

No. 26-30203

In the United States Court of Appeals for the Fifth Circuit

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

v.

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

v.

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

v.

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

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

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

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

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STATEMENT REGARDING ORAL ARGUMENT

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

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INTRODUCTION

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

The results are sobering. Although Louisiana prohibits abortion with very narrow exceptions, nearly 1,000¹ Louisiana babies are illegally

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

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

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

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

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

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

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

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

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

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

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

JURISDICTIONAL STATEMENT

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

ISSUE PRESENTED

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

STATEMENT OF THE CASE

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

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

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

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

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

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

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

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

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

B. The 2023 REMS Floods Louisiana with Illegal Mifepristone.

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

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

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

Get Abortion Pill Online in Louisiana · Order Here

You can buy an abortion pill online and get it by mail in Louisiana. The FDA has approved abortion pills by mail. Aid Access 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). Therefore Aid Access can provide abortion services to all 50 U.S. states including Louisiana.

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

Louisiana abortion pill online orders:

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

ROA.1304.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

SUMMARY OF ARGUMENT

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

LEGAL STANDARD

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

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

ARGUMENT

I. PLAINTIFFS ARE LIKELY TO SUCCEED ON THE MERITS.

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

A. Louisiana Has Article III Standing.

Start with standing. “To establish standing ... a plaintiff must demonstrate (i) that she has suffered or likely will suffer an injury in fact, (ii) that the injury likely was caused or will be caused by the defendant, and (iii) that the injury likely would be redressed by the requested judicial relief.” *Alliance*, 602 U.S. at 380. A “general principle” governing this inquiry is that “courts may make ‘commonsense inferences’ when

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

a. Violations of state law

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

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

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

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

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

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

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

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

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

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

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

b. Inability to enforce state law

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

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

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

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

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

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

would implicate the “government’s interest in enforcing” the law and “appreciably injure its interests”).

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

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

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

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

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

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

* * *

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1033), Kerestes (ROA.1035), Aiken 2017² (ROA.1038)) had either a pelvic examination or ultrasound prior to taking the drugs—a safeguard that goes above and beyond even the in-person dispensing safeguard FDA stripped away. In other words, most participants in the five studies principally relied upon by FDA were mailed mifepristone only *after* receiving either an in-person examination or an ultrasound. FDA was therefore unquestionably correct in admitting that “the studies [it] reviewed are *not adequate on their own* to establish the safety of the model of dispensing mifepristone by mail.” ROA.1093 (emphasis added).

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

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

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

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

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

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

The Manufacturers³ also face no irreparable harm; the equities and the public interest weigh in favor of preserving the Fifth Circuit’s decision; and any complaints about the scope of relief are misplaced.

A. The Manufacturers Face No Irreparable Harm.

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

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

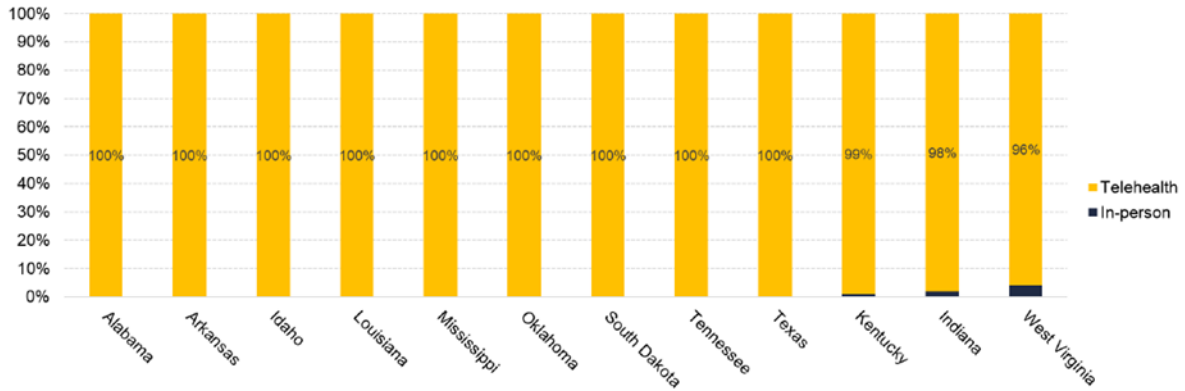
³ In the Supreme Court, the federal Defendants declined to participate in briefing surrounding the stay panel’s decision to preliminarily stay the 2023 REMS. For that reason, Plaintiffs here focus on the Manufacturers.

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

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

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

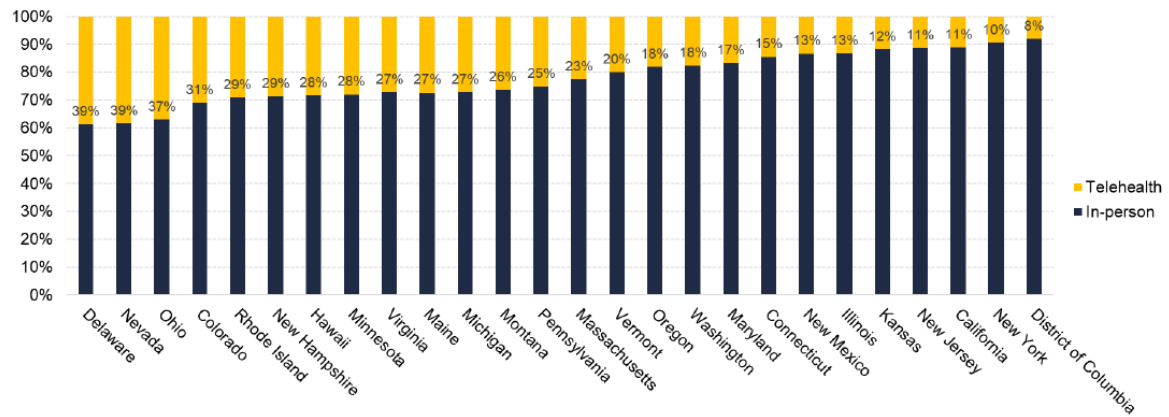
January to June 2025, percent provided via telehealth in states where abortion is banned



Source: [Society of Family Planning](#), December 2025

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

January to June 2025, percent provided via telehealth in states where abortion and telehealth are permitted



Source: [Society of Family Planning](#), December 2025

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

B. The Balance of the Equities Favors a Stay.

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

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

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

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

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

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

All this makes for an easy equities analysis.

C. The Public Interest Likewise Favors Preliminary Relief.

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

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

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

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

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

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

CONCLUSION

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

Dated: June 15, 2026

Respectfully submitted,

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CERTIFICATE OF SERVICE

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

/s/ J. Benjamin Aguiñaga
J. BENJAMIN AGUIÑAGA

CERTIFICATE OF COMPLIANCE

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

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

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

/s/ J. Benjamin Aguiñaga
J. BENJAMIN AGUIÑAGA

Dated: June 15, 2026

No. 26-30203

In the United States Court of Appeals for the Fifth Circuit

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

v.

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

v.

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

v.

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

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

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**U.S. District Court
Western District of Louisiana (Lafayette)
CIVIL DOCKET FOR CASE #: 6:25-cv-01491-DCJ-DJA
Internal Use Only**

Louisiana et al v. U S Food & Drug Administration et al
Assigned to: Judge David C Joseph
Referred to: Magistrate Judge David J Ayo
Case in other court: 5CCA, 26-30203
Cause: 05:551 Administrative Procedure Act

Date Filed: 10/03/2025
Jury Demand: None
Nature of Suit: 899 Other Statutes:
Administrative Procedures Act/Review or
Appeal of Agency Decision
Jurisdiction: Federal Question

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Date Filed	#	Docket Text
10/06/2025	<u>1</u>	COMPLAINT against U S Food & Drug Administration, U S Dept of Health & Human Services, Robert F Kennedy, Jr, Martin Makary, George Francis Tidmarsh (Filing fee \$405, receipt number ALAWDC-6416152) filed by State Louisiana, Rosalie Markezich. (Attachments: # <u>1</u> Exhibit 1: Society of Family Planning, # <u>2</u> Exhibit 2: Society of Family Planning, # <u>3</u> Exhibit 3: 2021 FDA Letter, # <u>4</u> Exhibit 4: Dr. Margaret Carpenter indictment, # <u>5</u> Exhibit 5: Center for Drug Evaluation

& Research Application, # 6 Exhibit 6: Mifepristone, StatPearls, # 7 Exhibit 7: The Facts on Mifepristone, # 8 Exhibit 8: Medication Abortion, # 9 Exhibit 9: 2023 FDA-Approved Label, # 10 Exhibit 10: 2021 FDA Letter to AAPLOG, # 11 Exhibit 11: Center for Drug Evaluation & Research Application, # 12 Exhibit 12: Comparison of rates, # 13 Exhibit 13: Abortion Pill Harms Women, # 14 Exhibit 14: Comparative Acuity, # 15 Exhibit 15: Will a doctor be able to tell, # 16 Exhibit 16: How do you know # 17 Exhibit 17: Am. Coll. of Obstetricians & Gynecologists Practice, # 18 Exhibit 18: #AbortionChangesYou, # 19 Exhibit 19: Population Council, # 20 Exhibit 20: 2002 Citizen Petition, # 21 Exhibit 21: Robert O'Harrow Jr, # 22 Exhibit 22: Hannah Levintova, # 23 Exhibit 23: Letter from Center for Drug Evaluation, # 24 Exhibit 24: 2000 FDA Approval Letter, # 25 Exhibit 25: 2019 FDA ANDA Approval Letter, # 26 Exhibit 26: FDA Center for Drug Evaluation, # 27 Exhibit 27: 2000 FDA Approval Memo, # 28 Exhibit 28: Identification of Drug & Biological Products, # 29 Exhibit 29: 2011 FDA Supplemental Approval Letter, # 30 Exhibit 30: 2011 REMS for NDA, # 31 Exhibit 31: 2016 FDA Letter to AAPLOG, # 32 Exhibit 32: 2020 Letter from ACOG, # 33 Exhibit 33: Students for Life of America, # 34 Exhibit 34: 2023 FDA Letter to Students, # 35 Exhibit 35: 2021 FDA Center for Drug Evaluation, # 36 Exhibit 36: Oral History Interview, # 37 Exhibit 37: White House, Readout, # 38 Exhibit 38: White House, Press Briefing, # 39 Exhibit 39: Ian Millhiser, # 40 Exhibit 40: White House, Remarks by President Biden Before, # 41 Exhibit 41: White House, Remarks by President Biden, # 42 Exhibit 42: White House, FACT SHEET, # 43 Exhibit 43: White House, Remarks by President Biden, # 44 Exhibit 44: Exec. Order No. 14076, # 45 Exhibit 45: Exec. Order No. 14079, # 46 Exhibit 46: Presidential Memorandum, # 47 Exhibit 47: White House, FACT SHEET, # 48 Exhibit 48: Press Release, HHS, HHS, # 49 Exhibit 49: Press Release, HHS, # 50 Exhibit 50: Center for Drug Evaluation & Research, Application Number: 020687O, # 51 Exhibit 51: Center for Drug Evaluation & Research, Application Numbers: 020687, # 52 Exhibit 52: FDA Adverse Events Reporting, # 53 Exhibit 53: Kathi A. Aultman, # 54 Exhibit 54: Specifications for Preparing, # 55 Exhibit 55: Christiana A. Cirucci, # 56 Exhibit 56: Pam Belluck, # 57 Exhibit 57: 2019 REMS Single Shared, # 58 Exhibit 58: HHS, Marking, # 59 Exhibit 59: Press Release, HHS, HHS, # 60 Exhibit 60: White House, FACT SHEET, # 61 Exhibit 61: HHS, Secretarys Report, # 62 Exhibit 62: Abuzz, Abortion Pill Access, # 63 Exhibit 63: Abuzz, Need abortion care, # 64 Exhibit 64: A Safe Choice, Home, # 65 Exhibit 65: A Safe Choice, Online Consultation Form, # 66 Exhibit 66: Choices Rising, # 67 Exhibit 67: MAP, # 68 Exhibit 68: Scott Calvert, # 69 Exhibit 69: Rachel Roubein, # 70 Exhibit 70: Rebecca Grant, # 71 Exhibit 71: Aid Access, # 72 Exhibit 72: Elissa Nadworny, # 73 Exhibit 73: Abigail Brooks, # 74 Exhibit 74: Pam Belluck, # 75 Exhibit 75: Caroline Kitchener, Alone in a bathroom: The fear and uncertainty oft, # 76 Exhibit 76: Her

		<p>Safe Harbor, Abortion Pills Online, # <u>77</u> Exhibit 77: Pam Belluck, A day with one abortion pill prescriber, N.Y. Times, # <u>78</u> Exhibit 78: Abuzz, FAQs, # <u>79</u> Exhibit 79: ACT, Who We Are, # <u>80</u> Exhibit 80: ACT, What We Do, # <u>81</u> Exhibit 81: ACT, FAQs, # <u>82</u> Exhibit 82: ACT, Resources, # <u>83</u> Exhibit 83: Alaa Elassar, # <u>84</u> Exhibit 84: Rosemary Westwood, # <u>85</u> Exhibit 85: Katherine Donlevy, # <u>86</u> Exhibit 86: Lorena O'Neil, # <u>87</u> Exhibit 87: Press Release, ACT, # <u>88</u> Exhibit 88: Press Release, Protecting, # <u>89</u> Exhibit 89: Rosemary Westwood, # <u>90</u> Exhibit 90: Governor Kathy Hochul, # <u>91</u> Exhibit 91: Society of Family Planning, # <u>92</u> Exhibit 92: Rosalie Markezich, # <u>93</u> Exhibit 93: Exhibit 5: Medicaid, # <u>94</u> Exhibit 94: Julie O'Donoghue, # <u>95</u> Exhibit 95: LDH Medicaid, # <u>96</u> Exhibit 96: Marc Roemer, # <u>97</u> Exhibit 97: Hospital Services Provider, # <u>98</u> Exhibit 98: Louisiana Medicaid Hospital Ambulatory, # <u>99</u> Exhibit 99: Louisiana Medicaid Hospital, # <u>100</u> Exhibit 100: Louisiana Medicaid Hospital Ambulatory Surgery Fee Schedule: Non-Rural, # <u>101</u> Exhibit 101: Medicaid Services, # <u>102</u> Exhibit 102: State Hospitals, # <u>103</u> Exhibit 103: Small Rural Hospital, # <u>104</u> Exhibit 104: Louisiana Medicaid Hospital Provider Inpatient Per Diem Rates, # <u>105</u> Exhibit 105: Pam Belluck, # <u>106</u> Exhibit 106: AP, Texas, # <u>107</u> Exhibit 107: Caroline Kitchner, # <u>108</u> Exhibit 108: Secretary Kennedy, # <u>109</u> Exhibit 109: Evita Solutions, # <u>110</u> Exhibit 110: Letter from Robert F. Kennedy, # <u>111</u> Civil cover sheet)(aty,Huettemann, Caitlin) Modified on 10/7/2025 to modify docket text. Crick, S). (Entered: 10/06/2025), (QC'ed on 10/07/2025, by Crick, S)</p>
10/06/2025		CASE Assigned to Judge David C Joseph and Magistrate Judge David J Ayo. (crt,Crick, S) (Entered: 10/07/2025)
10/07/2025	<u>2</u>	SUMMONS ISSUED as to U S Attorney, U S Attorney General, U S Food & Drug Administration, Martin Makary, George Francis Tidmarsh, U S Dept of Health & Human Services, Robert F Kennedy, Jr. (crt,Crick, S) (Entered: 10/07/2025)
10/09/2025	<u>3</u>	SUMMONS ISSUED as to U S Attorney, U S Attorney General, Robert F Kennedy Jr. (crt,Crick, S) (Entered: 10/09/2025)
10/09/2025	<u>4</u>	MOTION for Erik C. Baptist to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6420762) by State Louisiana, Rosalie Markezich. Motions referred to David J Ayo. Motion Ripe Deadline set for 10/9/2025. (Attachments: # <u>1</u> Proposed order)(aty,Huettemann, Caitlin) (Entered: 10/09/2025), (QC'ed on 10/09/2025, by Crick, S)
10/09/2025	<u>5</u>	MOTION for Erin M. Hawley to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6421078) by All Plaintiffs. Motions referred to David J Ayo. Motion Ripe Deadline set for 10/9/2025. (Attachments: # <u>1</u> Proposed order)(aty,Huettemann, Caitlin) (Entered: 10/09/2025), (QC'ed

		on 10/09/2025, by Crick , S)
10/09/2025	<u>6</u>	MOTION for Julie Marie Blake to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6421086) by All Plaintiffs. Motions referred to David J Ayo. Motion Ripe Deadline set for 10/9/2025. (Attachments: # <u>1</u> Proposed order)(aty,Huettemann, Caitlin) (Entered: 10/09/2025), (QC'ed on 10/09/2025, by Crick , S)
10/09/2025	<u>7</u>	MOTION for Frank W. Basgall to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6421099) by All Plaintiffs. Motions referred to David J Ayo. Motion Ripe Deadline set for 10/9/2025. (Attachments: # <u>1</u> Proposed order)(aty,Huettemann, Caitlin) (Entered: 10/09/2025), (QC'ed on 10/09/2025, by Crick , S)
10/09/2025	<u>8</u>	MOTION for Gabriella M. McIntyre to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6421103) by All Plaintiffs. Motions referred to David J Ayo. Motion Ripe Deadline set for 10/9/2025. (Attachments: # <u>1</u> Proposed order)(aty,Huettemann, Caitlin) (Entered: 10/09/2025), (QC'ed on 10/09/2025, by Crick , S)
10/09/2025	<u>9</u>	MOTION for Dalton A. Nichols to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6421116) by All Plaintiffs. Motions referred to David J Ayo. Motion Ripe Deadline set for 10/9/2025. (Attachments: # <u>1</u> Proposed order)(aty,Huettemann, Caitlin) (Entered: 10/09/2025), (QC'ed on 10/09/2025, by Crick , S)
10/10/2025	<u>10</u>	ORDER granting <u>4</u> Motion to Appear Pro Hac Vice for appearance of Erik C Baptist for State Louisiana, Rosalie Markezich. Signed by Magistrate Judge David J Ayo on 10/10/2025. (crt,Crick, S) (Entered: 10/10/2025)
10/10/2025	<u>11</u>	ORDER granting <u>6</u> Motion to Appear Pro Hac Vice for appearance of Julie Marie Blake for State Louisiana, Rosalie Markezich. Signed by Magistrate Judge David J Ayo on 10/10/2025. (crt,Crick, S) (Entered: 10/10/2025)
10/10/2025	<u>12</u>	ORDER granting <u>5</u> Motion to Appear Pro Hac Vice for appearance of Erin M Hawley for State Louisiana, Rosalie Markezich. Signed by Magistrate Judge David J Ayo on 10/10/2025. (crt,Crick, S) (Entered: 10/10/2025)
10/10/2025	<u>13</u>	ORDER granting <u>7</u> Motion to Appear Pro Hac Vice for appearance of Frank W Basgall for State Louisiana, Rosalie Markezich. Signed by Magistrate Judge David J Ayo on 10/10/2025. (crt,Crick, S) (Entered: 10/10/2025)
10/10/2025	<u>14</u>	ORDER granting <u>8</u> Motion to Appear Pro Hac Vice for appearance of Gabriella M McIntyre for State Louisiana, Rosalie Markezich. Signed by Magistrate Judge David J Ayo on 10/10/2025. (crt,Crick, S) (Entered: 10/10/2025)
10/10/2025	<u>15</u>	

		ORDER granting <u>9</u> Motion to Appear Pro Hac Vice for appearance of Dalton A Nichols for State Louisiana, Rosalie Markezich. Signed by Magistrate Judge David J Ayo on 10/10/2025. (crt,Crick, S) (Entered: 10/10/2025)
11/05/2025	<u>16</u>	SUMMONS Returned Executed by State Louisiana U S Food & Drug Administration served on 10/15/2025, answer due 12/15/2025; U S Dept of Health & Human Services served on 10/22/2025, answer due 12/22/2025; Robert F Kennedy, Jr served on 10/15/2025, answer due 12/15/2025; Martin Makary served on 10/15/2025, answer due 12/15/2025; George Francis Tidmarsh served on 10/22/2025, answer due 12/22/2025. (aty,Huettemann, Caitlin) Modified on 11/5/2025 to modify dates of service and answer due dates. (Crick, S). (Entered: 11/05/2025), (QC'ed on 11/05/2025, by Crick , S)
11/05/2025		(Court only) ***Set/Reset Answer Due: U S Food & Drug Administration answer due 12/15/2025; Robert F Kennedy, Jr answer due 12/15/2025; Martin Makary answer due 12/15/2025. Answer deadline modified as erroneous service date was entered at the time of e-filing. (crt,Crick, S) (Entered: 11/05/2025)
11/05/2025		NOTICE of Corrective Action to Caitlin Ann Huettemann on behalf of State Louisiana regarding <u>16</u> Summons Returned Executed as to USA,, Action taken: Docket text modified to reflect correct service date of 10/15/25 and answer due date of 12/15/25 as to U S Food & Drug Administration, Robert F Kennedy, Jr & Martin Makary as an incorrect service date was entered at the time of e-filing. (crt,Crick, S) (Entered: 11/05/2025)
11/26/2025	<u>17</u>	NOTICE of Appearance by Noah T Katzen on behalf of U S Food & Drug Administration, U S Dept of Health & Human Services, Robert F Kennedy, Jr, Martin Makary, George Francis Tidmarsh (Attorney Noah T Katzen added to party U S Food & Drug Administration(pty:dft), U S Dept of Health & Human Services(pty:dft), Robert F Kennedy, Jr(pty:dft), Martin Makary(pty:dft), George Francis Tidmarsh(pty:dft)) (aty,Katzen, Noah) Modified on 11/26/2025 to modify docket text. (Crick, S). (Entered: 11/26/2025), (QC'ed on 11/26/2025, by Crick , S)
11/26/2025	<u>18</u>	Consent MOTION for Extension of Time to File Answer with consent by All Defendants. Motions referred to David J Ayo. Motion Ripe Deadline set for 11/26/2025. (Attachments: # <u>1</u> Text of proposed order)(aty,Katzen, Noah) (Entered: 11/26/2025), (QC'ed on 11/26/2025, by Crick , S)
12/01/2025	<u>19</u>	ORDER granting <u>18</u> Motion for Extension of Time to Answer re <u>1</u> Complaint. U S Food & Drug Administration, U S Dept of Health & Human Services, Robert F Kennedy, Jr, Martin Makary, and George Francis Tidmarsh answer due 1/12/2026. Signed by Magistrate Judge David J Ayo on 12/1/2025. (crt,Chicola, C) (Entered: 12/01/2025)

12/17/2025

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MOTION for Preliminary Injunction, or MOTION for Preliminary Relief Under 5 U.S.C. § 705 by All Plaintiffs. Motion Ripe Deadline set for 12/17/2025. (Attachments: # 1 Exhibit 1 #WeCount Report April 2022 to June 2025 (Dec. 9, 2025), # 2 Exhibit 2 #WeCount Report Summary Slides with National and 51 State-Level Findings April 2022 to June 2025 (Dec. 9, 2025), # 3 Exhibit 3 Abigail R. A. Aiken et al., Research Letter, Provision of Abortion Medications Using Online Asynchronous Telemedicine Under Shield Laws in the US, 334(15) JAMA 1388 (Oct. 21, 2025), # 4 Exhibit 4 Robin Wallace et al, P040 - Expanding Access to Abortion with Mifepristone and Misoprostol Through 84 Days Estimated Gestational Duration, 151 Contraception 111117 (Nov. 2025), # 5 Exhibit 5 Governor Newsom Signs New Landmark Laws to Protect Reproductive Freedom, Patient Privacy Amid Trumps War on Women, Gov. Gavin Newsom (Sep. 26, 2025), # 6 Exhibit 6 US FDA Has Delayed Abortion Pill Safety Study, Bloomberg News Reports, Reuters (Dec. 8, 2025, at 14:23 PT), # 7 Exhibit 7 Elizabeth Troutman Mitchell, EXCLUSIVE: Makary Responds to Report Saying He Slow-Walked Abortion Pill Safety Review, Daily Signal (Dec. 9, 2025), # 8 Exhibit 8 Ian Lopez, RFK Jr. Says Biden Twisted the Data on Abortion Pill Safety, BL (Sep. 4, 2025, at 12:45 ET), # 9 Exhibit 9 U.S. Senator Bill Cassidy, M.D. (@SenBillCassidy), X (Dec. 12, 2025, at 13:05 PT), # 10 Exhibit 10 Video posted by Elizabeth Mitchell Troutman (@TheElizMitchell), X, at 02:022:19 (Dec. 9, 2025, at 14:56 PT), # 11 Exhibit 11 T. Elliot Gaiser et al., The Truth of Erasure: Universal Remedies for Universal Agency Actions, U. Chi. L. Rev. Online (Aug. 28, 2024), # 12 Exhibit 12 Letter from Elizabeth Warren et al. to FDA (Nov. 18, 2022), # 13 Exhibit 13 Aria Bendix, Why Abortions Rose After Roe Was Overturned, NBC News (Nov. 26, 2024, at 2:00 PT), # 14 Exhibit 14 Complaint, Rodriguez v. Coeytaux, No. 3:25-cv-00225, (S.D. Tex. July 20, 2025), # 15 Exhibit 15 Notice of Cease and Desist from Ken Paxton, Atty Gen. of Tex., to Remy Coeytaux (Aug. 14, 2025), # 16 Exhibit 16 FDA, REMS Single Shared System for Mifepristone 200MG (May 2021), # 17 Exhibit 17 REMS Compliance Program, FDA (Sep. 22, 2022), # 18 Exhibit 18 Declaration of John Voltz, M.D. (Nov. 17, 2025), # 19 Exhibit 19 Declaration of Kathleen Richard, LMSW (Nov. 12, 2025), # 20 Exhibit 20 Declaration of Kathleen Willis, M.D. (Dec. 15, 2025), # 21 Exhibit 21 Declaration of Christina Francis, M.D. (Dec. 12, 2025), # 22 Exhibit 22 Declaration of Michael J. New, Ph.D (Dec. 15, 2025), # 23 Exhibit 23 Declaration of Angela Parise, M.D. (Dec. 11, 2025), # 24 Exhibit 24 Declaration of Lindsey Sikes (Dec. 15, 2025), # 25 Exhibit 25 Declaration of Gabriella McIntyre (Dec. 16, 2025), # 26 Memorandum / Brief in Support of Plaintiff State of Louisiana and Rosalie Markzich's Motion for Preliminary Injunction for Preliminary Relief Under 5 U.S.C. § 705, # 27 Exhibit List, # 28 Proposed order Granting Plaintiff State of Louisiana and Rosalie Markzich's Motion for Preliminary Injunction for Preliminary Relief Under 5 U.S.C. §

		705)(aty,Huettemann, Caitlin). Added MOTION for Preliminary Relief and modified docket text on 12/17/2025 (Crick, S). (Entered: 12/17/2025), (QC'ed on 12/17/2025, by Crick , S)
12/17/2025		Set/Reset Deadlines as to <u>20</u> MOTION for Preliminary Injunction <i>or for Preliminary Relief Under 5 U.S.C. § 705</i> . Motion Ripe Deadline set for 12/17/2025. (crt,Crick, S) (Entered: 12/17/2025)
12/17/2025	<u>21</u>	ELECTRONIC MINUTE ENTRY: A Zoom Status Conference to determine briefing deadlines re MOTION for Preliminary Injunction, or MOTION for Preliminary Relief Under 5 U.S.C. § 705 filed by all Plaintiffs is set for Friday, 12/19/2025 at 9:30 AM via Zoom Video Conference before Judge David C Joseph. A Zoom link will be forwarded via email to all counsel of record. Signed by Judge David C Joseph on 12/17/2025. (crt,LaCombe, L) (Entered: 12/17/2025)
12/18/2025	<u>22</u>	MOTION for J. Benjamin Aguiaga to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6509312) by State Louisiana. Motions referred to David J Ayo. Motion Ripe Deadline set for 12/18/2025. (Attachments: # <u>1</u> Certificate of good standing, # <u>2</u> Proposed Order)(aty,Huettemann, Caitlin) Modified on 12/18/2025 to modify filer.(Crick, S). (Entered: 12/18/2025), (QC'ed on 12/18/2025, by Crick , S)
12/18/2025	<u>23</u>	MOTION to Participate in Status Conference & NOTICE of Intent to Move to Intervene by Danco Laboratories L L C (Attorney William Brock Most added to party Danco Laboratories L L C(pty:intv)) (aty,Most, William) Modified on 12/18/2025 to capture motion event. (Crick, S). (Entered: 12/18/2025), (QC'ed on 12/18/2025, by Crick , S)
12/18/2025	<u>24</u>	Ex Parte MOTION for Jessica L. Ellsworth to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6509765) by Danco Laboratories, LLC. Motions referred to David J Ayo. Motion Ripe Deadline set for 12/18/2025. (Attachments: # <u>1</u> Exhibit A (Certificate of Good Standing), # <u>2</u> Proposed order)(aty,Most, William) (Entered: 12/18/2025), (QC'ed on 12/18/2025, by Crick , S)
12/18/2025		Set/Reset Deadlines as to <u>23</u> MOTION to Participate in Status Conference. Motion Ripe Deadline set for 12/18/2025. (crt,Crick, S) (Entered: 12/18/2025)
12/18/2025	<u>25</u>	Proposed Briefing Schedule by State Louisiana, Rosalie Markezich re 21 Minute Entry,, Set Hearings, . (aty,Huettemann, Caitlin) Modified on 12/18/2025 to modify docket text. (Crick, S). (Entered: 12/18/2025), (QC'ed on 12/18/2025, by Crick , S)
12/18/2025	<u>26</u>	MOTION to Participate in Status Conference & NOTICE to Intervene by GenBioPro (Attorney John N Adcock added to party GenBioPro(pty:intvd)) (aty,Adcock, John) Modified on

