person dispensing requirement, New York, California, and other states have also passed aggressive "shield" laws that, among other things, permit doctors and clinics to omit identifying information from pill bottles—so that mifepristone can arrive in Louisiana without indicating who sent it. *See, e.g.*, ROA.2397-2406 (California law giving doctors "the option to prescribe abortion care medication to patients anonymously"). The stated intent: to prevent pro-life states from stopping the importation of abortion drugs.

Given those difficulties, Louisiana and Rosalie tried a different tack on September 19, 2025, when they filed a motion to intervene in the still-pending *Alliance* litigation. *See Missouri v. FDA*, No. 22-cv-223 (N.D. Tex. Sept. 19, 2025), ECF 264, 265. Following the Supreme Court's decision in *Alliance*, the States of Kansas, Idaho, and Missouri moved to intervene

in the *Alliance* district court to continue the litigation—and Louisiana and Rosalie sought to join that fight. On September 30, 2025, however, the *Alliance* district court transferred the case to the Eastern District of Missouri and denied Louisiana's and Rosalie's intervention motion as moot. *Missouri*, ECF 273 at 1. Four business days later, Louisiana and Rosalie filed their complaint in this case. ROA.82-132. They sought a stay, and ultimately vacatur, of the 2023 REMS, which causes irreparable harm to Louisiana and its citizens every day.

The importance of a preliminary stay of the 2023 REMS became blindingly clear after Plaintiffs filed this suit. Under pressure from pro-life states and advocates, Secretary Kennedy announced on September 19, 2025, that, "through the FDA, HHS will conduct a study of the safety of the current REMS, in order to determine whether modifications are necessary." ROA.2201. Yet on December 8, 2025, it was publicly reported that then-FDA Commissioner Marty Makary "ha[d] told agency officials to delay [a] safety review [of mifepristone] until after the midterm elections." ROA.2409. He later admitted that study data had not yet been acquired. *See* ROA.2419. Regardless, if FDA attempts to rescind or modify the 2023 REMS based on the results of its study, the governing

statutory framework imposes a timeline of nearly a year before that action could take effect. *See* 21 U.S.C. ¶ 355-1. So absent preliminary relief in this case, Louisiana and its citizens faced the prospect of unbounded and illegal mifepristone-induced abortions for years, if not longer. That was untenable—and so Plaintiffs sought a preliminary stay of the 2023 REMS. *See* ROA.2582-2612.

D. The District Court Denies Plaintiffs' Requested Relief and Grants a Stay of the Lawsuit.

On April 7, 2026, the district court issued a decision that did everything but grant a stay of the 2023 REMS. ROA.9084-9120. The district court observed—as two prior Fifth Circuit panels had observed—that Plaintiffs were likely to succeed on the merits of their arbitrary-and-capricious challenge to the 2023 REMS. That is partly because FDA improperly "based its decision on the absence of data [known as FAERS data] that it had only five years previously intentionally eliminated." ROA.9109. That is also because FDA improperly "relied on various literature relating to remote prescription of mifepristone—despite FDA's admission that the literature did not affirmatively support its position." ROA.9110 (citation omitted). The district court underscored this fact by pointing to Secretary Kennedy's and Commissioner Makary's public

statements that the 2023 REMS was plagued by a "lack of adequate consideration" and "recent safety concerns." ROA.9110-9111. Indeed, HHS announced it was duty-bound to study mifepristone because the Biden Administration had "removed mifepristone's in-person dispensing rule without studying the safety risks." ROA.85.

The district court also agreed that Louisiana has Article III standing to sue. It acknowledged that "the evidence in the record shows that the 'independent actors'—that is, the out-of-state medical providers prescribing mifepristone via telemedicine or mail—responded to the 2023 REMS by expanding mifepristone access to pro-life states like Louisiana in ways that were entirely predictable." ROA.9102-9103. And, "in that post-*Dobbs* regulatory environment," the court continued, "there is evidence that the 2023 REMS was approved without adequate consideration, at least in part, as part of an effort to circumvent anti-abortion states' ability to regulate abortion." ROA.9104. That predictable conduct, in turn, "cause[s] concrete and ongoing injury to Louisiana." *Id.*

The district court found "Louisiana has put forth sufficient evidence to demonstrate that it has suffered and continues to suffer pocketbook injury," ROA.9107—namely, record evidence of "more than $92,000 in

Medicaid costs incurred [by Louisiana] for emergency room care and hospitalizations required because of two mifepristone-induced abortions in 2025 in which the drugs were received from out-of-state prescribers" sending FDA-approved mifepristone. ROA.9108; *see also* ROA.2520-2521, ¶¶ 11–12. And while that evidence "alone [is] sufficient to establish Louisiana's standing, [] it is likely that many more Medicaid patients have required similar care due to complications from mifepristone," ROA.9108 (citing ROA.2521, ¶¶ 13–15; ROA.2515-2516, ¶¶ 7–8; ROA.2563, ¶¶ 14–16); *see also* ROA.435 (Medicaid-specific study finding significantly higher ER-visit acuity following chemical abortion). Indeed, the district court observed that such costs are "statistically certain" in the nearly 1,000 mifepristone cases arising each month in Louisiana—not just because FDA's own label emphasizes that emergency care will be required, but also because the record evidence shows that "many [Louisiana] women obtaining [mifepristone] abortions are likely to be on Medicaid." *Id.*; *see* ROA.2607-2609 (collecting citations).

All of this was in addition to sovereign injury. The district court found that the 2023 REMS "directly undermines the enforcement of [Louisiana's] laws." ROA.9105. And "Louisiana clearly has an interest in

vindicating its sovereign prerogative under basic principles of federalism." *Id.*

Relying on the same record evidence, the district court held that Louisiana is suffering irreparable harm absent a stay of the 2023 REMS. Given the federal Defendants' sovereign immunity, Louisiana cannot obtain a remedy for its ongoing "financial injury." ROA.9111. And "Louisiana suffers sovereign harm each time those laws are circumvented," and "[n]o remedy at law can redress that sovereign harm." *Id.*

Notwithstanding that it had just made the strongest case for granting Louisiana preliminary relief, the district court ended its decision by denying relief under a "balance of the equities and public interest" analysis and staying the litigation. The court's reasons are not altogether clear, but the following appear to be central: (1) the court did not wish to be "a forum for resolving moral or policy" (or scientific) disagreements, ROA.9111-9112; (2) the court was concerned that other courts across the country might generate "inconsistent judicial outcomes" on this issue, ROA.9114, ROA.9118; (3) the court did not wish to grant

"nationwide" relief, ROA.9115-9116; and (4) "FDA's review should be conducted and completed free from judicial interference," ROA.9118.

E. This Court Grants a Preliminary Stay of the 2023 REMS.

On May 1, 2026, a panel of this Court entered the preliminary stay of the 2023 REMS that Plaintiffs requested. The Court's opinion largely agreed with the district court in all material respects. On standing, the Court confirmed that Louisiana suffers economic injuries in the form of Medicaid costs—costs that "will almost certainly continue because nearly 1,000 women monthly—many of whom are on Medicaid—have mifepristone-induced abortions in Louisiana." ECF.119-1 at 11. And the record contains "hard evidence linking [those] thousands of dollars in Medicaid costs to care stemming from out-of-state mifepristone." ECF.119-1 at 12. The Court also confirmed that Louisiana is suffering sovereign harm from the 2023 REMS given that it "facilitates" illegal abortions in Louisiana, notwithstanding that "Louisiana law bans administering, prescribing, procuring, or selling a drug like mifepristone to end the life of an unborn human being." ECF.119-1 at 9–10.

On the "most critical" preliminary-relief factors, ECF.119-1 at 6, the Court likewise agreed with the district court. Joining the two prior

Fifth Circuit panels, the stay panel held that Plaintiffs are likely to succeed in this APA challenge to the 2023 REMS because: (1) "FDA gave 'dispositive weight' to the lack of adverse-event data in a reporting system (known as 'FAERS')" even though "FDA had previously eliminated the requirement to report mifepristone's adverse events to FAERS," ECF.119-1 at 13; and (2) "FDA 'relied on various literature relating to remote prescription of mifepristone—despite FDA's admission that the literature did not affirmatively support its position,'" *id.* Thus, Louisiana "has strongly shown a likelihood of winning its APA challenge to the 2023 REMS." ECF.119-1 at 14.

