Nos. 25A1207, 25A1208

In the Supreme Court of the United States

DANCO LABORATORIES, L.L.C.,
Applicant,

v.

LOUISIANA, ET AL.,
Respondents.

GENBIOPRO, INC.,
Applicant,

v.

LOUISIANA, ET AL.,
Respondents.

OPPOSITION TO DANCO LABORATORIES, L.L.C.'S AND GENBIOPRO, INC.'S APPLICATIONS FOR A STAY OR VACATUR

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Supreme Court Rule 29.6, Respondents each represent that they do not have any parent entities and do not issue stock.

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INTRODUCTION

While this Court was preparing to "return the issue of abortion to the people's elected representatives," *Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215, 232 (2022), the Biden Administration was preparing a plan that predictably would undermine that decision. That plan turned on the abortion drug mifepristone. For decades, the U.S. Food and Drug Administration (FDA) closely regulated mifepristone. One such regulation was an in-person dispensing requirement, which, among other things, ensured that a woman was operating free from coercion and that mifepristone would not pose a unique danger to her health.

Mere days after oral argument in *Dobbs*, however, the Biden Administration decided to permanently remove the in-person dispensing requirement. And when this Court decided *Dobbs*, President Biden immediately—that same day—directed his Administration to preserve the availability of mifepristone "in States that are banning or severely restricting abortion care." He threatened pro-life states, claiming that they "may not ban mifepristone." And he specifically pledged that mifepristone would be "as widely accessible as possible," including "by mail."

That effort culminated in the 2023 Risk Evaluation and Mitigation Strategy (REMS), which permanently removed the longstanding in-person dispensing requirement. President Biden's Department of Health and Human Services (HHS) would later cite the removal of the in-person dispensing requirement as one example of how, "[s]ince *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."

The 2023 REMS's effect on Louisiana has been astounding. Although Louisiana law generally prohibits abortion and the dispensing of mifepristone to pregnant women, out-of-state prescribers—freed from the in-person dispensing requirement—are causing approximately 1,000 illegal abortions in Louisiana each month by mailing FDA-approved mifepristone into the State. Those violations of Louisiana law, in turn, are directly causing tens of thousands of dollars of harm to Louisiana in the form of investigatory costs and Medicaid costs from statistically certain emergency room visits. Louisiana thus had no choice but to file this suit alongside one of her citizens, Rosalie Markezich, who tragically was coerced to abort her baby by an ex-boyfriend who took advantage of mail-order mifepristone under the 2023 REMS.

The 2023 REMS fails to comply with the Administrative Procedure Act. Three Fifth Circuit panels have now held as much. *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); CA5.ECF.119-1 (La.App.1016-34). FDA's position is that the 2023 REMS reflects a "lack of adequate consideration" and that the Biden Administration "removed mifepristone's in-person dispensing rule without studying the safety risks." And—perhaps most striking—FDA has affirmatively refused to defend the 2023 REMS in this litigation. Given these facts, the Fifth Circuit properly determined that Plaintiffs are entitled to a stay of the 2023 REMS.

Two abortion drug manufacturers, Danco and GenBioPro (GBP), now seek to

lift that stay—because they wish to increase their profits by selling more abortion drugs and otherwise avoid compliance costs that flow from a stay of the 2023 REMS. Setting aside that they have not identified a threat of irreparable harm requiring this Court's extraordinary intervention, the Manufacturers lack any serious merits arguments.

Their briefs almost exclusively attack Louisiana's Article III standing. But the "violation of [Louisiana's] laws" is a quintessential injury in fact—an injury to Louisiana's "sovereignty." *Vt. Agency of Nat. Res. v. U.S. ex rel. Stevens*, 529 U.S. 765, 771 (2000). The threat posed to "'the continued enforceability of [Louisiana's] own statutes'" likewise constitutes an injury in fact. *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)). And the classic pocketbook injuries bound up in those sovereign harms leave no room for doubt. *See Bost v. Ill. State Bd. of Elections*, 146 S. Ct. 513, 524 (2026) (Barrett, J., concurring in the judgment); *United States v. Texas*, 599 U.S. 670, 688 (2023) (Gorsuch, J., concurring).

Causation and redressability also are eminently straightforward: The 2023 REMS's removal of the in-person dispensing requirement "predictabl[y]," *Dep't of Comm. v. New York*, 588 U.S. 752, 768 (2019), prompted out-of-state doctors to begin mailing mifepristone into Louisiana to the tune of 1,000 abortions a month—in fact, that was President Biden's pledge. And without the 2023 REMS, there is no dispute that such prescribers could not lawfully (under federal law) continue blanketing Louisiana in mifepristone. If ever there were a case for "mak[ing] 'commonsense

inferences' when assessing Article III standing, including inferences about 'third party behavior,'" this is it. *First Choice Women's Res. Ctr., Inc. v. Davenport*, 2026 WL 1153029, at *8 (U.S. Apr. 29, 2026) (citing *Diamond Alt. Energy, LLC v. EPA*, 606 U.S. 100, 116 (2025)).

Perhaps sensing as much, the Manufacturers desperately try to paint this case as a redux of *FDA v. Alliance for Hippocratic Medicine*, 602 U.S. 367 (2024). It is not. *Alliance* had no occasion to consider the standing theories uniquely available to a plaintiff state. And the scope of Louisiana's challenge is comparatively narrower: The Fifth Circuit partial stay the *Alliance* Court considered "would have left Mifeprex (though not generic mifepristone) on the market, but only under the more stringent requirements imposed when FDA first approved Mifeprex in 2000—available only up to seven weeks of pregnancy, only when prescribed by doctors, and only with three in-person visits, among other requirements." *Id.* at 377. By contrast, the stay entered by the Fifth Circuit panel below leaves both Mifeprex and generic mifepristone on the market under the same conditions leading up to the promulgation of the 2023 REMS.

It is not obvious that this case is a likely candidate for certiorari. But, even if it were, the Manufacturers are not entitled to a stay of the Fifth Circuit's decision in advance of that review. The Manufacturers have no merits defense of the REMS (they say nothing about FDA's own refusal to defend it); they have no serious argument that their desire to make more money somehow outweighs Louisiana's own sovereign and economic harms absent a stay; and they have no claim that the public has any interest in perpetuating an unlawful agency action that the agency itself refuses to

defend, particularly where the very unlawfulness involves a failure to adequately assess safety risks. If the Court nonetheless were inclined to grant a stay, Plaintiffs would acquiesce in certiorari before judgment and oral argument before the summer recess.

BACKGROUND

1. 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. To that end, Louisiana law prohibits all abortions except those that are determined to be 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 narrow 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 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, hundreds of abortions are occurring 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." Dist.Ct.ECF.1-50 at 6 (La.App.256). 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." Dist.Ct.ECF.1-47 at 3 (La.App.242). 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." Dist.Ct.ECF.1-44 at 2 (La.App.233); *see* Dist.Ct.ECF.1-45 (La.App.237) (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 accordingly "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*." Dist.Ct.ECF.1-47 at 3 (La.App.242) (emphasis added); Dist.Ct.ECF.1-60 at 2–3 (La.App.413-14) (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 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." Dist.Ct.ECF.1-48 at 2 (La.App.244). "[W]e will double down," then-Secretary Becerra said, "and use every lever we have to protect access to abortion care." *Id.*; *see also* Dist.Ct.ECF.1-49 at 2, 4 (La.App.246, La.App.248); Dist.Ct.ECF.1-61 at 4, 7 (La.App.419, La.App.422); *accord* Dist.Ct.ECF.1-59 at 2 (La.App. 409) ("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, Dist.Ct.ECF.1-3 at 2 (La.App.121); Dist.Ct.ECF.1-50 at 9, 16 (La.App.259, La.App.266), 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; Dist.Ct.ECF.1-21 at 4 (La.App.231).

2. 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." Dist.Ct.ECF.1-106 at 2 (La.App.474). "We're confident people in ... every state ... will still be able to get abortion pills by mail," said another. *Id.* at 3.

To carry out this attack, organizations like AidAccess.org have blanketed the Internet with order forms for FDA-approved mifepristone, Dist.Ct.ECF.1-71 (La.App.441-43), extolling the ease with which New York and California doctors may immediately inject pills into locales from Baton Rouge to Lafayette:

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

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. Dist.Ct.ECF.1-2 at 36 (La.App.87). Just days before Louisiana filed its request for preliminary relief, 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. Dist.Ct.ECF.20-2 at 36 (La.App.519); Dist.Ct.ECF.20-22 at 1–2 (La.App.620-21).