		12/19/2025 to capture motion event and modify docket text. (Crick, S). (Entered: 12/18/2025), (QC'ed on 12/19/2025, by Crick , S)
12/18/2025	<u>27</u>	Ex Parte MOTION for Robert Katerberg to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6510616) by GenBioPro. Motions referred to David J Ayo. Motion Ripe Deadline set for 12/18/2025. (Attachments: # <u>1</u> Certificate of good standing)(aty,Adcock, John) Modified on 12/19/2025 to indicate proposed order included within PDF of main document. (Crick, S). (Entered: 12/18/2025), (QC'ed on 12/19/2025, by Crick , S)
12/18/2025		Motions Transferred regarding <u>26</u> MOTION to Participate in Status Conference & Notice of Intent to Intervene. Motions referred to Magistrate Judge David J Ayo. (crt,Crick, S) (Entered: 12/19/2025)
12/18/2025		Motions Transferred regarding <u>26</u> MOTION to Participate in Status Conference & Notice of Intent to Intervene. Motions referred to Judge David C Joseph. (crt,Crick, S) (Entered: 12/19/2025)
12/19/2025	<u>28</u>	MINUTES for proceedings held before Judge David C Joseph: STATUS CONFERENCE held on 12/19/2025. Danco Laboratories LLC's Motion to Participate in Status Conference <u>23</u> is GRANTED. GenBioPro's Motion to Participate in Status Conference <u>26</u> is DENIED as late-filed. After discussion with the parties, the following briefing scheduling is ORDERED: The Government's response to the Motion for Preliminary Injunction, along with the Government's Answer and any Rule 12 motion, shall be filed no later than January 23, 2026. All motions to intervene and any conditional responses to the Motion for Preliminary Injunction by the proposed intervenors shall be filed no later than January 30, 2026. Plaintiffs Reply to the Defendants response to the Preliminary Injunction Motion, as well as any response to any motion filed by Defendants and any responses by Plaintiffs or Defendants to any motions to intervene and conditional responses of the intervenors to the Preliminary Injunction Motion shall be filed no later than February 13, 2025. The Defendants' Reply in support of any Rule 12 or other motion shall be filed no later than February 20, 2026. A hearing is set for February 24, 2026, at 10:00 am in Courtroom 1, Lafayette, before Judge David Joseph regarding the Motion for Preliminary Injunction <u>20</u> . (Court Reporter: VTC) (crt,Craig, C) (Entered: 12/19/2025)
12/19/2025		Set/Reset Deadlines as to <u>20</u> MOTION for Preliminary Injunction <i>or for Preliminary Relief Under 5 U.S.C. § 705</i> MOTION for Preliminary Relief Under 5 USC 705. Motion day set for 2/24/2026 10:00 AM in Lafayette, Courtroom 1 before Judge David C Joseph. (crt,Craig, C) (Entered: 12/19/2025)
12/19/2025	<u>29</u>	MOTION for Substitution of Lead Attorney by Rosalie Markezich. Motions referred to David J Ayo. Motion Ripe

		Deadline set for 12/19/2025. (Attachments: # <u>1</u> Proposed order)(aty,Baptist, Erik) (Entered: 12/19/2025), (QC'ed on 12/22/2025, by Bunting , M)
12/22/2025	<u>30</u>	ORDER granting <u>22</u> Motion to Appear Pro Hac Vice for appearance of J Benjamin Aguinaga for State Louisiana,J Benjamin Aguinaga for Rosalie Markezich. Signed by Magistrate Judge David J Ayo on 12/19/2025. (crt,Bunting, M) (Entered: 12/22/2025)
12/22/2025	<u>31</u>	ORDER granting <u>24</u> Motion to Appear Pro Hac Vice for appearance of Jessica L Ellsworth for Danco Laboratories L L C. Signed by Magistrate Judge David J Ayo on 12/19/2025. (crt,Bunting, M) (Entered: 12/22/2025)
12/22/2025	<u>32</u>	ORDER granting <u>27</u> Motion to Appear Pro Hac Vice for appearance of Robert J Katerberg for GenBioPro Inc. Signed by Magistrate Judge David J Ayo on 12/19/2025. (crt,Bunting, M) (Entered: 12/22/2025)
12/22/2025		(Court only) ***Deadlines/Hearings terminated. Motion Ripe Deadline terminated. (crt,LaCombe, L) (Entered: 12/22/2025)
12/23/2025	<u>33</u>	ORDER granting <u>29</u> Motion Substitution of Lead Attorney. Erik C. Baptist is now Lead Attorney for Rosalie Markezich. Signed by Magistrate Judge David J Ayo on 12/23/2025. (crt,Bunting, M) (Entered: 12/23/2025)
01/16/2026	<u>34</u>	Joint MOTION for Extension of Time to File Response/Reply, MOTION to Continue Hearing by State Louisiana, George Francis Tidmarsh, Rosalie Markezich, Martin Makary, Robert F Kennedy, Jr, U S Dept of Health & Human Services, U S Food & Drug Administration. Motions referred to David J Ayo. Motion Ripe Deadline set for 1/16/2026. (Attachments: # <u>1</u> Proposed order)(aty,Huettemann, Caitlin) Modified on 1/20/2026 to add filers and modify motion event. (Crick, S). Added MOTION to Continue on 1/20/2026 (Crick, S). (Entered: 01/16/2026), (QC'ed on 01/20/2026, by Crick , S)
01/16/2026		Motions Transferred regarding <u>34</u> MOTION for Extension of Time to File Response/Reply MOTION to Continue., Set/Reset Deadlines as to <u>34</u> MOTION for Extension of Time to File Response/Reply MOTION to Continue.(Motion Ripe Deadline set for 1/16/2026.) Motions referred to Judge David C Joseph. (crt,Crick, S) (Entered: 01/20/2026)
01/20/2026	<u>35</u>	Ex Parte MOTION for Daphne O'Connor to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6547904) by GenBioPro Inc. Motions referred to David J Ayo. Motion Ripe Deadline set for 1/20/2026. (Attachments: # <u>1</u> Proposed order, # <u>2</u> Certificate of good standing)(aty,Adcock, John) (Entered: 01/20/2026), (QC'ed on 01/20/2026, by Crick , S)
01/20/2026	<u>36</u>	Ex Parte MOTION for Lisa Newman to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6547986) by

		GenBioPro Inc. Motions referred to David J Ayo. Motion Ripe Deadline set for 1/20/2026. (Attachments: # <u>1</u> Proposed order, # <u>2</u> Certificate of good standing)(aty,Adcock, John) (Entered: 01/20/2026), (QC'ed on 01/20/2026, by Crick , S)
01/20/2026	<u>37</u>	Ex Parte MOTION for Skye Perryman to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6547992) by GenBioPro Inc. Motions referred to David J Ayo. Motion Ripe Deadline set for 1/20/2026. (Attachments: # <u>1</u> Proposed order, # <u>2</u> Certificate of good standing)(aty,Adcock, John) (Entered: 01/20/2026), (QC'ed on 01/20/2026, by Crick , S)
01/20/2026	<u>38</u>	Ex Parte MOTION for Carrie Flaxman to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6547998) by GenBioPro Inc. Motions referred to David J Ayo. Motion Ripe Deadline set for 1/20/2026. (Attachments: # <u>1</u> Proposed order, # <u>2</u> Certificate of good standing)(aty,Adcock, John) (Entered: 01/20/2026), (QC'ed on 01/20/2026, by Crick , S)
01/20/2026	<u>39</u>	ORDER re <u>34</u> Motion for Extension of Time to File Response/Reply. Signed by Judge David C Joseph on 1/20/2026. (crt,Crick, S) (Entered: 01/20/2026)
01/21/2026	<u>40</u>	ORDER granting <u>38</u> Motion to Appear Pro Hac Vice for appearance of Carrie Flaxman for GenBioPro Inc. Signed by Magistrate Judge David J Ayo on 1/21/2026. (crt,Crick, S) (Entered: 01/21/2026)
01/21/2026	<u>41</u>	ORDER granting <u>37</u> Motion to Appear Pro Hac Vice for appearance of Skye L Perryman for GenBioPro Inc. Signed by Magistrate Judge David J Ayo on 1/21/2026. (crt,Crick, S) (Entered: 01/21/2026)
01/21/2026	<u>42</u>	ORDER granting <u>36</u> Motion to Appear Pro Hac Vice for appearance of Lisa Newman for GenBioPro Inc. Signed by Magistrate Judge David J Ayo on 1/21/2026. (crt,Crick, S) (Entered: 01/21/2026)
01/21/2026	<u>43</u>	ORDER granting <u>35</u> Motion to Appear Pro Hac Vice for appearance of Daphne O'Connor for GenBioPro Inc. Signed by Magistrate Judge David J Ayo on 1/21/2026. (crt,Crick, S) (Entered: 01/21/2026)
01/26/2026	<u>44</u>	MOTION for Alexander Vladimir Sverdlov to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6557750) by Danco Laboratories L L C. Motions referred to David J Ayo. Motion Ripe Deadline set for 1/26/2026. (Attachments: # <u>1</u> Proposed Order, # <u>2</u> Sverdlov COGS)(aty,Most, William) (Entered: 01/26/2026), (QC'ed on 01/26/2026, by Crick , S)
01/26/2026	<u>45</u>	MOTION for Danielle Desaulniers Stempel to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6557777) by Danco Laboratories L L C. Motions referred to David J Ayo. Motion Ripe Deadline set for 1/26/2026. (Attachments: # <u>1</u> Proposed Order, # <u>2</u> Stempel

		COGS)(aty,Most, William) (Entered: 01/26/2026), (QC'ed on 01/26/2026, by Crick , S)
01/26/2026	<u>46</u>	MOTION for Dana A. Raphael to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6557783) by Danco Laboratories L L C. Motions referred to David J Ayo. Motion Ripe Deadline set for 1/26/2026. (Attachments: # <u>1</u> Proposed Order, # <u>2</u> Raphael COGS)(aty,Most, William) (Entered: 01/26/2026), (QC'ed on 01/26/2026, by Crick , S)
01/27/2026	<u>47</u>	ORDER granting <u>46</u> Motion to Appear Pro Hac Vice for appearance of Dana A Raphael for Danco Laboratories L L C. Signed by Magistrate Judge David J Ayo on 1/27/2026. (crt,Crick, S) (Entered: 01/27/2026)
01/27/2026	<u>48</u>	ORDER granting <u>45</u> Motion to Appear Pro Hac Vice for appearance of Danielle Desaulniers Stempel for Danco Laboratories L L C. Signed by Magistrate Judge David J Ayo on 1/27/2026. (crt,Crick, S) (Entered: 01/27/2026)
01/27/2026	<u>49</u>	ORDER granting <u>44</u> Motion to Appear Pro Hac Vice for appearance of Aleks Sverdlov for Danco Laboratories L L C. Signed by Magistrate Judge David J Ayo on 1/27/2026. (crt,Crick, S) (Entered: 01/27/2026)
01/27/2026	<u>50</u>	MOTION to Stay <i>the Case</i> by All Defendants. Motions referred to David J Ayo. Motion Ripe Deadline set for 1/27/2026. (Attachments: # <u>1</u> Memorandum / Brief, # <u>2</u> Text of proposed order)(aty,Katzen, Noah) (Entered: 01/27/2026), (QC'ed on 01/27/2026, by Crick , S)
01/27/2026	<u>51</u>	MEMORANDUM in Opposition re <u>20</u> MOTION for Preliminary Injunction <i>or for Preliminary Relief Under 5 U.S.C. § 705</i> MOTION for Preliminary Relief Under 5 USC 705 filed by U S Food & Drug Administration, U S Dept of Health & Human Services, Robert F Kennedy, Jr, Martin Makary, George Francis Tidmarsh. (aty,Katzen, Noah) (Entered: 01/27/2026), (QC'ed on 01/27/2026, by Crick , S)
01/27/2026		Motions Transferred regarding <u>50</u> MOTION to Stay <i>the Case</i> . Motions referred to Judge David C Joseph. (crt,Crick, S) (Entered: 01/27/2026)
01/28/2026		(Court only) ***Deadlines/Hearings terminated. Motion ripe deadline terminated (crt,Taylor, L) (Entered: 01/28/2026)
02/03/2026	<u>52</u>	MOTION to Intervene with opposition, MOTION for Leave to File Opposition, MOTION for Leave to File Motion to Dismiss by Danco Laboratories L L C. Motions referred to David J Ayo. Motion Ripe Deadline set for 2/3/2026. (Attachments: # <u>1</u> Memorandum / Brief, # <u>2</u> Exhibit Declaration of Abigail Long, # <u>3</u> Proposed pleading Proposed Motion to Dismiss, # <u>4</u> Proposed pleading Proposed Memorandum in Support of Motion to Dismiss and in Opposition to Plaintiffs' Motion for Preliminary Relief, # <u>5</u> Proposed order)(aty,Ellsworth, Jessica) Modified on 2/5/2026 to indicate <u>58</u> Corrected signature pages

		submitted. (Crick, S). Added MOTIONs for Leave to File on 2/5/2026 and modified docket text. (Crick, S). (Entered: 02/03/2026), (QC'ed on 02/05/2026, by Crick , S)
02/03/2026	<u>53</u>	CORPORATE DISCLOSURE STATEMENT by Danco Laboratories L L C. (aty,Ellsworth, Jessica) (Entered: 02/03/2026), (QC'ed on 02/05/2026, by Crick , S)
02/03/2026	<u>54</u>	MOTION to Intervene with opposition, MOTION for Leave to File Conditional Opposition to <u>20</u> MOTION for Preliminary Relief, MOTION for Leave to File Conditional Motion to Dismiss by GenBioPro Inc. Motions referred to David J Ayo. Motion Ripe Deadline set for 2/3/2026. (Attachments: # <u>1</u> Memorandum / Brief, # <u>2</u> Affidavit Declaration of Evan Masingill, # <u>3</u> Proposed order, # <u>4</u> Proposed pleading Conditional Memorandum in Opposition to Plaintiffs Motion for Preliminary Relief, # <u>5</u> Affidavit Declaration of Robert Katerberg, # <u>6</u> Proposed exhibit Ex. A - 2023 REMS, # <u>7</u> Proposed exhibit Ex. B - GenBioPro Citizen Petition, # <u>8</u> Proposed exhibit Ex. B-1 - Vol. 1, Citizen Petition Appx, # <u>9</u> Proposed exhibit Ex. B-2 - Vol. 2, Citizen Petition Appx, # <u>10</u> Proposed exhibit Ex. B-3 - Vol. 3, Citizen Petition Appx, # <u>11</u> Proposed exhibit Ex. B-4 - Vol. 4, Citizen Petition Appx, # <u>12</u> Proposed exhibit Ex. B-5 - Vol. 5, Citizen Petition Appx, # <u>13</u> Proposed exhibit Ex. B-6 - Vol. 6, Citizen Petition Appx, # <u>14</u> Proposed exhibit Ex. B-7 - Vol. 7, Citizen Petition Appx, # <u>15</u> Proposed exhibit Ex. B-8 - Vol. 8, Citizen Petition Appx, # <u>16</u> Proposed exhibit Ex. B-9 - Vol. 9, Citizen Petition Appx, # <u>17</u> Proposed exhibit Ex. C - FDA Denial of AAPLOG Citizen Petition, # <u>18</u> Proposed exhibit Ex. D - FDA Interim Response to GenBioPro Citizen Petition, # <u>19</u> Proposed exhibit Ex. E - Dilek JAMA Article, # <u>20</u> Proposed exhibit Ex. F - Ctr on Repro Health et al. Comment ISO GenBioPro Citizen Petition, # <u>21</u> Proposed exhibit Ex. G - Woodcock Declaration, # <u>22</u> Proposed exhibit Ex. H - ACOG Citizen Petition, # <u>23</u> Proposed exhibit Ex. I - Hasselbacher Comment ISO GenBioPro Citizen Petition, # <u>24</u> Proposed exhibit Ex. J - BU Programs Comment ISO GenBioPro Citizen Petition, # <u>25</u> Proposed exhibit Ex. K - Comment by Legal Voice ISO GenBioPro Citizen Petition, # <u>26</u> Proposed pleading Conditional Motion to Dismiss)(aty,Katerberg, Robert) Modified on 2/5/2026 to indicate <u>57</u> Corrected signature pages submitted. (Crick, S). Added MOTIONs for Leave to File on 2/5/2026 (Crick, S). (Entered: 02/03/2026), (QC'ed on 02/05/2026, by Crick , S)
02/03/2026	<u>55</u>	CORPORATE DISCLOSURE STATEMENT by GenBioPro Inc identifying Corporate Parent Xenia Holdco L L C for GenBioPro Inc. (aty,Katerberg, Robert) (Entered: 02/03/2026), (QC'ed on 02/05/2026, by Crick , S)
02/03/2026		Motions Transferred regarding <u>52</u> MOTION to Intervene with opposition MOTION for Leave to File, <u>54</u> MOTION to Intervene with opposition MOTION for Leave to File., Set/Reset Deadlines as to <u>52</u> MOTION to Intervene with

		opposition MOTION for Leave to File, <u>54</u> MOTION to Intervene with opposition MOTION for Leave to File.(Motion Ripe Deadline set for 2/3/2026.) Motions referred to Judge David C Joseph. (crt,Crick, S) (Entered: 02/05/2026)
02/04/2026	<u>56</u>	MOTION for Martin Edward Whelan III to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6575355) by Ethics and Public Policy Center. Motions referred to David J Ayo. Motion Ripe Deadline set for 2/4/2026. (Attachments: # <u>1</u> Certificate of good standing, # <u>2</u> Proposed order)(Attorney Michelle Ward Ghetti added to party Ethics and Public Policy Center(pty:am))(aty,Ghetti, Michelle) (Entered: 02/04/2026), (QC'ed on 02/04/2026, by Crick , S)
02/04/2026	<u>57</u>	CORRECTIVE DOCUMENT entitled Corrected Motion to Intervene and Accompanying Materials filed by GenBioPro Inc regarding <u>54</u> MOTION to Intervene with opposition . (Attachments: # <u>1</u> Memorandum / Brief Corrected Memorandum / Brief, # <u>2</u> Proposed pleading Corrected Conditional Memorandum in Opposition to Plaintiffs' Motion for Preliminary Relief, # <u>3</u> Proposed pleading Corrected Conditional Motion to Dismiss)(aty,Katerberg, Robert) (Entered: 02/04/2026), (QC'ed on 02/05/2026, by Crick , S)
02/04/2026	<u>58</u>	CORRECTIVE DOCUMENT entitled Corrected Signature Pages for Motion to Intervene, Memorandum in Support, Proposed Motion to Dismiss, and Proposed Memorandum in Support filed by Danco Laboratories L L C regarding <u>52</u> MOTION to Intervene with opposition . (Attachments: # <u>1</u> Memorandum / Brief Corrected Memorandum, # <u>2</u> Proposed pleading Corrected Proposed Motion to Dismiss, # <u>3</u> Proposed pleading Corrected Proposed Memorandum)(aty,Ellsworth, Jessica) (Entered: 02/04/2026), (QC'ed on 02/05/2026, by Crick , S)
02/05/2026		(Court only) ***Deadlines/Hearings terminated. motion ripe deadline termed for doc 52 and 54 (crt,Taylor, L) (Entered: 02/06/2026)
02/06/2026	<u>59</u>	ORDER granting <u>56</u> Motion to Appear Pro Hac Vice for appearance of Martin Edward Whelan, III for Ethics & Public Policy Center. Signed by Magistrate Judge David J Ayo on 2/6/2026. (crt,Crick, S) (Entered: 02/06/2026)
02/06/2026	<u>60</u>	MOTION for Christopher Mills to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6580248) by Samaritan's Purse, Family Research Council, Martha Shuping, M.D., American Association of Pro-Life Obstetricians and Gynecologists. Motions referred to David J Ayo. Motion Ripe Deadline set for 2/6/2026. (Attachments: # <u>1</u> Proposed order, # <u>2</u> Certificate of good standing)(Attorney Brian Wade Arabie added to party Samaritan's Purse(pty:selreq), Attorney Brian Wade Arabie added to party Family Research Council(pty:selreq), Attorney Brian Wade Arabie added to party Martha Shuping, M.D.(pty:selreq), Attorney Brian Wade

		Arabie added to party American Association of Pro-Life Obstetricians and Gynecologists(pty:selreq))(aty,Arabie, Brian) (Entered: 02/06/2026), (QC'ed on 02/06/2026, by Crick , S)
02/09/2026	<u>61</u>	ORDER granting <u>60</u> Motion to Appear Pro Hac Vice for appearance of Christopher E Mills for American Association of Pro-Life Obstetricians & Gynecologists, Family Research Council, Samaritans Purse, Martha Shuping. Signed by Magistrate Judge David J Ayo on 2/9/2026. (crt,Crick, S) (Entered: 02/09/2026)
02/10/2026	<u>62</u>	MOTION for Leave to File AMICUS BRIEF with consent by Family Research Council, Martha Shuping. Motions referred to David J Ayo. Motion Ripe Deadline set for 2/10/2026. (Attachments: # <u>1</u> Proposed order, # <u>2</u> Proposed pleading)(aty,Arabie, Brian) (Entered: 02/10/2026), (QC'ed on 02/10/2026, by Bunting , M)
02/10/2026	<u>63</u>	Unopposed MOTION to Combine Responses and Set Page Limit by All Plaintiffs. Motions referred to David J Ayo. Motion Ripe Deadline set for 2/10/2026. (Attachments: # <u>1</u> Proposed order)(aty,Baptist, Erik) (Entered: 02/10/2026), (QC'ed on 02/10/2026, by Bunting , M)
02/10/2026		Motions Transferred regarding <u>62</u> MOTION for Leave to File AMICUS BRIEF with consent , <u>63</u> Unopposed MOTION to Combine Responses and Set Page Limit . Motions referred to Judge David C Joseph. (crt,Bunting, M) (Entered: 02/10/2026)
02/11/2026	<u>64</u>	MOTION for Cody S. Barnett to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6588306) by State of Nebraska. Motions referred to David J Ayo. Motion Ripe Deadline set for 2/11/2026. (Attachments: # <u>1</u> Certificate of good standing, # <u>2</u> Proposed order)(Attorney Rachel Thyre Vogeltanz added to party State of Nebraska(pty:mov))(aty,Vogeltanz, Rachel) (Entered: 02/11/2026), (QC'ed on 02/11/2026, by Bunting , M)
02/11/2026	<u>65</u>	ORDER granting <u>62</u> Motion for Leave to File. Signed by Judge David C Joseph on 2/11/2026. (crt,Bunting, M) (Entered: 02/11/2026)
02/11/2026	<u>66</u>	AMICUS BRIEF in Support re <u>20</u> MOTION for Preliminary Injunction <i>or for Preliminary Relief Under 5 U.S.C. § 705</i> MOTION for Preliminary Relief Under 5 USC 705 filed by Family Research Council, Martha Shuping. (crt,Bunting, M) (Entered: 02/11/2026)
02/11/2026	<u>67</u>	ORDER granting <u>63</u> Motion to Combine Responses and Set Page Limit. Plaintiffs brief is limited to thirty pages. Signed by Judge David C Joseph on 2/11/2026. (crt,Bunting, M) (Entered: 02/11/2026)
02/11/2026	<u>68</u>	Ex Parte MOTION for Olivia F. Summers to Appear Pro Hac Vice <i>on behalf of the American Center for Law & Justice</i> (Admission fee: \$105, receipt number ALAWDC-6589202) by

		American Center for Law & Justice. Motions referred to David J Ayo. Motion Ripe Deadline set for 2/11/2026. (Attachments: # <u>1</u> Exhibit Certificate of Good Standing, # <u>2</u> Proposed order)(Attorney Kevin S Vogeltanz added to party American Center for Law & Justice(pty:am))(aty,Vogeltanz, Kevin) (Entered: 02/11/2026), (QC'ed on 02/12/2026, by Bunting , M)
02/11/2026	<u>69</u>	MOTION for J. Marc Wheat to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6589526) by Advancing American Freedom. Motions referred to David J Ayo. Motion Ripe Deadline set for 2/11/2026. (Attachments: # <u>1</u> Certificate of good standing certificate of good standing from Virginia Supreme Court, # <u>2</u> Certificate of good standing certificate of good standing 5th circuit, # <u>3</u> Proposed order proposed order for pro hace vice motion)(Attorney Ben E Clayton added to party Advancing American Freedom(pty:am))(aty,Clayton, Ben) Modified to reflect deficient status on 2/12/2026 (Bunting, M). Modified on 2/25/2026 to indicate <u>241</u> Current Certificate of Good Standing submitted. (Crick, S). (Entered: 02/11/2026), (QC'ed on 02/12/2026, by Bunting , M)
02/12/2026	<u>70</u>	NOTICE of Deficiency to Ben E Clayton on behalf of Advancing American Freedom regarding <u>69</u> MOTION for J. Marc Wheat to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6589526). Reason: The above item requires a certificate of good standing of recent date. Please refer to LR83.2.6 for more specific requirements. (crt,Bunting, M) (Entered: 02/12/2026)
02/12/2026	<u>71</u>	ORDER granting <u>64</u> Motion to Appear Pro Hac Vice for appearance of Cody S Barnett for State of Nebraska. Signed by Magistrate Judge David J Ayo on 2/12/2026. (crt,Bunting, M) (Entered: 02/12/2026)
02/12/2026	<u>72</u>	ORDER granting <u>68</u> Motion to Appear Pro Hac Vice for appearance of Olivia F Summers for American Center for Law & Justice. Signed by Magistrate Judge David J Ayo on 2/12/2026. (crt,Bunting, M) (Entered: 02/12/2026)
02/12/2026	<u>73</u>	MOTION for Leave to File with consent by Women Injured by Abortion, The Justice Foundation, Center Against Forced Abortions, The National Association of Christian Lawmakers. Motions referred to David J Ayo. Motion Ripe Deadline set for 2/12/2026. (Attachments: # <u>1</u> Proposed pleading, # <u>2</u> Proposed order)(Attorney Troy Houston Middleton, IV added to party Women Injured by Abortion(pty:am), Attorney Troy Houston Middleton, IV added to party The Justice Foundation(pty:am), Attorney Troy Houston Middleton, IV added to party Center Against Forced Abortions(pty:am), Attorney Troy Houston Middleton, IV added to party The National Association of Christian Lawmakers(pty:am))(aty,Middleton, Troy) (Entered: 02/12/2026), (QC'ed on 02/12/2026, by Bunting , M)
02/12/2026	<u>74</u>	

		MOTION for Allan E. Parker to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6591125) by Women Injured by Abortion, National Association of Christian Lawmakers, Justice Foundation, Center Against Forced Abortions. Motions referred to David J Ayo. Motion Ripe Deadline set for 2/12/2026. (Attachments: # <u>1</u> Proposed order, # <u>2</u> Certificate of good standing)(aty,Middleton, Troy) Modified filers on 2/12/2026 (Bunting, M). (Entered: 02/12/2026), (QC'ed on 02/12/2026, by Bunting , M)
02/12/2026	<u>75</u>	MOTION for R. Clayton Trotter to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6591179) by Women Injured by Abortion, National Association of Christian Lawmakers, Justice Foundation, Center Against Forced Abortions. Motions referred to David J Ayo. Motion Ripe Deadline set for 2/12/2026. (Attachments: # <u>1</u> Proposed order, # <u>2</u> Certificate of good standing)(aty,Middleton, Troy) Modified filers on 2/12/2026 (Bunting, M). (Entered: 02/12/2026), (QC'ed on 02/12/2026, by Bunting , M)
02/12/2026	<u>76</u>	MOTION for Mary Jane Browning to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6591183) by Women Injured by Abortion, National Association of Christian Lawmakers, Justice Foundation, Center Against Forced Abortions. Motions referred to David J Ayo. Motion Ripe Deadline set for 2/12/2026. (Attachments: # <u>1</u> Proposed order, # <u>2</u> Certificate of good standing)(aty,Middleton, Troy) Modified filers on 2/12/2026 (Bunting, M). (Entered: 02/12/2026), (QC'ed on 02/12/2026, by Bunting , M)
02/12/2026		(Court only) ***Attorney added: Hunter W Lundy for Center Against Forced Abortions,Hunter W Lundy for The Justice Foundation,Hunter W Lundy for The National Association of Christian Lawmakers,Hunter W Lundy for Women Injured by Abortion. (crt,Bunting, M) (Entered: 02/12/2026)
02/12/2026		Motions Transferred regarding <u>73</u> MOTION for Leave to File with consent . Motions referred to Judge David C Joseph. (crt,Bunting, M) (Entered: 02/12/2026)
02/12/2026	<u>77</u>	MOTION for Leave to File AMICUS BRIEF with consent by American Association of Pro-Life Obstetricians & Gynecologists, Samaritans Purse. Motions referred to David J Ayo. Motion Ripe Deadline set for 2/12/2026. (Attachments: # <u>1</u> Proposed order, # <u>2</u> Proposed pleading)(aty,Arabie, Brian) (Entered: 02/12/2026), (QC'ed on 02/13/2026, by Bunting , M)
02/12/2026	<u>78</u>	MOTION for Linda Boston Schlueter to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6591284) by Trinity Legal Center, Leslie Wolbert, Tammi Morris, Carol Everett, Monty Patterson. Motions referred to David J Ayo. Motion Ripe Deadline set for 2/12/2026. (Attachments: # <u>1</u> Proposed order, # <u>2</u> Exhibit, # <u>3</u> Exhibit)(Attorney Brian Wade Arabie added to party Carol Everett(pty:mov), Attorney Brian Wade Arabie added to party Monty Patterson(pty:mov),