Similarly, the Court "agree[d] with the district court that Louisiana has shown it is suffering irreparable harm, largely for the same reasons Louisiana has shown injury for standing purposes." *Id.* Specifically, "the 2023 REMS injures Louisiana by undermining its laws protecting unborn human life and also by causing it to spend Medicaid funds on emergency care for women harmed by mifepristone"—and "[b]oth injuries are irreparable." *Id.*

On the balance of the equities and the public interest, however, this Court parted ways with the district court. The Court began by

emphasizing that "neither the FDA nor the public has any interest in enforcing a regulation that violates federal law." ECF.119-1 at 15 (citation modified). That is especially so here where the Fifth Circuit has "now three times found that the agency's progressive relaxation of mifepristone's guardrails likely lacked a basis in data and scientific literature"—and "FDA itself now concedes the regulations were marred by 'procedural deficits' and a 'lack of adequate consideration.'" *Id.* "The public interest is not served by perpetuating a medical practice whose safety the agency admits was inadequately studied. Indeed, the public interest demands the opposite." ECF.119-1 at 15–16. And to the extent the Manufacturers face "compliance costs" and decreased "mifepristone profits," those "pale beside Louisiana's sovereign interest in its laws protecting the unborn and the public's interest in not exposing women to unsafe medical procedures." ECF.119-1 at 16.

The Court then explained why the district court's concerns were misplaced. With respect to whether a court must adjudicate moral and scientific disputes in this case, this Court said no: "Despite dealing with the charged subject of abortion, at bottom the case is an APA challenge to a regulation, a task courts routinely undertake." ECF.119-1 at 16–17.

With respect to the district court's desire to let the alleged FDA review proceed apace, the Court observed that "[g]ranting a stay would do nothing to prevent FDA from completing its review of mifepristone's safety protocols." ECF.119-1 at 17. In fact, "[a]s Louisiana points out, it 'makes no sense to deny preliminary relief on the grounds that agency action is so unlawful that the agency openly concedes a review is necessary.'" *Id.* And who knows when, if ever, the alleged review will conclude (or even begin in earnest): This Court explained that "FDA cannot even say when its review will conclude—perhaps over a year from now because it has not finished collecting data." *Id.* With respect to the possibility of conflicting judicial outcomes across the country, the Court noted that this "does not absolve courts from deciding the cases before them." ECF.119-1 at 18. And with respect to the prospect of nationwide relief, the Court—like the parties—did not identify any narrower form of relief that would redress Louisiana's harm; so, the panel simply said that nothing forecloses such relief under the APA. *Id.*

Intervenor-Defendants Danco and GenBioPro (the Manufacturers) immediately sought a stay of the Fifth Circuit's order. On May 14, 2026, the Supreme Court granted the Manufacturers' applications for stay in

an unreasoned order, pending disposition of this appeal and a decision on certiorari. *Danco Lab'ys, LLC v. Louisiana*, 146 S. Ct. 1192 (2026). Justice Thomas dissented on the ground that—as Judge Ho wrote in *Alliance II*—the shipping of FDA-approved mifepristone into Louisiana "violates the Comstock Act." *Id.* at 1193 (Thomas, J., dissenting) (citation omitted). In his view, therefore, the Manufacturers were "not entitled to a stay of an adverse order based on lost profits from their criminal enterprise." *Id.* Justice Alito likewise dissented on the ground that the Manufacturers "have not shown that they face any imminent risk of irreparable injury." *Id.* at 1196 (Alito, J., dissenting). In reaching that conclusion, Justice Alito explained that the 2023 REMS is the central piece of "the perpetration of a scheme to undermine our decision in *Dobbs*[.]" *Id.* at 1193.

SUMMARY OF ARGUMENT

I. As both the district court and the stay panel concluded, Plaintiffs are likely to succeed on the merits of their challenge to the 2023 REMS under the APA.

A. That is principally so because Louisiana has Article III standing, which flows from both economic injuries and sovereign injuries.

1. To start, the 2023 REMS is causing Louisiana to suffer economic injuries, and a favorable ruling would redress those injuries. In particular, Louisiana identified two unrebutted pocketbook injuries: (a) evidence of over $90,000 in Medicaid costs from just two hospitalizations caused by FDA-approved mifepristone unlawfully mailed into the State; and (b) over $17,000 in enforcement costs caused by FDA-approved mifepristone unlawfully mailed into the State. Those injuries are directly traceable to the 2023 REMS: Without the 2023 REMS's removal of the in-person dispensing requirement, there would be no mail-order, FDA-approved mifepristone in Louisiana, and thus no Medicaid costs or enforcement costs arising from such mifepristone. And by the same token, those injuries are redressable by a stay (and ultimately vacatur) of the REMS. As one of the Manufacturers' supporters put it, the 2023 REMS is the "lifeline" that allows for the infusion of FDA-approved mifepristone into Louisiana that is causing Louisiana's harm. *See* Press Release, *5th Circuit Limits Telehealth Provision of Abortion Pill*, Ctr. for Reproductive Rights (May 1, 2026), perma.cc/7D7N-AK3U. Naturally, removing that lifeline will mitigate, if not eliminate, Louisiana's harm.

2. Louisiana's economic injuries are bolstered by Louisiana's sovereign injuries, which independently constitute injuries in fact. The Supreme Court has long held that a state's ability to create and enforce a legal code is one of the quintessential functions of a state. Two distinct types of injuries strike at the core of that sovereign prerogative and are directly traceable to the REMS (and redressable by a stay and vacatur).

First, a violation of a sovereign's law is an Article III injury to the state's sovereignty. That is because, since the common law, such a violation has been understood to be a public wrong that offends the sovereign itself. And that is the situation here: Nobody disputes that Louisiana's pro-life laws are being violated some 1,000 times per month when out-of-state actors mail FDA-approved mifepristone into Louisiana. Those injuries in fact are directly traceable to the 2023 REMS, which greenlit the mailing of FDA-approved abortion drugs into Louisiana and other pro-life states. So, too, vacating the 2023 REMS would restore the in-person dispensing requirement, thereby redressing Louisiana's violation-of-law harms.

Second, Louisiana's inability to enforce its pro-life laws is an independent sovereign Article III injury. In a world with the in-person

dispensing requirement, Louisiana would be fully capable of enforcing its laws because prescribers would have to be physically present in the State to dispense mifepristone—and thus, they would be subject to regulation and apprehension in the State. But with the 2023 REMS's removal of that requirement, out-of-state prescribers may (and do, nearly 1,000 times a month) mail mifepristone into Louisiana with impunity. Here, too, that injury is directly traceable to the 2023 REMS. And restoring the in-person dispensing requirement would subject prescribers to regulation and prosecution, redressing Louisiana's injuries.

B. Turning to the merits, FDA correctly has declined to defend the 2023 REMS on APA review. That is so for two reasons that three panels of this Court (and two district judges) have adopted—and for a third reason adopted by Judge Ho and Justice Thomas.

First, FDA arbitrarily concluded that FAERS data supported removing the in-person dispensing requirement. As the panels in this Court have recognized, that is the definition of arbitrariness and capriciousness because FDA's own public statements repeatedly acknowledge that FAERS data *cannot* be used to indicate drug safety. That is because reporting is voluntary, and so FDA does not receive

reports for every adverse event that occurs. Worse, FDA is responsible for the absence of probative data: In 2016, the agency eliminated the requirement that abortion drug providers report serious adverse events other than death. It is thus plainly unreasonable for the agency to have both eliminated that requirement and then used the resulting absence of data to justify the 2023 REMS's removal of the in-person dispensing requirement.