There are real women and real-world harms behind those numbers. *See, e.g.*, Dist.Ct.ECF.20-23, ¶¶ 8–13, 15–16, 17–20 (La.App.641, La.App.642); Dist.Ct.ECF.20-18, ¶¶ 8–12 (La.App.591); Dist.Ct.ECF.20-19, ¶¶ 2–9 (La.App.594-95); Dist.Ct.ECF.20-24, ¶¶ 2–8 (La.App.645-46) (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. Dist.Ct.ECF.1-92 at ¶ 16 (La.App.471). She told her then-boyfriend that she wanted to raise their unborn baby. *Id.* ¶¶ 5, 10 (La.App.469-70). 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. *Id.* ¶¶ 7, 8, 9 (La.App.469-70). She pleaded with him, "Don't make me do this." *Id.* ¶ 11 (La.App.470). But he grew angry and erratic, his behavior escalating so much that she was terrified and took the drugs in front of him as a means to escape. *Id.* ¶¶ 12 (La.App.470). She ended up on a bathroom floor for an hour, and then a garage, as she began bleeding out—an unspeakable experience that continued "for about a week" and "still haunts [her]." *Id.* ¶¶ 14, 15, 18 (La.App.471).

Rosalie is not alone. Consider the well-known story of Margaret Carpenter, a New York doctor who mailed mifepristone to a Louisiana woman who forced the drug on her pregnant teenage daughter. Dist.Ct.ECF.1-4 (La.App.124-25); Dist.Ct.ECF.1-84 (La.App.445-54); Dist.Ct.ECF.1-85 (La.App.456-60). The teen faced a medical

emergency alone at home, called 911, and was rushed to the hospital in an ambulance after delivering a dead fetus. Dist.Ct.ECF.1-86 (La.App.462-64). 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. Dist.Ct.ECF.20-20, ¶¶ 11–12 (La.App.599). 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. *Id.* ¶ 13.

These stories are not just disturbing but entirely predictable. That is because, as the Fifth Circuit 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. Dist.Ct.ECF.1-9 at 8–9, 16 (La.App.134-35, La.App.142); Dist.Ct.ECF.20-21, ¶¶ 30–31 (La.App.608). And this was *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. Dist.Ct.ECF.20-21, ¶¶ 22–28, 41, 49 (La.App.606-08, La.App.612-13, La.App.615). 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. Dist.Ct.ECF.1-9 at 2

(La.App.128); Dist.Ct.ECF.20-21, ¶¶ 31–32, 38, 42–48 (La.App.608-09, La.App.613-15). What's more, there is good reason to believe that the emergency-room-visit rate is at least as high as 11%, Dist.Ct.ECF.20-21, ¶ 34 (La.App.610)—and FDA's own data demonstrates that dispensing mifepristone by mail exacerbates that rate. *See* Dist.Ct.ECF.1-13 at 2 (La.App.217); Dist.Ct.ECF.20-4 (La.App.553; *see also* Dist.Ct.ECF.1-50 at 75 (La.App.323); Dist.Ct.ECF.1-10 at 34–35 (La.App.180-81). 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.

3. 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. Dist.Ct.ECF.111 at 4 & n.4 (La.App.746). That also includes outstanding arrest warrants for Dr. Carpenter and the California doctor Rosalie's ex-boyfriend engaged, Dr. Remy Coeytaux. Dist.Ct.ECF.1-84 (La.App.445-54); Dist.Ct.ECF.1 at 46, ¶ 159 (La.App.46). 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." Dist.Ct.ECF.1-90 (La.App.466). New York 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 a

pill bottle with mifepristone can arrive in Louisiana without indicating who sent it. *See, e.g.*, *Governor Newsom signs new landmark laws to protect reproductive freedom, patient privacy amid Trump's war on women*, Gov. Gavin Newsom (Sept. 26, 2025), perma.cc/SB5E-V4QB (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. Dist.Ct.ECF.1 (La.App.001). 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 had 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." Dist.Ct.ECF.1-110 at 2 (La.App.478). Yet on December 8, 2025, it was publicly reported that FDA Commissioner Marty Makary "ha[d] told agency officials to delay [a] safety review [of mifepristone] until after the midterm elections." Dist.Ct.ECF.20-6 (La.App.556). He later admitted that study had not yet been acquired. Dist.Ct.ECF.20-7 (La.App.566-71). In other words, FDA would not consider taking action on the 2023 REMS until 2027 at the earliest. And if FDA attempts to rescind or modify the 2023 REMS, 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 at least two more years if not longer. That was untenable—and so Plaintiffs sought a preliminary stay of the 2023 REMS. *See* Dist.Ct.ECF.20-26 (La.App.647).

4. On April 7, 2026, the district court issued a decision that all but granted a stay of the 2023 REMS. Dist.Ct.ECF.258 (La.App.864-900). The district court observed—as two prior Fifth Circuit panels had observed—that Plaintiffs were likely to succeed on the merits of its 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." Dist.Ct.ECF.258 at 26 (La.App.889). 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." Dist.Ct.ECF.258 at 27 (La.App.890) (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." Dist.Ct.ECF.258 at 28 (La.App.891); *see* Dist.Ct.ECF.1 at 4 (La.App.004) (Secretary Kennedy's statement that the Biden Administration "removed mifepristone's in-person dispensing rule without studying the safety risks").

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." Dist.Ct.ECF.258 at 19–20 (La.App.882-83). And in fact, "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." Dist.Ct.ECF.258 at 21 (La.App.884). That predictable conduct, in turn, "cause[s] concrete and ongoing injury to Louisiana." *Id.*

That is principally sovereign injury given that the 2023 REMS "directly undermines the enforcement of its own laws." Dist.Ct.ECF.258 at 22 (La.App.885). "Louisiana clearly has an interest in vindicating its sovereign prerogative under basic principles of federalism," the court agreed. *Id.*

In tandem with that sovereign injury, the court explained, "Louisiana has put forth sufficient evidence to demonstrate that it has suffered and continues to suffer pocketbook injury." Dist.Ct.ECF.258 at 24 (La.App.887). It observed that such costs are "statistically certain" in the approximately 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* Dist.Ct.ECF.20-26 (La.App.647) (collecting citations). That is borne out in the record by "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." Dist.Ct.ECF.258 at 25 (La.App.888). 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," *id.*; *see* Dist.Ct.ECF.20-23, ¶¶ 14–16 (La.App.642); Dist.Ct.ECF.20-19, ¶¶ 7–8 (La.App.594-95) (attesting that Louisiana women on Medicaid have been rushed to emergency rooms due to adverse events caused by mifepristone); *see also* Dist.Ct.ECF.1-14 at 4 (La.App.226) (Medicaid-specific study finding significantly higher ER-visit acuity following chemical abortion).

Relying on the same record evidence, the district court also agreed that Louisiana is suffering irreparable harm absent a stay of the 2023 REMS. "[T]he 2023 REMS operates, arguably, in derogation of Louisiana law and interferes with

Louisiana's ability to enforce its laws and implement the policy choices of its citizens." Dist.Ct.258 at 28 (La.App.891). "Louisiana suffers sovereign harm each time those laws are circumvented," and "[n]o remedy at law can redress that sovereign harm." *Id.* Similarly, given the federal Defendants' sovereign immunity, Louisiana cannot obtain a remedy for its ongoing "financial injury." *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" 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, Dist.Ct.ECF.258 at 28–29 (La.App.891-92); (2) the court was concerned that other courts across the country might generate "inconsistent judicial outcomes" on this issue, Dist.Ct.ECF.258 at 31, 35 (La.App.894, La.App.898); (3) the court did not wish to grant "nationwide" relief, Dist.Ct.ECF.258 at 32–33 (La.App.895-96); and (4) "FDA's review should be conducted and completed free from judicial interference," Dist.Ct.ECF.258 at 35 (La.App.898).

5. On May 1, 2026, the Fifth Circuit entered the preliminary stay of the 2023 REMS that Plaintiffs requested. That court's opinion largely agreed with the district court in all material respects. On standing, the court confirmed that Louisiana is suffering sovereign harm from 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." CA5.ECF.119-1 at 9–10 (La.App.1024-25). The court also 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." CA5.ECF.119-1 at 11 (La.App.1026). And the record contains "hard evidence linking [those] thousands of dollars in Medicaid costs to care stemming from out-of-state mifepristone." CA5.ECF.119-1 at 12 (La.App.1027).