		Attorney Brian Wade Arabie added to party Leslie Wolbert(pty:mov), Attorney Brian Wade Arabie added to party Trinity Legal Center(pty:mov), Attorney Brian Wade Arabie added to party Tammi Morris(pty:mov))(aty,Arabie, Brian) (Entered: 02/12/2026), (QC'ed on 02/13/2026, by Bunting , M)
02/12/2026	<u>79</u>	MOTION for Leave to File AMICUS BRIEF with consent by Carol Everett, Tammi Morris, Monty Patterson, Trinity Legal Center, Leslie Wolbert. Motions referred to David J Ayo. Motion Ripe Deadline set for 2/12/2026. (Attachments: # <u>1</u> Proposed pleading)(aty,Arabie, Brian) Modified to reflect deficient status on 2/13/2026 (Bunting, M). Modified to remove deficient status on 2/13/2026 (Bunting, M). See <u>86</u> for Proposed Order and Appendix. (Entered: 02/12/2026), (QC'ed on 02/13/2026, by Bunting , M)
02/12/2026	<u>80</u>	Unopposed MOTION for Leave to File Amicus Brief in Support of Plaintiffs with consent by American Center for Law & Justice. Motions referred to David J Ayo. Motion Ripe Deadline set for 2/12/2026. (Attachments: # <u>1</u> Proposed order, # <u>2</u> Proposed pleading Amicus Brief)(aty,Vogeltanz, Kevin) (Entered: 02/12/2026), (QC'ed on 02/13/2026, by Bunting , M)
02/12/2026	<u>81</u>	MOTION for Leave to File Amicus Brief of EPPC with consent <i>of the parties</i> by Ethics & Public Policy Center. Motions referred to David J Ayo. Motion Ripe Deadline set for 2/12/2026. (Attachments: # <u>1</u> Proposed order Proposed Order Admitting EPPC Amicus Brief, # <u>2</u> Proposed pleading Proposed Amicus Brief of EPPC)(aty,Ghetti, Michelle) (Entered: 02/12/2026), (QC'ed on 02/13/2026, by Bunting , M)
02/13/2026	<u>82</u>	NOTICE of Deficiency to Brian Wade Arabie on behalf of Carol Everett, Tammi Morris, Monty Patterson, Trinity Legal Center, Leslie Wolbert regarding <u>79</u> MOTION for Leave to File AMICUS BRIEF with consent . Reason: Either no proposed order accompanied this motion, or the proposed order was not on a separate page. Please see LR7.3 for additional information. The motion cannot be referred to chambers until this deficiency is corrected. (crt,Bunting, M) (Entered: 02/13/2026)
02/13/2026		Motions Transferred regarding <u>80</u> Unopposed MOTION for Leave to File Amicus Brief in Support of Plaintiffs with consent , <u>81</u> MOTION for Leave to File Amicus Brief of EPPC with consent <i>of the parties</i> , <u>77</u> MOTION for Leave to File AMICUS BRIEF with consent . Motions referred to Judge David C Joseph. (crt,Bunting, M) (Entered: 02/13/2026)
02/13/2026	<u>83</u>	NOTICE of Appearance by Joseph Scott St John on behalf of 60 Members of Congress (Attorney Joseph Scott St John added to party 60 Members of Congress(pty:am)) (aty,St John, Joseph) (Entered: 02/13/2026), (QC'ed on 02/13/2026, by Bunting , M)
02/13/2026	<u>84</u>	MOTION for Leave to File Brief Amici Curiae of 60 Members of Congress with consent by 60 Members of Congress. Motions

		referred to David J Ayo. Motion Ripe Deadline set for 2/13/2026. (Attachments: # <u>1</u> Proposed pleading, # <u>2</u> Proposed order)(aty,St John, Joseph) (Entered: 02/13/2026), (QC'ed on 02/13/2026, by Bunting , M)
02/13/2026	<u>85</u>	MOTION for Heather Gebelin Hacker to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6592450) by 60 Members of Congress. Motions referred to David J Ayo. Motion Ripe Deadline set for 2/13/2026. (Attachments: # <u>1</u> Certificate of good standing, # <u>2</u> Proposed order)(aty,St John, Joseph) (Entered: 02/13/2026), (QC'ed on 02/13/2026, by Bunting , M)
02/13/2026		Motions Transferred regarding <u>84</u> MOTION for Leave to File Brief Amici Curiae of 60 Members of Congress with consent . Motions referred to Judge David C Joseph. (crt,Bunting, M) (Entered: 02/13/2026)
02/13/2026	<u>86</u>	CORRECTIVE DOCUMENT - PROPOSED ORDER filed as MOTION to Amend/Correct <u>79</u> MOTION for Leave to File AMICUS BRIEF with consent by Carol Everett, Tammi Morris, Monty Patterson, Trinity Legal Center, Leslie Wolbert. Motions referred to David J Ayo. Motion Ripe Deadline set for 2/13/2026. (Attachments: # <u>1</u> Appendix)(aty,Arabie, Brian) Modified event and docket text on 2/13/2026 (Bunting, M). (Entered: 02/13/2026), (QC'ed on 02/13/2026, by Bunting , M)
02/13/2026	<u>87</u>	MOTION for Leave to File Brief Amici Curiae with consent by State of Nebraska. Motions referred to David J Ayo. Motion Ripe Deadline set for 2/13/2026. (Attachments: # <u>1</u> Proposed order, # <u>2</u> Memorandum / Brief)(aty,Barnett, Cody) (Entered: 02/13/2026), (QC'ed on 02/13/2026, by Bunting , M)
02/13/2026		(Court only) Set/Reset Deadlines as to <u>79</u> MOTION for Leave to File AMICUS BRIEF with consent .(Motion Ripe Deadline set for 2/12/2026.), ***Motions terminated: <u>86</u> PROPOSED filed by Leslie Wolbert, Carol Everett, Monty Patterson, Tammi Morris, Trinity Legal Center. Reason for termination: Document filed in error as a Motion (crt,Bunting, M) (Entered: 02/13/2026)
02/13/2026		Motions Transferred regarding <u>79</u> MOTION for Leave to File AMICUS BRIEF with consent . Motions referred to Judge David C Joseph. (crt,Bunting, M) (Entered: 02/13/2026)
02/13/2026	<u>88</u>	MOTION for Sapna Khatri to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6593076) by I G H. Motions referred to David J Ayo. Motion Ripe Deadline set for 2/13/2026. (Attachments: # <u>1</u> Certificate of good standing)(aty,Matt, Meghan) Modified docket text on 2/13/2026 (Bunting, M). Modified on 2/13/2026 (Bunting, M). Modified on 2/20/2026 to modify filer.(Crick, S). (Entered: 02/13/2026), (QC'ed on 02/13/2026, by Bunting , M)
02/13/2026		

		Motions Transferred regarding <u>87</u> MOTION for Leave to File Brief Amici Curiae with consent . Motions referred to Judge David C Joseph. (crt,Bunting, M) (Entered: 02/13/2026)
02/13/2026	<u>89</u>	CORRECTIVE DOCUMENT entitled Proposed Order filed by I G H regarding <u>88</u> MOTION for 6:25-cv-01491 to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6593076) . (aty,Matt, Meghan) Modified on 2/20/2026 to modify filer. (Crick, S). (Entered: 02/13/2026), (QC'ed on 02/13/2026, by Bunting , M)
02/13/2026	<u>90</u>	ORDER granting <u>73</u> Motion for Leave to File Brief. Signed by Judge David C Joseph on 2/13/2026. (crt,Bunting, M) (Entered: 02/13/2026)
02/13/2026	<u>91</u>	ORDER granting <u>74</u> Motion to Appear Pro Hac Vice for appearance of Allan E Parker for Justice Foundation, Women Injury by Abortion, Center Against Forced Abortions and National Association of Christian Lawmakers. Signed by Magistrate Judge David J Ayo on 2/13/2026. (crt,Bunting, M) Modified docket text on 2/13/2026 (Bunting, M). (Entered: 02/13/2026)
02/13/2026	<u>92</u>	AMICUS BRIEF in Support re <u>20</u> MOTION for Preliminary Injunction <i>or for Preliminary Relief Under 5 U.S.C. § 705</i> MOTION for Preliminary Relief Under 5 USC 705 filed by Center Against Forced Abortions, Justice Foundation, National Association of Christian Lawmakers, Women Injured by Abortion. (crt,Bunting, M) (Entered: 02/13/2026)
02/13/2026	<u>93</u>	ORDER granting <u>75</u> Motion to Appear Pro Hac Vice for appearance of R Clayton Trotter for Center Against Forced Abortions,R Clayton Trotter for Justice Foundation,R Clayton Trotter for National Association of Christian Lawmakers,R Clayton Trotter for Women Injured by Abortion. Signed by Magistrate Judge David J Ayo on 2/13/2026. (crt,Bunting, M) (Entered: 02/13/2026)
02/13/2026	<u>94</u>	ORDER granting <u>76</u> Motion to Appear Pro Hac Vice for appearance of Mary J Browning for Center Against Forced Abortions,Mary J Browning for Justice Foundation,Mary J Browning for National Association of Christian Lawmakers,Mary J Browning for Women Injured by Abortion. Signed by Magistrate Judge David J Ayo on 2/13/2026. (crt,Bunting, M) (Entered: 02/13/2026)
02/13/2026	<u>95</u>	ORDER granting <u>77</u> Motion for Leave to File Brief. Signed by Judge David C Joseph on 2/13/2026. (crt,Bunting, M) (Entered: 02/13/2026)
02/13/2026	<u>96</u>	AMICUS BRIEF in Support re <u>20</u> MOTION for Preliminary Injunction <i>or for Preliminary Relief Under 5 U.S.C. § 705</i> MOTION for Preliminary Relief Under 5 USC 705 filed by American Association of Pro-Life Obstetricians & Gynecologists, Samaritans Purse. (crt,Bunting, M) (Entered: 02/13/2026)

		02/13/2026)
02/13/2026	<u>97</u>	ORDER granting <u>78</u> Motion to Appear Pro Hac Vice for appearance of Linda Boston Schlueter for Trinity Legal Center. Signed by Magistrate Judge David J Ayo on 2/13/2026. (crt,Bunting, M) (Entered: 02/13/2026)
02/13/2026	<u>98</u>	ORDER granting <u>80</u> Motion for Leave to File Amicus Brief. Signed by Judge David C Joseph on 2/13/2026. (crt,Bunting, M) (Entered: 02/13/2026)
02/13/2026	<u>99</u>	AMICUS BRIEF in Support re <u>20</u> MOTION for Preliminary Injunction <i>or for Preliminary Relief Under 5 U.S.C. § 705</i> MOTION for Preliminary Relief Under 5 USC 705 filed by American Center for Law & Justice. (crt,Bunting, M) (Entered: 02/13/2026)
02/13/2026	<u>100</u>	ORDER granting <u>81</u> Motion for Leave to File Brief. Signed by Judge David C Joseph on 2/13/2026. (crt,Bunting, M) (Entered: 02/13/2026)
02/13/2026	<u>101</u>	AMICUS BRIEF in Support re <u>20</u> MOTION for Preliminary Injunction <i>or for Preliminary Relief Under 5 U.S.C. § 705</i> MOTION for Preliminary Relief Under 5 USC 705 filed by Ethics & Public Policy Center. (crt,Bunting, M) (Entered: 02/13/2026)
02/13/2026	102	MINUTE ENTRY SETTING <u>50</u> MOTION to Stay <i>the Case</i> : Motion day set for 2/24/2026 10:00 AM in Lafayette, Courtroom 1 before Judge David C Joseph. Signed by Judge David C Joseph on 2/13/2026. (crt,Taylor, L) (Entered: 02/13/2026)
02/13/2026	<u>103</u>	MOTION for Leave to File Amicus brief with consent by Advancing American Freedom, Eagle Forum, Democrats for Life, Christian Medical & Dental Associations, Christian Law Association, Center for Urban Renewal & Education, Centennial Institute at Colorado Christian University, Fran Bevan, Association of Mature American Citizens Action, Americas Women, Americans United for Life, American Values, American Association of Senior Citizens, Alaska Family Council, Alabama Policy Institute, 60 Plus Association, Men & Women for a Representative Democracy in America Inc, Maryland Family Institute, Lutheran Center for Religious Liberty,Louisiana Family Forum, Alveda King, Tim Jones, International Conference of Evangelical Chaplain Endorsers, Human Coalition, Frontline Policy Council, Family Institute of Connecticut Action, Family Council in Arkansas, Gregory P Seltz, Rick Santorum, Priests for Life, Melissa Ortiz, North Carolina Values Coalition, New York State Conservative Party, National Right to Life, Men for Life, Young Americas Foundation, Women for Democracy in America Inc, Wisconsin Family Action Inc, Wagner Center, Suzi Voyles, Paul Stam, Family Foundation of Virginia. Motions referred to David J Ayo. Motion Ripe Deadline set for 2/13/2026. (Attachments: #

		<u>1</u> Proposed pleading, # <u>2</u> Proposed order)(aty,Clayton, Ben) Modified on 2/18/2026 to add filers and modify docket text. (Crick, S). (Entered: 02/13/2026), (QC'ed on 02/18/2026, by Crick , S)
02/13/2026	<u>104</u>	MOTION for L. Katie Buckner to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6593562), MOTION for Leave to File Amicus Curiae Brief by Students For Life of America. Motions referred to David J Ayo. Motion Ripe Deadline set for 2/13/2026. (Attachments: # <u>1</u> Proposed order, # <u>2</u> Motion to file Amicus Brief, # <u>3</u> Proposed order, # <u>4</u> Proposed Pleading)(Attorney R Bradley Lewis added to party Students For Life of America(pty:am))(aty,Lewis, R). Added MOTION for Leave to File and modified docket text on 2/18/2026 (Crick, S). (Entered: 02/13/2026), (QC'ed on 02/18/2026, by Crick , S)
02/13/2026	<u>105</u>	Ex Parte MOTION for Brennan Tyler Brooks to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6593716) by Heartbeat International, Inc.. Motions referred to David J Ayo. Motion Ripe Deadline set for 2/13/2026. (Attachments: # <u>1</u> Certificate of good standing, # <u>2</u> Proposed order)(Attorney Charles Kenneth Cicero, III added to party Heartbeat International, Inc.(pty:mov))(aty,Cicero, Charles) (Entered: 02/13/2026), (QC'ed on 02/17/2026, by Miletello , A)
02/13/2026	<u>106</u>	Ex Parte MOTION for Danielle Merry White to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6593733) by Heartbeat International, Inc.. Motions referred to David J Ayo. Motion Ripe Deadline set for 2/13/2026. (Attachments: # <u>1</u> Certificate of good standing, # <u>2</u> Proposed order)(aty,Cicero, Charles) (Entered: 02/13/2026), (QC'ed on 02/17/2026, by Miletello , A)
02/13/2026	<u>107</u>	MOTION for Mario Diaz to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6593658) by Concerned Women for America. Motions referred to David J Ayo. Motion Ripe Deadline set for 2/13/2026. (Attachments: # <u>1</u> Certificate of good standing cert for pro hac vice, # <u>2</u> Proposed order order for pro hac vice)(Attorney Ben E Clayton added to party Concerned Women for America(pty:am))(aty,Clayton, Ben) (Entered: 02/13/2026), (QC'ed on 02/17/2026, by Miletello , A)
02/13/2026	<u>108</u>	MOTION for Leave to File Amicus brief with consent by Concerned Women for America. Motions referred to David J Ayo. Motion Ripe Deadline set for 2/13/2026. (Attachments: # <u>1</u> Proposed Amicus brief, # <u>2</u> Proposed order)(aty,Clayton, Ben) Modified docket text on 2/17/2026 (Miletello, A). (Entered: 02/13/2026), (QC'ed on 02/17/2026, by Miletello , A)
02/13/2026	<u>109</u>	MOTION for Leave to File Amicus brief with consent by Calum Miller. Motions referred to David J Ayo. Motion Ripe Deadline set for 2/13/2026. (Attachments: # <u>1</u> Proposed amicus brief, # <u>2</u> Proposed order)(Attorney Ben E Clayton added to

		party Calum Miller(pty:am))(aty,Clayton, Ben) Modified docket text on 2/17/2026 (Miletello, A). (Entered: 02/13/2026), (QC'ed on 02/17/2026, by Miletello , A)
02/13/2026	<u>110</u>	Unopposed MOTION for Leave to File Amicus Brief with consent by Heartbeat International, Inc.. Motions referred to David J Ayo. Motion Ripe Deadline set for 2/13/2026. (Attachments: # <u>1</u> Proposed order, # <u>2</u> Proposed pleading Amicus Brief)(aty,Cicero, Charles) (Entered: 02/13/2026), (QC'ed on 02/17/2026, by Miletello , A)
02/13/2026		Motions Transferred regarding <u>108</u> MOTION for Leave to File Amicus brief, <u>109</u> MOTION for Leave to File Amicus brief, <u>110</u> Unopposed MOTION for Leave to File Amicus Brief. Motions referred to Judge David C Joseph. (crt,Miletello, A) (Entered: 02/17/2026)
02/13/2026		Motions Transferred regarding <u>103</u> MOTION for Leave to File Amicus brief with consent . Motions referred to Judge David C Joseph. (crt,Crick, S) (Entered: 02/18/2026)
02/13/2026		Motions Transferred regarding <u>104</u> MOTION for L. Katie Buckner to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6593562) MOTION for Leave to File., Set/Reset Deadlines as to <u>104</u> MOTION for L. Katie Buckner to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6593562) MOTION for Leave to File.(Motion Ripe Deadline set for 2/13/2026.) Motions referred to Judge David C Joseph. (crt,Crick, S) (Entered: 02/18/2026)
02/13/2026		(Court only) ***Party I G H added. See <u>88</u> Motion to Appear. (crt,Crick, S) (Entered: 02/20/2026)
02/13/2026	<u>191</u>	ORDER granting <u>160</u> Motion to Appear Pro Hac Vice for appearance of Ester Murdukhayeva for State of Arizona, State of California, State of Colorado, State of Connecticut, State of Delaware, District of Columbia, State of Hawaii, State of Illinois, State of Maine, State of Maryland, Commonwealth of Massachusetts, State of Minnesota, State of Nevada, State of New Jersey, State of New Mexico, State of New York, State of Oregon, State of Rhode Island, State of Vermont, State of Washington. Signed by Magistrate Judge David J Ayo on 2/13/2026. (crt,Crick, S) (Entered: 02/23/2026)
02/17/2026	<u>111</u>	MEMORANDUM in Support re <u>20</u> MOTION for Preliminary Injunction <i>or for Preliminary Relief Under 5 U.S.C. § 705</i> MOTION for Preliminary Relief Under 5 USC 705 filed by State Louisiana, Rosalie Markezich. (Attachments: # <u>1</u> Exhibit A-Toner Declaration, # <u>2</u> Exhibit B-Carrie Baker, Abortion Pills US History and Politics)(aty,Huettemann, Caitlin) (Entered: 02/17/2026), (QC'ed on 02/18/2026, by Crick , S)
02/17/2026	111	MEMORANDUM in Opposition re <u>50</u> MOTION to Stay <i>the Case</i> filed by State Louisiana, Rosalie Markezich. ADMINISTRATIVE ENTRY to capture event not included in

		111 Memorandum in Support. (crt,Crick, S) Modified on 2/18/2026 to add document number. (Crick, S). (Entered: 02/18/2026)
02/18/2026	<u>112</u>	NOTICE of Corporate Disclosure Statement Requirement re: <u>103</u> Motion for Leave to File sent to Ben E Clayton on behalf of 60 Plus Association, Advancing American Freedom, Alabama Policy Institute, Alaska Family Council, American Association of Senior Citizens, American Values, Americans United for Life, Americas Women, Association of Mature American Citizens Action, Fran Bevan, Centennial Institute at Colorado Christian University, Center for Urban Renewal & Education, Christian Law Association, Christian Medical & Dental Associations, Democrats for Life, Eagle Forum, Family Council in Arkansas, Family Foundation of Virginia, Family Institute of Connecticut Action, Frontline Policy Council, Human Coalition, International Conference of Evangelical Chaplain Endorsers, Louisiana Family Forum, Lutheran Center for Religious Liberty, Maryland Family Institute, Men & Women for a Representative Democracy in America Inc, Men for Life, National Right to Life, New York State Conservative Party, North Carolina Values Coalition, Priests for Life, Wagner Center, Wisconsin Family Action Inc, Women for Democracy in America Inc, Young Americas Foundation. Corporate Disclosure Statement due by 3/4/2026. (crt,Crick, S) (Entered: 02/18/2026)
02/18/2026	<u>113</u>	NOTICE of Corporate Disclosure Statement Requirement re: <u>104</u> Motion to Appear Pro Hac Vice, Motion for Leave to File sent to R Bradley Lewis on behalf of Students For Life of America. Corporate Disclosure Statement due by 3/4/2026. (crt,Crick, S) (Entered: 02/18/2026)
02/18/2026	<u>114</u>	MOTION for Maria Michelle Uzeta to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6598248) by Disability Rights Education and Defense Fund. Motions referred to David J Ayo. Motion Ripe Deadline set for 2/18/2026. (Attachments: # <u>1</u> Proposed order, # <u>2</u> Certificate of good standing)(Attorney Chloe Marie Chetta added to party Disability Rights Education and Defense Fund(pty:am))(aty,Chetta, Chloe) (Entered: 02/18/2026), (QC'ed on 02/18/2026, by Crick , S)
02/18/2026	<u>115</u>	MOTION for Mallory Tosch Hoggatt to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6598260) by U S Food & Drug Administration. Motions referred to David J Ayo. Motion Ripe Deadline set for 2/18/2026. (Attachments: # <u>1</u> Proposed order, # <u>2</u> Certificate of good standing)(Attorney Chloe Marie Chetta added to party U S Food & Drug Administration(pty:dft))(aty,Chetta, Chloe) Modified on 2/23/2026 to indicate <u>189</u> Corrected Motion to Appear Pro Hac Vice submitted. (Crick, S). (Entered: 02/18/2026), (QC'ed on 02/18/2026, by Crick , S)

02/18/2026	<u>116</u>	MOTION for Elizabeth R. June to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6598305) by U S Food & Drug Administration. Motions referred to David J Ayo. Motion Ripe Deadline set for 2/18/2026. (Attachments: # <u>1</u> Proposed order, # <u>2</u> Certificate of good standing)(aty,Chetta, Chloe) (Entered: 02/18/2026), (QC'ed on 02/18/2026, by Crick, S)
02/18/2026	<u>117</u>	ORDER granting <u>79</u> Motion for Leave to File. Signed by Judge David C Joseph on 2/18/2026. (crt,Crick, S) (Entered: 02/19/2026)
02/18/2026	<u>118</u>	AMICUS CURIAE BRIEF in Support re <u>20</u> MOTION for Preliminary Injunction <i>or for Preliminary Relief Under 5 U.S.C. § 705</i> MOTION for Preliminary Relief Under 5 USC 705 filed by Carol Everett, Tammi Morris, Monty Patterson, Trinity Legal Center, Leslie Wolbert. (crt,Crick, S) (Entered: 02/19/2026)
02/18/2026	<u>119</u>	ORDER granting <u>85</u> Motion to Appear Pro Hac Vice for appearance of Heather Gebelin Hacker for Members of Congress. Signed by Magistrate Judge David J Ayo on 2/18/2026. (crt,Crick, S) (Entered: 02/19/2026)
02/18/2026	<u>120</u>	ORDER granting <u>87</u> Motion for Leave to File. Signed by Judge David C Joseph on 2/18/2026. (crt,Crick, S) (Entered: 02/19/2026)
02/18/2026	<u>121</u>	AMICI CURIAE in Support re <u>20</u> MOTION for Preliminary Injunction <i>or for Preliminary Relief Under 5 U.S.C. § 705</i> MOTION for Preliminary Relief Under 5 USC 705 filed by State of Nebraska. (crt,Crick, S) (Entered: 02/19/2026)
02/18/2026	<u>122</u>	ORDER granting <u>103</u> Motion for Leave to File. Signed by Judge David C Joseph on 2/18/2026. (crt,Crick, S) (Entered: 02/19/2026)
02/18/2026	<u>123</u>	AMICI CURIAE BRIEF in Support re <u>20</u> MOTION for Preliminary Injunction <i>or for Preliminary Relief Under 5 U.S.C. § 705</i> MOTION for Preliminary Relief Under 5 USC 705 filed by 60 Plus Association, Advancing American Freedom Inc, Alabama Policy Institute, Alaska Family Council, American Association of Senior Citizens, American Values, Americans United for Life, Americas Women, Association of Mature American Citizens Action, Fran Bevan, Centennial Institute at Colorado Christian University, Center for Urban Renewal & Education, Christian Law Association, Christian Medical & Dental Associations, Democrats for Life, Eagle Forum, Family Council in Arkansas, Family Foundation of Virginia, Family Institute of Connecticut Action, Frontline Policy Council, Human Coalition, International Conference of Evangelical Chaplain Endorsers, Tim Jones, Alveda King, Louisiana Family Forum, Lutheran Center for Religious Liberty, Maryland Family Institute, Men & Women for a Representative Democracy in America Inc, Men for Life, National Religious

		Broadcasters, National Right to Life, New York State Conservative Party, North Carolina Values Coalition, Melissa Ortiz, Phyllis Schlaflys Pennsylvania Eagle Forum, Priests for Life, Rick Santorum, Gregory P Seltz, Paul Stam, Kathy Szeliga, Suzi Voyles, Wagner Center, Wisconsin Family Action Inc, Women for Democracy in America Inc, Young Americas Foundation. (crt,Crick, S) (Entered: 02/19/2026)
02/18/2026	<u>124</u>	ORDER granting <u>105</u> Motion to Appear Pro Hac Vice for appearance of Brennan Tyler Brooks for Heartbeat International Inc. Signed by Magistrate Judge David J Ayo on 2/18/2026. (crt,Crick, S) (Entered: 02/19/2026)
02/18/2026	<u>125</u>	ORDER granting <u>106</u> Motion to Appear Pro Hac Vice for appearance of Danielle M White for Heartbeat International Inc. Signed by Magistrate Judge David J Ayo on 2/18/2026. (crt,Crick, S) (Entered: 02/19/2026)
02/18/2026	<u>126</u>	ORDER granting <u>107</u> Motion to Appear Pro Hac Vice for appearance of Mario Diaz for Concerned Women for America. Signed by Magistrate Judge David J Ayo on 2/18/2026. (crt,Crick, S) (Entered: 02/19/2026)
02/18/2026	<u>127</u>	ORDER granting <u>108</u> Motion for Leave to File. Signed by Judge David C Joseph on 2/18/2026. (crt,Crick, S) (Entered: 02/19/2026)
02/18/2026	<u>128</u>	AMICUS BRIEF in Support re <u>20</u> MOTION for Preliminary Injunction <i>or for Preliminary Relief Under 5 U.S.C. § 705</i> MOTION for Preliminary Relief Under 5 USC 705 filed by Concerned Women for America. (crt,Crick, S) (Entered: 02/19/2026)
02/18/2026	<u>129</u>	ORDER granting <u>109</u> Motion for Leave to File. Signed by Judge David C Joseph on 2/18/2026. (crt,Crick, S) (Entered: 02/19/2026)
02/18/2026	<u>130</u>	BRIEF OF AMICUS CURIAE in Support re <u>20</u> MOTION for Preliminary Injunction <i>or for Preliminary Relief Under 5 U.S.C. § 705</i> MOTION for Preliminary Relief Under 5 USC 705 filed by Calum Miller. (crt,Crick, S) (Entered: 02/19/2026)
02/18/2026	<u>131</u>	ORDER granting <u>110</u> Motion for Leave to File. Signed by Judge David C Joseph on 2/18/2026. (crt,Crick, S) (Entered: 02/19/2026)
02/18/2026	<u>132</u>	AMICUS CURIAE BRIEF in Support re <u>20</u> MOTION for Preliminary Injunction <i>or for Preliminary Relief Under 5 U.S.C. § 705</i> MOTION for Preliminary Relief Under 5 USC 705 filed by Heartbeat International Inc. (crt,Crick, S) (Entered: 02/19/2026)
02/19/2026	<u>133</u>	MOTION for Robin M. Turner to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6599741) by Legal Voice, National Domestic Violence Hotline. Motions referred to David J Ayo. Motion Ripe Deadline set for