Second, FDA arbitrarily relied on scientific literature to justify removing the in-person dispensing requirement. As the panels of this Court have recognized, the agency relied on certain literature despite admitting that the literature did not affirmatively support the agency's removal of the in-person dispensing requirement. The most FDA could say was that those studies were not inconsistent with FDA's apparently predetermined conclusion that removing the in-person dispensing requirement would be safe. But that, of course, flunks the basic APA question of whether an agency's action is reasoned and reasonable—and even FDA has conceded that its cited literature was not adequate on its own to make a safety determination.

Third, as Judge Ho and Justice Thomas have written, the 2023 REMS is contrary to law because it violates the Comstock Act. The Act bars the shipment of abortion drugs, but the 2023 REMS's avowed purpose is to facilitate the shipment of abortion drugs—especially across state lines from pro-abortion states into pro-life states. That is precisely what the Comstock Act prohibits. And although the district court and the stay panel did not need to reach this issue, it provides an independent basis for determining that Plaintiffs are likely to succeed on the merits.

II. Beyond the merits, the remaining preliminary-relief factors weigh in favor of staying the 2023 REMS. That is principally because of the equities. The Manufacturers face no irreparable harm from a stay, whereas (as both the district court and stay panel agreed) Louisiana faces irreparable harms in the form of unrecoverable economic injuries and irremediable sovereign injuries. On top of that, the public interest favors a stay of the 2023 REMS. As the stay panel reiterated, neither FDA nor the public has any interest in enforcing a regulation that violates federal law. Indeed, FDA's concession that it did not give adequate consideration to safety risks posed by the 2023 REMS reinforces that the public interest demands a stay of the REMS.

The stay panel likewise correctly resolved the district court's remaining reasons for denying a § 705 stay of the REMS. Among those reasons, the district court was concerned about becoming entangled in moral and scientific disputes; that is incorrect, the stay panel noted, since this is a standard APA case, which courts handle every day. The district court also was concerned about the alleged ongoing FDA review—but nothing prohibits FDA from completing that review. And last, the district court was concerned about the likely nationwide effect of a stay and how that would intersect with potentially conflicting judicial decisions elsewhere. The stay panel rightly rejected that concern because the Supreme Court exists to resolve any such conflicts, and this Court's precedents squarely govern the scope of § 705 relief, particularly here where no one has been able to identify any narrower scope of relief that would redress Louisiana's harm.

Plaintiffs therefore respectfully request that the Court enter a § 705 stay of the 2023 REMS, just as the stay panel did.

LEGAL STANDARD

This Court "review[s] a district court's denial of a preliminary injunction for abuse of discretion." *Childress ex rel. Childress v. Tate*

Cnty. Sch. Dist., 384 F. App'x 430, 430 (5th Cir. 2010) (per curiam). "The failure to follow an applicable statute is always an abuse of discretion." *United States v. Klein*, 543 F.3d 206, 215 (5th Cir. 2008). Similarly, "[a] district court abuses its discretion if it (1) relies on clearly erroneous factual findings; (2) relies on erroneous conclusions of law; or (3) misapplies the law to the facts." *Villarreal v. Wells Fargo Bank, N.A.*, 814 F.3d 763, 767 (5th Cir. 2016) (citation omitted).

ARGUMENT

I. PLAINTIFFS ARE LIKELY TO SUCCEED ON THE MERITS.

Both the district court and a unanimous stay panel have already determined that Louisiana has standing to challenge the 2023 REMS and is likely to succeed on the merits. Those conclusions warrant a stay of the 2023 REMS in Plaintiffs' favor.

A. Louisiana Has Article III Standing.

Start with 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." *Alliance*, 602 U.S. at 380. A "general principle" governing this inquiry is that "courts may make 'commonsense inferences' when

assessing Article III standing, including inferences about 'third party behavior.'" *First Choice Women's Res. Centers, Inc. v. Davenport*, 146 S. Ct. 1114, 1125 (2026) (citing *Diamond Alt. Energy, LLC v. EPA*, 606 U.S. 100, 116 (2025)).

Here, as both the district court and the stay panel recognized, common sense makes this a straightforward inquiry. Louisiana has suffered, and continues to suffer, economic and sovereign injuries. And those injuries are each independently caused by the 2023 REMS and redressable by a stay of the REMS.

1. The 2023 REMS is causing Louisiana to suffer economic injuries, and a favorable ruling would redress those injuries.

a. "Pocketbook harm is a traditional Article III injury." *Bost v. Ill. State Bd. of Elections*, 607 U.S. 71, 84 (2026) (Barrett, J., concurring in the judgment). Such an injury exists "not only when a law directly imposes costs on a plaintiff, but also when a plaintiff reasonably incurs costs to mitigate or avoid the substantial risk of a harm caused by a [challenged action]." *Id.* (citation modified). "[A] loss of even a small amount of money is ordinarily an injury," *Czyzewski v. Jevic Holding Corp.*, 580 U.S. 451, 464 (2017)—"even *one dollar's worth of harm*"

suffices, *United States v. Texas*, 599 U.S. 670, 688 (2023) (Gorsuch, J., concurring) (emphasis added).

Here, Louisiana identified two unrebutted pocketbook injuries. *First*, Louisiana offered undisputed evidence of over $90,000 in Medicaid costs from just two hospitalizations caused by FDA-approved mifepristone unlawfully mailed into the State. ROA.2520-2521, ¶¶ 11–12; ROA.2592; ROA.2609. As FDA told this Court, "no one disputes that Medicaid costs constitute an Article III injury." ECF.74 at 22. Nor could they. *See Texas*, 599 U.S. at 690 (Gorsuch, J., concurring in the judgment) (Texas and Louisiana established an Article III injury because they "proved that, as a result [of the challenged Guidelines], they spend more money on everything from law enforcement to healthcare."); *Pennsylvania v. President United States*, 930 F.3d 543, 562, 564 (3d Cir. 2019), *as amended* (July 18, 2019), *rev'd and remanded sub nom. Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 591 U.S. 657 (2020) (finding likely "financial injury" because women losing employer coverage would "turn to state-funded services," including Medicaid), *cert. granted sub nom. Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 589 U.S. ___ (2020), *rev'd on other grounds*,

591 U.S. 657 (2020). Louisiana's quantifiable Medicaid expenditures are an injury in fact.

Second, Louisiana offered unrebutted evidence of enforcement costs. Investigations into just three instances of unlawfully mailed abortion drugs have cost the State over $17,000. *See* ROA.5731, ¶ 5–6. Those monetary costs were reasonably incurred to mitigate the harms Louisiana is facing and thus independently constitute an Article III injury. *See Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 153–55 & n.3 (2010) (finding that the costs of additional testing and preventive measures to guard against contamination risk created by agency action "satisfy the injury-in-fact prong"); *Bost*, 607 U.S. at 84 (Barrett, J., concurring in the judgment).

Financial costs borne by an unregulated party as a downstream consequence of an unlawful agency action have long been recognized as sufficient for standing. In *Motor Vehicle Manufacturers Association v. State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29 (1983), the Supreme Court entertained on the merits a challenge brought by insurance companies to the rescission of safety standards for new motor vehicles. Automobile manufacturers—not the insurers—were the

regulated entities. Yet the Court adjudicated the insurers' claim that the rescission was arbitrary and capricious without questioning their standing to sue. "At no point in that landmark opinion on the judicial review of agency actions did the Court state (or need to state) the obvious ...." *Corner Post, Inc. v. Bd. of Governors of the Fed. Rsrv. Sys.*, 603 U.S. 799, 834 (2024) (Kavanaugh, J., concurring). The "premise of *State Farm*"—that the unregulated, downstream insurers had an available remedy and no redressability problem—"was presumably obvious to all involved." *Id.* at 835. Louisiana's position here is identical in structure: an unregulated party bearing direct financial costs from rescission of a protective rule.

b. Louisiana's economic injuries are directly traceable to the 2023 REMS. The but-for causation here is straightforward: Without the 2023 REMS's removal of the in-person dispensing requirement, there would be no mail-order, FDA-approved mifepristone in Louisiana. If there is no mail-order, FDA-approved mifepristone, there are no Medicaid costs or enforcement expenditures arising from it. So every dollar Louisiana has spent on hospitalizations caused by mailed mifepristone—and every dollar spent investigating violations of its laws by out-of-state

prescribers—traces directly to the deregulatory action that made mail-order dispensing possible in the first place. The 2023 REMS did not marginally increase a preexisting cost; it created an entirely new category of harm that would not exist but for FDA's decision to eliminate the in-person dispensing requirement.