On the most important preliminary-relief factors, the Fifth Circuit likewise agreed with the district court. Joining the two prior Fifth Circuit panels, the panel below 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," CA5.ECF.119-1 at 13 (La.App.1028); 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.* Louisiana "has [thus] strongly shown a likelihood of winning its APA challenge to the 2023 REMS." CA5.ECF.119-1 at 14 (La.App.1029).

Similarly, the Fifth Circuit "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, the Fifth Circuit 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." CA5.ECF.119-1 at 15 (La.App.1030) (alteration and citation omitted). 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." CA5.ECF.119-1 at 15–16 (La.App.1030-31). 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." CA5.ECF.119-1 at 16 (La.App.1031).

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, the Fifth Circuit 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." CA5.ECF.119-1 at 16–17 (La.App.1031-32). With respect to the district

court's desire to let the alleged FDA review proceed apace, the Fifth Circuit observed that "[g]ranting a stay would do nothing to prevent FDA from completing its review of mifepristone's safety protocols." CA5.ECF.119-1 at 17 (La.App.1032). 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 begin or conclude: "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 Fifth Circuit noted that this "does not absolve courts from deciding the cases before them"—and "[i]f disagreement emerges, we have a Supreme Court." CA5.ECF.119-1 at 18 (La.App.1033). And with respect to the prospect of nationwide relief, the Fifth Circuit—like the parties—did not identify any narrower form of relief that would redress Louisiana's harm; so, the Fifth Circuit simply said that nothing forecloses such relief under the APA. *Id.*

ARGUMENT

The Manufacturers are not entitled to a stay or vacatur of the Fifth Circuit's decision pending appeal. As always, a threshold question is whether there is "a reasonable probability that this Court will grant certiorari" in this case. *See Maryland v. King*, 567 U.S. 1301, 1302 (2012) (Roberts, C.J., in chambers) (quotation marks omitted). The answer to that question depends on what prompted this Court to grant review in *Alliance*. If, as the unanimous decision ultimately signaled, it was

the significant standing issue that this Court found certworthy, then this case, by contrast, is an unlikely candidate for certiorari because Louisiana's standing theory is exceptionally strong. But, if the Court thought *Alliance* certworthy because it involved abortion and mifepristone, *cf. Trump v. CASA, Inc.*, 606 U.S. 831, 877–78 (2025) (Kavanaugh, J., concurring), then this case similarly bears that feature.

Regardless, that threshold inquiry aside, a stay is unwarranted because the Manufacturers have failed to satisfy the other prerequisites for a stay or vacatur pending appeal: (I) they are unlikely to succeed on the merits of any appeal; and (II) the remaining equities and public-interest inquiries cut in favor of preserving the Fifth Circuit's decision. But, if the Court thinks otherwise, then (III) Plaintiffs would acquiesce in certiorari before judgment to ensure the efficient disposition of this case.

I. THE MANUFACTURERS ARE UNLIKELY TO SUCCEED ON THE MERITS.

The Manufacturers struggle right out of the gate on the merits. They devote the bulk of their briefs to disputing Louisiana's standing to sue, leaving only a few pages for defending the substance of the 2023 REMS. But both lower courts rightly concluded that Louisiana has standing. And FDA's own refusal to defend the 2023 REMS on the merits confirms that both lower courts also rightly concluded that Louisiana is likely to succeed in its APA challenge to the 2023 REMS.

A. Louisiana Has Article III Standing.

Start with standing. "To establish standing, as this Court has often stated, 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, the Court recently reiterated, is that "courts may make 'commonsense inferences' when assessing Article III standing, including inferences about 'third party behavior.'" *First Choice Women's Res. Ctr., Inc.*, 2026 WL 1153029, at *8 (citing *Diamond Alt. Energy, LLC*, 606 U.S. at 116).

Here, as both lower courts recognized, common sense makes this a straightforward inquiry. Louisiana has suffered, and continues to suffer, sovereign and economic injuries in fact. And those injuries are both caused by the 2023 REMS and redressable by a stay of the REMS.

1. Louisiana is suffering sovereign and economic injuries in fact.

Beginning with the injury-in-fact element, "[a]n injury in fact must be 'concrete,' meaning that it must be real and not abstract." *Alliance*, 602 U.S. at 381. It "also must be particularized" in that it "must affect 'the plaintiff in a personal and individual way' and not be a generalized grievance." *Id.* Two textbook injuries in fact are relevant here: Louisiana's sovereign harm and Louisiana's pocketbook harm.

a. One classic Article III injury is harm to a state's "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 such a code "is one of the quintessential functions of a State." *Diamond v. Charles*, 476 U.S. 54, 65 (1986). And "[b]ecause 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 this sovereign interest.

The *first* is a violation of a sovereign's laws. A "violation of [a sovereign's] laws" is an Article III injury to that sovereign's "sovereignty." *Stevens*, 529 U.S. at 771. 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*, 146 S. Ct. 564, 574–77 (2026) (Thomas, J., concurring) (cataloguing historical sources including Blackstone and Locke). And 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, 778.

The *second* is an obstacle to the enforceability of a sovereign's laws. "[A] State 'clearly has a legitimate interest in the continued enforceability of its own statutes.'" *Cameron*, 595 U.S. at 277 (citing *Maine*, 477 U.S. at 137). "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'");

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."). That also is why there is a storied tradition of another sovereign—the United States—suing to stave off state and local interference with federal laws and operations. *See, e.g.*, *Arizona v. United States*, 567 U.S. 387 (2012); *see also United States v. Missouri*, 114 F.4th 980, 984 (8th Cir. 2024) (finding injury in fact 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, because state officials withdraw resources and manpower that further the enforcement of federal law"); *United States v. King Cnty., Wash.*, 122 F.4th 740, 750 (9th Cir. 2024) (finding injury in fact because a challenged county executive order prevented Immigration and Customs Enforcement from conducting charter flights at a particular airfield).

Against this historical backdrop, both lower courts correctly recognized that Louisiana is suffering sovereign Article III injuries—approximately 1,000 every month, to be precise. Nobody disputes that Louisiana law criminalizes, with narrow exceptions, the dispensing, distribution, or delivery of mifepristone to a pregnant woman. La. R.S. 40:1061(C); La. R.S. 14:87.9(A). Nobody disputes that, if a narrow exception applies, Louisiana law requires mifepristone to be administered, dispensed, or provided in person by the prescribing physician. La. R.S. 40:1061.11(A). And nobody disputes that approximately 1,000 independent violations of these laws occur

in Louisiana each month when out-of-state actors mail FDA-approved mifepristone into Louisiana.

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*, 146 S. Ct. at 574 (Thomas, J., concurring). That alone is a cognizable "injury in fact" that ends this inquiry. *See Stevens*, 529 U.S. at 774. But these injuries also illustrate the threat to the "'continued enforceability of [Louisiana's] own statutes'" in which Louisiana "'clearly has a legitimate interest.'" *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 any mine-run prescriber 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 introduces a new way of violating Louisiana's laws—namely, through out-of-state prescribers who mail mifepristone into Louisiana while avoiding capture in Louisiana. Because that new tactic accounts for the overwhelming majority (if not all) illegal abortions in Louisiana today, the practical impact on Louisiana's laws is to render them useless. That, too, is a textbook Article III injury.

Note what the Manufacturers do not say in response. They do not confront the fact that a violation of a sovereign's laws is itself an Article III injury. *See* Danco.Appl.22–27; GBP.Appl.23–24. Nor could they dispute that fact: Historical

sources like Blackstone and Locke and cases like *Stevens* squarely decide that question. That is all the Court need recognize before moving on to the remaining elements of the standing analysis.