		2/19/2026. (Attachments: # <u>1</u> Proposed order, # <u>2</u> Certificate of good standing)(Attorney Rebekka C Veith added to party Legal Voice(pty:am), Attorney Rebekka C Veith added to party National Domestic Violence Hotline(pty:am))(aty,Veith, Rebekka) (Entered: 02/19/2026), (QC'ed on 02/19/2026, by Crick , S)
02/19/2026	<u>134</u>	ORDER granting <u>104</u> Motion to Appear Pro Hac Vice for appearance of L Katie Buckner for Students For Life of America. Signed by Judge David C Joseph on 2/19/2026. (crt,Crick, S) (Entered: 02/19/2026)
02/19/2026	<u>135</u>	ORDER granting <u>104</u> Motion for Leave to File. Signed by Judge David C Joseph on 2/19/2026. (crt,Crick, S) (Entered: 02/19/2026)
02/19/2026	<u>136</u>	AMICUS BRIEF in Support re <u>20</u> MOTION for Preliminary Injunction <i>or for Preliminary Relief Under 5 U.S.C. § 705</i> MOTION for Preliminary Relief Under 5 USC 705 filed by Students For Life of America. (crt,Crick, S) (Entered: 02/19/2026)
02/19/2026	<u>137</u>	ORDER granting <u>114</u> Motion to Appear Pro Hac Vice for appearance of Maria Michelle Uzeta for Disability Rights Education & Defense Fund. Signed by Magistrate Judge David J Ayo on 2/19/2026. (crt,Crick, S) (Entered: 02/19/2026)
02/19/2026	<u>138</u>	ORDER granting <u>115</u> Motion to Appear Pro Hac Vice for appearance of Katherine Mallory Tosch Hoggatt for U S Food & Drug Administration. Signed by Magistrate Judge David J Ayo on 2/19/2026. (crt,Crick, S) (Entered: 02/19/2026)
02/19/2026	<u>139</u>	ORDER granting <u>116</u> Motion to Appear Pro Hac Vice for appearance of Elizabeth R June for U S Food & Drug Administration. Signed by Magistrate Judge David J Ayo on 2/19/2026. (crt,Crick, S) (Entered: 02/19/2026)
02/19/2026	<u>140</u>	ORDER granting <u>84</u> Motion for Leave to File. Signed by Judge David C Joseph on 2/19/2026. (crt,Crick, S) (Entered: 02/19/2026)
02/19/2026	<u>141</u>	BRIEF OF AMICI CURIAE in Support re <u>20</u> MOTION for Preliminary Injunction <i>or for Preliminary Relief Under 5 U.S.C. § 705</i> MOTION for Preliminary Relief Under 5 USC 705 filed by Members of Congress. (crt,Crick, S) (Entered: 02/19/2026)
02/19/2026	<u>142</u>	MOTION Substitute Pleading re <u>116</u> MOTION for Elizabeth R. June to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6598305), <u>139</u> Order on Motion to Appear Pro Hac Vice by Disability Rights Education & Defense Fund. Motions referred to David J Ayo. Motion Ripe Deadline set for 2/19/2026. (Attachments: # <u>1</u> Proposed order, # <u>2</u> Proposed pleading Corrected Motion for Admission Pro Hac Vice by Elizabeth June)(aty,Chetta, Chloe) Modified on 2/23/2026 to indicated <u>186</u> Corrected Motion to Appear Pro Hac Vice submitted.(Crick, S). (Entered: 02/19/2026), (QC'ed on

		02/20/2026, by Crick , S)
02/19/2026	<u>143</u>	MOTION Substitute Pleading re <u>115</u> MOTION for Mallory Tosch Hoggatt to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6598260), <u>138</u> Order on Motion to Appear Pro Hac Vice by Disability Rights Education & Defense Fund. Motions referred to David J Ayo. Motion Ripe Deadline set for 2/19/2026. (Attachments: # <u>1</u> Proposed order, # <u>2</u> Proposed pleading Corrected Motion for Admission Pro Hac Vice by Katherine Mallory Tosch Hoggatt)(aty,Chetta, Chloe) (Entered: 02/19/2026), (QC'ed on 02/20/2026, by Crick , S)
02/19/2026	<u>144</u>	MOTION for Kathryn Arnett to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6601268) by MEDICAL STUDENTS FOR CHOICE. Motions referred to David J Ayo. Motion Ripe Deadline set for 2/19/2026. (Attachments: # <u>1</u> Certificate of good standing, # <u>2</u> Proposed order)(Attorney Alexandra DiBiase Moody added to party MEDICAL STUDENTS FOR CHOICE(pty:am))(aty,Moody, Alexandra) (Entered: 02/19/2026), (QC'ed on 02/20/2026, by Crick , S)
02/19/2026	<u>145</u>	MOTION for Jayme Jonat to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6601278) by MEDICAL STUDENTS FOR CHOICE. Motions referred to David J Ayo. Motion Ripe Deadline set for 2/19/2026. (Attachments: # <u>1</u> Proposed order, # <u>2</u> Certificate of good standing)(aty,Moody, Alexandra) (Entered: 02/19/2026), (QC'ed on 02/20/2026, by Crick , S)
02/19/2026	<u>146</u>	MOTION for Charlotte Baigent to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6601279) by MEDICAL STUDENTS FOR CHOICE. Motions referred to David J Ayo. Motion Ripe Deadline set for 2/19/2026. (Attachments: # <u>1</u> Proposed order, # <u>2</u> Certificate of good standing)(aty,Moody, Alexandra) (Entered: 02/19/2026), (QC'ed on 02/20/2026, by Crick , S)
02/19/2026	<u>147</u>	MOTION for Katharine G. Zeigler to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6601280) by MEDICAL STUDENTS FOR CHOICE. Motions referred to David J Ayo. Motion Ripe Deadline set for 2/19/2026. (Attachments: # <u>1</u> Proposed order, # <u>2</u> Certificate of good standing)(aty,Moody, Alexandra) (Entered: 02/19/2026), (QC'ed on 02/20/2026, by Crick , S)
02/20/2026	<u>148</u>	MOTION for Leave to File Amicus Brief in Support of Defendants & Opposition to <u>20</u> Motion for Preliminary Injunction with consent by I G H. Motions referred to David J Ayo. Motion Ripe Deadline set for 2/20/2026. (Attachments: # <u>1</u> Proposed order, # <u>2</u> Proposed pleading)(aty,Matt, Meghan) Modified on 2/20/2026 to modify filer and docket text. (Crick, S). (Entered: 02/20/2026), (QC'ed on 02/20/2026, by Crick , S)
02/20/2026		

		Motions Transferred regarding <u>148</u> MOTION for Leave to File Amicus Brief with consent. Motions referred to Judge David C Joseph. (crt,Crick, S) (Entered: 02/20/2026)
02/20/2026	<u>149</u>	ORDER granting <u>133</u> Motion to Appear Pro Hac Vice for appearance of Robin M Turner for Legal Voice, National Domestic Violence Hotline. Signed by Magistrate Judge David J Ayo on 2/20/2026. (crt,Crick, S) (Entered: 02/20/2026)
02/20/2026	<u>150</u>	ORDER granting <u>147</u> Motion to Appear Pro Hac Vice for appearance of Katharine G Zeigler for Medical Students for Choice. Signed by Magistrate Judge David J Ayo on 2/20/2026. (crt,Crick, S) (Entered: 02/20/2026)
02/20/2026	<u>151</u>	ORDER granting <u>144</u> Motion to Appear Pro Hac Vice for appearance of Kathryn Arnett for Medical Students for Choice. Signed by Magistrate Judge David J Ayo on 2/20/2026. (crt,Crick, S) (Entered: 02/20/2026)
02/20/2026	<u>152</u>	ORDER granting <u>145</u> Motion to Appear Pro Hac Vice for appearance of Jayme Jonat for Medical Students for Choice. Signed by Magistrate Judge David J Ayo on 2/20/2026. (crt,Crick, S) (Entered: 02/20/2026)
02/20/2026	<u>153</u>	ORDER granting <u>146</u> Motion to Appear Pro Hac Vice for appearance of Charlotte Baigent for Medical Students for Choice. Signed by Magistrate Judge David J Ayo on 2/20/2026. (crt,Crick, S) (Entered: 02/20/2026)
02/20/2026	<u>154</u>	MOTION for Leave to File Brief of Amici Curiae National Domestic Violence Hotline and Legal Voice with consent by Legal Voice, National Domestic Violence Hotline. Motions referred to David J Ayo. Motion Ripe Deadline set for 2/20/2026. (Attachments: # <u>1</u> Proposed order, # <u>2</u> Proposed pleading Brief of Amici Curiae National Domestic Violence Hotline and Legal Voice)(aty,Veith, Rebekka) (Entered: 02/20/2026), (QC'ed on 02/20/2026, by Crick , S)
02/20/2026		Motions Transferred regarding <u>154</u> MOTION for Leave to File Brief of Amici Curiae National Domestic Violence Hotline and Legal Voice with consent . Motions referred to Judge David C Joseph. (crt,Crick, S) (Entered: 02/20/2026)
02/20/2026	<u>155</u>	Unopposed MOTION for Leave to File Amicus Brief with consent by 100 Reproductive Health, Rights, and Justice Organizations. Motions referred to David J Ayo. Motion Ripe Deadline set for 2/20/2026. (Attachments: # <u>1</u> Proposed order, # <u>2</u> Proposed pleading Amicus Brief In Support Of Defendants, # <u>3</u> Appendix List of Amici Curiae)(Attorney Jamila Asha Johnson added to party 100 Reproductive Health, Rights, and Justice Organizations(pty:mov))(aty,Johnson, Jamila) (Entered: 02/20/2026), (QC'ed on 02/23/2026, by Crick , S)
02/20/2026	<u>156</u>	MOTION for Leave to File with consent <i>Amicus Brief Opposing Plaintiff's Motion for Preliminary Injunction</i> by Janet A Woodcock, Norman E Sharpless, Joshua M Sharfstein,

		Stephen Ostroff, David A Kessler, Jane E Henney, Margaret Hamburg, Michael A Friedman, Robert M Califf. Motions referred to David J Ayo. Motion Ripe Deadline set for 2/20/2026. (Attachments: # <u>1</u> Proposed pleading, # <u>2</u> Proposed exhibit, # <u>3</u> Proposed order)(Attorney Mandie E Landry added to part Former and Acting Commissioners of the FDA(pty:am))(aty, Landry, Mandie) Modified on 2/23/2026 to add filers and modify docket text. (Crick, S). (Entered: 02/20/2026), (QC'ed on 02/23/2026, by Crick , S)
02/20/2026	<u>157</u>	Corporate Disclosure Statement filed by Students For Life of America. (aty,Lewis, R) Modified on 2/23/2026 to more accurately describe document submitted and remove docket entry relationship.(Crick, S). (Entered: 02/20/2026), (QC'ed on 02/23/2026, by Crick , S)
02/20/2026	<u>158</u>	MOTION for Leave to File Memorandum of Law for Amici States in Opposition to Plaintiffs' Motion for a Stay with consent by State of Hawai'i, State of Arizona, State of California, State of Colorado, State of Connecticut, State of Delaware, State of Illinois, State of Maine, State of Maryland, State of Minnesota, State of Nevada, State of New York, Commonwealth of Massachusetts, State of New Jersey, State of Vermont, State of New Mexico, State of Washington, State of Oregon, State of Rhode Island, District of Columbia. Motions referred to David J Ayo. Motion Ripe Deadline set for 2/20/2026. (Attachments: # <u>1</u> Proposed pleading, # <u>2</u> Proposed order)(Attorney Jacob Kennedy Weixler added to party State of Hawai'i(pty:am), State of Arizona(pty:am), State of California(pty:am), State of Colorado(pty:am), State of Connecticut(pty:am), State of Delaware(pty:am), State of Illinois(pty:am), State of Maine(pty:am), State of Maryland(pty:am), State of Minnesota(pty:am), State of Nevada(pty:am), State of New York(pty:am), Commonwealth of Massachusetts(pty:am), State of New Jersey(pty:am), State of Vermont(pty:am), State of New Mexico(pty:am), State of Washington(pty:am), State of Oregon(pty:am), State of Rhode Island(pty:am), District of Columbia(pty:am))(aty, Weixler, Jacob) Modified on 2/23/2026 to modify docket text. (Crick, S). (Entered: 02/20/2026), (QC'ed on 02/23/2026, by Crick , S)
02/20/2026	<u>159</u>	MOTION for Jessica R. Amunson to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6603678) by 100 Reproductive Health, Rights, and Justice Organizations. Motions referred to David J Ayo. Motion Ripe Deadline set for 2/20/2026. (Attachments: # <u>1</u> Certificate of good standing, # <u>2</u> Proposed order)(aty,Johnson, Jamila) (Entered: 02/20/2026), (QC'ed on 02/23/2026, by Crick , S)
02/20/2026	<u>160</u>	MOTION for Ester Murdukhayeva to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6603717) by Commonwealth of Massachusetts, District of Columbia, State of Arizona, State of California, State of Colorado, State of Connecticut, State of Delaware, State of Hawai'i, State of

		Illinois, State of Maine, State of Maryland, State of Minnesota, State of Nevada, State of New Jersey, State of New Mexico, State of New York, State of Oregon, State of Rhode Island, State of Vermont, State of Washington. Motions referred to David J Ayo. Motion Ripe Deadline set for 2/20/2026. (Attachments: # <u>1</u> Certificate of good standing, # <u>2</u> Proposed order)(aty, Weixler, Jacob) (Entered: 02/20/2026), (QC'ed on 02/23/2026, by Crick , S)
02/20/2026	<u>161</u>	First MOTION for Alan Schoenfeld to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6603715) by Former U S Dept of Justice Officials. Motions referred to David J Ayo. Motion Ripe Deadline set for 2/20/2026. (Attachments: # <u>1</u> Proposed order, # <u>2</u> Certificate of good standing)(Attorney Richard Gerard Perque added to party Alan Schoenfeld(pty:selreq), Attorney Richard Gerard Perque added to party Kimberly A Parker(pty:selreq), Attorney Richard Gerard Perque added to party Maitland Lilja Io Jones(pty:selreq), Attorney Richard Gerard Perque added to party Arielle K Herzberg(pty:selreq), Attorney Richard Gerard Perque added to party Kyle Edwards Haugh(pty:selreq))(aty,Perque, Richard) Modified on 2/24/2026 to modify filers. See <u>237</u> Order. (Crick, S). (Entered: 02/20/2026), (QC'ed on 02/23/2026, by Crick , S)
02/20/2026	<u>162</u>	First MOTION for Kimberly A. Parker to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6603787) by Former U S Dept of Justice Officials. Motions referred to David J Ayo. Motion Ripe Deadline set for 2/20/2026. (Attachments: # <u>1</u> Proposed order, # <u>2</u> Certificate of good standing)(aty,Perque, Richard) Modified on 2/24/2026 to modify filer. See <u>237</u> Order. (Crick, S). (Entered: 02/20/2026), (QC'ed on 02/23/2026, by Crick , S)
02/20/2026	<u>163</u>	FILED IN ERROR. THIS DOCUMENT IS A DUPLICATE OF DOCUMENT <u>157</u> . Corporate Disclosure Statement by Students For Life of America. Motions referred to David J Ayo. Motion Ripe Deadline set for 2/20/2026. (aty,Lewis, R) Modified on 2/23/2026 to modify docket text to more accurately describe document filed and to indicate this is a duplicate pleading filed in error. (Crick, S). (Entered: 02/20/2026), (QC'ed on 02/23/2026, by Crick , S)
02/20/2026	<u>164</u>	First MOTION for Kyle Edwards Haugh to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6603804) by Former U S Dept of Justice Officials. Motions referred to David J Ayo. Motion Ripe Deadline set for 2/20/2026. (Attachments: # <u>1</u> Proposed order, # <u>2</u> Certificate of good standing)(aty,Perque, Richard) Modified on 2/24/2026 to modify filer. See <u>237</u> Order.(Crick, S). (Entered: 02/20/2026), (QC'ed on 02/23/2026, by Crick , S)
02/20/2026	<u>165</u>	First MOTION for Maitland Lilja Io Jones to Appear Pro Hac Vice (Admission fee: \$105, receipt number

		ALAWDC-6603825) by Former U S Dept of Justice Officials. Motions referred to David J Ayo. Motion Ripe Deadline set for 2/20/2026. (Attachments: # <u>1</u> Proposed order, # <u>2</u> Certificate of good standing)(aty,Perque, Richard) Modified on 2/24/2026 to modify filer. See <u>237</u> Order. (Crick, S). (Entered: 02/20/2026), (QC'ed on 02/23/2026, by Crick , S)
02/20/2026	<u>166</u>	First MOTION for Arielle K. Herzberg to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6603847) by Former U S Dept of Justice Officials. Motions referred to David J Ayo. Motion Ripe Deadline set for 2/20/2026. (Attachments: # <u>1</u> Proposed order, # <u>2</u> Certificate of good standing)(aty,Perque, Richard) Modified on 2/24/2026 to modify filer. See <u>237</u> Order. (Crick, S). (Entered: 02/20/2026), (QC'ed on 02/23/2026, by Crick , S)
02/20/2026	<u>167</u>	First MOTION for Leave to File Amicus Curiae Brief with consent in Opposition to <u>20</u> Motion for Preliminary Injunctin by Former U S Dept of Justice Officials. Motions referred to David J Ayo. Motion Ripe Deadline set for 2/20/2026. (Attachments: # <u>1</u> Proposed order, # <u>2</u> Proposed pleading)(aty,Perque, Richard) Modified on 2/23/2026 to create docket entry relationship. (Crick, S). Modified on 2/24/2026 to modify filer. See <u>237</u> Order. (Crick, S). (Entered: 02/20/2026), (QC'ed on 02/23/2026, by Crick , S)
02/20/2026	<u>168</u>	Certificate of Good Standing re <u>104</u> Motion to Appear Pro Hac Vice filed by Students For Life of America. (aty,Lewis, R) Modified on 2/23/2026 to more accurately describe document. (Crick, S). (Entered: 02/20/2026), (QC'ed on 02/23/2026, by Crick , S)
02/20/2026	<u>169</u>	MOTION for Leave to File Amicus Brief in Support of <u>20</u> Motion for Preliminary Injunction with consent by Disability Rights Education & Defense Fund. Motions referred to David J Ayo. Motion Ripe Deadline set for 2/20/2026. (Attachments: # <u>1</u> Proposed order, # <u>2</u> Memorandum / Brief, # <u>3</u> Proposed pleading Amicus Brief of Disability Rights Education and Defense Fund and Others)(aty,Chetta, Chloe) Modified on 2/23/2026 to create docket entry relationship.(Crick, S). (Entered: 02/20/2026), (QC'ed on 02/23/2026, by Crick , S)
02/20/2026	<u>170</u>	Unopposed MOTION for Leave to File Amicus Brief in Opposition to <u>20</u> Motion for Preliminary Injunction with consent by American College of Obstetricians & Gynecologists. Motions referred to David J Ayo. Motion Ripe Deadline set for 2/20/2026. (Attachments: # <u>1</u> Proposed order, # <u>2</u> Proposed pleading)(Attorney Malcolm Clark Lloyd added to party American College of Obstetricians & Gynecologists)(pty:am))(aty,Lloyd, Malcolm) Modified on 2/23/2026 to modify docket text and create docket entry relationship. (Crick, S). (Entered: 02/20/2026), (QC'ed on 02/23/2026, by Crick , S)
02/20/2026	<u>171</u>	

		MOTION for Kathryn Saba to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6604070) by AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS (ACOG). Motions referred to David J Ayo. Motion Ripe Deadline set for 2/20/2026. (Attachments: # <u>1</u> Exhibit Certificate of Good Standing for Kathryn Saba, # <u>2</u> Proposed order Proposed Order)(aty,Lloyd, Malcolm) (Entered: 02/20/2026), (QC'ed on 02/23/2026, by Crick , S)
02/20/2026	<u>172</u>	MOTION for Leave to File Amicus Brief with consent by Medical Students for Choice. Motions referred to David J Ayo. Motion Ripe Deadline set for 2/20/2026. (Attachments: # <u>1</u> Proposed order, # <u>2</u> Proposed pleading)(aty,Moody, Alexandra) (Entered: 02/20/2026), (QC'ed on 02/23/2026, by Crick , S)
02/20/2026	<u>173</u>	MOTION for Meaghan Davant to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6604073) by AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS (ACOG). Motions referred to David J Ayo. Motion Ripe Deadline set for 2/20/2026. (Attachments: # <u>1</u> Exhibit Certificate of Good Standing for Meaghan Davant, # <u>2</u> Proposed order Proposed Order)(aty,Lloyd, Malcolm) (Entered: 02/20/2026), (QC'ed on 02/23/2026, by Crick , S)
02/20/2026	<u>174</u>	MOTION for Molly Meegan to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6604077) by AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS (ACOG). Motions referred to David J Ayo. Motion Ripe Deadline set for 2/20/2026. (Attachments: # <u>1</u> Exhibit Certificate of Good Standing for Molly Meegan, # <u>2</u> Proposed order Proposed Order)(aty,Lloyd, Malcolm) (Entered: 02/20/2026), (QC'ed on 02/23/2026, by Crick , S)
02/20/2026	<u>175</u>	MOTION for Nicole Marton to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6604080) by AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS (ACOG). Motions referred to David J Ayo. Motion Ripe Deadline set for 2/20/2026. (Attachments: # <u>1</u> Exhibit Certificate of Good Standing for Nicole Marton, # <u>2</u> Proposed order Proposed Order)(aty,Lloyd, Malcolm) (Entered: 02/20/2026), (QC'ed on 02/23/2026, by Crick , S)
02/20/2026	<u>176</u>	MOTION for Shannon Selden to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6604104) by AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS (ACOG). Motions referred to David J Ayo. Motion Ripe Deadline set for 2/20/2026. (Attachments: # <u>1</u> Exhibit Certificate of Good Standing for Shannon Selden, # <u>2</u> Proposed order Proposed Order)(aty,Lloyd, Malcolm) (Entered: 02/20/2026), (QC'ed on 02/23/2026, by Crick , S)
02/20/2026		(Court only) ***Deadline terminated. See <u>157</u> Corporate Disclosure Statement. (crt,Crick, S) (Entered: 02/23/2026)
02/20/2026		

		Motions Transferred regarding <u>156</u> MOTION for Leave to File with consent <i>Amicus Brief Opposing Plaintiff's Motion for Preliminary Injunction</i> , <u>158</u> MOTION for Leave to File Memorandum of Law for Amici States in Opposition to Plaintiffs' Motion for a Stay with consent . Motions referred to Judge David C Joseph. (crt,Crick, S) (Entered: 02/23/2026)
02/20/2026		NOTICE of Corrective Action to R Bradley Lewis on behalf of Students For Life of America regarding <u>163</u> MOTION for Disclosure of Rule 7.1 Disclosure Statement . Action taken: Terminated <u>163</u> Motion for Disclosure. Duplicate Corporate Disclosure Statement electronically filed in error as motion. (crt,Crick, S) (Entered: 02/23/2026)
02/20/2026		Motions Transferred regarding <u>170</u> Unopposed MOTION for Leave to File Amicus Brief with consent , <u>167</u> First MOTION for Leave to File Amicus Curiae Brief with consent , <u>169</u> MOTION for Leave to File Amicus Brief of Disability Rights Education and Defense Fund and Others with consent . Motions referred to Judge David C Joseph. (crt,Crick, S) (Entered: 02/23/2026)
02/20/2026		Motions Transferred regarding <u>172</u> MOTION for Leave to File Amicus Brief with consent . Motions referred to Judge David C Joseph. (crt,Crick, S) (Entered: 02/23/2026)
02/20/2026		Motions Transferred regarding <u>155</u> Unopposed MOTION for Leave to File Amicus Brief with consent . Motions referred to Judge David C Joseph. (crt,Crick, S) (Entered: 02/23/2026)
02/23/2026	<u>177</u>	CORPORATE DISCLOSURE STATEMENT by Heartbeat International Inc. (aty,Cicero, Charles) (Entered: 02/23/2026), (QC'ed on 02/23/2026, by Bunting , M)
02/23/2026	<u>178</u>	NOTICE of Corporate Disclosure Statement Requirement re: <u>114</u> Motion to Appear Pro Hac Vice sent to Chloe Marie Chetta on behalf of Disability Rights Education & Defense Fund. Corporate Disclosure Statement due by 3/9/2026. (crt,Crick, S) (Entered: 02/23/2026)
02/23/2026	<u>179</u>	NOTICE of Corporate Disclosure Statement Requirement re: <u>118</u> Memorandum in Support of Motion sent to Brian Wade Arabie on behalf of Trinity Legal Center. Corporate Disclosure Statement due by 3/9/2026. (crt,Crick, S) (Entered: 02/23/2026)
02/23/2026	<u>180</u>	NOTICE of Corporate Disclosure Statement Requirement re: <u>128</u> Memorandum in Support of Motion sent to Ben E Clayton on behalf of Concerned Women for America. Corporate Disclosure Statement due by 3/9/2026. (crt,Crick, S) (Entered: 02/23/2026)
02/23/2026	<u>181</u>	NOTICE of Corporate Disclosure Statement Requirement re: <u>154</u> Motion for Leave to File sent to Rebekka C Veith on behalf of Legal Voice, National Domestic Violence Hotline. Corporate Disclosure Statement due by 3/9/2026. (crt,Crick, S) (Entered: 02/23/2026)

02/23/2026	<u>182</u>	NOTICE of Corporate Disclosure Statement Requirement re: <u>159</u> Motion to Appear Pro Hac Vice sent to Jamila Asha Johnson on behalf of 100 Reproductive Health Rights & Justice Organizations. Corporate Disclosure Statement due by 3/9/2026. (crt,Crick, S) (Entered: 02/23/2026)
02/23/2026	<u>183</u>	NOTICE of Corporate Disclosure Statement Requirement re: <u>170</u> Motion for Leave to File sent to Malcolm Clark Lloyd on behalf of American College of Obstetricians & Gynecologists. Corporate Disclosure Statement due by 3/9/2026. (crt,Crick, S) (Entered: 02/23/2026)
02/23/2026	<u>184</u>	NOTICE of Corporate Disclosure Statement Requirement re: <u>172</u> Motion for Leave to File sent to Alexandra DiBiase Moody on behalf of Medical Students for Choice. Corporate Disclosure Statement due by 3/9/2026. (crt,Crick, S) (Entered: 02/23/2026)
02/23/2026	<u>185</u>	ORDER granting <u>142</u> Motion to Substitute Pleading and Correct Docket. Signed by Magistrate Judge David J Ayo on 2/23/2026. (crt,Crick, S) (Entered: 02/23/2026)
02/23/2026	<u>186</u>	CORRECTED MOTION for Elizabeth R June to Appear Pro Hac Vice by Disability Rights Education & Defense Fund. Motions referred to Magistrate Judge David J Ayo. Motion Ripe Deadline set for 2/23/2026. (Attachments: # <u>1</u> Certificate of good standing, # <u>2</u> Proposed order)(crt,Crick, S) (Entered: 02/23/2026)
02/23/2026		(Court only) ***Motions terminated: <u>186</u> MOTION for Elizabeth R June to Appear Pro Hac Vice filed by Disability Rights Education & Defense Fund. Reason for termination: See <u>139</u> Order & <u>185</u> Order granting Elizabeth June to Appear Pro Hac Vice and corrected her representation (crt,Crick, S) (Entered: 02/23/2026)
02/23/2026	<u>187</u>	ORDER granting <u>143</u> Motion to Substitute Pleading and to Correct Docket. Signed by Magistrate Judge David J Ayo on 2/23/2026. (crt,Crick, S) (Entered: 02/23/2026)
02/23/2026	188	ELECTRONIC ORDER granting <u>88</u> Motion to Appear Pro Hac Vice for appearance of Sapna Khatri for I G H. Signed by Magistrate Judge David J Ayo on 2/23/2026. (crt,Chicola, C) (Entered: 02/23/2026)
02/23/2026	<u>189</u>	CORRECTED MOTION for Katherine Mallory Tosch Hoggatt to Appear Pro Hac Vice by Disability Rights Education & Defense Fund. Motions referred to Magistrate Judge David J Ayo. Motion Ripe Deadline set for 2/23/2026. (Attachments: # <u>1</u> Certificate of good standing, # <u>2</u> Proposed order)(crt,Crick, S) (Entered: 02/23/2026)
02/23/2026		(Court only) ***Motions terminated: <u>189</u> MOTION for Katherine Mallory Tosch Hoggatt to Appear Pro Hac Vice filed by Disability Rights Education & Defense Fund. Reason for termination: See <u>138</u> Order & <u>185</u> Order granting Katherine Mallory Tosch Hoggatt to appear pro hac vice and corrected her

		representation (crt,Crick, S) (Entered: 02/23/2026)
02/23/2026	<u>190</u>	ORDER granting <u>159</u> Motion to Appear Pro Hac Vice for appearance of Jessica Ring Amunson for 100 Reproductive Health Rights & Justice Organizations. Signed by Magistrate Judge David J Ayo on 2/23/2026. (crt,Crick, S) (Entered: 02/23/2026)
02/23/2026	<u>192</u>	ORDER granting <u>161</u> Motion to Appear Pro Hac Vice for appearance of Alan Schoenfeld for Kyle Edwards Haugh, Arielle K Herzberg, Maitland Lilja Io Jones, Kimberly A Parker, Alan Schoenfeld. Signed by Magistrate Judge David J Ayo on 2/23/2026. (crt,Crick, S) (Entered: 02/23/2026)
02/23/2026	<u>193</u>	ORDER granting <u>162</u> Motion to Appear Pro Hac Vice for appearance of Kimberly A Parker for Kyle Edwards Haugh, Arielle K Herzberg, Maitland Lilja Io Jones, Kimberly A Parker, Alan Schoenfeld. Signed by Magistrate Judge David J Ayo on 2/23/2026. (crt,Crick, S) (Entered: 02/23/2026)
02/23/2026	<u>194</u>	ORDER granting <u>164</u> Motion to Appear Pro Hac Vice for appearance of Kyle Edwards Haugh for Kyle Edwards Haugh, Arielle K Herzberg, Maitland Lilja Io Jones, Kimberly A Parker, Alan Schoenfeld. Signed by Magistrate Judge David J Ayo on 2/23/2026. (crt,Crick, S) (Entered: 02/23/2026)
02/23/2026	195	ELECTRONIC MINUTE ENTRY: All amici shall mail a courtesy copy of their brief to the chambers of the undersigned. Signed by Judge David C Joseph on 2/23/2026. (crt,Taylor, L) (Entered: 02/23/2026)
02/23/2026	<u>196</u>	ORDER granting <u>165</u> Motion to Appear Pro Hac Vice for appearance of Maitland Lilja Io Jones for Kyle Edwards Haugh, Arielle K Herzberg, Maitland Lilja Io Jones, Kimberly A Parker, Alan Schoenfeld. Signed by Magistrate Judge David J Ayo on 2/23/2026. (crt,Crick, S) (Entered: 02/23/2026)
02/23/2026	<u>197</u>	ORDER granting <u>166</u> Motion to Appear Pro Hac Vice for appearance of Arielle K Herzberg for Kyle Edwards Haugh, Arielle K Herzberg, Maitland Lilja Io Jones, Kimberly A Parker, Alan Schoenfeld. Signed by Magistrate Judge David J Ayo on 2/23/2026. (crt,Crick, S) (Entered: 02/23/2026)
02/23/2026	<u>198</u>	ORDER granting <u>171</u> Motion to Appear Pro Hac Vice for appearance of Kathryn Campbell Saba for American College of Obstetricians & Gynecologists. Signed by Magistrate Judge David J Ayo on 2/23/2026. (crt,Crick, S) (Entered: 02/23/2026)
02/23/2026	<u>199</u>	ORDER granting <u>173</u> Motion to Appear Pro Hac Vice for appearance of Meaghan Hannan Davant for American College of Obstetricians & Gynecologists. Signed by Magistrate Judge David J Ayo on 2/23/2026. (crt,Crick, S) (Entered: 02/23/2026)
02/23/2026	<u>200</u>	ORDER granting <u>174</u> Motion to Appear Pro Hac Vice for appearance of Molly A Meegan for American College of Obstetricians & Gynecologists. Signed by Magistrate Judge