Department of Commerce v. New York is instructive. There, several states challenged the addition of a citizenship question to the Census, arguing that noncitizen households would under-respond and reduce federal funding allocated by population. The Supreme Court credited that theory—not "on mere speculation about the decisions of third parties," but on "the predictable effect of Government action on the decisions of third parties." 588 U.S. 752, 768 (2019).

This is an *a fortiori* case. In *Department of Commerce*, the Supreme Court did not know whether noncitizens would in fact be undercounted—that is why the Court needed to invoke the "likely" and "predictable" responses of noncitizens. Here, no prognostication is necessary: The mailings are already occurring—nearly 1,000 packages per month—and the resulting costs are already documented. Louisiana's theory "does not rest on mere speculation about the decisions of third parties." *Id.* It rests

on the undisputed reality that FDA authorized a form of drug distribution that did not previously exist, and every financial consequence of that distribution traces back to the authorization. *See Diamond Alt. Energy, LLC*, 606 U.S. at 125 ("The government generally may not target a business or industry through stringent and allegedly unlawful regulation, and then evade the resulting lawsuits by claiming that the targets of its regulation should be locked out of court as unaffected bystanders.").

c. Louisiana's economic injuries also are redressable. "[C]ausation and redressability … are often 'flip sides of the same coin.'" *Alliance*, 602 U.S. at 380. So for the same reasons explained above, reinstating the 2023 REMS would redress Louisiana's economic harm by ending the mailings of FDA-approved mifepristone into Louisiana that is causing the State's economic harm.

Redressability is satisfied even when "a favorable decision" will not "relieve … *every* injury," *Larson v. Valente*, 456 U.S. 228, 243 n.15 (1982), and even if redress is not certain but is only "likely," *Diamond Alt. Energy, LLC*, 606 U.S. at 114. Louisiana easily meets this standard. And the Manufacturers' own supporters confirm this. The National

Organization for Women and Center for Reproductive Rights claims that reinstating the in-person dispensing requirement would remove a "lifeline" enabling women in pro-life states to access abortion. Press Release, *This Was a Blatantly Political Ruling That Endangers Women's Lives*, Nat'l Org. for Women (May 2, 2026), perma.cc/YP5J-9PTP; Press Release, *5th Circuit Limits Telehealth Provision of Abortion Pill*, Ctr. for Reproductive Rights (May 1, 2026), perma.cc/7D7N-AK3U. If reinstating the in-person requirement would cut off the "lifeline" that funnels FDA-approved mifepristone into Louisiana, it follows that Louisiana's Medicaid and enforcement costs traceable to that flow would likely be redressed. *Dep't of Comm.*, 588 U.S. at 768.

Because Louisiana's documented Medicaid and enforcement costs flow directly from the 2023 REMS's removal of the in-person dispensing requirement and would be eliminated by its reinstatement, Louisiana has Article III standing.

2. The 2023 REMS is causing Louisiana to suffer sovereign injuries, and a favorable ruling would redress those injuries.

Beyond its economic injuries, Louisiana is also suffering harm to its "sovereign interest[]" in "creat[ing] and enforc[ing] a legal code." *Alfred*

L. Snapp & Son, Inc. v. Puerto Rico, 458 U.S. 592, 601 (1982). The power to create and enforce a legal code "is one of the quintessential functions of a State." *Diamond v. Charles*, 476 U.S. 54, 65 (1986). "Because the State alone is entitled to create a legal code, only the State has the [requisite] kind of 'direct stake' ... in defending the standards embodied in that code." *Id.*; *Heath v. Alabama*, 474 U.S. 82, 93 (1985) ("Foremost among the prerogatives of sovereignty is the power to create and enforce a criminal code.").

Embedded within these principles are two distinct, but related, types of injuries that strike at the core of state sovereignty: violations of state law and the inability to enforce those laws. Here, the 2023 REMS inflicts two distinct sovereign injuries on Louisiana: It generates nearly 1,000 independent violations of state law each month, and it renders those laws practically impossible to enforce.

a. Violations of state law

A "violation of [a sovereign's] laws" is an Article III injury to its "sovereignty." *Vt. Agency of Nat. Res. v. U.S. ex rel. Stevens*, 529 U.S. 765, 771 (2000). This fact flows from the historical understanding of crimes as "public wrong[s]" that are "injur[ies] to the sovereign in its sovereign

capacity." *Ellingburg v. United States*, 607 U.S. 163, 179 (2026) (Thomas, J., concurring) (cataloguing historical sources, including Blackstone and Locke). As Blackstone explained long ago, the sovereign "is supposed by the law to be the person injured by every infraction of the public rights belonging to that community, and is therefore in all cases the proper prosecutor for every public offense." 4 William Blackstone, *Commentaries on the Laws of England* at 2. That is why the King could sue for public wrongs. Indeed, as the *Stevens* Court held, a violation of federal law is "the United States' injury in fact" that gives a *qui tam* relator—as "partial assign[ee]" of the United States' claim—"Article III standing" to sue under the False Claims Act. 529 U.S. at 773 & n.4, 774, 778.

i. Against this historical backdrop, the district court and the stay panel correctly held that Louisiana is suffering sovereign Article III injuries. Nobody disputes that Louisiana's pro-life laws are being violated every month when out-of-state actors mail FDA-approved mifepristone into Louisiana. La. R.S. 40:1061(C); La. R.S. 14:87.9(A) (banning mifepristone dispensation for nearly all abortions); La. R.S. 40:1061.11(A) (requiring in-person dispensing for any permitted prescriptions). Each such "violation of [Louisiana's] laws" is an Article III

injury to Louisiana's "sovereignty." *Stevens*, 529 U.S. at 771. Or, put in historical terms, each such violation is a "public wrong" that "injur[es] [Louisiana] in its sovereign capacity." *Ellingburg*, 607 U.S. at 179 (Thomas, J., concurring). These violations constitute cognizable "injur[ies] in fact." *Stevens*, 529 U.S. at 774.

ii. These violations of Louisiana's laws are directly traceable to the 2023 REMS. The chain of causation begins with the challenged policy—the removal of the in-person dispensing requirement—and ends with the very next step: the mailing of FDA-approved mifepristone into Louisiana in violation of state law. In contrast to *Alliance*, Louisiana's sovereign injury requires no "follow-on" events. *See* 602 U.S. at 391. Rather, the act of mailing mifepristone into Louisiana in violation of state law *is itself* the sovereign injury.

As explained above, moreover, Louisiana does not "rest on mere speculation about the decisions of third parties." *Dep't of Comm.*, 588 U.S. at 768. To the contrary, the Manufacturers do not (and cannot) dispute that nearly 1,000 independent violations of Louisiana's laws occur *each* month. Louisiana's sovereign standing rests on the *actual* decisions of the Manufacturers' certified prescribers, repeated 1,000 times every month

in Louisiana. "Because Article III 'requires no more than *de facto* causality,'" *id.*, and it does not require that the named defendants be "the sole cause" of the asserted injury, *Texas v. United States*, 50 F.4th 498, 519 (5th Cir. 2022), the causal link between the 2023 REMS and Louisiana's sovereign injuries is plain.