Sidestepping one sovereign injury in fact, the Manufacturers complain that nothing "prevent[s] Louisiana from creating or enforcing its abortion prohibitions." GBP.Appl.23; *see* Danco.Appl.25 ("Louisiana [] suffers no sovereign injury because nothing in the REMS undermines Louisiana's ability to legislate and enforce abortion restrictions as it sees fit."). So, they conclude, there is no Article III injury to see here. That ignores that Louisiana is injured every time its state law is violated. Further, Louisiana suffers a *second* sovereign injury in fact due to its inability to enforce its own laws. Indeed, a law is effectively meaningless where external forces combine to thwart its promises. *Cf. Louisiana v. Callais*, 2026 WL 1153054, at *22 (U.S. Apr. 29, 2026) (Kagan, J., dissenting) ("'In the century that followed,' the Fifteenth Amendment 'proved little more than a parchment promise.'"). And that is the case here: *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." 597 U.S. at 338 (Kavanaugh, J., concurring). As far as pro-life states like Louisiana are concerned, however, their democratic processes—and their chosen laws—have been rendered hollow by the 2023 REMS, which undermine the promise of *Dobbs*. That attack on the "continued enforceability of [Louisiana's] own statutes'" is unquestionably a cognizable Article III injury on its own. *Cameron*, 595 U.S. at 277 (citing *Maine*, 477 U.S. at 137).

b. To add "extra icing on a cake already frosted," *Yates v. United States*, 574 U.S. 528, 557 (2015) (Kagan, J., dissenting), Louisiana's sovereign harm carries with it pocketbook injuries that are themselves independent Article III injuries in fact. "Pocketbook harm is a traditional Article III injury." *Bost*, 146 S. Ct. at 524 (Barrett, J., concurring in the judgment); *see Texas*, 599 U.S. at 688 (Gorsuch, J., concurring) ("Nor does anyone dispute that even one dollar's worth of harm is traditionally enough to 'qualify as concrete injur[y] under Article III.'"). "That is so not only when a law directly imposes costs on a plaintiff, but also when a plaintiff 'reasonably incur[s] costs to mitigate or avoid' the 'substantial risk' of a harm caused by a [challenged action]." *Bost*, 146 S. Ct. at 524 (Barrett, J., concurring in the judgment) (citation and quotation marks omitted).

Here, Louisiana identified two unrebutted pocketbook injuries. *First*, Louisiana substantiated pocketbook injuries related to its attempted enforcement activities against mail-order mifepristone. Although Louisiana has been unable to hold any individual accountable for the hundreds of illegal mailings of mifepristone into Louisiana each month, the investigations into just three of those crimes have cost the State over $17,000. *See* Dist.Ct.ECF.111 at 4 & n.4 (La.App.746). Those monetary costs were reasonably incurred to mitigate the harms Louisiana is facing and thus constitute an Article III injury. *See Bost*, 146 S. Ct. at 524 (Barrett, J., concurring in the judgment). *Second*, Louisiana substantiated pocketbook injuries in the form of Medicaid costs arising from hospitalizations caused by FDA-approved mifepristone mailed into Louisiana—over $90,000 in costs traced to just two

abortions alone. Dist.Ct.ECF.20-26 at 6, 23 (La.App.657, La.App.674). As FDA told the Fifth Circuit, "no one disputes that Medicaid costs constitute an Article III injury." CA5.ECF.74 at 22 (La.App.989). That is exactly right. Both lower courts agreed, Dist.Ct.ECF.258 at 23–25 (La.App.886-88); CA5.ECF.119-1 at 12 (La.App.1027)—and even today the Manufacturers do not dispute that fact. *Cf. Texas*, 599 U.S. at 690 (Gorsuch, J., concurring in the judgment) (noting that 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").[1]

2. Louisiana's injuries are traceable to, and redressable by vacatur of, the 2023 REMS.

Because Louisiana is suffering sovereign and economic harm, the only real dispute raised by the Manufacturers is whether Louisiana also has established causation and redressability. It has. And in fact, neither Manufacturer appears to actually contest redressability.

a. "The second and third standing requirements—causation and redressability—are often 'flip sides of the same coin.'" *Alliance*, 602 U.S. at 380. "If a defendant's action causes an injury, enjoining the action ... will typically redress that

[1] GBP (but not Danco) claims that Louisiana failed to show that its "asserted injuries are ... likely to recur." GBP.Appl.24–25. That claim is bizarre, not least because it ignores the fact that nobody has ever disputed: Louisiana is facing approximately 1,000 mailings of mifepristone every month. GBP also ignores the evidentiary record showing, and the lower court findings affirming, that this flood of mifepristone is statistically certain to generate Medicaid costs. GBP never refuted any of that evidence, or disputed that Medicaid costs qualify as Article III injuries. It is thus troubling to see an assertion that is directly contrary to the record and GBP's litigation choices.

injury." *Id.* at 381; *see id.* at 385 (a plaintiff must "show a predictable chain of events leading from the government action to the asserted injury"). And vice versa. That the Manufacturers do not (indeed, cannot) dispute redressability gives the causation game away. In contexts like this, moreover, "courts may make 'commonsense inferences' when assessing Article III standing, including inferences about 'third party behavior.'" *First Choice Women's Res. Ctr., Inc.*, 2026 WL 1153029, at *8 (citing *Diamond Alt. Energy, LLC*, 606 U.S. at 116). "Because Article III 'requires no more than *de facto* causality,'" the standing analysis properly may rest "on the predictable effect of Government action on the decisions of third parties." *Dep't of Comm.*, 588 U.S. at 768 (citation omitted).

On this score, *Department of Commerce* is instructive. In *Department of Commerce*, several states challenged the addition of a citizenship question to the Census. In confirming their standing to sue, this Court credited their theory that, "if noncitizen households are undercounted" by a small percentage, "they will lose out on federal funds that are distributed on the basis of state population." 588 U.S. at 767. That theory would only work, however, if in fact noncitizen households were undercounted. And that "depend[ed] on the independent action of third parties choosing to violate their legal duty to respond to the census." *Id.* The Court resolved that assumption not "on mere speculation about the decisions of third parties," but on "the predictable effect of Government action on the decisions of third parties." *Id.* at 768. Reasoning that the record suggested "historically" lower response rates by noncitizen households, the Court concluded that the plaintiffs had "met their burden

of showing that third parties will likely react in predictable ways to the citizenship question." *Id.*

This is an *a fortiori* case for standing. In *Department of Commerce*, the Court did not know whether, in fact, noncitizens would be undercounted—that is why the Court needed to invoke the "likely" and "predictable" responses of noncitizens. But no such prognostication is necessary here: Nobody disputes that a cabal of third parties has acted in response to 2023 REMS's removal of the in-person dispensing requirement by mailing 1,000 packages of mifepristone into Louisiana each month. The literal act of mailing violates Louisiana's laws causing sovereign harm—and the concomitant economic harms bound up in that sovereign harm are the natural consequences of the mailing. *See Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 153–55 & n.3 (2010) (finding the requisite causation given "a significant risk" that bees traveling from field to field would contaminate genetically unaltered alfalfa fields after stopping at nearby genetically altered alfalfa fields).

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 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.").

The day this Court decided *Dobbs*, former President Biden publicly set his sights on those pro-life states that would seek to "ban or severely restrict access to medication for reproductive health care" after *Dobbs*. Dist.Ct.ECF.1-47 at 3

(La.App.242). In the same breath, 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.* He followed that directive up with threats to those states ("states may not ban mifepristone"), and he pledged "to allow mifepristone to continue to be prescribed by telehealth and sent by mail." Dist.Ct.ECF.1-60 at 2–3 (La.App.413-14). He added executive orders promising "abortion care, including medication"—"especially for those who live in States that are banning or severely restricting abortion care." Dist.Ct.ECF.20-26 (La.App.647) (collecting citations). 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 amidst unprecedented efforts by Republican officials at the national and state level to restrict access to abortion," Dist.Ct.ECF.1-59 at 2 (La.App.409)—specifically citing, among other measures, the removal of the in-person dispensing requirement, Dist.Ct.ECF.1-61 at 7 (La.App.422). Small wonder, then, that prescribers in pro-abortion states—freed from the in-person dispensing requirement—have proceeded precisely as former President Biden envisioned: by mailing mifepristone into pro-life states.[2]

[2] Understandably, Danco chafes (Danco.Appl.25–26 n.8) at having to account for President Biden's and his administration's public statements explaining their mission to inject mifepristone into pro-life states after *Dobbs*. To the extent Danco protests that these statements are not in the administrative record, however, Danco's protest makes no sense. Danco cites no authority for the proposition that the Article III standing analysis is limited to the administrative record—because that proposition is wrong. The rule of *SEC v. Chenery Corp.*, 318 U.S. 80 (1943), invoked by Danco applies—by its plain terms—only to the permissible bases for "judg[ing]" the agency action itself, *id.* at 87, not to whether a particular plaintiff has standing to challenge that action in the first place.