		David J Ayo on 2/23/2026. (crt,Crick, S) (Entered: 02/23/2026)
02/23/2026	<u>201</u>	ORDER granting <u>175</u> Motion to Appear Pro Hac Vice for appearance of Nicole Amanda Marton for American College of Obstetricians & Gynecologists. Signed by Magistrate Judge David J Ayo on 2/23/2026. (crt,Crick, S) (Entered: 02/23/2026)
02/23/2026	<u>202</u>	ORDER granting <u>176</u> Motion to Appear Pro Hac Vice for appearance of Shannon Rose Selden for American College of Obstetricians & Gynecologists. Signed by Magistrate Judge David J Ayo on 2/23/2026. (crt,Crick, S) (Entered: 02/23/2026)
02/23/2026	<u>203</u>	ORDER granting <u>148</u> Motion for Leave to File. Signed by Judge David C Joseph on 2/23/2026. (crt,Crick, S) (Entered: 02/23/2026)
02/23/2026	<u>204</u>	AMICI CURIAE BRIEF in Opposition re <u>20</u> MOTION for Preliminary Injunction <i>or for Preliminary Relief Under 5 U.S.C. § 705</i> MOTION for Preliminary Relief Under 5 USC 705 filed by I G H. (crt,Crick, S) (Entered: 02/23/2026)
02/23/2026	<u>205</u>	ORDER granting <u>154</u> Motion for Leave to File. Signed by Judge David C Joseph on 2/23/2026. (crt,Crick, S) (Entered: 02/23/2026)
02/23/2026	<u>206</u>	AMICI CURIAE BRIEF in Opposition re <u>20</u> MOTION for Preliminary Injunction <i>or for Preliminary Relief Under 5 U.S.C. § 705</i> MOTION for Preliminary Relief Under 5 USC 705 filed by Legal Voice, National Domestic Violence Hotline. (crt,Crick, S) (Entered: 02/23/2026)
02/23/2026	<u>207</u>	ORDER granting <u>156</u> Motion for Leave to File. Signed by Judge David C Joseph on 2/23/2026. (crt,Crick, S) (Entered: 02/23/2026)
02/23/2026	<u>208</u>	AMICI CURIAE BRIEF in Opposition re <u>20</u> MOTION for Preliminary Injunction <i>or for Preliminary Relief Under 5 U.S.C. § 705</i> MOTION for Preliminary Relief Under 5 USC 705 filed by Robert M Califf, Michael A Friedman, Margaret Hamburg, Jane E Henney, David A Kessler, Stephen Ostroff, Joshua M Sharfstein, Norman E Sharpless, Janet A Woodcock. (Attachments: # <u>1</u> Exhibit)(crt,Crick, S) (Entered: 02/23/2026)
02/23/2026	<u>209</u>	ORDER granting <u>158</u> Motion for Leave to File. Signed by Judge David C Joseph on 2/23/2026. (crt,Crick, S) (Entered: 02/23/2026)
02/23/2026	<u>210</u>	AMICUS BRIEF in Opposition re <u>20</u> MOTION for Preliminary Injunction <i>or for Preliminary Relief Under 5 U.S.C. § 705</i> MOTION for Preliminary Relief Under 5 USC 705 filed by State of Arizona, State of California, State of Colorado, State of Connecticut, State of Delaware, District of Columbia, State of Hawaii, State of Illinois, State of Maine, State of Maryland, Commonwealth of Massachusetts, State of Minnesota, State of Nevada, State of New Jersey, State of New Mexico, State of New York, State of Oregon, State of Rhode Island, State of

		Vermont, State of Washington. (crt,Crick, S) (Entered: 02/23/2026)
02/23/2026	<u>211</u>	CORPORATE DISCLOSURE STATEMENT by Ethics & Public Policy Center. (aty,Ghetti, Michelle) (Entered: 02/23/2026), (QC'ed on 02/23/2026, by Crick , S)
02/23/2026	<u>212</u>	CORPORATE DISCLOSURE STATEMENT by Legal Voice, National Domestic Violence Hotline. (aty,Veith, Rebekka) (Entered: 02/23/2026), (QC'ed on 02/23/2026, by Bunting , M)
02/23/2026	<u>213</u>	NOTICE of Corporate Disclosure Statement Requirement re: <u>148</u> Motion for Leave to File sent to Meghan K Matt on behalf of I G H. Corporate Disclosure Statement due by 3/9/2026. (crt,Crick, S) (Entered: 02/23/2026)
02/23/2026	<u>214</u>	CORPORATE DISCLOSURE STATEMENT by Disability Rights Education & Defense Fund. (aty,Uzeta, Maria) (Entered: 02/23/2026), (QC'ed on 02/23/2026, by Bunting , M)
02/23/2026		(Court only) ***Deadlines/Hearings terminated. See <u>212</u> & <u>214</u> Corporate Disclosure Statements. (crt,Bunting, M) (Entered: 02/23/2026)
02/23/2026	<u>215</u>	CORPORATE DISCLOSURE STATEMENT by Concerned Women for America. (aty,Clayton, Ben) (Entered: 02/23/2026), (QC'ed on 02/24/2026, by Crick , S)
02/23/2026	<u>216</u>	CORPORATE DISCLOSURE STATEMENT by 60 Plus Association, Advancing American Freedom Inc, Alabama Policy Institute, Alaska Family Council, American Association of Senior Citizens, American Values, Americans United for Life, Americas Women, Association of Mature American Citizens Action, Fran Bevan, Centennial Institute at Colorado Christian University, Center for Urban Renewal & Education, Christian Law Association, Christian Medical & Dental Associations, Democrats for Life, Eagle Forum, Family Council in Arkansas, Family Foundation of Virginia, Family Institute of Connecticut Action, Frontline Policy Council, Human Coalition, International Conference of Evangelical Chaplain Endorsers, Tim Jones, Alveda King, Louisiana Family Forum, Lutheran Center for Religious Liberty, Maryland Family Institute, Men & Women for a Representative Democracy in America Inc, Men for Life, National Religious Broadcasters, National Right to Life, New York State Conservative Party, North Carolina Values Coalition, Melissa Ortiz, Phyllis Schlaflys Pennsylvania Eagle Forum, Priests for Life, Rick Santorum, Gregory P Seltz, Paul Stam, Kathy Szeliga, Suzi Voyles, Wagner Center, Wisconsin Family Action Inc, Women for Democracy in America Inc, Young Americas Foundation. (aty,Clayton, Ben) (Entered: 02/23/2026), (QC'ed on 02/24/2026, by Crick , S)
02/23/2026	<u>217</u>	ORDER granting <u>155</u> Motion for Leave to File. Signed by Judge David C Joseph on 2/23/2026. (crt,Crick, S) (Entered: 02/23/2026)

		02/24/2026)
02/23/2026	<u>218</u>	BRIEF AS AMICI CURIAE in Opposition re <u>20</u> MOTION for Preliminary Injunction <i>or for Preliminary Relief Under 5 U.S.C. § 705</i> MOTION for Preliminary Relief Under 5 USC 705 filed by 100 Reproductive Health Rights & Justice Organizations. (crt,Crick, S) (Entered: 02/24/2026)
02/23/2026	<u>219</u>	ORDER granting <u>167</u> Motion for Leave to File. Signed by Judge David C Joseph on 2/23/2026. (crt,Crick, S) (Entered: 02/24/2026)
02/23/2026	<u>220</u>	BRIEF AS AMICI CURIAE in Opposition re <u>20</u> MOTION for Preliminary Injunction <i>or for Preliminary Relief Under 5 U.S.C. § 705</i> MOTION for Preliminary Relief Under 5 USC 705 filed by Former U S Dept of Justice Officials. (crt,Crick, S) Modified on 2/24/2026 to modify filers. See <u>237</u> Order. (Crick, S). (Entered: 02/24/2026)
02/23/2026	<u>221</u>	ORDER granting <u>169</u> Motion for Leave to File. Signed by Judge David C Joseph on 2/23/2026. (crt,Crick, S) (Entered: 02/24/2026)
02/23/2026	<u>222</u>	AMICUS BRIEF re <u>20</u> MOTION for Preliminary Injunction <i>or for Preliminary Relief Under 5 U.S.C. § 705</i> MOTION for Preliminary Relief Under 5 USC 705 filed by Disability Rights Education & Defense Fund. (crt,Crick, S) (Entered: 02/24/2026)
02/23/2026	<u>223</u>	ORDER granting <u>170</u> Motion for Leave to File. Signed by Judge David C Joseph on 2/23/2026. (crt,Crick, S) (Entered: 02/24/2026)
02/23/2026	<u>224</u>	AMICUS BRIEF in Opposition re <u>20</u> MOTION for Preliminary Injunction <i>or for Preliminary Relief Under 5 U.S.C. § 705</i> MOTION for Preliminary Relief Under 5 USC 705 filed by American College of Obstetricians & Gynecologists. (crt,Crick, S) (Entered: 02/24/2026)
02/23/2026	<u>225</u>	ORDER granting <u>172</u> Motion for Leave to File. Signed by Judge David C Joseph on 2/23/2026. (crt,Crick, S) (Entered: 02/24/2026)
02/23/2026	<u>226</u>	AMICUS CURIAE in Opposition re <u>20</u> MOTION for Preliminary Injunction <i>or for Preliminary Relief Under 5 U.S.C. § 705</i> MOTION for Preliminary Relief Under 5 USC 705 filed by Medical Students for Choice. (crt,Crick, S) (Entered: 02/24/2026)
02/23/2026		(Court only) ***Deadline terminated. See <u>215</u> Corporate Disclosure Statement. (crt,Crick, S) (Entered: 02/24/2026)
02/23/2026		(Court only) ***Deadlines terminated. See <u>216</u> Corporate Disclosure Statement. (crt,Crick, S) (Entered: 02/24/2026)
02/24/2026	<u>227</u>	First MOTION Correct and Amend Docket re <u>166</u> First

		<p>MOTION for Arielle K. Herzberg to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6603847), <u>167</u> First MOTION for Leave to File Amicus Curiae Brief with consent , <u>165</u> First MOTION for Maitland Lilja Io Jones to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6603825), <u>161</u> First MOTION for Alan Schoenfeld to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6603715), <u>164</u> First MOTION for Kyle Edwards Haugh to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6603804), <u>162</u> First MOTION for Kimberly A. Parker to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6603787) by Former U.S. Department of Justice Officials. Motions referred to David J Ayo. Motion Ripe Deadline set for 2/24/2026. (Attachments: # <u>1</u> Proposed order)(Attorney Richard Gerard Perque added to party Former U.S. Department of Justice Officials(pty:am))(aty,Perque, Richard) (Entered: 02/24/2026), (QC'ed on 02/24/2026, by Crick , S)</p>
02/24/2026		<p>Motions Transferred regarding <u>227</u> First MOTION Correct and Amend Docket re <u>166</u> First MOTION for Arielle K. Herzberg to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6603847), <u>167</u> First MOTION for Leave to File Amicus Curiae Brief with consent. Motions referred to Judge David C Joseph. (crt,Crick, S) (Entered: 02/24/2026)</p>
02/24/2026	<u>228</u>	<p>CORPORATE DISCLOSURE STATEMENT by 100 Reproductive Health Rights & Justice Organizations identifying Other Affiliate, Aspiration Tech for Endora. (aty,Johnson, Jamila) Modified on 2/24/2026 to modify docket text and add other affiliate. (Crick, S). (Entered: 02/24/2026), (QC'ed on 02/24/2026, by Crick , S)</p>
02/24/2026	<u>229</u>	<p>MINUTES for proceedings held before Judge David C Joseph. MOTION HEARING held on 2/24/2026 re <u>20</u> MOTION for Preliminary Injunction or for Preliminary Relief and <u>50</u> MOTION to Stay the Case. After considering oral arguments, motions and memoranda submitted as well as the applicable law, the Court took the matters under advisement. A written ruling will follow. The Court GRANTED <u>52</u> Motion to Intervene and <u>54</u> Motion to Intervene. The Court ORDERED the FDA, through counsel, to file a brief within seven (7) days addressing the FDA's authority to issue interim orders addressing the prescribing or distribution of a drug if confronted with concerning information during its review process. (Court Reporter: Beth Delatte) (crt,LaCombe, L) (Entered: 02/24/2026)</p>
02/24/2026		<p>(Court only) ***Deadline terminated. See <u>228</u> Corporate Disclosure Statement. (crt,Crick, S) (Entered: 02/24/2026)</p>
02/24/2026	<u>230</u>	<p>MOTION to Dismiss For Failure to State a Claim, MOTION to Dismiss for Lack of Jurisdiction by Danco Laboratories L L C. Motions referred to Magistrate Judge David J Ayo.</p>

		(Attachments: # <u>1</u> Memorandum / Brief)(crt,Crick, S) (Entered: 02/24/2026)
02/24/2026	<u>231</u>	Conditional MEMORANDUM in Opposition re <u>20</u> MOTION for Preliminary Injunction <i>or for Preliminary Relief Under 5 U.S.C. § 705</i> MOTION for Preliminary Relief Under 5 USC 705 filed by GenBioPro Inc. (Attachments: # <u>1</u> Declaration of Robert Katerberg, # <u>2</u> Ex. A - 2023 REMS, # <u>3</u> Ex. B - GenBioPro Citizen Petition, # <u>4</u> Ex. B-1 - Vol. 1, Citizen Petition Appx, # <u>5</u> Ex. B-2 - Vol. 2, Citizen Petition Appx, # <u>6</u> Ex. B-3 - Vol. 3, Citizen Petition Appx, # <u>7</u> Ex. B-4 - Vol. 4, Citizen Petition Appx, # <u>8</u> Ex. B-5 - Vol. 5, Citizen Petition Appx, # <u>9</u> Ex. B-6 - Vol. 6, Citizen Petition Appx, # <u>10</u> Ex. B-7 - Vol. 7, Citizen Petition Appx, # <u>11</u> Ex. B-8 - Vol. 8, Citizen Petition Appx, # <u>12</u> Ex. B-9 - Vol. 9, Citizen Petition Appx, # <u>13</u> Ex. C - FDA Denial of AAPLOG Citizen Petition, # <u>14</u> Ex. D - FDA Interim Response to GenBioPro Citizen Petition, # <u>15</u> Ex. E - Dilek JAMA Article, # <u>16</u> Ex. F - Ctr on Repro Health et al. Comment ISO GenBioPro Citize, # <u>17</u> Ex. G - Woodcock Declaration, # <u>18</u> Ex. H - ACOG Citizen Petition, # <u>19</u> Ex. I - Hasselbacher Comment ISO GenBioPro Citizen Petition, # <u>20</u> Ex. J - BU Programs Comment ISO GenBioPro Citizen Petition, # <u>21</u> Ex. K - Comment by Legal Voice ISO GenBioPro Citizen Petition)(crt,Crick, S) (Entered: 02/24/2026)
02/24/2026	<u>232</u>	Conditional MOTION to Dismiss For Failure to State a Claim, MOTION to Dismiss for Lack of Jurisdiction by GenBioPro Inc. Motions referred to Magistrate Judge David J Ayo. (crt,Crick, S) (Entered: 02/24/2026)
02/24/2026	<u>233</u>	CORPORATE DISCLOSURE STATEMENT by American Association of Pro-Life Obstetricians & Gynecologists. (aty,Arabie, Brian) (Entered: 02/24/2026), (QC'ed on 02/24/2026, by Crick , S)
02/24/2026	<u>234</u>	CORPORATE DISCLOSURE STATEMENT by Family Research Council. (aty,Arabie, Brian) (Entered: 02/24/2026), (QC'ed on 02/24/2026, by Crick , S)
02/24/2026	<u>235</u>	CORPORATE DISCLOSURE STATEMENT by Samaritans Purse. (aty,Arabie, Brian) (Entered: 02/24/2026), (QC'ed on 02/24/2026, by Crick , S)
02/24/2026	<u>236</u>	PROPOSED ORDER re <u>69</u> Motion to Appear Pro Hac Vice, Referred to Magistrate Judge David J Ayo. Motion Ripe Deadline set for 2/24/2026. (crt,Mitchell, P) (Entered: 02/24/2026), (QC'ed on 02/24/2026, by Mitchell , P)
02/24/2026	<u>237</u>	ORDER granting <u>227</u> Motion Correct & Amend Docket. Signed by Judge David C Joseph on 2/24/2026. (crt,Crick, S) (Entered: 02/24/2026)
02/24/2026		(Court only) *** Party Maitland Lilja Io Jones, Kimberly A Parker, Alan Schoenfeld, Kyle Edwards Haugh and Arielle K Herzberg terminated. See <u>237</u> Order. (crt,Crick, S) (Entered: 02/24/2026)

		02/24/2026)
02/24/2026	<u>238</u>	MOTION for Alyssa Howard to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6609661) by Robert M Califf, Michael A Friedman, Margaret Hamburg, Jane E Henney, David A Kessler, Stephen Ostroff, Joshua M Sharfstein, Norman E Sharpless, Janet A Woodcock. Motions referred to David J Ayo. Motion Ripe Deadline set for 2/24/2026. (Attachments: # <u>1</u> Exhibit Certificate of Good Standing, # <u>2</u> Proposed order)(aty, Landry, Mandie) (Entered: 02/24/2026), (QC'ed on 02/25/2026, by Crick , S)
02/24/2026	<u>239</u>	MOTION for Margaret Dotzel to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6609665) by Robert M Califf, Michael A Friedman, Margaret Hamburg, Jane E Henney, David A Kessler, Stephen Ostroff, Joshua M Sharfstein, Norman E Sharpless, Janet A Woodcock. Motions referred to David J Ayo. Motion Ripe Deadline set for 2/24/2026. (Attachments: # <u>1</u> Exhibit Certificate of Good Standing, # <u>2</u> Proposed order)(aty, Landry, Mandie) (Entered: 02/24/2026), (QC'ed on 02/25/2026, by Crick , S)
02/24/2026	<u>240</u>	MOTION for William Schultz to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6609666) by Robert M Califf, Michael A Friedman, Margaret Hamburg, Jane E Henney, David A Kessler, Stephen Ostroff, Joshua M Sharfstein, Norman E Sharpless, Janet A Woodcock. Motions referred to David J Ayo. Motion Ripe Deadline set for 2/24/2026. (Attachments: # <u>1</u> Proposed order, # <u>2</u> Exhibit Certificate of Good Standing)(aty, Landry, Mandie) (Entered: 02/24/2026), (QC'ed on 02/25/2026, by Crick , S)
02/24/2026	230	MEMORANDUM in Opposition re <u>20</u> MOTION for Preliminary Injunction <i>or for Preliminary Relief Under 5 U.S.C. § 705</i> MOTION for Preliminary Relief Under 5 USC 705 filed by Danco Laboratories L L C. ADMINISTRATIVE ENTRY to capture opposition included within 230 Motion to Dismiss. (crt,Crick, S) Modified on 2/25/2026 to add document number. (Crick, S). (Entered: 02/25/2026)
02/25/2026	<u>241</u>	AMENDED DOCUMENT by Advancing American Freedom Inc. Amendment to <u>69</u> MOTION for J. Marc Wheat to Appear Pro Hac Vice (Admission fee: \$105, receipt number ALAWDC-6589526) <i>cert of good standing</i> . (aty, Clayton, Ben) (Entered: 02/25/2026), (QC'ed on 02/25/2026, by Crick , S)
02/25/2026		Motions Transferred regarding 230 MOTION to Dismiss For Failure to State a Claim MOTION to Dismiss for Lack of Jurisdiction, <u>232</u> MOTION to Dismiss For Failure to State a Claim MOTION to Dismiss for Lack of Jurisdiction. Motions referred to Judge David C Joseph. (crt,Taylor, L) (Entered: 02/25/2026)
02/25/2026		Set/Reset Deadlines as to <u>69</u> MOTION for J. Marc Wheat to Appear Pro Hac Vice (Admission fee: \$105, receipt number

		ALAWDC-6589526). Motion Ripe Deadline set for 2/25/2026. (crt,Crick, S) (Entered: 02/25/2026)
02/25/2026	<u>242</u>	ORDER granting <u>238</u> Motion to Appear Pro Hac Vice for appearance of Alyssa Howard for Robert M Califf, Michael A Friedman, Margaret Hamburg, Jane E Henney, David A Kessler, Stephen Ostroff, Joshua M Sharfstein, Norman E Sharpless, Janet A Woodcock. Signed by Magistrate Judge David J Ayo on 2/25/2026. (crt,Crick, S) (Entered: 02/25/2026)
02/25/2026	<u>243</u>	ORDER granting <u>239</u> Motion to Appear Pro Hac Vice for appearance of Margaret M Dotzel for Robert M Califf, Michael A Friedman, Margaret Hamburg, Jane E Henney, David A Kessler, Stephen Ostroff, Joshua M Sharfstein, Norman E Sharpless, Margaret M Dotzel for Janet A Woodcock. Signed by Magistrate Judge David J Ayo on 2/25/2026. (crt,Crick, S) (Entered: 02/25/2026)
02/25/2026	<u>244</u>	ORDER granting <u>240</u> Motion to Appear Pro Hac Vice for appearance of William B Schultz for Robert M Califf, Michael A Friedman, Margaret Hamburg, Jane E Henney, David A Kessler, Stephen Ostroff, Joshua M Sharfstein, Norman E Sharpless, Janet A Woodcock. Signed by Magistrate Judge David J Ayo on 2/25/2026. (crt,Crick, S) (Entered: 02/25/2026)
02/25/2026		(Court only) ***Motions terminated: <u>236</u> PROPOSED ORDER re <u>69</u> Motion to Appear Pro Hac Vice., Referred to Magistrate Judge David J Ayo. Reason for termination: See <u>241</u> Certificate of Good Standing. (crt,Crick, S) (Entered: 02/26/2026)
02/26/2026	<u>245</u>	ORDER granting <u>69</u> Motion to Appear Pro Hac Vice for appearance of J Marc Wheat for Advancing American Freedom Inc. Signed by Magistrate Judge David J Ayo on 2/26/2026. (crt,Crick, S) (Entered: 02/26/2026)
02/27/2026	<u>246</u>	NOTICE OF FILING OF OFFICIAL TRANSCRIPT of Proceedings for motion hearing held on 2/24/2026 before Judge David C Joseph. Court Reporter Beth Delatte, Telephone number (337) 593-5222. Total pages: 63. Transcript may be viewed at the court public terminal or purchased through the Court Reporter before the deadline for Release of Transcript Restriction. After that date it may be obtained through PACER or the Court Reporter. Redaction Request due 3/23/2026. Redacted Transcript Deadline set for 4/2/2026. Release of Transcript Restriction set for 6/1/2026. (crt,Elstrott Delatte, B) (Entered: 02/27/2026), (QC'ed on 03/02/2026, by Alexander , E)
02/27/2026	<u>247</u>	MOTION to Withdraw Kyle Edwards Haugh as Attorney by Former U S Dept of Justice Officials. Motions referred to David J Ayo. Motion Ripe Deadline set for 2/27/2026. (Attachments: # <u>1</u> Proposed order)(aty,Haugh, Kyle) (Entered: 02/27/2026), (QC'ed on 03/02/2026, by Crick , S)
03/02/2026	<u>248</u>	

		ORDER granting <u>247</u> Motion to Withdraw as Attorney. Attorney Kyle Edwards Haugh terminated. Signed by Magistrate Judge David J Ayo on 3/2/2026. (crt,Crick, S) (Entered: 03/02/2026)
03/03/2026	<u>249</u>	CORPORATE DISCLOSURE STATEMENT by I G H. (aty,Matt, Meghan) (Entered: 03/03/2026), (QC'ed on 03/03/2026, by Crick , S)
03/03/2026		(Court only) ***Deadline terminated. See <u>249</u> Corporate Disclosure Statement. (crt,Crick, S) (Entered: 03/03/2026)
03/03/2026	<u>250</u>	Supplemental Brief by U S Food & Drug Administration, U S Dept of Health & Human Services, Robert F Kennedy, Jr, Martin Makary . (aty,Katzen, Noah) Modified on 3/3/2026 to modify docket text. (Crick, S). (Entered: 03/03/2026), (QC'ed on 03/03/2026, by Crick , S)
03/09/2026	<u>251</u>	CORPORATE DISCLOSURE STATEMENT by Medical Students for Choice. (aty,Jonat, Jayme) (Entered: 03/09/2026), (QC'ed on 03/09/2026, by Crick , S)
03/09/2026	<u>252</u>	CORPORATE DISCLOSURE STATEMENT by American College of Obstetricians & Gynecologists. (aty,Lloyd, Malcolm) (Entered: 03/09/2026), (QC'ed on 03/09/2026, by Crick , S)
03/09/2026		(Court only) ***Deadlines terminated. See <u>251</u> & <u>252</u> Corporate Disclosure Statements. (crt,Crick, S) (Entered: 03/09/2026)
03/10/2026	<u>253</u>	MEMORANDUM in Opposition re 230 MOTION to Dismiss For Failure to State a Claim MOTION to Dismiss for Lack of Jurisdiction, <u>232</u> MOTION to Dismiss For Failure to State a Claim MOTION to Dismiss for Lack of Jurisdiction filed by State Louisiana, Rosalie Markezich. (Attachments: # <u>1</u> Exhibit Exhibit 1 - ACLU Reproductive Health Rights and Justice Groups Letter to Biden Administration on Mifepristone (March 16 2021))(aty,Aguinaga, J) (Entered: 03/10/2026), (QC'ed on 03/11/2026, by Crick , S)
03/16/2026	<u>254</u>	SECOND NOTICE of Corporate Disclosure Statement Requirement, re: <u>179</u> Notice of Corporate Disclosure Statement Requirement, sent to Brian Wade Arabie on behalf of Trinity Legal Center. Show Cause Response due by 3/30/2026. (crt,Mitchell, P) (Entered: 03/16/2026)
03/17/2026	<u>255</u>	CORPORATE DISCLOSURE STATEMENT by Trinity Legal Center. (aty,Arabie, Brian) (Entered: 03/17/2026), (QC'ed on 03/17/2026, by Crick , S)
03/17/2026		(Court only) ***Deadline terminated. See <u>255</u> Corporate Disclosure Statement. (crt,Crick, S) (Entered: 03/17/2026)
03/17/2026	<u>256</u>	REPLY to Response to Motion re 230 MOTION to Dismiss For Failure to State a Claim MOTION to Dismiss for Lack of

		Jurisdiction filed by Danco Laboratories L L C. (aty,Ellsworth, Jessica) (Entered: 03/17/2026), (QC'ed on 03/18/2026, by Crick , S)
03/17/2026	<u>257</u>	REPLY to Response to Motion re <u>232</u> MOTION to Dismiss For Failure to State a Claim MOTION to Dismiss for Lack of Jurisdiction filed by GenBioPro Inc. (aty,Katerberg, Robert) (Entered: 03/17/2026), (QC'ed on 03/18/2026, by Crick , S)
04/07/2026	<u>258</u>	MEMORANDUM RULING: IT IS HEREBY ORDERED that Defendants' MOTION TO STAY THE CASE [Doc. 50] is GRANTED. IT IS FURTHER ORDERED that Plaintiffs' MOTION FOR PRELIMINARY RELIEF UNDER 5 U.S.C. § 705 [Doc. 20] is DENIED WITHOUT PREJUDICE. IT IS FURTHER ORDERED that Danco's MOTION TO DISMISS [Doc. 230] and GenBioPro's MOTION TO DISMISS [Doc. 232] are hereby DENIED WITHOUT PREJUDICE. Signed by Judge David C Joseph on 4/7/2026. (crt,Casebonne, D) (Entered: 04/07/2026)
04/08/2026	<u>259</u>	NOTICE OF APPEAL as to <u>258</u> Order on Motion to Dismiss for Failure to State a Claim, Order on Motion to Dismiss/Lack of Jurisdiction, Order on Motion to Stay, Order on Motion for Preliminary Injunction, Order on Motion for Miscellaneous Relief, by State Louisiana, Rosalie Markezich. (Filing fee \$605, receipt number ALAWDC-6692082) (aty,Huettemann, Caitlin) (Entered: 04/08/2026), (QC'ed on 04/08/2026, by WalkerSld , B)
04/08/2026		NOTICE of Appeal Transcript Order Requirement regarding <u>259</u> Notice of Appeal. Pursuant to FRAP 10(b), the Appellant must file the transcript order form regardless of whether transcripts are necessary. Access the 5th Circuit site by clicking here . Hover over the Forms Fees & Guides tab, Forms, Court Reporter Forms, Transcript Order Form. In following the instructions on the form, please note manual notification to the court reporter and the 5th Circuit Court of Appeals is STILL REQUIRED. (crt,WalkerSld, B) (Entered: 04/08/2026)
04/15/2026		USCA Case Number 26-30203 for <u>259</u> Notice of Appeal, filed by State Louisiana, Rosalie Markezich. (crt,WalkerSld, B) (Entered: 04/17/2026)
04/21/2026	<u>260</u>	TRANSCRIPT REQUEST by State Louisiana, Rosalie Markezich for proceedings held on 02/24/2026 before Judge David C Joseph to Court Reporter: Court Reporter Beth Delatte: Transcript is already on file in the Clerks Office (aty,Huettemann, Caitlin) Modified text on 4/21/2026 (WalkerSld, B). (Entered: 04/21/2026), (QC'ed on 04/21/2026, by WalkerSld , B)
04/22/2026		Set Deadline for Clerk re <u>259</u> Notice of Appeal: Certify Appeal Record (26-30203) by Clerk to COA 5/7/2026. (crt,WalkerSld,