This was an entirely "predictable chain of events," *Alliance*, 602 U.S. at 385, because it was by design. *See Diamond Alt. Energy, LLC*, 606 U.S. at 125 ("The government generally may not target … through … regulation, and then evade the resulting lawsuits by claiming that the targets … should be locked out of court as unaffected bystanders."). The day the Supreme Court decided *Dobbs*, President Biden publicly set his sights on those pro-life states that "severely restrict access to medication for reproductive health care." ROA.956. He directed his Secretary of Health and Human Services "to identify all ways to ensure that mifepristone is as widely accessible as possible ... including when prescribed through telehealth and sent by mail." *Id.* His administration followed up with threats ("states may not ban mifepristone") and pledged "to allow mifepristone to continue to be prescribed by telehealth and sent by mail." ROA.1230-1231. And his Department of Health and Human

Services publicly announced that, "[s]ince *Dobbs*, HHS has worked to protect and expand access to reproductive care," specifically highlighting the removal of the in-person dispensing requirement as fulfillment of that goal. ROA.1226; ROA.1239. It is no surprise then that prescribers in pro-abortion states—freed from the in-person dispensing requirement—have proceeded precisely as envisioned: by mailing mifepristone into pro-life states in violation of those states' laws. As Justice Alito put it, this "scheme to undermine [the] decision in *Dobbs*" "would not have been possible under FDA regulations had the Federal Government not taken steps in 2021 and 2023 to facilitate mail-order abortions." *Danco Lab'ys, LLC*, 146 S. Ct. at 1193–94 (Alito, J., dissenting).

iii. Vacating the 2023 REMS would restore the in-person dispensing requirement and redress Louisiana's violation-of-law harms. The mailing of FDA-approved mifepristone into Louisiana would once again violate federal regulations. And the so-called "shield" laws in pro-abortion states intended to protect those who mail mifepristone extraterritorially would accomplish exactly nothing. As one abortion historian explained after this Court gave Louisiana interim relief in this case, "[t]his would be the silver bullet that [a pro-life state legislature] has been looking for in

terms of shutting down access to abortion . . . . If [a pro-life state] wants to go after doctors in other states . . . shield laws won't protect those doctors if the federal law no longer allows them to operate via telehealth." Sophia Paffenroth, *The Supreme Court is deciding the fate of mail-order abortion pills. How will it affect Mississippians?*, Mississippi Today (May 12, 2026), perma.cc/2WR4-YSR9. Reinstating the in-person dispensing requirement would thus directly redress Louisiana's sovereign injuries by eliminating the federal-law mechanism that permits—and even incentivizes—the monthly violations of Louisiana's laws.

b. Inability to enforce state law

The second sovereign injury caused by the 2023 REMS is the inability to enforce Louisiana's pro-life laws. "[A] State 'clearly has a legitimate interest in the continued enforceability of its own statutes.'" *Cameron v. EMW Women's Surgical Ctr., P.S.C.*, 595 U.S. 267, 277 (2022) (citing *Maine v. Taylor*, 477 U.S. 131, 137 (1986)). "This means that a State's opportunity to defend its laws in federal court should not be lightly cut off." *Id.*

That is why there is a storied tradition of states suing to stave off federal interference with state laws and operations. *See, e.g.*, *Bowen v.*

Pub. Agencies Opposed to Social Sec. Entrapment, 477 U.S. 41, 50 n.17 (1986) (affirming that California "plainly" had Article III standing "because it alleged 'a judicially cognizable interest in the preservation of its own sovereignty, and a diminishment of that sovereignty by the alleged interference in its employment relations with its public employees'"); *Taylor*, 477 U.S. at 136–37 (holding that a state has "a sufficient stake in the outcome of the controversy" to satisfy Article III where the application of federal law will render its own law unenforceable); *Alaska v. U.S. Dep't of Transp.*, 868 F.2d 441, 444 (D.C. Cir. 1989) (Starr, J.) ("Inasmuch as this preemptive effect is the injury of which petitioners complain, we are satisfied that the States meet the standing requirements of Article III.").

It is also why the United States can sue to stop state and local interference with federal laws and operations. *See, e.g.*, *Arizona v. United States*, 567 U.S. 387 (2012) (United States preemption challenge to Arizona immigration statute); *United States v. Missouri*, 114 F.4th 980, 984 (8th Cir. 2024) (finding injury because "[t]he United States has a legally protected interest in enforcing federal law" and "[t]he United States presented uncontroverted evidence that implementation of the

[challenged state law] impaired that interest"); *United States v. King Cnty., Wash.*, 122 F.4th 740, 750 (9th Cir. 2024) (finding injury because a challenged county executive order prevented Immigration and Customs Enforcement from conducting charter flights at a particular airfield).

The Supreme Court's irreparable injury cases further confirm that states have standing to challenge federal statutes and regulations that thwart the enforceability of state law. If there were no sovereign injury where—as here—a federal agency renders state law unenforceable, then there would be no irreparable injury when a federal court enjoins the enforcement of a state's law. Yet a long line of precedent holds that irreparable injury occurs when a court enjoins the enforcement of state (or federal) law. *See Trump v. CASA, Inc.*, 606 U.S. 831, 861 (2025) ("'[A]ny time a State is enjoined by a court from effectuating statutes enacted by representatives of its people, it suffers a form of irreparable injury'" (quoting *Maryland v. King*, 567 U.S. 1301, 1303 (2012) (Roberts, C.J., in chambers)); *Abbott v. Perez*, 585 U.S. 579, 602 (2018) (barring a state from enforcing its election statute "would seriously and irreparably harm the State"); *Trump v. Int'l Refugee Assistance Project*, 582 U.S. 571, 581–82 (2017) (per curiam) (refusing to stay a lower court injunction

would implicate the "government's interest in enforcing" the law and "appreciably injure its interests").

i. Here, the 2023 REMS renders the "'continued enforceability of [Louisiana's] own statutes'" impossible. *Cameron*, 595 U.S. at 277 (citing *Maine*, 477 U.S. at 137). In a world with the in-person dispensing requirement, Louisiana would be fully capable of enforcing its abortion laws—for prescribers would be physically present in Louisiana and thus subject to apprehension within Louisiana's borders. But that is not the world today: The 2023 REMS's removal of the in-person dispensing requirement permits out-of-state prescribers to mail mifepristone into Louisiana with impunity. Because that new tactic accounts for the overwhelming majority (if not all) of illegal abortions in Louisiana today, the practical impact on Louisiana's laws is to render them useless. Louisiana "plainly" has Article III standing "because it allege[s] 'a judicially cognizable interest in the preservation of its own sovereignty.'" *Bowen*, 477 U.S. at 50 n.17.

Dobbs promised a "restor[ation] [of] the people's authority to address the issue of abortion through the processes of democratic self-government established by the Constitution." *Dobbs v. Jackson Women's*

Health Org., 597 U.S. 215, 338 (2022) (Kavanaugh, J., concurring). But for pro-life states like Louisiana, their democratic processes—and their chosen laws—have been rendered hollow by the 2023 REMS. That attack on the "continued enforceability of [Louisiana's] own statutes'" is unquestionably a cognizable Article III injury. *Cameron*, 595 U.S. at 277 (citing *Maine*, 477 U.S. at 137).

ii. The unenforceability of Louisiana law is directly traceable to the 2023 REMS. The 2023 REMS's removal of the in-person dispensing requirement permits out-of-state prescribers to mail mifepristone into Louisiana while evading apprehension within Louisiana's borders. Without the REMS, prescribers would be required to be physically present in Louisiana to lawfully dispense FDA-approved mifepristone under FDA's regulations—and a prescriber physically present in Louisiana is subject to Louisiana's enforcement authority. The 2023 REMS is thus the but-for cause not only of the monthly violations but also of Louisiana's inability to do anything about them. Given that Article III "requires no more than *de facto* causality," *Dep't of Comm.*, 588 U.S. at 768, traceability plainly exists.

iii. The unenforceability of Louisiana's law is redressable by vacatur of the 2023 REMS. Again, reinstatement would require any prescriber dispensing FDA-approved mifepristone to be physically present in Louisiana—and subject to apprehension, prosecution, and the full force of Louisiana's pro-life laws. Vacating the 2023 REMS would thus restore the State's practical ability to enforce its statutes, redressing its inability-to-enforce injury.

Because the 2023 REMS generates ongoing, undisputed violations of Louisiana's law and renders that law practically unenforceable, Louisiana's sovereign injuries are concrete, traceable to the REMS, and redressable by its vacatur. Accordingly, Louisiana has Article III standing.