If there were any doubt about this "predictable chain of events," *Alliance*, 602 U.S. at 385, "commonsense [] inferences ... make it sufficiently 'predictable' that invalidating [the 2023 REMS] would likely redress [Louisiana's] injur[ies]," *Diamond Alt. Energy, LLC*, 606 U.S. at 120. This is, after all, what the Manufacturers' associates are saying publicly. Consider the National Organization for Women, which claims that the reinstatement of the in-person dispensing requirement would remove "an essential lifeline for people who live in abortion-ban states." 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. Or, consider the Center for Reproductive Rights, which claims that the reinstatement of the in-person dispensing requirement would destroy "a lifeline, particularly for patients in states that restrict abortion[.]" Press Release, *5th Circuit Limits Telehealth Provision of Abortion Pill*, Ctr. for Reproductive Rights (May 1, 2026), perma.cc/7D7N-AK3U. Or, consider the Guttmacher Institute, which claims that reinstating the in-person dispensing requirement "would severely restrict access to mifepristone in every state[.]" News Release, *Fifth Circuit Decision Directs FDA to Restrict Mifepristone Access*, Guttmacher Inst. (May 1, 2026), perma.cc/4YRB-K359; *see* Br. of Family Research Council as *Amicus Curiae* at 3–6 (collecting citations). That is textbook redressability for Louisiana, which seeks to halt the flood of FDA-approved mifepristone mailed into the State. And it is proof positive that Louisiana's injuries are traceable to the 2023 REMS. *Dep't of Comm.*, 588 U.S. at 768 (standing satisfied based "on the predictable effect of Government action on the decisions of third parties").

b. The Manufacturers struggle to articulate any coherent opposition to this commonsense analysis.

i. To start, the Manufacturers whiff on the direct causation between the 2023 REMS's removal of the in-person dispensing requirement and the resulting mailing of mifepristone in violation of Louisiana law, which itself is a cognizable Article III injury. As explained above, the mailing is, of course, the "predictable" consequence of the removal of the in-person dispensing requirement. Resisting that commonsense inference, however, the Manufacturers worry about the supposedly "speculative" and "attenuated" links between those two things. *See* Danco.Appl.22; GBP.Appl.18, 23 (emphasizing "a chain of independent third-party choices: out-of-state prescribers decide to provide mifepristone; patients decide to seek it; and pharmacies or mail-order providers decide to dispense it"). That worry is unfounded—because the Manufacturers did not dispute below and do not dispute today that these links hold approximately 1,000 times every month in Louisiana. Louisiana's standing theory "thus does not rest on mere speculation about the decisions of third parties." *Dep't of Comm.*, 588 U.S. at 768. It rests instead on the actual decisions of third parties, repeated 1,000 times every month in Louisiana. And the decisions to dispense FDA-approved mifepristone into Louisiana—not any subsequent decision—constitute the first cognizable Article III injuries to Louisiana. That is causation in its tightest form.

ii. Apparently recognizing as much, the Manufacturers resort to hyperbole about the lower courts allegedly resisting this Court's decisions in *Texas* and *Alliance*. In fact, Danco goes so far (at 6, 33) as to accuse the Fifth Circuit judges below of not

being "neutral," "abdicat[ing]" their judicial role, and "circumvent[ing]" this Court's precedents. Snark aside, the Manufacturers well know that neither *Texas* nor *Alliance* squarely addresses the issues in this case.

By its own terms, *Texas* addressed "only" the "extraordinarily unusual" and "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—here, by making more arrests." 599 U.S. at 684–85, 686. That, of course, is not a question here. For that reason, the most the Manufacturers can pry (Danco.Appl.20; GBP.Appl.20, 27) from *Texas* is a passing statement that, when a state asserts standing based on a challenged policy's "indirect effects on state revenues or state spending," the state's "claim for standing can become more attenuated." *Id.* at 680 n.3. But that statement does not address direct sovereign harms, nor does it even categorically reject standing theories based on indirect harms to state funding. *Cf. id.* at 690 (Gorsuch, J., concurring in the judgment) ("[The states] also proved that, as a result [of the challenged Guidelines], they spend more money on everything from law enforcement to healthcare."). So, footnote 3 does not move the needle for the Manufacturers.

GBP (but not Danco) tries to twist the very last sentence of footnote 3—"In short, none of the various theories of standing asserted by the States in this case overcomes the fundamental Article III problem with this lawsuit"—in its favor. GBP.Appl.23–24. In particular, GBP digs back through the *Texas* district court opinion to see what standing theories were raised, finds one it thinks sufficiently

relevant (the Guidelines "led to individuals 'committing[] more crimes in Texas'"), and concludes that this Court rejected that theory (and so should reject Louisiana's standing here, too). GBP misreads footnote 3. The point of that final sentence was to say that, whatever the various standing theories, none could overcome the problem that "the Federal Judiciary [cannot] in effect order the Executive Branch to take enforcement actions against violators of federal law—here, by making more arrests." 599 U.S. at 685. That point has exactly nothing to do with how the increased commission of crimes may affect an Article III analysis.

Moreover, the "more crimes" theory in *Texas* was that the challenged Guidelines led to the appearance of more aliens on Texas streets, who happened to commit "more crimes in Texas." *Texas v. United States*, 606 F. Supp. 3d 437, 467 (S.D. Tex. 2022). That is fundamentally different from Louisiana's theory here, which is that removal of the in-person dispensing requirement for a drug predictably is leading to thousands of violations of the very state law prohibiting the mailing of that drug into the State—violations that themselves constitute sovereign harm and carry attendant economic harms.

Turning to *Alliance*, the Manufacturers are desperate (Danco.Appl.22–23; GBP.Appl.27–29) to shoehorn this case into the *Alliance* Court's rejection of "a sweeping doctrinal change" that would give "virtually every citizen [] standing to challenge virtually every government action that they do not like." 602 U.S. at 392. But that shoe does not fit. For one thing, no plaintiff in *Alliance* was a state that enjoys a unique and "'judicially cognizable interest in the preservation of its own

sovereignty.'" *Bowen*, 477 U.S. at 50 n.17. For another thing, the core causation issue identified in *Alliance* does not exist here. There, the Court held that "the law has never permitted doctors to challenge the government's loosening of general public safety requirements simply because more individuals might then show up at emergency rooms or in doctors' offices with follow-on injuries." 602 U.S. at 391. In this case, by contrast, the principal, relevant chain of causation begins with the challenged policy (the removal of the in-person dispensing requirement in the 2023 REMS) and ends with the very next step in the chain (an out-of-state actor's mailing mifepristone into Louisiana). Nor is more than one step necessary for Louisiana's second sovereign injury in fact: its inability to enforce its own laws. The 2023 REMS makes that impossible. As discussed above, no speculation is necessary to appreciate how either of those direct harms plays out every month in the State.

The Manufacturers try to reframe the Court's consideration of this issue by making it principally and myopically about the State's Medicaid costs that the State suffers further down the chain. By their reasoning, if the *Alliance* doctors could not sue over costs they incurred, how could Louisiana sue over costs it incurs from paying a doctor's invoice? Danco.Appl.21; GBP.Appl.21. That reasoning makes two mistakes.

One, it overlooks that the State has identified intervening sovereign injuries—and that the enforcement costs and Medicaid costs that follow are bound up in those sovereign injuries. Louisiana's claim to standing is thus one of the most obvious claims this Court has seen because it binds together a classic injury to a sovereign's "sovereignty," *Stevens*, 529 U.S. at 771, and a classic "[p]ocketbook harm," *Bost*, 146

S. Ct. at 524 (Barrett, J., concurring in the judgment).

Two, the Manufacturers overlook that the State's Medicaid costs are directly traceable to both the 2023 REMS and the State's resulting sovereign injuries. As the Fifth Circuit recognized—and as the Manufacturers have never disputed—"Louisiana provided hard evidence linking thousands of dollars in Medicaid costs to care stemming from out-of-state mifepristone." CA5.ECF.119-1 at 12 (La.App.1027); *see* Dist.Ct.ECF.111 at 5 (La.App.747); Dist.Ct.ECF.20-26 at 21–23 (La.App.672-74) (carefully cataloguing this evidence); *cf. Alliance*, 602 U.S. 390–91 (finding record deficient given no evidence showing a diversion of time and resources). The Manufacturers appear to assume that this connection is insufficient simply because it can be construed as indirect. As just explained, it is not indirect. But more importantly, this Court has never categorically forbidden reliance on "indirect effects on state revenues or state spending." *Texas*, 599 U.S. at 680 n.3. Rightly so, as that would gut numerous other cases such as *Department of Commerce*. *See id.* at 688 (Gorsuch, J., concurring in the judgment); *id.* at 718 (Alito, J., dissenting). So, even if Louisiana's enforcement and Medicaid costs were deemed "indirect," Louisiana's standing theory in this case would remain intact for the reasons explained above.

iii. The Manufacturers also try (Danco.Appl.23; GBP.Appl.23–24) to shift the blame for Louisiana's injuries to the actual prescribers launching drugs by mail and pro-abortion states that have erected state laws purporting to shield those prescribers from liability. But that blame-shifting does not work because the conduct by those prescribers and states is meaningful and possible *only because* FDA first deleted the

in-person dispensing requirement in the 2023 REMS. Without the 2023 REMS, prescribers could not lawfully (under federal law) mail mifepristone into Louisiana. And if they could not do so, the so-called "shield laws" in pro-abortion states intended to protect those who mail mifepristone extraterritorially would accomplish exactly nothing. "Article III 'requires no more than *de facto* causality.'" *Dep't of Comm.*, 588 U.S. at 768. 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 Manufacturers thus cannot scapegoat their own prescribers to save the federal regulation that permits those prescribers to carry out their attacks in the first place.