		B) (Entered: 04/22/2026)
04/23/2026	<u>261</u>	ORDER of USCA as to <u>259</u> Notice of Appeal, filed by State Louisiana, Rosalie Markezich that the motion of Reproductive Health Initiativefor Telehealth Equity & Solutions, Hey Jane, and IGH d/b/a Abortion onDemand, to file an amicus brief in opposition of the Appellants motion for § 705 stay or injunction pending appeal is GRANTED. (crt,WalkerSld, B) (Entered: 04/28/2026)
04/24/2026	<u>262</u>	MEMORANDUM ORDER of USCA as to <u>259</u> Notice of Appeal, filed by State Louisiana, Rosalie Markezich that the motion of Legal Voice to file an amicusresponse as to the Appellants motion for § 705 stay or injunction pendingappeal is GRANTED. IT IS FURTHER ORDERED that the motion of Honeybee Health, Inc., to file an amicus response as to the Appellants motion for § 705 stay or injunction pending appeal is GRANTED. IT IS FURTHER ORDERED that the motion of Vet Voice Foundation to file an amicus response as to the Appellants motion for § 705 stay or injunction pending appeal is GRANTED. IT IS FURTHER ORDERED that the motion of Disability Rights Education and Defense Fund and eight other organizations to file an amicus response as to the Appellants motion for § 705 stay or injunction pending appeal is GRANTED. (crt,WalkerSld, B) (Entered: 04/28/2026)
05/01/2026	<u>263</u>	MEMORANDUM ORDER of USCA as to <u>259</u> Notice of Appeal, filed by State Louisiana, Rosalie Markezich that the motion to stay the 2023 REMS under 5 U.S.C. § 705 pending appeal is GRANTED. (USCA #26-30203) IT IS FURTHER ORDERED that the alternative motion for injunction pending appeal is DENIED AS MOOT. (crt,WalkerSld, B) (Entered: 05/01/2026)
05/01/2026	<u>264</u>	NOTICE OF CROSS APPEAL as to <u>258</u> Order on Motion to Dismiss for Failure to State a Claim, Order on Motion to Dismiss/Lack of Jurisdiction, Order on Motion to Stay, Order on Motion for Preliminary Injunction, Order on Motion for Miscellaneous Relief, by Danco Laboratories L L C. (Filing fee \$605, receipt number ALAWDC-6739136) (aty,Ellsworth, Jessica) (Entered: 05/01/2026), (QC'ed on 05/04/2026, by WalkerSld , B)
05/01/2026	<u>265</u>	

		<p>NOTICE OF APPEAL as to <u>258</u> Order on Motion to Dismiss for Failure to State a Claim, Order on Motion to Dismiss/Lack of Jurisdiction, Order on Motion to Stay, Order on Motion for Preliminary Injunction, Order on Motion for Miscellaneous Relief, by GenBioPro Inc. (Filing fee \$605, receipt number ALAWDC-6739165) (aty,Katerberg, Robert) (Entered: 05/01/2026), (QC'ed on 05/04/2026, by WalkerSld , B)</p>
05/04/2026		<p>NOTICE of Appeal Transcript Order Requirement regarding <u>265</u> Notice of Appeal and <u>264</u> Notice of Cross Appeal. Pursuant to FRAP 10(b), the Appellant must file the transcript order form regardless of whether transcripts are necessary. Access the 5th Circuit site by clicking here. Hover over the Forms Fees & Guides tab, Forms, Court Reporter Forms, Transcript Order Form.</p> <p>In following the instructions on the form, please note manual notification to the court reporter and the 5th Circuit Court of Appeals is STILL REQUIRED. (crt,WalkerSld, B) (Entered: 05/04/2026)</p>

Louisiana et al v. U S Food & Drug Administration et al (6:25-cv-01491-DCJ-DJA)

Tab 2

**UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
LAFAYETTE DIVISION**

THE STATE OF LOUISIANA,
by and through its Attorney General,
LIZ MURRILL, and ROSALIE
MARKEZICH,

PLAINTIFFS,

v.

U.S. FOOD AND DRUG
ADMINISTRATION, et al.

DEFENDANTS.

Civ. No.: 6:25-cv-01491

Judge: David C. Joseph

Mag. Judge: David J. Ayo

NOTICE OF APPEAL

Pursuant to Federal Rule of Appellate Procedure 3(a), Plaintiffs the State of Louisiana, by and through its Attorney General Liz Murrill, and Rosalie Markezich (“Plaintiffs”) hereby appeal to the United States Court of Appeals for the Fifth Circuit the Court’s Memorandum Ruling (ECF No. 258) denying Plaintiffs’ Motion for Preliminary Relief under 5 U.S.C. § 705 (ECF No. 20) and granting the Government’s Motion to Stay the Case (ECF No. 50).

Dated: April 8, 2026

s/ Erik C. Baptist

Erin M. Hawley
Temp. LA Bar No. 918497
Erik C. Baptist (Lead)
Temp. LA Bar No. 918496
Julie Marie Blake
Temp. LA Bar No. 918492
Frank W. Basgall
Temp. LA Bar No. 918493
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Counsel for Plaintiff Rosalie Markezich

Respectfully submitted,

s/ Caitlin Huettemann

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Attorney General
J. Benjamin Aguiñaga*
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TX Bar No. 24101435
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Counsel for Plaintiff State of Louisiana

*Admitted pro hac vice

CERTIFICATE OF SERVICE

I hereby certify that on April 8, 2026, pursuant to Federal Rule of Civil Procedure 5(b)(2)(C), a true and correct copy of the foregoing memorandum, and all attachments thereto, was served by CM/ECF.

Respectfully submitted,

/s/ Caitlin Huettemann
CAITLIN HUETTEMANN (La #40402)

Tab 3

**UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF LOUISIANA
LAFAYETTE DIVISION**

THE STATE OF LOUISIANA, by and
through its Attorney General, LIZ
MURRILL, and ROSALIE MARKEZICH,

Plaintiffs,

v.

U.S. FOOD AND DRUG
ADMINISTRATION, *et al.*,

Defendants.

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

DANCO LABORATORIES, LLC'S NOTICE OF APPEAL

Notice is hereby given that Intervenor-Defendant Danco Laboratories, LLC appeals to the United States Court of Appeals for the Fifth Circuit from the memorandum ruling entered on April 7, 2026, (ECF No. 258), which denied Danco's motion to dismiss, as well as all adverse rulings, orders, findings, and conclusions included in and leading up to that order.

Dated: May 1, 2026

Respectfully submitted,

/s/ Jessica L. Ellsworth

Jessica L. Ellsworth*
Alexander V. Sverdlov*
Danielle Desaulniers Stempel*
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**admitted pro hac vice*

Counsel for Danco Laboratories, LLC

Tab 4

**UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF LOUISIANA
LAFAYETTE DIVISION**

THE STATE OF LOUISIANA, by and through its
Attorney General, LIZ MURRILL, and ROSALIE
MARKEZICH,

Plaintiffs,

v.

U.S. FOOD AND DRUG ADMINISTRATION,
et al.,

Defendants.

Civil Action No. 6:25-cv-01491

Judge: David C. Joseph

Mag. Judge: David J. Ayo

**INTERVENOR-DEFENDANT
GENBIOPRO, INC.'S NOTICE OF APPEAL**

Intervenor-Defendant GenBioPro, Inc. (“GenBioPro”) hereby appeals to the United States Court of Appeals for the Fifth Circuit from the portion of the Court’s April 7, 2026 Memorandum Ruling (ECF No. 258) that denies GenBioPro’s Motion to Dismiss (ECF No. 232). This appeal is based on the Court of Appeals’ pendent appellate jurisdiction because the “underpinnings” of GenBioPro’s Motion to Dismiss are “inextricably intertwined” with the Court’s denial of Plaintiffs’ motion for preliminary injunction in the same Memorandum Ruling, from which denial Plaintiffs appealed on April 8, 2026 (ECF No. 259) pursuant to 28 U.S.C. § 1292(a)(1). *Jiao v. Xu*, 28 F.4th 591, 596 (5th Cir. 2022).

Dated: May 1, 2026

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Tab 5

**UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
LAFAYETTE DIVISION**

**THE STATE OF LOUISIANA, BY AND
THROUGH ITS ATTORNEY GENERAL,
LIZ MURRILL, AND ROSALIE
MARKEZICH**

CIVIL DOCKET NO. 6:25-cv-01491

VERSUS

JUDGE DAVID C. JOSEPH

**U.S. FOOD AND DRUG
ADMINISTRATION, ET AL**

**MAGISTRATE JUDGE DAVID J.
AYO**

MEMORANDUM RULING

This case was brought by the State of Louisiana and Louisiana resident Rosalie Markezich (“Plaintiffs”) against the U.S. Food and Drug Administration (“FDA”) and several related agency heads¹ (collectively, the “Government”), challenging the legality of FDA’s 2023 agency action removing the in-person dispensing requirement for the abortion drug, mifepristone. Shortly after filing the lawsuit, Plaintiffs moved for preliminary injunctive relief, which was quickly followed by a flurry of motions by the Government and other parties in interest, including the drug’s manufacturers, Danco Laboratories, LLC (“Danco”) and GenBioPro, Inc. (“GenBioPro”). Also filed with the Court were twenty-two (22) amicus briefs authored by persons and organizations with a variety of viewpoints.²

¹ The defendants in this matter are the U.S. Food and Drug Administration (“FDA”); Martin Makary, in his official capacity as Commissioner of Food and Drugs at FDA; George Francis Tidmarsh, in his official capacity as the Director of FDA’s Center for Drug Evaluation and Research; the U.S. Department of Health and Human Services (“HHS”); and Robert F. Kennedy, Jr., in his official capacity as the Secretary of HHS.

² Amicus briefs were filed in support of the Plaintiffs’ motion by the following entities: (i) Family Research Council and Martha Shuping, M.D. [Doc. 66]; (ii) Women Injured by

The Court heard oral argument on the pending motions on February 24, 2026, and at that time granted motions to intervene by the two drug manufacturers. [Docs. 52, 54, 229, 246]. Now before the Court for consideration are: (i) a MOTION FOR PRELIMINARY RELIEF UNDER 5 U.S.C. § 705 [Doc. 20] filed by Plaintiffs; (ii) a MOTION TO STAY THE CASE [Doc. 50] filed by the Government; (iii) a MOTION TO DISMISS [Doc. 230] filed by Intervenor-Defendant Danco; and (iv) a MOTION TO DISMISS [Doc. 232] filed by Intervenor-Defendant GenBioPro.³

Abortion, The Justice Foundation and its Center Against Forced Abortions, and the National Association of Christian Lawmakers [Doc. 92]; (iii) American Association of Pro-Life Obstetricians and Gynecologists and Samaritan's Purse [Doc. 96]; (iv) The American Center for Law and Justice [Doc. 99]; (v) Ethics and Public Policy Center [Doc. 101]; (vi) Women and Families Harmed by Mifepristone and Former Abortion Providers [Doc. 118]; (vii) Advancing American Freedom, Inc., et al [Doc. 123]; (viii) Concerned Women for America [Doc. 128]; (ix) Dr. Calum Miller [Doc. 130]; (x) Heartbeat International [Doc. 132]; (xi) Students for Life of America [Doc. 136]; (xii) Senator Bill Cassidy, M.D., Representative Christopher H. Smith, and 58 Members of Congress [Doc. 141]; and (xiii) the States of Nebraska, Alabama, Alaska, Arkansas, Georgia, Idaho, Indiana, Iowa, Kansas, Mississippi, Missouri, Montana, North Dakota, Ohio, Oklahoma, South Carolina, South Dakota, Texas, Utah, West Virginia, and Wyoming [Doc. 121].

Amicus briefs were filed in opposition to the Plaintiffs' Motion by the following entities: (i) IGH PLLC d/b/a Abortion on Demand, Hey Jane, and The Reproductive Health Initiative for Telehealth Equity & Solutions (RHITES) [Doc. 204]; (ii) National Domestic Violence Hotline and Legal Voice [Doc. 206]; (iii) Former Commissioners and Acting Commissioners of the U.S. Food and Drug Administration [Doc. 208]; (iv) the States of New York, Arizona, California, Colorado, Connecticut, Delaware, Hawaii, Illinois, Maine, Maryland, Massachusetts, Minnesota, Nevada, New Jersey, New Mexico, Oregon, Rhode Island, Vermont, Washington, and the District of Columbia filed an amicus brief in opposition to the Defendants' Motion to Stay [Doc. 210]; (v) Over 100 Reproductive Health, Rights, and Justice Organizations [Doc. 218]; (vi) Former U.S. Department of Justice Officials [Doc. 220]; (vii) Disability Rights Education and Defense Fund and Others [Doc. 222]; (viii) American College of Obstetricians & Gynecologists, et al [Doc. 224]; and (ix) Medical Students for Choice [Doc. 226].

³ Plaintiffs' Motion for Preliminary Injunction is opposed by the Defendants [Doc. 51] and by the Intervenor-Defendants [Docs. 230, 231], and Plaintiffs filed a single brief both in reply to the Defendants' opposition brief and in opposition to the Defendants' Motion to Stay [Doc. 111]. Plaintiffs oppose the Motions to Dismiss filed by Danco and GenBioPro [Doc. 253], and Danco and GenBioPro filed reply briefs [Docs. 256, 257, respectively].

After a review of the record and the complex regulatory and judicial history of this subject matter, the Court declines to grant the Plaintiffs § 705 relief at this time. The record shows that FDA is currently in the process of “conducting its own review of the evidence” with respect to the current Risk Evaluation and Mitigation Strategies (“REMS”), “to determine whether modifications are necessary.” [Doc. 1-110]. And “courts owe significant deference to the politically accountable entities with the ‘background, competence, and expertise to assess public health.’” *FDA v. Am. Coll. of Obstetricians & Gynecologists*, 141 S. Ct. 578, 578-79 (2021) (Roberts, C.J., concurring in grant of application for stay).

Indeed, given the information available – and, importantly, the dearth of information upon which FDA previously acted to significantly loosen safety restrictions for prescribing mifepristone – the equities and the public interest weigh heavily in favor of FDA completing the job that the law requires it to do. Put differently, at this juncture, it is the completion of FDA’s promised good faith, evidence-based, and expeditious review of the mifepristone REMS, not “government by lawsuit,” that this Court finds to be in the public interest. *See United States v. Texas*, 599 U.S. 670, 704 (2023) (Gorsuch, J., concurring).

The Motions to Dismiss filed by the drug manufacturers Danco and GenBioPro [Docs. 230, 232, respectively] move to dismiss on the bases that Plaintiffs: (i) lack Article III standing; (ii) are outside “zone of interests” of the APA and Comstock Act; (iii) have failed to exhaust their claims administratively pursuant to 21 C.F.R. § 10.45(b); (iv) have asserted claims not yet ripe for adjudication; and (v) that on the merits their claims fail to state a claim upon which relief can be granted. This ruling addresses the Intervenor’s primary contention – the threshold jurisdictional issue of the Plaintiffs’ standing to bring this action. But because the Court grants the Government’s motion to stay this case pending completion of FDA’s mifepristone REMS review, the Court declines to substantively address the remaining issues raised by Intervenor at this time. Intervenor may renew their Motions to Dismiss upon the Court’s lifting of the stay.

For these reasons and as further detailed below, the Court finds that the Government’s Motion to Stay the Case [Doc. 50] should be GRANTED. Plaintiffs’ Motion for Preliminary Relief Under 5 U.S.C. § 705 [Doc. 20] is DENIED without prejudice to refile upon the Court lifting the stay. Likewise, the two Motions to Dismiss filed by Intervenors [Docs. 230, 232] are DENIED without prejudice to refile upon the Court lifting the stay. This action will remain STAYED until further order of the Court.

FACTUAL BACKGROUND AND PROCEDURAL HISTORY

I. Regulatory History of Mifepristone⁴

This case arises under the Federal Food, Drug, and Cosmetic Act, as amended, 21 U.S.C. ch. 9., the principal federal statute governing the regulation of food, drugs, medical devices, and cosmetics in the United States. The U.S. Department of Health and Human Services (“HHS”) is charged with the responsibility for implementing that law and has delegated the obligation to FDA, its subagency. Under federal law, FDA is responsible for ensuring that drugs marketed in the United States are safe and effective.

To that end, a drug sponsor seeking approval – typically the manufacturer or prospective marketer – must submit an application to FDA demonstrating that the drug is safe and effective for its intended use. *Alliance IV*, 602 U.S. at 375, citing 21 U.S.C. § 355(d). The application must generally include proposed labeling that

⁴ Although the Court provides herein a summary of the complex regulatory history pertinent to its ruling, a more exhaustive regulatory history is provided in *All. for Hippocratic Med. v. FDA*, 78 F.4th 210, 233 (5th Cir. 2023) (“*Alliance III*”), *rev’d and remanded sub nom., FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 375 (2024) (“*Alliance IV*”).

specifies, among other things, the drug’s dosage, directions for use, and the specific conditions the drug is approved to treat. *Id.* at 375, *citing* 21 C.F.R. §§ 201.5, 314.50 (2022). FDA may also impose additional conditions on a drug’s prescription and use when it finds that enhanced safety measures are necessary. *Id.*, *citing* 21 U.S.C. § 355-1(f)(3). Such conditions may include prescriber training, dispensing limitations, or patient-monitoring requirements. *Id.*

In 2000, FDA approved a new drug application for mifepristone tablets under its Subpart H regulations, 21 C.F.R. § 314.500. *Id.* This newly approved drug was marketed under the brand name Mifeprex and was used to terminate pregnancies through seven weeks of gestation (the “2000 Approval”).⁵ *Alliance IV*, 602 U.S. at 375. To help ensure that Mifeprex would be used safely and effectively, FDA placed further restrictions on the drug’s use and distribution. *Id.* Among other requirements, only physicians were permitted to prescribe or supervise the prescription of Mifeprex, and patients were required to follow a regimen involving three in-person visits with a physician. *Id.* FDA also required prescribing physicians to report hospitalizations, blood transfusions, and other serious adverse events to the drug sponsor, which in turn was obligated to report those events to FDA. *Id.*

⁵ In 1992, FDA promulgated the “Subpart H” regulations, which permit the accelerated approval of drugs intended to treat serious or life-threatening illnesses based on evidence of meaningful therapeutic benefit. *See* 21 C.F.R. § 314.500. Recognizing that such approvals rest on an expedited evidentiary basis, Subpart H also authorized post-approval restrictions “to assure safe use.” *Id.* § 314.520. Mifepristone was approved under this framework. In 2007, Congress codified and expanded these post-approval safety authorities by establishing Risk Evaluation and Mitigation Strategies (REMS), which are designed to ensure that a drug’s benefits outweigh its risks. *See All. for Hippocratic Med. v. FDA*, 2023 WL 2913725, at *21 (5th Cir. Apr. 12, 2023) (“*Alliance II*”), *citing* 21 U.S.C. § 355-1 (a)(1)-(2).

In 2015, Mifeprex’s distributor, Danco, submitted a supplemental new drug application seeking to amend Mifeprex’s labeling and to relax some of the restrictions that FDA had imposed. *Id.* In 2016, FDA approved the proposed changes, which: (i) deemed Mifeprex safe to terminate pregnancies up to ten weeks rather than seven weeks; (ii) allowed healthcare providers such as nurse practitioners to prescribe Mifeprex; and (iii) approved a dosing regimen that reduced the number of required in-person visits from three to one. *Id.* at 375-76. In addition, FDA approved a change in the prescribers’ adverse event reporting obligations to require prescribers to report only fatalities (collectively, the “2016 Amendments”). *Id.* at 376.

In April 2019, FDA approved an application for generic mifepristone, manufactured by GenBioPro (the “2019 Generic Application”). *Id.* FDA established the same conditions of use for generic mifepristone as for Mifeprex. *Id.* Then, in April 2021, at the height of the COVID-19 pandemic, FDA again relaxed the requirements for Mifeprex and generic mifepristone, announcing that it would temporarily “exercise enforcement discretion” to allow “dispensing mifepristone through the mail ... or through mail-order pharmacy” (the “2021 Nonenforcement Decision”). *Id.*

In January 2023, FDA issued its most recent REMS for mifepristone (the “2023 REMS”), which codified and refined prior changes, including, among other things: (i) the removal of an in-person dispensing requirement; (ii) permitting certified pharmacies to dispense mifepristone (including by mail); and (iii) otherwise continuing the post-2016 framework, including limited adverse-event reporting (primarily deaths). *Alliance III*, 78 F.4th at 247.

II. History of Mifepristone Litigation in the Fifth Circuit

In 2022, physicians providing pregnancy-related health care, including emergency care after unsuccessful medication abortions using mifepristone, and national organizations of such physicians, brought an action in a Texas district court under the Administrative Procedure Act (“APA”) against FDA, HHS, and agency officials. *See All. for Hippocratic Med. v. FDA*, 668 F. Supp. 3d 507, 560 (N.D. Tex. Apr. 7, 2023) (“*Alliance I*”). These plaintiffs challenged both the lawfulness of FDA’s initial approval of mifepristone (which had occurred more than 20 years earlier), and each post-approval action (at that time, the 2016 Amendments, 2019 Generic Approval, and 2021 Nonenforcement Decision). *Id.* After concluding that the plaintiffs had standing, the *Alliance I* district court entered a preliminary injunction staying the 2000 Approval of mifepristone and each of the subsequent agency actions – effectively removing the drug from the market pending a full trial on the merits. *Id.*

FDA and Danco appealed the injunction to the Fifth Circuit and asked for an emergency stay of the district court’s order pending appeal. The Fifth Circuit granted a partial stay, temporarily reinstating FDA’s original 2000 Approval of Mifeprex. *Alliance II*, 2023 WL 2913725, at *21. This partial stay permitted the drug to remain available only under the earlier, more restrictive conditions but left in place the district court’s injunction as to later regulatory changes. *Id.* Specifically, the *Alliance II* court found that the plaintiffs were likely to succeed on the merits of their claims under 5 U.S.C. § 706(2)(A) in at least two respects. *Id.* at *17.

First, the *Alliance II* court determined that FDA had failed to examine the relevant data when adopting the 2016 Amendments – relying instead on data that included the very safeguards the 2016 REMS had therein dispensed with. *Id.* And second, in a similar vein, FDA thereafter relied on the absence of non-fatal adverse-event reports in FDA’s Adverse Event Reporting System (“FAERS”) after eliminating the requirement that such events even be reported. *Id.* As to the latter error, the Fifth Circuit pointedly explained that “[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.” *Id.*

Thus, the Fifth Circuit concluded that the *Alliance* plaintiffs were likely to succeed on the merits of their APA challenges with respect to FDA’s decisions beginning with the 2016 Amendments and “all subsequent actions.” *Id.* at *17-21. Following the Fifth Circuit’s partial stay, FDA and Danco sought a full stay from the United States Supreme Court, which they obtained, thereby preserving the current regulatory regime during the pendency of the appeal. *Danco Lab’s, LLC v. All. for Hippocratic Med.*, 143 S. Ct. 1075 (2023).

Then, in August 2023, a different panel of the Fifth Circuit addressed the merits appeal of the *Alliance I* administrative stay and preliminary injunction. *See generally Alliance III*, 78 F.4th at 233. The merits panel agreed with the *Alliance II* court’s determination that both the individual doctors and the plaintiff medical associations had Article III standing. And in assessing FDA’s 2016 Amendments and the 2021 Nonenforcement Decision, the *Alliance III* court agreed that FDA had acted arbitrarily and capriciously and otherwise abused its discretion under 5 U.S.C.

§ 706(2)(A) when it, among other things: (i) failed to consider the cumulative effect of the 2016 Amendments; (ii) failed to consider whether it needed to continue to collect data of non-fatal adverse events in light of the “major” 2016 changes to the mifepristone REMS; (iii) gave dispositive weight in making the 2021 Non-Enforcement Decision to FAERS data that had been compromised by FDA’s 2016 removal of non-fatal reporting requirements; and (iv) relied on literature that did not support its position in making the 2021 Nonenforcement Decision.⁶ *Id.*

Specifically, the *Alliance III* court found that the studies underpinning FDA’s approval of the 2016 Amendments failed to consider any data that cumulatively evaluated the effect of implementing each of its proposed “major” changes, which included:

... increasing the maximum gestational age from forty-nine days to seventy days; allowing non-physicians to prescribe mifepristone; removing the requirement that the administration of misoprostol and the subsequent follow-up appointment be conducted in person; eliminating prescribers’ obligation to report non-fatal adverse events; switching the method of administration for misoprostol from oral to buccal; and changing the dose of mifepristone (600 mg to 200 mg) and misoprostol (400 mcg to 800 mcg).

Id. at 246.

Instead, the *Alliance III* court found that the “FDA neither considered the effects as a whole, nor explained why it declined to do so[,]” even though FDA had acknowledged that “[t]he cumulative effect of the 2016 Amendments is

⁶ The merits panel disagreed with the district court’s determination that plaintiffs were likely to succeed on their challenge to FDA’s 2000 Approval of Mifeprex and 2019 Approval of generic mifepristone. *Id.* at 256. Accordingly, the Fifth Circuit vacated the district court’s order as to those agency actions. *Id.*

unquestionably an important aspect of the problem[.]” *Id.* The court also determined that FDA’s failure to consider whether it needed to continue to collect data of non-fatal adverse events in light of the “major” changes to the mifepristone REMS was likely arbitrary and capricious. *Id.* at 246-47.

As to the 2021 Nonenforcement decision (that was later formalized in the 2023 REMS at issue here), the *Alliance III* court found, in essence, that FDA had based its decision on the absence of data that it had only five years previously intentionally eliminated – finding that “considerable evidence shows that FAERS data is insufficient to draw general conclusions about adverse events.” *Id.* at 249. The Court also found that FDA had “relied on various literature relating to remote prescription of mifepristone” in spite of “FDA’s admission that the literature did not affirmatively support its position.” *Id.* at 250.

In 2024, the Supreme Court reversed, finding that the *Alliance* plaintiffs lacked Article III standing to challenge FDA’s regulatory actions. *Alliance IV*, 602 U.S. at 396-97. The Court explained that Article III’s case-or-controversy requirement confines federal judicial power to actual “personal stake” injuries. And because the plaintiff doctors and physician associations did not prescribe, use, manufacture, sell, or otherwise face regulation stemming from FDA’s actions, their asserted injuries were speculative and not fairly traceable to the challenged FDA actions. *Id.* at 385-86.

In so finding, the Court emphasized that sincere legal, moral, ideological, and policy objections to another’s conduct – here, the prescription and use of mifepristone – standing alone, do not satisfy Article III’s standing requirements. *Id.* at 396.

Accordingly, the Supreme Court reversed the Fifth Circuit and remanded for further proceedings consistent with its opinion. *Id.* at 397.

III. Recent Actions of FDA

Important to the Court’s determination here, on September 19, 2025, undoubtedly aware of the mifepristone regulatory deficiencies identified by the Fifth Circuit in the *Alliance* cases, FDA agreed to undergo a thorough review of the mifepristone REMS. Specifically, in direct response to a letter sent to HHS by the Attorneys General of 22 states,⁷ HHS Secretary Kennedy and FDA Commissioner Makary responded with a letter agreeing to conduct a comprehensive safety review of the mifepristone REMS, including the 2023 REMS at issue here. [Doc. 1-110].

In their letter, Secretary Kennedy and Commissioner Makary stated that, “[s]ince its original approval, the FDA has received reports of serious adverse events in patients who took mifepristone,” and consequently, FDA’s review would “study[] the adverse consequences reported in relation to mifepristone to ensure the REMS are sufficient to protect women from unstated risks.” [*Id.*]. FDA premised this review on a frank acknowledgement of the “lack of adequate consideration underlying the prior REMS approvals” as well as “recent studies raising concerns about the safety of mifepristone as currently administered,” including those that “indicate potential dangers that may attend offering mifepristone without sufficient medical support or supervision.” [*Id.*]. The letter promised to ensure that FDA’s analysis and any

⁷ The letter, sent by Kansas Attorney General Kris Kobach and 21 other AGs on July 31, 2025, asked for a comprehensive review of mifepristone or, alternatively, a removal of the drug from the market pending additional safety testing.

resulting revisions to the mifepristone REMS would be “grounded in Gold Standard Science.” [*Id.*]. Commissioner Makary publicly acknowledged that the review of mifepristone safety was underway as of January 2026.⁸

IV. The Instant Lawsuit

On October 6, 2025, the State of Louisiana and Rosalie Markezich filed the instant lawsuit, challenging FDA’s January 2023 REMS, and particularly, the removal of the in-person dispensing requirement and authorization of dispensation of the drug by mail and telehealth.⁹ Plaintiffs claimed injuries include: (i) harm to state sovereignty; (ii) increased Medicaid expenditures, including over \$92,000 in 2025 emergency room and hospitalization costs from two mifepristone-induced abortions and projections of hundreds of thousands of dollars in similar costs; and (iii) public-health harms, including statistically-certain emergency room visits and risks of serious and sometimes fatal infections and bleeding. Plaintiffs seek preliminary relief to stay or set aside the 2023 REMS under 5 U.S.C. § 705, or an injunction mandating that FDA enforce mifepristone’s previous in-person dispensing requirement. In response, the Government asks this Court to stay the litigation while FDA conducts its review of the mifepristone REMS.