* * *

The Supreme Court has repeatedly admonished lower courts not to "make standing law more complicated than it needs to be." *Diamond Alt. Energy, LLC*, 606 U.S. at 125 (citation omitted). That admonition is directly appropriate here. Louisiana's standing "is evident"—and the district court and the stay panel correctly recognized as much. *Id.*

B. FDA Correctly Has Refused to Defend the 2023 REMS on the Merits.

There is a reason FDA has refused to defend the 2023 REMS, and there is a reason that now three separate Fifth Circuit panels and two district judges have held that the 2023 REMS is likely unlawful: The 2023 REMS fails APA review six ways to Sunday.

At the outset, as the stay panel wrote, it is wrong to suggest that Plaintiffs are asking any court to second-guess FDA's "scientific" determinations. "This case ... does not ask courts to resolve such matters," but is instead an ordinary "APA challenge to a regulation, a task courts routinely undertake." ECF.119-1 at 16–17. Under the APA, an agency "must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *State Farm*, 463 U.S. at 43 (citation modified). It is then incumbent upon the reviewing court to assess "whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Id.* (citation modified). Where, as here, an agency changes its longstanding position, it must adequately explain itself and "show that there are good reasons

for the new policy." *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221 (2016).

Applying these basic principles, the district court and the stay panel, like its predecessors in the *Alliance* litigation, correctly concluded that FDA's removal of its longstanding in-person dispensing requirement likely violates the APA. *First*, FDA erred in giving "dispositive weight" to FAERS data. ECF.119-1 at 13. *Second*, FDA erred in relying on various literature that the agency admitted was "not adequate on [its] own" to establish the safety of mail-order mifepristone. ECF.119-1 at 14. *Third*, the 2023 REMS is contrary to law because it violates the plain text of the Comstock Act.

1. FDA arbitrarily concluded that FAERS data supported removing the in-person dispensing safeguard.

a. As the various courts have unanimously concluded, FDA principally flunks arbitrary-and-capricious review because it gave dispositive weight to adverse event data in FAERS in the safety review. Rather than dispute FDA's scientific determination, the courts found the agency's own explanation deficient. For good reason: FDA's *own* public

statements repeatedly acknowledge that FAERS data *cannot* be used to indicate drug safety.

FDA cautions that "[r]ates of occurrence [for an adverse event] cannot be established with [FAERS] reports." ROA.1108. That is because reporting is "voluntary," and thus "FDA does not receive reports for every adverse event … that occurs." *Id.* Indeed, FDA's website warns: (1) "[t]he number of suspected reactions in FAERS should not be used to determine the likelihood of a side effect occurring," *id.*; and (2) "FAERS data cannot be used to calculate the incidence of an adverse event or medication error in the U.S. population," ROA.1106. Summarizing the utility of the data, FDA says that "the FAERS data by themselves are not an indicator of the safety profile of the drug." ROA.1108.

Yet in removing the longstanding safeguard of in-person dispensing, FDA used FAERS data for just those prohibited purposes. The agency said that it "analyzed the FAERS data" from parts of 2020 and 2021 "to determine if there was a difference in adverse events when in-person dispensing was and was not enforced." ROA.374; *see also* ROA.1075-1078. It was plainly arbitrary for FDA to have dispositively relied on data that the agency conceded "are not an indicator of the safety

profile of a drug" and "cannot be used to calculate the incidence of an adverse event," ROA.1106-1108, to indicate the safety profile of the drug and calculate the incidence of adverse events.

As this Court has pointed out, moreover, FDA is responsible for the paucity of FAERS data. That is because, in 2016, the agency removed the requirement that abortion drug providers report serious adverse events other than deaths to FDA. ROA.415. As the Court has said, "[o]bviously, '[i]t's unreasonable for an agency to eliminate a reporting requirement for a thing and then use the resulting absence of data to support its decision.'" ECF.119-1 at 13. "This ostrich's-head-in-the-sand approach is deeply troubling—especially" for a high-risk drug that "necessitates a REMS program … and a 'Black Box' warning." *Alliance I*, 2023 WL 2913725, at *17. And that is a textbook arbitrary-and-capricious problem.

b. The Manufacturers have thus far defended FDA's reliance on FAERS data on the ground that most prescription drugs do not require adverse event reporting. But most prescription drugs do not carry a Black Box warning and send roughly 1 in 25 women to the emergency room. Regardless, this Court and others did not find that FDA *should* require adverse event reporting, but that FDA's decision to remove a

longstanding safeguard *based on* concededly unreliable data was arbitrary and capricious.

Similarly, the Manufacturers have argued that Congress directed FDA to rely on FAERS data when making safety determinations. It did no such thing. 21 U.S.C. § 355-1(a)(1)(E) directs FDA to consider adverse event reports (which are not the same thing as FAERS data) in determining whether to *require* REMS safeguards in approving a new drug. And § 355-1(b)(3) similarly defines "new safety data" to include "adverse event report[s]" (but not FAERS data) for the purpose of *requiring* REMS safeguards on drugs approved without them. In short, there is zero statutory support for the argument that Congress directed FDA to rely on FAERS data in *removing* REMS safeguards.

2. FDA arbitrarily relied on scientific literature to justify removing the in-person dispensing requirement.

The stay panel also correctly held that FDA's "reli[ance] on various literature ... despite FDA's admission that the literature did not affirmatively support its position" likely violates the APA. ECF.119-1 at 13.

Illustrating the point, FDA has conceded that "the studies [it] reviewed are *not adequate on their own* to establish the safety of the model of dispensing mifepristone by mail." ROA.1093 (emphasis added). Full stop. That concession conclusively establishes that FDA's reliance on the studies was unreasonable. In fact, the best FDA could say for the studies was that they were "not inconsistent with" its apparently predetermined conclusion that removing the initial in-person visit would be safe. *Id.* That is cold comfort to women taking these high-risk drugs without the safeguards FDA once declared crucial. It also violates the APA. *See State Farm*, 463 U.S. at 52 ("The agency must explain the evidence which is available, and must offer a rational connection between the facts found and the choice made." (citation modified)).

Though FDA has never made such an argument, the Manufacturers have argued that agencies may make decisions in the "absence of data" and that FDA "reasonably predicted" in-person dispensing could be eliminated without compromising women's safety. *Cf. FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021). Not so. Under the governing framework, FDA must *reject* an application or modification for a drug unless "adequate tests," test "results," and "[]sufficient information"

demonstrate the drug safe for use "under the conditions … in the proposed labeling." 21 U.S.C. § 355(d) (initial approval); 21 C.F.R. § 314.71 (modification).

Ironically, it is the Manufacturers who invite this Court to delve into scientific deep waters. They have defended FDA's reliance on the literature by arguing that the studies did not identify any new or increased risks without in-person dispensing. Again, that is beside the point. FDA's own rationale flunks arbitrary and capricious review. But it is also wrong. To the extent the studies showed anything, it was an *increase* in risk. FDA admitted that "the literature [for 'mail order dispensing studies with telemedicine visits'] suggests there may be more frequent ED/urgent care visits related to the use of mifepristone when dispensed by mail." ROA.1088. FDA also observed that one study found that "those without an examination or ultrasound prior to medical abortion were more likely to require procedural interventions and had more unplanned clinical encounters." ROA.1085. And FDA noted that a second study showed that the rate of emergency department visits (5.8 percent) in a "telemedicine + mail group" exceeded the label (2.0 to 4.6 percent) and was almost three times higher than for women who had an

in-person visit (2.1 percent). ROA.1086. Meanwhile, yet another study saw hospitalization rates soar beyond the less-than-1-percent figure on the label to reach 3 percent of women mailed abortion drugs (not including seven patients hospitalized without follow-up information). ROA.1082. All of these deficiencies explain why FDA found these studies inadequate. ROA.1093. It was plainly arbitrary and capricious for FDA to nevertheless rely on them.