Last, the Manufacturers invoke *Washington v. FDA*, 108 F.4th 1163 (9th Cir. 2024), throughout their applications, but that decision is distinguishable on numerous levels. To take just three: (1) it rested only on "highly speculative allegations" in a complaint, *id.* at 1174, not facts substantiated by evidence as here; (2) it did not consider whether the actual violation of a state's laws is a cognizable Article III injury, *see id.* at 1176–77; and (3) it did not consider whether Medicaid costs directly bound up with a sovereign injury fell within the predictable chain of events, *see id.* at 1174–76. Although *Washington* bears superficial similarity to this case, it rested on a fundamentally different record and addressed materially different theories.

* * *

This 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 given the Manufacturers' best efforts to confound standing law in ways that only lawyers could. Louisiana's standing "is evident"—and both lower courts correctly recognized as much. *Id.*

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

Turning to the true merits, the short shrift given by the Manufacturers (only about five pages each) betrays the futility of raising the issue. 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, the Manufacturers are wrong insofar as they suggest the courts have impermissibly second-guessed FDA's "scientific" determinations. The courts merely held FDA to Congress's requirements for agency decision-making. 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." *Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (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, each court—including the Fifth Circuit panel

below—correctly concluded that FDA's removal of its longstanding in-person dispensing requirement likely violates the APA. *First*, the FDA erred in giving "dispositive weight" to FAERS data. CA5.ECF.119-1 at 13 (La.App.1028). *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. CA5.ECF.119-1 at 14 (La.App.1029). And *third*, Danco's two-paragraph exhaustion argument is not serious.

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 the FDA's scientific determination, the lower 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." Dist.Ct.ECF.1-52 at 5 (La.App.394). 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," Dist.Ct.ECF.1-52 at 3 (La.App.392). 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." Dist.Ct.ECF.1-52 at 5 (La.App.394).

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." Dist.Ct.ECF.1-10 at 27 (La.App.173); *see also* Dist.Ct.ECF.1-51 at 21–24 (La.App.361-64). 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," Dist.Ct.ECF.1-52 at 3–5 (La.App.392-94), to calculate the incidence of adverse events.

As the Fifth Circuit has previously 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 death to FDA. Dist.Ct.ECF.1-11 at 28 (La.App.214). That makes for an easy arbitrary-and-capricious analysis. As the Fifth Circuit 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.'" CA5.ECF.119-1 at 13 (La.App.1028). "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.

b. GBP defends FDA's reliance on FAERS data on the ground that most

prescription drugs do not require adverse event reporting. GBP.Appl.31. But most prescription drugs do not carry a Black Box warning and send roughly 1 in 25 women to the emergency room. Regardless, the lower courts did not find that FDA *should* require adverse event reporting, but that the FDA's decision to remove a longstanding safeguard *based* on concededly unreliable data was arbitrary and capricious.

GBP also strangely argues that Congress directed the 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.

For its part, Danco dismisses the voluntary nature of FAERS reporting by recycling its argument that the Manufacturers are responsible for reporting adverse events that come to their attention. Danco.Appl.29. But drug manufacturers lack any meaningful ability to track problems on the ground. Nowhere near America's emergency rooms, these companies rely entirely on—you guessed it—voluntary reporting of busy doctors. Indeed, FDA conceded in its 2023 decisional document that the drug manufacturer data contained *only* the eight adverse events identified in FAERS. Dist.Ct.ECF.1-51 at 22 (La.App.362); Dist.Ct.ECF.1-10 at 20 (La.App.166)

(acknowledging some adverse events may not be reported because reporting is voluntary).

Last, GBP aggressively claims that FAERS data is *overinclusive*. GBP.Appl.31. To be sure, the dataset does not include a causal analysis. Thus, a woman who dies of a suicide post-abortion may be included in the FAERS data. But there is no question that the FAERS database fails to accurately capture adverse events. For instance, according to the FDA adverse event summary through 12/31/2018, there were 97 ectopic pregnancies reported out of the 3.7 million women who had taken mifepristone through that date. *See* AE Report through 12/31/2018: perma.cc/64LH-RXG5. Six years later (12/31/2024), there were still only 97 ectopic pregnancies reported. *See* AE Report through 12/31/2024: perma.cc/F8QL-BUQX. While the number of women taking mifepristone more than doubled to 7.5 million, there were zero ectopic pregnancies reported during that 6-year span. The only explanation is that adverse events are not voluntarily being reported to FAERS.

2. FDA arbitrarily concluded that scientific literature supported removing the in-person dispensing requirement.

The Fifth Circuit 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. CA5.ECF.119-1 at 13 (La.App.1028).

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." Dist.Ct.ECF.1-51 at 39 (La.App.379) (emphasis added). Full stop. That concession conclusively establishes that the 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 the 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.").

Danco—in an argument never made by FDA—argues 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. Danco.Appl.30 (quoting *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).

GBP defends FDA's reliance on the literature by arguing that the studies "did not identify any new or increased risks" without in-person dispensing. GBP.Appl.30. That is wrong. To the extent the studies showed anything, it was an *increase* in risk. FDA admitted that "the literature suggests there may be more frequent ED/urgent care visits related to the use of mifepristone when dispensed by mail." Dist.Ct.ECF.1-51 at 34 (La.App.374). FDA 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."

Dist.Ct.ECF.1-51 at 31 (La.App.371). FDA likewise noted that a second study showed that the rate of emergency department visits (5.8 percent) in a "telemedicine plus 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). Dist.Ct.ECF.1-51 at 32 (La.App.372). 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). Dist.Ct.ECF.1-51 at 28 (La.App.368). It was plainly arbitrary and capricious for FDA to blow past these warning signs.

GBP is also wrong to claim that the fifteen studies reviewed by the FDA all support "the conclusion that dispensing by mail, courier, or through pharmacies was safe and effective." GBP.Appl.32–33; *see also* Danco.Appl.30 (asserting that "all the studies supported that it was safe to remove the in-person dispensing requirement"). To the contrary, FDA explicitly discredited 4 studies (Rocca, Hyland, Endler, Norten); stated 2 were not generalizable to the U.S. population (Grossman, Wiebe); said 3 were of limited usefulness or had limited certainty of results (Upadhyay, Aiken 2021, Reynolds-Wright); and warned that 1 needed to be interpreted carefully (Anger). *See* Br. of AAPLOG as *Amicus Curiae* at 18-24. Plus, the vast majority of study participants in the remaining five studies 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 the FDA stripped away.

In sum, FDA violated the APA by relying on FAERS data that the agency

concedes is 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, *FDA v. ACOG*, No. 20A34, at 4, 13 (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 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." Dist.Ct.ECF.1-110 at 2 (La.App.478).

3. Danco's exhaustion argument is meritless.

Finally, the Court should dismiss out of hand Danco's two-paragraph argument (Danco.Appl.27–28) that Plaintiffs were required to exhaust their claims before the FDA. That is wrong twice over.

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.

Second, and in any event, courts do not require exhaustion where one of the

"traditionally recognized" exceptions applies. *Wash. Ass'n for Television & Child. v. FCC*, 712 F.2d 677, 682 (D.C. Cir. 1983). At least three apply here. *One* is abuse of process arising from an agency's failure to adhere to its rules. *See Alliance I*, 2023 WL 2913725, at *16; *see also* W*ay 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* Krupka, *supra*, at 957–63. 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. A *second* exception is futility: Because FDA's very position in this litigation is a refusal to immediately stay the 2023 REMS, FDA of course would have refused to immediately stay the 2023 REMS in agency proceedings. *See, e.g.*, *Alliance II*, 78 F.4th at 255. And a *third* exception "is 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 injuries to Louisiana articulated above and below.