⁸ *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, FDA, <https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation> (last updated Feb. 2, 2026).

⁹ Plaintiff Markezich alleges that in October 2023, her then-boyfriend used her email address to obtain mifepristone (and a second drug, misoprostol) from a physician in California via mail order. [Doc. 1, ¶ 10]. She alleges that she did not want to take the drug, was pressured by him, and that the result of taking the medication caused the termination of her pregnancy and ongoing distress and trauma. [*Id.*].

On February 24, 2026, the Court granted the Motions to Intervene filed by mifepristone manufacturers Danco and GenBioPro [Docs. 52 and 54, respectively], and thereafter, the Intervenors' Motions to Dismiss were filed into the record. [Docs. 230 and 232, respectively].

LAW AND ANALYSIS

I. Legal Standards

A. APA Standard of Review

The APA was designed by Congress to act as “a check upon administrators whose zeal might otherwise have carried them to excesses not contemplated in legislation creating their offices.” *United States v. Morton Salt Co.*, 338 U.S. 632, 644 (1950). It requires federal courts to “hold unlawful and set aside agency action, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law.” 5 U.S.C. § 706(2)(A). The standard set forth by the Fifth Circuit is clear:

... [A]n 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.’” An agency violates these rules where it “entirely fail[s] to consider an important aspect of the problem,” or offers “an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.”

Alliance III, 78 F.4th at 245 (internal citations omitted).

To be sure, the arbitrary and capricious standard is narrow, and courts must be careful not to “substitute” their own “policy judgment for that of the agency.” *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021). But ultimately, Congress has vested federal courts with the responsibility to “ensure that the agency ‘examined the

relevant data and articulated a satisfactory explanation for its action.” *Sierra Club v. EPA*, 939 F.3d 649, 664 (5th Cir. 2019). And applying this standard, courts may vacate agency decisions containing “unexplained inconsistencies in the rulemaking record.” *Id.*

If an agency’s deliberative process falls short of the APA’s requirements, Section 705 authorizes courts to stay an agency action while the action undergoes judicial review. 5 U.S.C. § 705. “In the same way that a preliminary injunction is the temporary form of a permanent injunction, a stay is the temporary form of vacatur.” *Alliance III*, 78 F.4th at 254, quoting *Monsanto Co. v. Geerston Seed Farms*, 561 U.S. 139, 165 (2010).

B. Injunctive Relief Pursuant to 5 U.S.C. § 705

Here, Plaintiffs urge the Court in their Motion for Preliminary Relief to issue an order under § 705 of the APA, “staying or postponing the effective date of the [2023 REMS].” [Doc. 20]. Because “a stay [under the APA] has the practical effects of an injunction,” the preliminary injunction factors applicable to Federal Rule of Civil Procedure 65 motions apply. *Alliance III*, 78 F.4th at 242, citing 28 U.S.C. § 1292(a) and *Alliance II*, 2023 WL 291375, at *3 n.3; see also *Colorado v. EPA*, 989 F.3d 874, 883 (10th Cir. 2021). “Injunctive relief is an extraordinary and drastic remedy, not to be granted routinely, but only when the movant, by a clear showing, carries the burden of persuasion.” *Louisiana v. Biden*, 575 F. Supp. 3d 680, 691 (W.D. La. Dec. 16, 2021), *aff’d*, 55 F.4th 1017 (5th Cir. 2022), citing *Holland Am. Ins. Co. v. Succession of Roy*, 777 F.2d 992, 997 (5th Cir. 1985). “To be entitled to a preliminary injunction, a movant must establish: (1) a likelihood of success on the merits; (2) a

substantial threat of irreparable injury; (3) that the threatened injury if the injunction is denied outweighs any harm that will result if the injunction is granted; and (4) that the grant of an injunction will not disserve the public interest.” *Id.* at 691, quoting *Ladd v. Livingston*, 777 F.3d 286, 288 (5th Cir. 2015); *Alliance III*, 78 F.4th at 241.

C. Motion to Stay

The above notwithstanding, a district court always retains the inherent authority to stay a proceeding “to control the disposition of the causes on its docket ...” *Crimson Bldg. Co. v. Plutus Grp., LLC*, 2020 WL 13616911, at *1 (N.D. Tex. Feb. 24, 2020), quoting *United States v. Rainey*, 757 F.3d 234, 241 (5th Cir. 2014) (internal quotation marks omitted). In staying a case pursuant to this authority, the Court should “balance between the harm of moving forward [with the litigation] and the harm of holding back.” *Ali v. Quarterman*, 607 F.3d 1046, 1049 (5th Cir. 2010). Additionally, the Court should consider whether a stay is warranted in light of activity in a related action and other “present day realities.” *In re Beebe*, 1995 WL 337666, at *3-4 (5th Cir. May 15, 1995); see also *Landis v. N. Am. Co.*, 299 U.S. 248, 258 (1936).

As the Supreme Court has explained, “[e]specially in cases of extraordinary public moment, [a plaintiff] may be required to submit to delay not immoderate in extent and not oppressive in its consequences if the public welfare or convenience will thereby be promoted.” *Clinton v. Jones*, 520 U.S. 681, 706-07 (1997), citing *Landis*, 299 U.S. at 256. And district courts regularly stay proceedings to allow an agency to pursue further action on the rulemaking at issue. See, e.g., *Town & Cnty. of*

Nantucket v. Burgum, 2025 WL 3120419, at *2 (D.D.C. 2025), citing *Code v. McHugh*, 139 F. Supp. 3d 465, 466 (D.D.C. 2015); *FBME Bank Ltd. v. Lew*, 142 F. Supp. 3d 70, 76 (D.D.C. 2015); *Sierra Club v. Van Antwerp*, 560 F. Supp. 2d 21, 26 (D.D.C. 2008).

II. Standing

As a threshold matter, the Court is first charged with the important jurisdictional task of determining whether the Plaintiffs have standing to challenge the 2023 REMS. As previously discussed, the *Alliance* litigation was ultimately dismissed by the Supreme Court for those plaintiffs' lack of standing to challenge the mifepristone REMS. *Alliance IV*, 602 U.S. at 396-97. And here, both the Government and Intervenors argue in their briefing that the Plaintiffs lack standing for their requested relief. [Docs. 51, 230, 231]. Intervenors Danco and GenBioPro also specifically seek dismissal of this action on that basis. [Docs. 230, 232].

The Court will therefore first carefully evaluate Plaintiffs' Article III standing. Standing is "built on a single basic idea – the idea of the separation of power." *Alliance IV*, 602 U.S. at 378. "Article III requires a plaintiff to show that she has suffered an injury-in-fact that is fairly traceable to the defendant's allegedly unlawful conduct and likely to be redressed by the requested relief." *Haaland v. Brackeen*, 599 U.S. 255, 291-92 (2023), citing *California v. Texas*, 593 U.S. 659, 668-69 (2021); see also *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992).

To establish standing, "a plaintiff must demonstrate: (i) that she has suffered or likely will suffer an injury-in-fact; (ii) that the injury likely was caused or will be caused by the defendant; and (iii) that the injury likely would be redressed by the requested judicial relief." *Texas v. United States*, 126 F.4th 392, 407 (5th Cir. 2025),

quoting Alliance IV, 602 U.S. at 380. “The second and third standing requirements – causation and redressability – are often ‘flip sides of the same coin,’” meaning if “a defendant’s action causes an injury, enjoining the action or awarding damages for the action will typically redress that injury. So the two key questions in most standing disputes are injury-in-fact and causation.” *Texas*, 126 F.4th at 407, *quoting Alliance IV*, 602 U.S. at 380-81.

The Court is also cognizant that at earlier stages of litigation, such as in adjudicating a motion for injunctive relief, the manner and degree of evidence required to show standing may be less than at later stages. *Speech First, Inc. v. Fenves*, 979 F.3d 319, 329-30 (5th Cir. 2020), *as revised* (Oct. 30, 2020), *citing Lujan*, 504 U.S. at 561 (“each element [of standing] must be supported ... with the manner and degree of evidence required at the successive stages of the litigation”); *see also Barber v. Bryant*, 860 F.3d 345, 352 (5th Cir. 2017), *citing Lujan*, 504 U.S. at 561 (“Since they are not mere pleading requirements but rather an indispensable part of the plaintiff’s case, each element must be supported ... with the manner and degree of evidence required at the successive stages of litigation.”). Thus, at this stage, it is the Plaintiffs’ burden to put forth facts establishing that they have standing to seek the requested § 705 relief.

Louisiana argues that it has standing both because: (i) the 2023 REMS causes sovereign harm by facilitating abortions that violate numerous Louisiana state

laws,¹⁰ [Doc. 20-26, p. 24]; and (ii) it continues to suffer ongoing financial injury resulting from the 2023 REMS and has already paid hundreds of thousands of dollars through Louisiana Medicaid for emergency room medical care stemming from mifepristone use by residents. [*Id.*, p. 26]. In response, Defendants argue primarily that Louisiana lacks standing because it “do[es] not prescribe or use mifepristone” and the 2023 REMS Modification does not “require[] [Louisiana] to do anything or to refrain from doing anything” and the indirect causal chain between the REMS and Louisiana’s alleged injury is too speculative or attenuated to establish standing. [Docs. 51, 230, 231]. Put another way, because Louisiana is not a regulated party, the Defendants allege that Louisiana is unable to establish traceability between

¹⁰ Louisiana 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, La. R.S. § 14:87.7, and La. R.S. § 14:87.8.1.

Important here, Louisiana has also enacted a criminal prohibition on the prescribing and dispensing of mifepristone for purposes of inducing an abortion and classifies mifepristone as a Schedule IV controlled and dangerous substance under its drug laws. *See* La. R.S. § 14:87.1(2)(a) (“‘Abortion-inducing drug’ means any drug or chemical, or any combination of drugs or chemicals, or any other substance when used with the intent to cause an abortion.”); La. R.S. § 40:964.

And if those criminal prohibitions were not clear, Louisiana’s longstanding policy, enacted into statute, states, in part:

It is the intention of the Legislature of Louisiana to regulate, prohibit, or restrict abortion to the fullest extent permitted by the decisions of the Supreme Court of the United States. The legislature does solemnly declare, find, and reaffirm the longstanding public policy of this state that every unborn child is a human being from the moment of conception and is, therefore, a legal person for purposes under the laws of this state and Constitution of Louisiana.

La. R.S. § 40:1061.1 (A)(1).

Louisiana’s claimed sovereign and financial injuries and FDA’s promulgation of the 2023 REMS. [*Id.*].

Although the Supreme Court has observed that establishing standing is “ordinarily substantially more difficult” for unregulated parties – particularly where causation rests on “the unfettered choices of independent actors” – it has also made clear that standing may exist where such actors predictably respond to the challenged action. *Lujan*, 504 U.S. at 560-61; *see also California*, 593 U.S. at 675, *citing Dep’t of Com v. New York*, 588 U.S. 752, 768 (2019). The Fifth Circuit treats this inquiry as part of the traceability analysis, not injury-in-fact. *See Reule v. Jackson*, 114 F.4th 360, 367 (5th Cir. 2024), *cert. denied*, 145 S. Ct. 1431 (2025). Thus, even where injury is undisputed, standing fails if the causal chain is too speculative. *Alliance IV*, 602 U.S. at 383.

As previously discussed, in *Alliance IV*, the Supreme Court dismissed for lack of standing where the plaintiff doctors and medical associations had no direct involvement with mifepristone, no cognizable economic injury, and no obligation to participate in abortion care, rendering any causal chain to FDA’s actions too speculative. 602 U.S. at 385-86, 393-94. In the same vein, the Government attempts to distinguish this Court’s standing analysis in *Louisiana v. EEOC*, 784 F. Supp. 3d 886 (W.D. La. 2025), arguing that, unlike the regulatory mandate there, the 2023 REMS imposes no obligations on the State. The Government further argues that any Medicaid-based economic harm is too attenuated.

After careful consideration, the Court finds that Defendants’ arguments fall short at this stage. Here, 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. On July 8, 2022, then-President Biden issued Executive Order 14076,¹¹ which expressly sought to protect and expand access to “*healthcare service delivery* and promote access to critical reproductive healthcare services, including abortion” in the wake of *Dobbs*. [Doc. 1-45, pp. 2-3] (emphasis added). And in a “Factsheet” issued by the White House

¹¹ Section 1 of EO 14076, enacted just one week after the *Dobbs* decision was issued, is entitled “Policy” and states:

Nearly 50 years ago, *Roe v. Wade*, 410 U.S. 113 (1973), articulated the United States Constitution’s protection of women’s fundamental right to make reproductive healthcare decisions. These deeply private decisions should not be subject to government interference. Yet today, fundamental rights — to privacy, autonomy, freedom, and equality — have been denied to millions of women across the country.

Eliminating the right recognized in *Roe* has already had and will continue to have devastating implications for women’s health and public health more broadly. Access to reproductive healthcare services is now threatened for millions of Americans, and especially for those who live in States that are banning or severely restricting abortion care. Women’s health clinics are being forced to close — including clinics that offer other preventive healthcare services such as contraception — leaving many communities without access to critical reproductive healthcare services. Women seeking abortion care — especially those in low-income, rural, and other underserved communities — now have to travel to jurisdictions where services remain legal notwithstanding the cost or risks.

In the face of this health crisis, the Federal Government is taking action to protect healthcare service delivery and promote access to critical reproductive healthcare services, including abortion. It remains the policy of my Administration to support women’s right to choose and to protect and defend reproductive rights. Doing so is essential to justice, equality, and our health, safety, and progress as a Nation.

Exec. Order No. 14,076, 88 Fed. Reg. 42,831 (July 7, 2023) (emphasis added).

on April 12, 2023, the administration touted, among other things, actions taken by FDA to “protect[] access to [abortion] care nationwide.” [Doc. 1-60].

Thus, in that post-*Dobbs* regulatory environment, 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. Likewise, there is evidence that the consequences of this action were predictable – out-of-state providers and related entities would expand access to mifepristone in ways designed to reach into jurisdictions like Louisiana. These actions cause concrete and ongoing injury to Louisiana, as further discussed below.

But first, Louisiana’s claimed injury must be put within the appropriate framework. The Constitution’s Supremacy Clause declares that federal laws “shall be the supreme law of the land” when conflicting with state laws. U.S. CONST. art. VI, cl. 2. This includes the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, *et seq.*, and the resulting authority vested in FDA to approve and regulate drugs. Nevertheless, respect for the federal nature of our government is also paramount – “a system in which ... the National Government, anxious though it may be to vindicate and protect federal rights and federal interests, always endeavors to do so in ways that will not unduly interfere with the legitimate activities of the [states].” *Younger v. Harris*, 401 U.S. 37, 44 (1971). The Supreme Court has consistently considered federalism concerns when, for example, determining the reach of federal law. *See, e.g., Sackett v. EPA*, 598 U.S. 651, 683 (2023); *U.S. Forest Serv. v. Cowpasture River Pres. Ass’n*, 590 U.S. 604, 621 (2020).

Here, Louisiana alleges that an unlawful use of federal regulatory power by an administrative agency directly undermines the enforcement of its own laws and forces it to incur additional costs.¹² *See Texas v. United States*, 809 F.3d 134, 153 (5th Cir. 2015) (“States have a sovereign interest in the power to create and enforce a legal code.”). Of course, if this Court or others ultimately determine that FDA acted lawfully in its removal of the in-person dispensing requirement for mifepristone, then Louisiana would have no judicial recourse under the APA.¹³ After all, this would directly implicate the Constitution’s Supremacy Clause and the power vested by Congress in FDA to regulate drugs. U.S. CONST. art. VI, cl. 2; *see also GenBioPro, Inc.*, 144 F.4th at 273 (4th Cir. 2025) (finding that although state law determines whether “abortion may be performed at all,” federal law “permits the FDA to regulate how mifepristone must be prescribed and dispensed *if and when* a medication abortion is performed.”).

On the other hand, if FDA did not act lawfully under the APA but rather exceeded or abused the power vested in it by Congress as Plaintiffs contend, then Louisiana clearly has an interest in vindicating its sovereign prerogative under basic principles of federalism. And the Fifth Circuit has twice indicated in *Alliance II* and *Alliance III* that FDA was likely arbitrary and capricious under the APA in removing

¹² *See supra* note 10.

¹³ For the avoidance of doubt, this does not mean that medical providers would then be free to ignore the laws of the states in which they prescribe mifepristone without fear of criminal prosecution. As recently put by the Fourth Circuit Court of Appeals, “the text of the [Food, Drug and Cosmetic Act] suggests that Congress intended to create a regulatory floor, not a ceiling” on drug regulation by the states. *GenBioPro, Inc. v. Raynes*, 144 F.4th 258, 274 (4th Cir. 2025). But that issue is not before the Court here.

mifepristone's in-person dispensing requirement. *Alliance II*, 2023 WL 2913725, at *17; *Alliance III*, 78 F.4th at 241-48.

To be sure, there are factors other than the 2023 REMS that influence the arrival of mifepristone in Louisiana. For example, some states have enacted “shield laws” to protect medical practitioners in their states from extradition for prescribing and illegally shipping mifepristone into jurisdictions where it has been prohibited. *See generally What Are Shield Laws?*, CTR. FOR REPROD. RTS., (Oct. 9, 2025), <https://reproductiverights.org/resources/what-are-shield-laws/>; *see also, e.g., CAL. PENAL CODE § 847.5(b)-(c)*. There are also the usual practical and investigatory impediments faced by state law enforcement when engaging in drug interdiction efforts. And these may be even more significant than the 2023 REMS in influencing the accessibility of mifepristone to Louisiana residents. But there can be little doubt that the 2023 REMS is a factor, which is all that is required for Louisiana to show injury-in-fact and traceability. *See Texas v. United States*, 50 F.4th 498, 519 (5th Cir. 2022) (“DACA is not the sole cause of the State’s injury, but DACA has exacerbated it. That is sufficient.”). Thus, even if the 2023 REMS is not the “sole cause” of Louisiana’s sovereign harms, it has surely “exacerbated” them; “that is sufficient” for standing to assert its claims. *Id.*

Furthermore, “[m]onetary costs are of course an injury” for standing purposes. *Texas*, 599 U.S. at 676. And “even one dollar’s worth of harm is traditionally enough to” confer standing. *Id.* at 688 (Gorsuch, J., concurring). A state’s increased medical costs, such as increased Medicaid costs due to a federal agency action, can constitute

a “pocket-book injury” sufficient to satisfy the injury-in-fact requirement of standing. *Texas v. United States*, 126 F.4th 392, 411 n.22 (5th Cir. 2025) (collecting cases).

Here, Louisiana has put forth sufficient evidence to demonstrate that it has suffered and continues to suffer pocketbook injury. Under the federal Medicaid statute, Louisiana is required to cover medical assistance for eligible pregnant women, which includes inpatient and outpatient medical services. 42 U.S.C. §§ 1396(a)(viii), (a)(1)-(2). Louisiana is required to pay a portion of the total Medicaid costs, *id.* § 1396a(a)(2), and the federal government will pay between 50 percent and 83 percent, *id.* § 1396d(b). Crucially, FDA’s “own documents” show that “emergency room care is statistically certain” in mifepristone cases. *Alliance II*, 2023 WL 2913725, at *10. And according to FDA’s own 2023 label, 2.9-4.6 percent of women who receive an in-person visit with a doctor, are prescribed mifepristone, and take it as directed will require an emergency room visit. [Doc. 1-9, p. 9]. Empirical evidence indicates that the emergency room visitation and hospitalization rate may be closer to ten percent for patients with an estimated gestational duration of 78-84 days. [Doc. 1-13, p. 2]; [Doc. 20-4, p. 2].¹⁴ And rates may also be higher when mifepristone is dispensed by mail. [Doc. 1-10, pp. 34-35].

Plaintiffs further estimate that, on average, about 1,000 mifepristone-induced abortions are occurring per month in Louisiana. [Doc. 20-2, p. 36]; [Doc. 20-22, pp. 1-2]. And, according to Plaintiffs’ expert, many of these women obtaining abortions are likely to be on Medicaid. [Doc. 20-22, pp. 2-3]. In support of this

¹⁴ See [https://www.contraceptionjournal.org/article/S0010-7824\(25\)00308-7/abstract](https://www.contraceptionjournal.org/article/S0010-7824(25)00308-7/abstract) for the complete study.

contention, Plaintiffs have supplied evidence from the Louisiana Department of Health identifying more than \$92,000 in Medicaid costs incurred 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. [Doc. 20-20, pp. 4-5, ¶¶ 11-12]. These two incidents alone are sufficient to establish Louisiana’s standing, but it is likely that many more Medicaid patients have required similar care due to complications from mifepristone. [*Id.*, pp. 4-5, ¶¶ 10, 13-15]; [Doc. 20-19, pp. 3-4, ¶¶ 7-8]; [Doc. 20-23, p. 4, ¶¶ 14-16].

And regardless of whether Louisiana’s financial harm is the \$92,000 previously discussed or far more than that, Louisiana’s harm is more than zero. *See Texas*, 50 F.4th at 517-18 (“The record does not indicate precisely what portion of all costs for illegal aliens is spent on DACA recipients, but no one disputes that some are.”). Accordingly, because “even one dollar’s worth of harm” is sufficient, Louisiana has put forth sufficient evidence to demonstrate a substantial likelihood of success in proving it has suffered financial injury for standing purposes. *Texas*, 599 U.S. at 688 (Gorsuch, J., concurring).

For all of these reasons, Louisiana has established injury that is traceable to FDA’s actions and redressable, at least in part, by the relief requested herein. Louisiana therefore has standing to challenge the 2023 REMS on the record before the Court.¹⁵

¹⁵ Because the Court determines that the State of Louisiana has standing, it need not consider standing for *Markezich*. *Biden v. Nebraska*, 600 U.S. 477, 489 (2023) (“If at least one plaintiff has standing, the suit may proceed.”), *citing Rumsfeld v. Forum for Acad. & Institutional Rts., Inc.*, 547 U.S. 47, 52 n.2 (2006).

III. Analysis Under Rule 65

With standing established for these purposes, the Court next considers whether Plaintiffs have carried their burden under the Rule 65 framework applicable to the Plaintiffs' requested § 705 relief.¹⁶

A. Likelihood of Success on the Merits

“The exact quantum of evidence that a plaintiff must present to satisfy the likelihood-of-success factor varies from case to case.” *League of United Latin Am. Citizens v. Abbott*, 809 F. Supp. 3d 502, 546 (W.D. Tex. 2025), citing *Jefferson Cmty. Health Care Ctrs., Inc. v. Jefferson Par. Gov't*, 849 F.3d 615, 626 (5th Cir. 2017) (“[T]here is no particular degree of likelihood of success that is required in every case. ...”). “The Fifth Circuit applies a ‘sliding scale’ approach, whereby a plaintiff who makes a strong showing on the other three preliminary injunction factors bears a lesser burden on the likelihood-of-success requirement (and vice versa).” *Id.*, citing *TitleMax of Texas, Inc v. City of Dallas*, 142 F.4th 322, 328 (5th Cir. 2025). Thus, “[w]here the other factors are strong,” the movant need only show “some likelihood of success on the merits” to obtain a preliminary injunction. *Id.*

As discussed above, in *Alliance III*, the Fifth Circuit found that FDA, in promulgating the 2021 Nonenforcement Decision, had based its decision on the absence of data that it had only five years previously intentionally eliminated – finding that “considerable evidence shows that FAERS data is insufficient to draw

¹⁶ The Plaintiffs do not squarely address in their briefing the application of the Rule 65 factors as they apply to Plaintiff Markezich. The Court therefore limits its analysis to Plaintiff Louisiana.

general conclusions about adverse events.” *Alliance III*, 78 F.4th at 249. The Court also found that FDA had “relied on various literature relating to remote prescription of mifepristone – despite FDA’s admission that the literature did not affirmatively support its position.” *Id.* at 250.

To be sure, the 2023 REMS had not yet been put into effect when suit was filed in *Alliance I*. Therefore, those plaintiffs did not specifically challenge the 2023 REMS, as the Plaintiffs do here. But the Fifth Circuit’s analysis in *Alliance III* found fault with both the 2016 Amendments and the 2021 Nonenforcement Decision – and included in its discussion that “in January 2023, FDA amended mifepristone’s REMS ... formalizing the change” rendered in the 2021 Nonenforcement Decision. *Id.* at 247. Likewise, in rejecting a mootness challenge by FDA, the *Alliance III* court described the 2023 REMS as merely a “final form of a previous, identical policy,” removing mifepristone’s in-person dispensing requirement. *Id.* at 248-49.

Accordingly, Plaintiffs’ challenge to the 2023 REMS focuses on the very same failure to engage in reasoned decision-making under the APA when FDA modified the mifepristone regulatory regime. *Id.* at 245, 255. And the Supreme Court, in vacating the Fifth Circuit’s opinion in *Alliance III*, addressed only those plaintiffs’ lack of Article III standing to bring an APA challenge. *Alliance IV*, 602 U.S. at 396-97. The *Alliance III* court’s reasoning is therefore due strong consideration in weighing Plaintiffs’ likelihood of success on the merits.

Further, HHS Secretary Kennedy and FDA Commissioner Makary essentially acknowledged APA procedural deficits with respect to mifepristone in their September 19, 2025, letter, stating that FDA’s intention to review the mifepristone

regulatory framework was precipitated by “the lack of adequate consideration underlying the prior REMS approvals” and recent safety concerns. [Doc. 1-110]. Thus, the Court concludes that Plaintiffs are likely to succeed on the merits of their 2023 REMS challenge.

B. Irreparable Injury

The Court has already found that Louisiana demonstrated an injury-in-fact, and those same facts establish irreparable harm. An irreparable harm is one that has “no adequate remedy at law.” *Louisiana v. Biden*, 55 F.4th 1017, 1033-34 (5th Cir. 2022). Here, the 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. *Louisiana v. EEOC*, 705 F. Supp. 3d 643, 653 (W.D. La. 2024).

No remedy at law can redress that sovereign harm. By permitting medical providers to prescribe mifepristone remotely, the 2023 REMS facilitates the distribution of mifepristone into Louisiana notwithstanding contrary law. Louisiana suffers sovereign harm each time those laws are circumvented. And Louisiana has also demonstrated financial injury that cannot be “remedied where, as here, the defendant is entitled to sovereign immunity.” *Alliance III*, 78 F.4th at 251.

C. Balance of Harms/Public Interest

No one disputes that “[a]bortion presents a profound moral issue.” *Dobbs*, 597 U.S. at 223; *see also Alliance IV*, 602 U.S. at 376, 396 (noting both the longstanding controversy surrounding mifepristone and plaintiffs’ “sincere legal, moral, ideological, and policy objections”). But this Court is not a forum for resolving moral or policy disagreements. Its task is to apply established legal standards to the record

before it. That inquiry turns on legally cognizable harms to the parties and the public interest, not on the weight of competing moral views. And where, as here, the issues implicate scientific and medical judgments committed by Congress to an agency with specialized knowledge, that limitation carries particular force.

Having previously discussed the ongoing harm suffered by Plaintiff Louisiana, the Court starts its analysis by looking at the interests of the Government. First, the Court notes that “anytime the Government is enjoined ... ‘it suffers a form of irreparable injury.’” *Alliance III*, 78 F.4th at 251, quoting *Maryland v. King*, 567 U.S. 1301, 1303 (2012) (Roberts, C.J., in chambers). Specific to this matter, FDA is charged with implementing federal statutes governing the safety and efficacy of drugs through an evidence-based administrative rule-making process. *Alliance IV*, 602 U.S. at 374-75.

In carrying out that mandate, the agency evaluates scientific and clinical data, makes factual findings based on the administrative record, and, where appropriate, considers public comments. See *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 617 (1973) (explaining that FDA approval requires adequate, well-controlled clinical investigations by qualified experts, not anecdotal or uncontrolled data). The agency must also “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 United States, Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). This science-based regime derives from and is limited to the confines of its Congressional mandate.

And FDA, being a component of the Executive Branch, operates as an agency ultimately accountable to the President. The public interest in the proper function of FDA and its scientifically grounded, congressionally authorized protocol is substantial. The Intervenors also have a substantial financial interest in this matter. Any change in the current regulatory regime governing the prescription of mifepristone, which has now been in place for five years, would affect their profit margins and compliance costs.

No doubt Louisiana has a great interest in this issue as well. *Dobbs* returned the issue of abortion to the people of the States and their elected representatives, including regulation of abortion methods, procedures, and the use of related drugs. 597 U.S. at 302. The 2023 REMS clearly facilitates easier access to mifepristone for Louisiana residents. But the Court must also take into consideration that any interim relief ordered by this Court would not relieve Louisiana of its duty to enforce its own laws. In practice, even with the remedy requested herein, mifepristone would likely continue to reach those who seek it, as our country's decades of experience with the war on illegal drugs clearly and painfully demonstrates.¹⁷ Meanwhile, Louisiana retains many meaningful, boots-on-the-ground law enforcement mechanisms to mitigate its sovereign and financial harms while FDA completes its ongoing review.