It is also wrong to claim (as the Manufacturers have) that the fifteen studies reviewed by FDA all support the conclusion that dispensing by mail, courier, or through pharmacies is safe and effective. To the contrary, FDA explicitly discredited 4 studies (Rocca (ROA.1029), Hyland (ROA.1031), Endler (ROA.1039), Norten (ROA.1039)); stated 2 were not generalizable to the U.S. population (Grossman (ROA.1029), Wiebe (ROA.1029)); said 3 were of limited usefulness or had limited certainty of results (Upadhyay (ROA.1030), Aiken 2021 (ROA.1036-1037), Reynolds-Wright (ROA.1037-1038)); and warned that 1 needed to be interpreted carefully (Anger (ROA.1033)). Plus, the vast majority of study participants in the remaining five studies (Grossman (2021 Contraception) (ROA.1029), Raymond (ROA.1032), Chong (ROA.1032-

1033), Kerestes (ROA.1035), Aiken 2017[2] (ROA.1038)) had either a pelvic examination or ultrasound prior to taking the drugs—a safeguard that goes above and beyond even the in-person dispensing safeguard FDA stripped away. In other words, most participants in the five studies principally relied upon by FDA were mailed mifepristone only *after* receiving either an in-person examination or an ultrasound. FDA was therefore unquestionably correct in admitting that "the studies [it] reviewed are *not adequate on their own* to establish the safety of the model of dispensing mifepristone by mail." ROA.1093 (emphasis added).

In sum, FDA violated the APA by relying on FAERS data that the agency concedes are not an indicator of mifepristone's "safety profile" and scientific literature it admitted was "not adequate." The arbitrariness of FDA's decision is heightened because it conflicts with decades of agency findings concluding that the in-person office visit was both "necessary" and "minimally burdensome." Appl. for Stay at 4, 13, *FDA v. ACOG*, No. 20A34, (U.S. Aug. 26, 2020) (2020 FDA Stay Appl.). While an agency may change its mind, it must adequately explain its reasons for doing so. *State*

[2] FDA fails to mention in its decisional document that 58% of women who participated in this study had their gestational age confirmed through ultrasound prior to taking mifepristone.

Farm, 463 U.S. at 56. This doesn't come close. No wonder the current FDA has conceded that the 2023 REMS approval "lack[ed] [] adequate consideration." ROA.2201.

3. The 2023 REMS is also contrary to law because it violates the Comstock Act.

Although the district court did not need to proceed further, it bears noting that the 2023 REMS independently violates the APA in light of the Comstock Act. The Act prohibits using "the mails" to send any "drug … advertised or described in a manner calculated to lead another to use or apply it for producing abortion." 18 U.S.C. § 1461. It also forbids using a "common carrier or interactive computer service" to ship "any drug ... designed, adapted, or intended for producing abortion." *Id.* § 1462(c). The 2023 REMS authorizes the widespread shipping of abortion drugs. Yet as Judge Ho explained, mailing drugs that cause abortion is "precisely what the Comstock Act prohibits." *Alliance II*, 78 F.4th at 268 (Ho, J., concurring in part and dissenting in part); *accord Danco Lab'ys, LLC*, 146 S. Ct. at 1193 (Thomas, J., dissenting) (agreeing with Judge Ho). Under straightforward statutory interpretation principles, the 2023 REMS is contrary to law—and that is an independent basis for determining that Plaintiffs are likely to succeed on the merits.

II. THE REMAINING FACTORS WEIGH IN FAVOR OF PRELIMINARY RELIEF.

The Manufacturers[3] also face no irreparable harm; the equities and the public interest weigh in favor of preserving the Fifth Circuit's decision; and any complaints about the scope of relief are misplaced.

A. The Manufacturers Face No Irreparable Harm.

Prior briefing demonstrates that the Manufacturers have no serious claim of irreparable harm. *See Labrador v. Poe*, 144 S. Ct. 921, 929 (2024) (Kavanaugh, J., concurring in the grant of stay) ("If the moving party has not demonstrated irreparable harm, then this Court can avoid delving into the merits."). Their historical lead argument is that they face "substantial uncertainty" about their obligations and next steps following the Fifth Circuit's decision. That claim of uncertainty is contrived, *see infra*, but more importantly, no case from this Court suggests that ascertaining proper legal compliance (a run-of-the-mill business chore) is somehow irreparable harm.

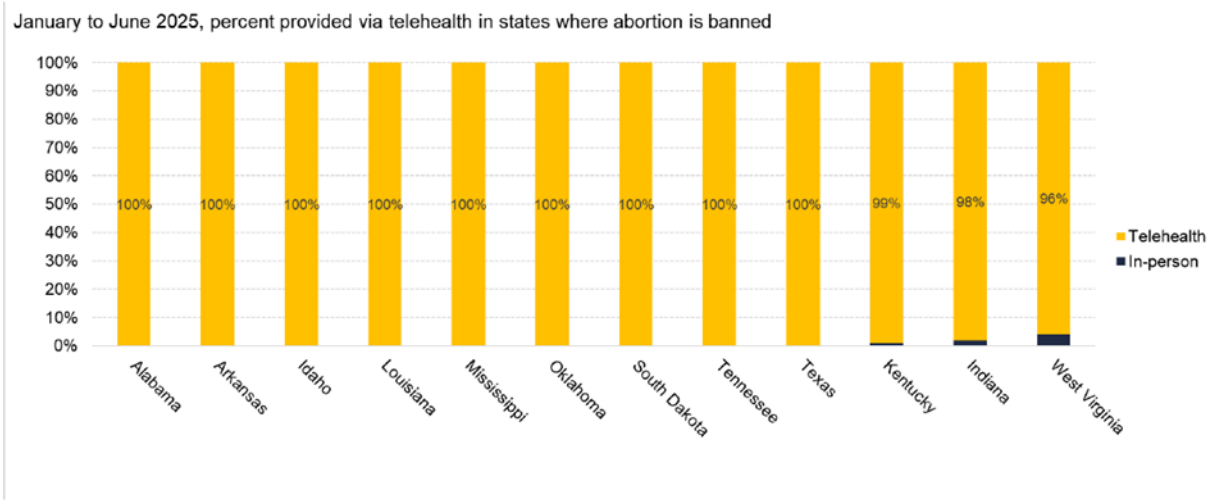
Here, too, common sense leads the way: The Manufacturers' real fear is that, with a stay of the 2023 REMS in place, they might not be

[3] In the Supreme Court, the federal Defendants declined to participate in briefing surrounding the stay panel's decision to preliminarily stay the 2023 REMS. For that reason, Plaintiffs here focus on the Manufacturers.

able to sell as many abortion drugs as they would like. Danco's counsel was candid about this when previously pressed by Justice Alito. *See* Oral Arg. Tr. at 52, *FDA v. All. for Hippocratic Med.*, No. 23-235 (U.S.) (Q: "And so I gather your injury is that you think you're going to sell more if the restrictions that previously were in place were lifted." A: "Yes."). Increasing one's profits is a fine business strategy, but it is not a serious claim of irreparable harm that justifies denying Plaintiffs' requested relief.