II. THE REMAINING FACTORS CUT AGAINST A STAY.

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

A. The Manufacturers Face No Irreparable Harm from the Fifth Circuit's Decision.

Start with the Manufacturers' cursory gestures (a paragraph each?) at

irreparable harm. The Manufacturers' visible discomfort with trying to suggest they face some vague conception of irreparable harm is an easy tell that this factor alone should sink their applications. *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 lead argument is that they face "substantial uncertainty" about their obligations and next steps following the Fifth Circuit's decision. Danco.Appl.35; *see* GBP.Appl.35 (citing "immediate uncertainty" and "compliance costs"). That claim of uncertainty is contrived, *see infra*, but more importantly, they do not cite a single case suggesting 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, under the Fifth Circuit's decision, they might not be able to sell as many abortion drugs as they would like. *See* GBP.Appl.35 ("lost sales"); Danco.Appl.36 ("source of revenue"). 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 the extraordinary relief of a Supreme Court stay pending appeal.[3]

[3] Danco (but not GBP) hints that the Fifth Circuit's decision may render Danco "unable to continue operating." Danco.Appl.36. That is seriously misleading. Danco's cited declaration says that, if Danco "were prevented from distributing our product,

B. The Balance of the Equities Favors Preserving the Fifth Circuit's Decision.

The foregoing makes the balancing of the equities easy. There is no question that Louisiana would suffer irreparable harm if this Court stayed the Fifth Circuit's decision. 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 lower courts agreed, "because FDA 'is entitled to sovereign immunity,' Louisiana's financial harms are [] irremediable." CA5.ECF.119-1 at 15 (La.App.1030); *accord* Dist.Ct.ECF.258 at 28 (La.App.891). 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.'" CA5.ECF.119-1 at 14 (La.App.1029). And "[o]nce lost, that sovereign prerogative of protecting unborn life cannot be regained by legal remedy." CA5.ECF.119-1 at 14–15 (La.App.1029-30).

The Manufacturers do not 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.

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we will not be generating revenue." Danco.App.60a. The declaration goes on to say that "[t]he failure to generate revenue for anything longer than a de minimis period of time would cause grave concerns and could result in the effective closure of our business." *Id.* There is nothing in the Fifth Circuit's decision or anywhere else that would prevent Danco from distributing its product—and thus, there is nothing to Danco's innuendo that it somehow might have to close its doors.

Resisting this fact, the Manufacturers try (GBP.Appl.37–38; Danco.Appl.36–37) to undercut Louisiana's irreparable harm by complaining that Louisiana unduly delayed in seeking preliminary relief. But they do not try to suggest that this Court would find both lower courts to have abused their discretion in rejecting this tired argument. Moreover, the timeline of 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.*, Dist.Ct.ECF.20-20, ¶ 14 (La.App.600). 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. Dist.Ct.ECF.20-26 at 8 (La.App.659). 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." Louisiana immediately sought preliminary relief. *Id.* As both lower courts 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 Favors Preserving the Fifth Circuit's Decision.

That leaves only the public-interest inquiry—and that analysis, too, is easy. The Manufacturers do not acknowledge, much less refute, the Fifth Circuit's point that 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." CA5.ECF.119-1 at 15 (La.App.1030) (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." CA5.ECF.119-1 at 15–16 (La.App.1030-31). The Manufacturers' silence on these points effectively concedes all this. And in all events, the points the Manufacturers do raise are unavailing.

1. The Manufacturers claim that Louisiana does not need preliminary relief because FDA's supposed ongoing review might end in Louisiana's favor. Danco.Appl.37; GBP.Appl.36. But that logic breaks down on its own terms: (1) if the

review were to end with FDA's determination that the in-person dispensing requirement should be reinstated, then that would justify the Fifth Circuit's stay of the 2023 REMS today; and (2) if the review were to end with FDA retaining the 2023 REMS, Louisiana would still be entitled to a stay of the REMS based on the rationale the agency put forth in 2023. Either way, the alleged existence of an ongoing study does not somehow justify withholding preliminary relief today. As the Fifth Circuit explained, "[g]ranting a stay [of the 2023 REMS] would do nothing to prevent FDA from completing its review of mifepristone's safety protocols." CA5.ECF.119-1 at 17 (La.App.1032). And "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.*

All this, moreover, assumes the review will take place. Louisiana was forced to seek preliminary relief on the heels of the FDA Commissioner's internal directive to delay any review until 2027. During the preliminary-relief proceedings, FDA repeatedly has represented that it is still only collecting data. And regrettably, doubt on this front has only grown in recent days, as public reporting indicates that the Commissioner has internally attempted to delay the initiation of any study "until late 2026 or even 2027," when FDA can secure a contractor and new data-monitoring system. Philip Wegmann et al., *The Antiabortion Movement Is Turning on Trump*, Wall Street Journal (May 3, 2026), perma.cc/SZV5-AEPJ. The same reporting relays his direct statements of "indifference to policy around [mifepristone]": "I don't think about the abortion pill," he said. This news thus underscores the appropriateness of

preserving the preliminary relief to which Louisiana is entitled right now.

2. GBP tries on the federal government's mantle, complaining that the Fifth Circuit's decision "harms the *federal* government's sovereign interest in the uniform, nationwide implementation of its regulatory judgments." GBP.Appl.36. But the federal government did not run to this Court claiming as much. And even if it had done so, the government would collide with the black-letter rule that "neither the FDA nor the public has any interest in enforcing a regulation that violates federal law." CA5.ECF.119-1 at 15 (La.App.1030) (citation and alteration omitted). GBP's pretending to be the federal government thus goes nowhere.

3. The Manufacturers also try to undercut the appropriateness of preliminary relief by pointing out that other states who have brought challenges similar to Louisiana's have not sought preliminary relief, and some (Florida and Texas) recently consented to a stay of their suit pending FDA's alleged review. GBP.Appl.38 & n.2; Danco.Appl.41–42. But the Manufacturers omit that—unlike Louisiana here—the plaintiffs in *Florida v. FDA*, No. 25-cv-126 (N.D. Tex.), have challenged a wide array of mifepristone regulations, tracing all the way back to FDA's 2000 approval of mifepristone itself. Given that timeline, the *Florida* plaintiffs will benefit from (and may, in fact, need) a stay of their lawsuit pending FDA's alleged review because they will rely on "[t]he reopening doctrine" as a basis for challenging FDA actions that might otherwise fall outside the APA's six-year limitations period. *Florida*, ECF 56 at 24. In addition, the *Florida* plaintiffs—and the other states with similar challenges—have no need for a motion to stay the 2023 REMS because Louisiana's

success in this suit would have the practical consequence of providing relief to the *Florida* plaintiffs unless a court identifies a way to provide relief to Louisiana alone. For these reasons, the Manufacturer's attempts to drive a wedge between Louisiana and her sister states is unavailing.

4. Finally, the Manufacturers protest that the Fifth Circuit's decision will burden physicians, pharmacies, and individuals who wish to obtain mifepristone by mail. Danco.Appl.36; GBP.Appl.35–36. But that just runs into the Fifth Circuit's determination—unacknowledged by the Manufacturers—that "[t]he public interest is not served by perpetuating a medical practice whose safety the agency admits was inadequately studied." CA5.ECF.119-1 at 15–16 (La.App.1030-31). The Manufacturers may disagree over whether the 2023 REMS is lawful, but they must admit that, if Louisiana prevails on the merits, then this public-interest determination must follow.

To the extent the Manufacturers infuse this argument with complaints about alleged and widespread uncertainty under a stay of the 2023 REMS, that rhetoric is severely overblown. When a court vacates or stays an agency rule, the pre-rule status quo automatically springs back into effect.[4] That is basic administrative law—and it

[4] *See, e.g.*, *Action on Smoking & Health v. C.A.B.*, 713 F.2d 795, 797 (D.C. Cir. 1983) ("by vacating or rescinding [a recission rule], the judgment of this court had the effect of reinstating the rules previously in force"); *Keystone-Conemaugh Projects LLC v. EPA*, 100 F.4th 434, 446 (3d Cir. 2024) ("When a court vacates an agency's rule, it restores the status quo before the invalid rule took effect..."); *Cumberland Med. Ctr. v. Sec'y of Health & Human Servs.*, 781 F.2d 536, 538 (6th Cir. 1986) ("the current rule being invalid from its inception, the prior regulation is reinstated"); *Paulsen v. Daniels*, 413 F.3d 999, 1008 (9th Cir. 2005) ("The effect of invalidating an agency rule is to reinstate the rule previously in force.").

is straightforward. Without acknowledging this precedent, Danco claims (Danco.Appl.5, 16–17, 35) to be blindly following the declaration of Janet Woodcock, a named *Alliance* defendant responsible for approving multiple mifepristone applications. Without citing any legal authority or agency precedent, she disputed that a stayed REMS "could simply snap back" to the prior REMS. Danco.App.113a. That claim is legally baseless—and Danco cannot seriously argue otherwise to artificially give life to Danco's preferred "chaos" narrative.