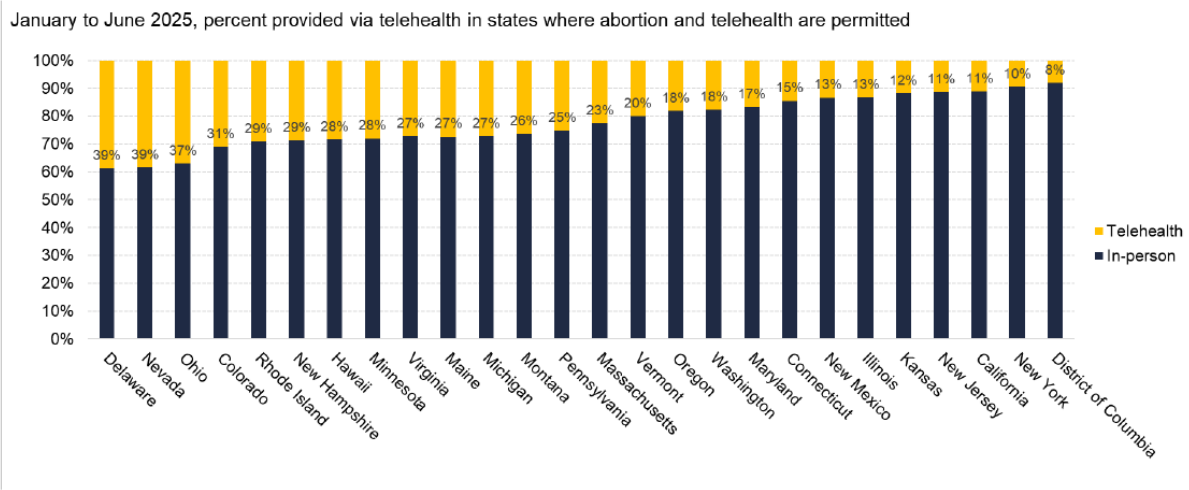
Moreover, Plaintiffs' relief would not meaningfully disrupt "lawful" mail-order abortion-drug sales (setting aside their illegality under the Comstock Act). In states like New York and California, mail-order abortions account for only 10 and 11 percent of all abortions, respectively. ROA.2333. The worry about losing sales comes mostly from pro-life states, where mail-order abortions account for 100 percent of all abortions:

Where abortion is banned, nearly all abortions were provided via telehealth under shield laws



Source: Society of Family Planning, December 2025

Where abortion and telehealth are permitted, the share of abortions provided via telehealth varied widely



Source: Society of Family Planning, December 2025

ROA.2333; ROA.2335. The Manufacturers cannot transform "lost profits from their criminal enterprise" into irreparable harm. *See Danco Lab'ys, LLC*, 146 S. Ct. at 1193 (Thomas, J., dissenting).

B. The Balance of the Equities Favors a Stay.

The foregoing makes the balancing of the equities easy. There is no question that Louisiana suffers irreparable harm while the 2023 REMS is in effect. That is so as to the financial injuries—*i.e.*, enforcement costs and Medicaid costs—Louisiana has suffered, and continues to suffer, as long as the 2023 REMS is in effect. As both the district court and the stay panel agreed, "because FDA 'is entitled to sovereign immunity,' Louisiana's financial harms are [] irremediable." ECF.119-1 at 15; *accord* ROA.9111. And as the stay panel put it, Louisiana's sovereign harm is likewise irreparable: "Every abortion facilitated by [the 2023 REMS] cancel's Louisiana's ban on medical abortions and undermines its policy that 'every unborn child is a human being from the moment of conception and is, therefore, a legal person.'" ECF.119-1 at 14. "Once lost, that sovereign prerogative of protecting unborn life cannot be regained by legal remedy." ECF.119-1 at 14–15.

FDA and the Manufacturers have yet to seriously dispute Louisiana's irreparable harm. And that irreparable harm wins the day in the balancing of the equities—because, as just explained, the Manufacturers have virtually nothing on their side of the ledger other than a desire to increase their own profits by selling more abortion drugs. Nor does the FDA have any interest in maintaining an unlawful regulation. *See* ECF.119-1 at 15.

Resisting this fact, the Manufacturers have tried to undercut Louisiana's irreparable harm by complaining that Louisiana unduly delayed in seeking preliminary relief. But neither the district court nor the stay panel credited that complaint—and that was not an abuse of discretion. Moreover, the timeline surrounding Louisiana's request is not a signal that the State faces no irreparable harm (it does); it is instead a product of the extraordinarily difficult situation in which Louisiana finds itself. The Manufacturers' prescribers are blanketing the State in mifepristone anonymously, which makes it nearly impossible to identify the source of any given drug. The Manufacturers' prescribers also are telling individuals who take mifepristone to lie (*e.g.*, claim a miscarriage) to doctors and nurses about the real cause of any adverse events they

suffer. *See, e.g.*, ROA.2521, ¶ 14; ROA.2515-2516, ¶ 7; ROA.2532, ¶ 37; *see also* ROA.2563, ¶ 17; ROA.91-92, ¶ 39 (citing examples); ROA.108-109, ¶¶ 92-93. And the only reason Louisiana finally was able to obtain statewide mifepristone data in 2025 is that the Manufacturers' prescribers disclosed that information to a pro-abortion nonprofit. In every way, therefore, Louisiana is being stymied by the Manufacturers' own prescribers. The Manufacturers thus have no legitimate basis to complain that Louisiana did not more expeditiously build out this lawsuit and request relief.

That says nothing, moreover, of the deference Louisiana gave to FDA to resolve this problem. Louisiana spent significant time in 2025 pressing for an agency-based solution. Louisiana even held off on requesting preliminary relief in light of Secretary Kennedy's September 2025 promise that HHS "will conduct a study" of the 2023 REMS. ROA.2594. But Louisiana could not wait any longer when, in December 2025, news broke that the FDA Commissioner had ordered agency officials "to delay [a] safety review [of mifepristone] until after the midterm elections." ROA.2409. Louisiana then immediately sought preliminary relief. As the district court and the stay panel recognized,

there is no ground to deny relief on supposed delay grounds, particularly where Louisiana is likely to prevail in this suit and is suffering ongoing irreparable harm.

All this makes for an easy equities analysis.

C. The Public Interest Likewise Favors Preliminary Relief.

That leaves only the public-interest inquiry—and that analysis, too, is easy. This Court has already gotten this part right: Louisiana wins this inquiry if it wins the merits (as it is likely to do). In particular, "neither the FDA nor the public has any interest in enforcing a regulation that violates federal law." ECF.119-1 at 15 (citation and alteration omitted). Moreover, given FDA's concessions about the "procedural deficits" and "lack of adequate consideration" undergirding the 2023 REMS, "[t]he public interest is not served by perpetuating a medical practice whose safety the agency admits was inadequately studied. Indeed, the public interest demands the opposite." ECF.119-1 at 15–16.

D. The District Court's Remaining Concerns Are Misplaced.

Finally, the stay panel correctly recognized that the district court's remaining reasons for denying preliminary relief are misplaced.

For example, while the district court worried about having to adjudicate moral and scientific disputes, the stay panel dispelled that worry: "Despite dealing with the charged subject of abortion, at bottom the case is an APA challenge to a regulation, a task courts routinely undertake." ECF.119-1 at 16–17. Similarly, the district court identified a concern with letting the alleged FDA review proceed apace, but the stay panel observed that "[g]ranting a stay would do nothing to prevent FDA from completing its review of mifepristone's safety protocols." ECF.119-1 at 17. "As Louisiana points out, it 'makes no sense to deny preliminary relief on the grounds that agency action is so unlawful that the agency openly concedes a review is necessary.'" *Id.* And FDA's promises thus far on the timeline of its safety review have rung hollow: "FDA cannot even say when its review will conclude—perhaps over a year from now because it has not finished collecting data." *Id.*

Last, with respect to the possibility of conflicting judicial outcomes across the country, the stay panel noted that this possibility "does not absolve courts from deciding the cases before them." ECF.119-1 at 18. And although a stay of the REMS under § 705 necessarily would have nationwide effect, neither the district court, the stay panel, nor the

parties have been able to identify any narrower form of relief that would redress Louisiana's harm; so, as the stay panel said, nothing forecloses such relief under the APA. *Id.*

CONCLUSION

The Court should grant a § 705 stay of the 2023 REMS.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on June 15, 2026, I filed the foregoing brief with the Court's CM/ECF system, which will automatically send an electronic notice of filing to all counsel of record.

/s/ J. Benjamin Aguiñaga
J. BENJAMIN AGUIÑAGA

CERTIFICATE OF COMPLIANCE

Pursuant to Fifth Circuit Rule 32.3, the undersigned certifies that this motion complies with:

(1) the type-volume limitations of Federal Rule of Appellate Procedure 32(a)(7) because it contains 12,957 words; and

(2) the typeface requirements of Rule 32(a)(5) and the type-style requirements of Rule 32(a)(6) because it has been prepared in a proportionally spaced typeface (14-point Century Schoolbook) using Microsoft Word 2016 (the same program used to calculate the word count).

/s/ J. Benjamin Aguiñaga
J. BENJAMIN AGUIÑAGA

Dated: June 15, 2026