Danco's associated worries about marketing mifepristone are likewise overblown. Danco cannot deny that it "already has [the] drug labels and documentation to comply with the [previous] mifepristone REMS." *Alliance II*, 78 F.4th at 252. And insofar as the Manufacturers might need their prescribers to recertify compliance with the in-person dispensing requirement, the record shows that Danco and GenBioPro prescribers need only complete a brief, one-page form to do so. Dist.Ct.ECF.20-16 at 5–8 (La.App.583-86).

The Fifth Circuit correctly saw through the Manufacturers' "exaggerate[d]" claims of an impending crisis under the Fifth Circuit's decision. CA5.ECF.119-1 at 16 (La.App.1031). This Court should, too, and summarily dismiss the Manufacturers' rhetoric.

D. The Manufacturers' Complaints About the Scope of Relief Are Meritless.

Perhaps recognizing their weaknesses, the Manufacturers repeatedly imply that this case raises questions about the availability and scope of universal relief under the APA. *E.g.*, Danco.Appl.17, 39, 41; GBP.Appl.1, 14, 35–36. But, although

some Members of the Court have written that "this Court will have to address [this issue] sooner or later," *Texas*, 599 U.S. at 702 (Gorsuch, J., concurring in the judgment), this is not the vehicle for that discussion.

That is because the narrowest interpretation of available relief under the APA would be to construe it as coterminous with the "traditional forms of equitable relief." *Id.*; *but see id.* at 701–02 ("Nor do I mean to equate vacatur of agency action with universal injunctions."); *CASA*, 606 U.S. at 847 n.10 ("Nothing we say today resolves the distinct question whether the Administrative Procedure Act authorizes federal courts to vacate federal agency action."). If that interpretation were correct,[5] however, it would implicate the ordinary rule that "injunctive relief should be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs." *CASA*, 606 U.S. at 852 (quoting *Califano v. Yamasaki*, 442 U.S. 682, 702 (1979) (alterations omitted)). And that is the Manufacturers' problem here: Nobody in this case has been able to figure out how to grant only Louisiana complete relief given the indiscriminate, nationwide attacks from prescribers and activists in pro-abortion states that FDA has facilitated. Indeed, to make this point concrete, every day individuals in states like California, New York, and Massachusetts—freed from the in-person dispensing requirement—are prescribing and mailing mifepristone into

[5] Although the question is not squarely presented here, Louisiana's position—in line with decisions from virtually every federal court of appeals—is that the APA does provide for non-party specific relief under both § 705 and § 706. *See* CA5.ECF.12-1 at 23 (La.App.834); Dist.Ct.ECF.20-26 at 16–17 (La.App.667-68) (preserving this position); *see also Griffin v. HM Fla.-ORL, LLC*, 144 S. Ct. 1, 2 n.1 (U.S.) (Kavanaugh, J., respecting the denial of the application for stay) (noting that the APA gives federal courts the unique statutory authority to act directly against unlawful agency actions).

Louisiana.

The Manufacturers and FDA have long known about this problem. The district court pressed FDA on this point, and FDA had no answer. CA5.ECF.12-1 at 24 (La.App.857) ("Q: 'I asked plaintiffs' counsel if she could conceive of any remedy limited to the parties of this case, Rule 65 remedy. Can you think of any?' A: 'We aren't proposing any narrowing of relief....' Q: 'All right. I'm asking you: Can you think of any way, as a technical matter, to do that in this case?' A: 'I can't, Your Honor.'" (citation omitted)). Plaintiffs pressed the Manufacturers and FDA on this point in the Fifth Circuit—and, again, they offered no answer. *See id.* at 23–24 ("[I]t is not Louisiana's fault that only a universal § 705 stay could remedy Louisiana's harm. Louisiana would be open to a Louisiana-specific remedy—except that no one can figure out how to build one considering the indiscriminate, nationwide attacks from doctors and activists in pro-abortion states that FDA has facilitated."). And still today, while loudly complaining about the "nationwide" stay entered below, the Manufacturers do not offer a single alternative solution that would grant Louisiana the relief to which it is entitled.

That is why the Manufacturers' feints at potential questions about the availability and scope of universal relief under the APA are meritless: Even if the Court treated APA relief as limited by traditional equitable principles, *see* Danco.Appl.42, the stay entered by the Fifth Circuit would remain valid. A court would not deny a person injunctive relief against his neighbor's loud music just because other neighbors might likewise benefit from the injunction (or others who

were enjoying the music might oppose the injunction). *See CASA*, 606 U.S. at 851–52. So, too, the Fifth Circuit properly rejected the Manufacturers' argument that a court should level down by denying Louisiana relief to which it is entitled simply because that relief "incidentally" affects non-parties. *Id.* at 851.[6]

III. IF THE COURT WERE INCLINED TO STAY THE FIFTH CIRCUIT'S DECISION, PLAINTIFFS WOULD ACQUIESCE IN CERTIORARI BEFORE JUDGMENT AND ORAL ARGUMENT BEFORE THE SUMMER RECESS.

Although the Manufacturers are not entitled to a stay or vacatur, Plaintiffs respectfully submit that, if the Court believed otherwise, the appropriate course would be to grant certiorari before judgment and set this case for argument before the summer recess. *See* Danco.Appl.1, 44. That is so because the Fifth Circuit has now issued three separate decisions addressing the merits of Plaintiffs' APA claims. And both the district court below and the Fifth Circuit have provided opinions addressing Louisiana's standing. It thus would make little sense to send this case back to the Fifth Circuit for proceedings that, in all likelihood, will not change the posture of this case. Moreover, sending the case back to the Fifth Circuit with an

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[6] Both Manufacturers vaguely gesture at questions about whether § 705 authorizes a preliminary stay or injunction at all—gestures that do not lead anywhere. For its part, Danco complains (Danco.Appl.39–40) that § 705 uses the word "postpone," which does not fairly capture a post-promulgation stay. But § 705 also uses the phrase "preserve status or rights," which necessarily contemplates a stay of the agency action after the agency has taken effect. Citing no authority, GBP proposes (GBP.Appl.36–37) that "preservation" of rights should be limited to preserving the challenged action. But that would render the phrase "preserve status or rights" superfluous because a court does not need authority to maintain a challenged agency action throughout the pendency of the litigation. The only plausible understanding of the text is that it authorizes precisely the sort of stay entered by the Fifth Circuit, to preserve the rights that existed before the unlawful action took effect. *See Labrador*, 144 S. Ct. at 930 (Kavanaugh, J., concurring in the grant of stay) (explaining different potential perspectives of the relevant status quo).

effective denial of preliminary relief in place would perpetuate the very harms Louisiana is suffering. Finally, given that the Fifth Circuit previously expedited proceedings in this context, the same would likely be true here—which means the parties would be back again before this Court in a few months.

To avoid these issues, Plaintiffs would acquiesce in certiorari before judgment and argument before the summer recess if the Court were otherwise inclined to stay or vacate the Fifth Circuit's decision pending appeal. Argument before the summer recess is key to Plaintiffs' acquiescence in certiorari before judgment. Otherwise, Louisiana will continue to suffer irreparable harm indefinitely: While this Court considers the pending applications, approximately 1,000 abortions are taking place in Louisiana every month, undermining its "prerogative of protecting unborn life"—a prerogative that "cannot be regained by legal remedy." CA5.ECF.119-1 at 14–15 (La.App.1029-30).

Mindful of the compressed timeline, Plaintiffs also respectfully submit that—if the Court were inclined to go this route—Plaintiffs would not oppose foregoing additional briefing in favor of oral argument on the application papers. *See, e.g.*, *Trump v. CASA, Inc.*, No. 24A884 (U.S.). Alternatively, Plaintiffs would not oppose a briefing schedule requiring the filing of simultaneous briefs. *See, e.g.*, *TikTok, Inc. v. Garland*, No. 24A587 (U.S.).

Plaintiffs hasten to reiterate their principal position, however, that the Manufacturers are not entitled to stay or vacatur of the Fifth Circuit's decision—and, if the Court agrees, then that would moot Plaintiffs' alternative position discussed

here in Section III.

CONCLUSION

The Court should deny the Manufacturers' applications.

Respectfully submitted,

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