The Court next turns to the public interest and begins with the premise, as recognized by the *Alliance III* court, that “[t]here is generally no public interest in the

¹⁷ In 2025, for instance, cocaine production reached record levels despite fifty-five years of counter-narcotics enforcement efforts by the United States and other nations. *World Drug Report 2025*, UNITED NATIONS OFF. ON DRUGS & CRIME (June 13, 2025).

perpetuation of unlawful agency action.” *Louisiana*, 55 F.4th at 1035. But the Court also notes that the Supreme Court fully stayed the preliminary injunction issued by the *Alliance I* district court, as affirmed in part by the Fifth Circuit in *Alliance II*, (including its injunction of the 2021 Nonenforcement Decision). *Danco Lab’s, LLC*, 143 S. Ct. 1075. This effectively allowed the challenged FDA actions with respect to mifepristone to continue throughout the course of the appeal. And, of course, that injunction was ultimately vacated for lack of standing. *Alliance IV*, 602 U.S. at 396-97.

Here, unlike in the *Alliance* cases, FDA does not defend its decision-making on the merits but instead acknowledges deficits and requests a stay to complete a fulsome review of the merits of Plaintiffs’ claims – a review that was announced before this lawsuit was filed and has already been initiated. [Doc. 1-110]. FDA also has the authority to take interim actions to ensure drug safety if new information is discovered during the pendency of its review. *See generally* [Doc. 250].

Also weighing on its analysis is the Court’s understanding that this case arises amid multiple parallel lawsuits across the country addressing the same regulatory issues surrounding access to mifepristone, creating a substantial risk of inconsistent judicial outcomes on a question of nationwide importance.¹⁸ Although not styled as

¹⁸ *See Mifepristone Litigation and Federal Action Tracker*, UCLA LAW CTR. ON REPROD. HEALTH, LAW, & POLICY (last updated Apr. 2026), <https://law.ucla.edu/academics/centers/center-reproductive-health-law-and-policy/mifepristone-litigation-and-federal-action-tracker>.

At the time of the parties’ briefing, five other states are challenging either the approval of mifepristone or subsequent actions easing restrictions. *See Missouri v. FDA*, No. 4:25-cv-1580-CMS (E.D. Mo.) (Missouri, Idaho, and Kansas challenging actions easing REMS restrictions); *Florida v. FDA*, No. 7:25-cv-126-O (N.D. Tex.) (Florida and Texas challenging

a universal injunction, the relief sought by Plaintiffs would, as a practical matter, have a nationwide effect. As the Supreme Court recently observed, such sweeping relief creates asymmetry because a plaintiff “must win just one suit to secure sweeping relief,” whereas the Government “must win everywhere” to avoid it. *Trump v. CASA, Inc.*, 606 U.S. 831, 855 (2025). It also risks “rushed, high-stakes, [and] low-information” decision-making in consequential cases. *Id.* at 855-56, quoting *Labrador v. Poe ex rel. Poe*, 144 S. Ct. 921, 927 (2024) (Gorsuch, J., concurring).

These concerns are reinforced by settled limits on equitable relief, which require that remedies be tailored to the plaintiff’s injury and may not be “more burdensome ... than necessary.” *Texas*, 599 U.S. at 702 (Gorsuch, J., concurring), quoting *Califano v. Yamasaki*, 442 U.S. 682, 702 (1979) (internal quotation marks omitted). “Faithful application of those principles suggests that an extraordinary remedy like vacatur would demand truly extraordinary circumstances to justify it.” *Id.* at 702 (Gorsuch, J., concurring).

This is because, like “universal injunctions, vacatur can stymie the orderly review of important questions, lead to forum shopping ... and facilitate efforts to evade the APA’s normal rulemaking processes.” *Id.* at 703 (Gorsuch, J., concurring). “Vacatur can also sweep up nonparties who may not wish to receive the benefit of the

approval of mifepristone and actions easing REMS restrictions). Other plaintiffs have challenged FDA’s restrictions as too burdensome. See *Purcell v. Kennedy*, 2025 WL 3101785 (D. Haw. Oct. 30, 2025) (finding that FDA violated the APA by failing to provide a reasoned explanation for its burdensome conditions on the prescription of mifepristone, which that court determined appeared to be unwarranted relative to the drug’s safety); *Washington v. FDA*, No. 1:23-cv-3026-TOR, 2025 WL 1888794 (E.D. Wash. 2025) (plaintiffs challenge REMS as too restrictive); *Whole Woman’s Health All. v. FDA*, No. 3:23-cv-19 (W.D. Va.) (same). This list does not include a multitude of citizen petitions.

court’s decision,” which, here, would include the 18 states and other amici that filed briefs urging denial of Plaintiffs’ Motion. *Id.* (Gorsuch, J., concurring); *see also, e.g., supra* note 2. As a result, vacatur improperly applied, “strains our separation of powers” because “it exaggerates the role of the Judiciary in our constitutional order, allowing individual judges to act more like a legislature by decreeing the rights and duties of people nationwide.” *Id.* (Gorsuch, J., concurring). All told, although federal courts are vested with much authority, the Constitution does not establish, nor does this Court condone, “government by lawsuit.” *Id.* at 704, *quoting* ROBERT H. JACKSON, *THE STRUGGLE FOR JUDICIAL SUPREMACY* 286-87 (1941).

Next, the Court finds it appropriate to look at the substance of the alleged deficiencies pointed to by Plaintiffs in weighing the equities of issuing interim relief. No doubt, the State has shown evidence of ongoing harm owing to the 2023 REMS. But the APA deficiencies pointed to by the Plaintiffs and found by the Fifth Circuit in *Alliance III* show only that the 2023 REMS was “taken without sufficient consideration of the effects those changes would have on patients” due to a lack of underlying data. *Alliance III*, 78 F.4th at 253. Those same deficiencies likewise prevent this Court from determining whether FDA’s in-person dispensing requirement is scientifically necessary to ensure mifepristone is “safe” and “effective.” *Id.* at 245; *see also* 21 U.S.C. § 355(b)(1)(i).

On the one hand, a proper science-driven evaluation may lead FDA to conclude that the in-person dispensing requirement is necessary to comply with FDA’s mandate to ensure that mifepristone is “safe and effective” for use, 21 U.S.C. § 355(b)(1)(i), and Plaintiffs offer substantial evidence supporting that possibility. On

the other hand, FDA may determine, after a thorough and scientifically-driven process, that such a requirement is not required. This Court is ill-equipped to make this determination, particularly where FDA has thus far failed to even collect the data necessary to comply with the APA's requirement that it "examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" *Alliance III*, 78 F.4th at 245, quoting *Motor Vehicle Mfrs.*, 463 U.S. at 43. And ultimately it is FDA, not this Court, that possesses the expertise to evaluate scientific evidence and make public health judgments.¹⁹

At bottom, the APA does not charge the judiciary with the task of supplanting the role of federal agencies in promulgating regulations. See *Prometheus Radio Project*, 592 U.S. at 423. Rather, it is quite simply meant to be "a check" upon administrators to ensure that they are doing their job as directed by Congress. *Morton Salt Co.*, 338 U.S. at 644 (1950). Here, FDA has acknowledged its own deficits and has initiated an ongoing review of mifepristone.

Finally, this Court finds that prudence in issuing injunctive relief is warranted here because the 2023 REMS has governed a nationally integrated regulatory scheme

¹⁹ See, e.g., *FDA*, 141 S. Ct. at 578-79 (Roberts, C.J., concurring in grant of application for stay) ("[C]ourts owe significant deference to the politically accountable entities with the 'background, competence, and expertise to assess public health.'"); *Cytori Therapeutics, Inc. v. Food & Drug Admin.*, 715 F.3d 922, 927 (D.C. Cir. 2013) (Kavanaugh, J.) ("A court is ill-equipped to second-guess that kind of agency scientific judgment under the guise of the APA's arbitrary and capricious standard."); *Otsuka Pharm. Co. v. Burwell*, 302 F. Supp. 3d 375, 403 (D.D.C. 2016) (Jackson, J.) ("To begin with, the FDA is an expert agency charged with making precisely these sorts of highly technical determinations, and its interpretation ... is premised on 'the agency's evaluations of scientific data within its area of expertise.'"), *aff'd sub nom. Otsuka Pharm. Co. v. Price*, 869 F.3d 987 (D.C. Cir. 2017).

for five years (since the promulgation of the 2021 Nonenforcement Decision), and imposing sweeping relief now risks the “patchwork” of judicial remedy the Court has warned against. *CASA*, 606 U.S. at 872 (Kavanaugh, J., concurring). There are now at least five other lawsuits in federal courts around the nation addressing issues similar to those before the Court. *See supra* note 18. And again, FDA’s ongoing review of the mifepristone REMS indicates both responsiveness to Congress’s directive that drugs be “safe and effective,” 21 U.S.C. § 355, as well as accountability to the public. *See DHS v. Regents of the Univ. of California*, 591 U.S. 1, 16 (2020), quoting *Franklin v. Massachusetts*, 505 U.S. 788, 796 (1992) (“The APA ‘sets forth the procedures by which federal agencies are accountable to the public and their actions subject to review by the courts.’”). FDA’s review should be conducted and completed free from judicial interference.

Therefore, for the reasons discussed, the Court declines to grant the Plaintiffs § 705 relief at this time. Given the length of time the 2023 REMS has been in effect, reliance interests on that scheme throughout the nation, the sweeping effect any remedy would have across states with differing abortion laws, and most importantly, FDA’s recognition of its own shortcomings in regulating mifepristone and ongoing fulsome review of the mifepristone REMS, the Court will afford the agency a time-limited period of deference to complete its review and carry out the responsibilities assigned to it by Congress. This case will therefore be stayed.

But the stay granted to FDA will not remain open-ended. FDA has an obligation to act with all deliberate speed to review its past actions and complete a thorough analysis that addresses the deficiencies it has acknowledged. The parties

and the American public deserve nothing less. Should the agency fail to complete its review and make any necessary revisions to the REMS within a reasonable timeframe, the Court's analysis – and the weight accorded to these factors – will inevitably change.

CONCLUSION

Considering the foregoing,

IT IS HEREBY ORDERED that Defendants' MOTION TO STAY THE CASE [Doc. 50] is GRANTED, and this matter is STAYED pending completion of FDA's ongoing review of the mifepristone REMS and issuance of any resulting agency decision.

IT IS FURTHER ORDERED that Plaintiffs' MOTION FOR PRELIMINARY RELIEF UNDER 5 U.S.C. § 705 [Doc. 20] is DENIED WITHOUT PREJUDICE and with permission to refile, as appropriate, following completion of FDA's review or upon a lifting of the stay upon a material change in circumstances.

IT IS FURTHER ORDERED, pursuant to Plaintiffs' request at the motions hearing on February 24, 2026, that FDA produce the entirety of the administrative record to Plaintiffs' counsel within sixty (60) days.

IT IS FURTHER ORDERED that Danco's MOTION TO DISMISS [Doc. 230] and GenBioPro's MOTION TO DISMISS [Doc. 232] are hereby DENIED WITHOUT PREJUDICE and with permission to refile, as appropriate, following completion of FDA's review or upon a lifting of the stay upon a material change in circumstances.

IT IS FURTHER ORDERED that FDA shall file a report on or before six (6) months from the date of this Order providing the Court with the status of its review in terms of process and any updated timeframe for completion of review. Within

fourteen (14) days after FDA completes its REMS review, FDA shall file a brief advising the Court of any agency action and proposing a schedule for further proceedings, if necessary.

THUS, DONE AND SIGNED in Chambers on this 7th day of April 2026.



DAVID C. JOSEPH
UNITED STATES DISTRICT JUDGE

Tab 6

United States Court of Appeals
for the Fifth Circuit

United States Court of Appeals
Fifth Circuit

FILED

May 1, 2026

Lyle W. Cayce
Clerk

No. 26-30203

STATE OF LOUISIANA, *by & through its Attorney General, Liz Murrill;*
ROSALIE MARKEZICH,

Plaintiffs—Appellants,

versus

FOOD & DRUG ADMINISTRATION; MARTY MAKARY, *Commissioner,*
U.S. Food and Drug Administration; RICHARD PAZDUR, *in his official*
capacity as Director, Center for Drug Evaluation & Research, US Food & Drug
Administration; UNITED STATES DEPARTMENT OF HEALTH AND
HUMAN SERVICES; ROBERT F. KENNEDY, JR., *Secretary, U.S.*
Department of Health and Human Services,

Defendants—Appellees,

versus

DANCO LABORATORIES, L.L.C.; GENBIOPRO, INCORPORATED,

Intervenors—Appellees.

Appeal from the United States District Court
for the Western District of Louisiana
USDC No. 6:25-CV-1491

Before SOUTHWICK, DUNCAN, and ENGELHARDT, *Circuit Judges*.

STUART KYLE DUNCAN, *Circuit Judge*:

In *Dobbs v. Jackson Women’s Health Organization*, 597 U.S. 215 (2022), the Supreme Court returned the regulation of abortion to the states. In response, the Biden Administration directed federal agencies to “expand access to . . . medication abortion.” Exec. Order No. 14076, 87 Fed. Reg. 42053 (July 8, 2022). The next year, the Food and Drug Administration (FDA) formally altered its safety guidelines for the abortion drug mifepristone. Under the new regulation, the drug could now be prescribed online and dispensed through the mail, without any need for an in-person visit to a doctor.

In 2025, Louisiana challenged the new regulation in federal court under the Administrative Procedure Act (APA). It argued that FDA’s justifications for remotely dispensing mifepristone were based on flawed or nonexistent data. It also documented how the new regulation had resulted in numerous illegal abortions in Louisiana and in Louisiana paying thousands in Medicaid bills for women harmed by mifepristone. Louisiana sought a stay of the regulation while the litigation proceeded.

In response, FDA conceded it had failed to adequately study whether remotely prescribing mifepristone is safe. But the agency resisted staying the regulation, arguing it was in the midst of a comprehensive review of mifepristone protocols. The agency, however, could not say when that review might be complete and admitted it was still collecting data.

The district court agreed that Louisiana was likely to win its challenge to the mifepristone regulation and was suffering irreparable harm from it. Nonetheless, the court declined to stay the regulation based on its balancing of the equities and the public interest. Louisiana appealed to our court and sought a stay pending appeal under 5 U.S.C. § 705.

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We grant the stay.

I

We briefly describe (A) FDA’s actions with respect to mifepristone, (B) prior challenges to those actions, and (C) the present suit.

A

FDA determines whether drugs are safe and effective before they can be marketed in the United States. *See* Federal Food, Drug, and Cosmetic Act, ch. 675, 52 Stat. 1040 (1938) (FDCA); *FDA v. All. for Hippocratic Med. (Alliance III)*, 602 U.S. 367, 374–75 (2024). In that role, FDA may conclude that a drug requires enhanced guardrails—such as prescription only by “health care providers” or “in certain health care settings.” 21 U.S.C. § 355-1(f)(3). Such guardrails are called Risk Evaluation and Mitigation Strategies, or REMS.

When FDA approved mifepristone in 2000, the REMS allowed only doctors to prescribe it after “three in-person visits” and directed they report serious adverse events. *Alliance III*, 602 U.S. at 375. Since then, the guardrails have been progressively lowered. In 2016, FDA announced that nurse practitioners could prescribe mifepristone after only one in-person doctor visit and that doctors needed to report only fatalities (the “2016 Amendments”). *Id.* at 375–76. In 2021, FDA stopped enforcement of the one-visit requirement, thus allowing mifepristone to be dispensed “through the mail . . . or through a mail-order pharmacy” (the “2021 Non-Enforcement Decision”).¹ That “removal of the in-person dispensing requirement” was formalized in 2023 (the “2023 REMS”). *All. for Hippocratic Med. v. FDA (Alliance II)*, 78 F.4th 210, 226 (5th Cir. 2023), *rev’d*

¹ FDA also approved GenBioPro’s generic mifepristone for use in 2019. *Alliance III*, 602 U.S. at 376.

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on other grounds, 602 U.S. 367 (2024); *Risk Evaluation and Mitigation Strategy (REMS) Single Shared System for Mifepristone 200 MG*, FDA (Jan. 2023), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2023_01_03_REMS_Full.pdf.

B

In 2022, a group of physicians providing pregnancy-related healthcare brought an APA challenge to the 2000 mifepristone approval, the 2016 Amendments, and the 2021 Non-Enforcement Decision. *See All. for Hippocratic Med. v. FDA*, 668 F. Supp. 3d 507, 560 (N.D. Tex. 2023), *vacated*, 117 F.4th 336 (5th Cir. 2024) (mem.). After the district court granted a preliminary injunction, our court affirmed in part, ruling plaintiffs were likely to win their challenge to the 2021 Non-Enforcement Decision. *See All. for Hippocratic Med. v. FDA (Alliance I)*, No. 23-10362, 2023 WL 2913725, at *17–18, 17 n.5 (5th Cir. Apr. 12, 2023); *Alliance II*, 78 F.4th at 227, 247–51.² The Supreme Court reversed, however, on the grounds that the plaintiff physicians lacked standing. *Alliance III*, 602 U.S. at 396–97.

In September 2025, FDA began a comprehensive review of mifepristone, including the 2023 REMS. When announcing the review, FDA conceded the “lack of adequate consideration underlying the prior REMS approvals.” The review is not complete—as of April 2026, the agency reports it is still collecting data.³

² We also explained that the 2021 Non-Enforcement Decision “remains in force” because it was formalized by the 2023 REMS. *Alliance II*, 78 F.4th at 248.

³ *See Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, FDA, <https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation>.

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C

In October 2025, the State of Louisiana and Rosalie Markezich (collectively, “Louisiana”) challenged the 2023 REMS under the APA. The district court allowed mifepristone manufacturers Danco and GenBioPro (collectively, “Danco”) to intervene as defendants.

Louisiana moved to preliminarily stay the 2023 REMS under 5 U.S.C. § 705. The district court declined, however. Despite finding Louisiana had standing, was likely to succeed on the merits, and was suffering irreparable harm, the court found the balance-of-the-equities and public-interest factors favored denying a stay.

As to the equities, the court reasoned that FDA has a strong interest in continuing its scientific review of mifepristone and that the intervenor companies have a “substantial financial interest” in selling the drug. While acknowledging Louisiana’s “great interest” in stopping the inflow of out-of-state mifepristone, the court thought the drug would “likely continue” to reach Louisianans regardless of a stay, like other illegal drugs. It also emphasized that Louisiana retained “many meaningful, boots-on-the-ground law enforcement mechanisms to mitigate its sovereign and financial harms while FDA completes its ongoing review.”

As to the public interest, the court acknowledged that the public has no interest in continuing unlawful agency action and that FDA “does not defend its decision-making [in the 2023 REMS] on the merits.” Nonetheless, the agency desired “a stay [of the case] to complete a fulsome review” of mifepristone. The court also noted “multiple parallel lawsuits” challenging the 2023 REMS and worried about the “substantial risk of inconsistent judicial outcomes.” Finally, while again acknowledging the “deficiencies” in the 2023 REMS, the court believed it was “ill-equipped”

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to evaluate the validity of an in-person dispensing requirement, “particularly where FDA has thus far failed to even collect the data necessary” to do so.

The court therefore declined Louisiana’s request to stay the 2023 REMS. Instead, the court granted FDA’s request to stay the entire case so the agency could “complete its review.” The court warned, though, that “FDA has an obligation to act with all deliberate speed to review its past actions and complete a thorough analysis that addresses the deficiencies it has acknowledged.”

Louisiana appealed and moved for a stay of the 2023 REMS pending appeal under 5 U.S.C. § 705.

II

Under 5 U.S.C. § 705, courts may “issue all necessary and appropriate process to postpone the effective date of an agency action or to preserve status or rights pending conclusion of the review proceedings.”

A party seeking a stay under § 705 must show (1) it is strongly likely to succeed on the merits; (2) it will be irreparably harmed without a stay; (3) its harm is not outweighed by harm to other parties; and (4) the public interest favors a stay. *Wages & White Lion Invs., L.L.C. v. FDA*, 16 F.4th 1130, 1135–36 (5th Cir. 2021); *Tex. League of United Latin Am. Citizens v. Hughs*, 978 F.3d 136, 143 (5th Cir. 2020). The first two factors are the most critical. *Valentine v. Collier*, 956 F.3d 797, 801 (5th Cir. 2020) (per curiam).

III

Louisiana contends the district court misapplied the § 705 stay factors. Specifically, it argues the court abused its discretion in ruling that the last two factors outweighed its successful showing on the first two. FDA’s response does not address the merits—*i.e.*, whether its removal of mifepristone’s in-person dispensing requirement was arbitrary and

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capricious. Instead, it argues that Louisiana should have first asked the district court for a stay. It then argues, contrary to the district court’s ruling, that Louisiana lacks standing. For its part, Danco argues Louisiana lacks standing, failed to administratively exhaust its claims, and fails all four stay factors.

We address each of these arguments in turn.

A

We first address the two threshold arguments that Louisiana (1) should have first asked the district court for a stay and (2) failed to administratively exhaust its claims. Both arguments fail.

1

FDA contends that, under Federal Rule of Appellate Procedure 8, Louisiana was required to first ask the district court for a stay pending appeal. *See* FED. R. APP. P. (FRAP) 8(a)(1)(A), (C). We disagree. While that it is the “ordinar[y]” practice, *see* FRAP 8(a)(1), it is not required if “moving first in the district court would be impracticable,” *see id.* FRAP 8(a)(2)(A)(i). Here, it was.

Not only had the district court already denied Louisiana’s motion to stay the 2023 REMS under § 705, but the court had also stayed the entire case pending completion of FDA review. Given that, it would have been “pointless” to ask the district court to stay the 2023 REMS pending appeal. *Whole Woman’s Health v. Paxton*, 972 F.3d 649, 653 (5th Cir. 2020); *see also, e.g., Homans v. City of Albuquerque*, 264 F.3d 1240, 1243 (10th Cir. 2001) (“[W]e have excused this requirement where another application to the district court would serve little purpose.”).

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2

Danco argues Louisiana failed to administratively exhaust its claims. “As a general rule, claims not presented to the agency may not be made for the first time to a reviewing court,” *Wash. Ass’n for Television & Child. v. FCC*, 712 F.2d 677, 680 (D.C. Cir. 1983), unless “resort to administrative remedies [would be] clearly useless,” *Tesoro Refin. & Mktg. Co. v. FERC*, 552 F.3d 868, 874 (D.C. Cir. 2009) (alteration in original) (quotation omitted).

Our court previously rejected this argument in *Alliance I* and *II*. See *Alliance I*, 2023 WL 2913725, at *15–16; *Alliance II*, 78 F.4th at 255. True, those decisions were reversed on standing, see *Alliance III*, 602 U.S. at 396–97, but their reasoning on exhaustion was persuasive. As they concluded, these challenges were “properly exhausted,” *Alliance I*, 2023 WL 2913725, at *15, because FDA’s denials of citizen petitions discussed the 2021 Non-Enforcement Decision and “show[ed] that FDA was committed to implementing these changes,” *Alliance II*, 78 F.4th at 255. Danco gives us no reason to think that, today, FDA would administratively stay the 2023 REMS, which formalized the 2021 decision. *Ibid.*

Accordingly, we reject the argument that Louisiana was required to administratively exhaust its claims before bringing this suit.

B

We turn to standing. Louisiana must show it “has suffered an injury traceable to the defendant which the court’s judgment would likely redress.” *Deanda v. Becerra*, 96 F.4th 750, 755 (5th Cir. 2024).

On appeal, FDA and Danco dispute the district court’s ruling that Louisiana has standing. Specifically, they contend that by removing mifepristone’s in-person dispensing requirement, the 2023 REMS caused no injury either to Louisiana’s sovereignty or its treasury. We disagree.

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1

First, sovereign injury. Louisiana has a “sovereign interest in the power to create and enforce a legal code.” *Texas v. United States*, 809 F.3d 134, 153 (5th Cir. 2015) (quotation omitted).⁴

With certain exceptions, Louisiana law bans administering, prescribing, procuring, or selling a drug like mifepristone to end the life of an unborn human being. *See* LA. STAT. ANN. § 40:1061(C) (2022) (“No person may knowingly administer to, prescribe for, or procure for, or sell to any pregnant woman any medicine, drug, or other substance with the specific intent of causing or abetting the termination of the life of an unborn human being.”).⁵

An avowed purpose of the 2023 REMS was to expand access to medication abortion. *See* Exec. Order No. 14076, 87 Fed. Reg. 42053 (July 8, 2022) (in the wake of *Roe*’s overruling, directing federal agencies to “expand access to . . . medication abortion” by “protect[ing] healthcare service delivery and promot[ing] access to . . . abortion”). Predictably, the regulation has had that effect in Louisiana, despite the fact that its laws ban the practice.

⁴ *See also Alfred L. Snapp & Son, Inc. v. P.R. ex rel. Barez*, 458 U.S. 592, 601 (1982) (explaining a state’s “exercise of sovereign power over individuals and entities within the relevant jurisdiction . . . involves the power to create and enforce a legal code, both civil and criminal”); *Kentucky v. Biden*, 23 F.4th 585, 599 (6th Cir. 2022) (explaining national vaccine mandate “implicates states’ power to make and enforce policies and regulations, as well as states’ traditional prerogative to superintend their citizens’ health and safety”).

⁵ *See also* LA. STAT. ANN. § 14:87.1(1)(a)(i) (2022) (defining “abortion” or “induced abortion” to include “[a]dministering, prescribing, or providing any abortion-inducing drug, potion, medicine, or any other substance, device, or means to a pregnant female”); *id.* § 14:87.1(2)(a) (defining “[a]bortion-inducing drug” as “any drug or chemical, or combination of drugs or chemicals, or any other substance when used with the intent to cause an abortion”); *id.* § 14.87.1(1)(b)(i)–(v) (excluding from definition of “abortion” various procedures, including for saving unborn child’s or mother’s life or for removing ectopic and medically futile pregnancies).

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By ending the in-person dispensing requirement, FDA opened the door for mifepristone to be remotely prescribed to Louisiana women. The record shows that the policy now facilitates nearly 1,000 illegal abortions in Louisiana per month.

This evidence also easily shows causation and redressability. As the district court explained, “out-of-state medical providers” have responded to the 2023 REMS by “expanding mifepristone access to pro-life states like Louisiana in ways that [are] entirely predictable.” That should surprise no one: after all, ensuring out-of-state medical providers could prescribe mifepristone to women in states that restrict abortion was a goal of the regulation. *See, e.g., First Choice Women’s Res. Ctrs., Inc. v. Davenport*, No. 24-781, slip op. at 12 (U.S. Apr. 29, 2026) (confirming “courts may make ‘commonsense inferences’ when assessing Article III standing, including inferences about ‘third party behavior’” (quoting *Diamond Alt. Energy LLC v. EPA*, 606 U.S. 100, 116 (2025))). Finally, a decision in Louisiana’s favor would redress this injury because mifepristone could no longer be remotely prescribed to Louisianans.

FDA and Danco counter that the 2023 REMS only makes it “more difficult to police” violations of Louisiana law. Not so. The policy does not merely “increase[] crime or disorder, or impose[] indirect compliance costs for state law enforcement.” *Washington v. FDA*, 108 F.4th 1163, 1177 (9th Cir. 2024). Rather, the 2023 REMS sanctions and facilitates conduct with the express purpose of undermining Louisiana’s legal restrictions on abortion. The regulation creates an effective way for an out-of-state prescriber to place the drug in the hands of Louisianans in defiance of Louisiana law.

In sum, the agency’s 2023 REMS causes “federal interference with the enforcement of [Louisiana] law,” which gives Louisiana standing to

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challenge it. *Texas*, 809 F.3d at 153; *see also Wyoming ex rel. Crank v. United States*, 539 F.3d 1236, 1242 (10th Cir. 2008) (“injury-in-fact” shown when federal agency’s legal interpretation “interfere[d] with Wyoming’s ability to enforce its legal code”); *Maine v. Taylor*, 477 U.S. 131, 137 (1986) (“[A] State clearly has a legitimate interest in the continued enforceability of its own statutes.”).

2

Next, financial injury. A State’s “expenditures in providing emergency medical services” constitute an injury for standing purposes. *Texas v. United States*, 50 F.4th 498, 518 (5th Cir. 2022).

Louisiana identifies \$92,000 it paid in Medicaid costs from two women who needed emergency care in 2025 from complications caused by out-of-state mifepristone. Such costs will almost certainly continue because nearly 1,000 women monthly—many of whom are on Medicaid—have mifepristone-induced abortions in Louisiana.

Confirming this, FDA’s 2023 mifepristone label reports that 2.9 to 4.6 percent of women prescribed mifepristone *in-person* will require emergency care. *See Alliance I*, 2023 WL 2913725, at *10 (FDA’s “own documents . . . prove that emergency room care is statistically certain in hundreds of thousands of cases”). Remotely dispensing the drug will only exacerbate those risks, as the district court found. *See* DC Dkt. No. 1-10 at 35 (“[T]he literature suggests there may be more frequent ED/urgent care visits related to the use of mifepristone when dispensed by mail . . .”). Accordingly, Louisiana has shown that it suffers financial injury caused by the 2023 REMS.

Despite acknowledging that “Medicaid costs constitute an Article III injury,” FDA and Danco argue that the relation between out-of-state mifepristone and Louisiana’s costs is too attenuated. Both rely on *Alliance*

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III, which held that the link between the challenged regulations and plaintiff doctors’ monetary injuries was “too speculative or otherwise too attenuated.” 602 U.S. at 390. That case is distinguishable, however.

As the Supreme Court explained in *Alliance III*, the doctors failed to prove that FDA’s deregulation of mifepristone caused them to divert time from other patients or that it produced higher insurance costs. *Id.* at 390–91. But *Alliance III* had no reason to address whether the agency’s actions would cause States to pay higher Medicaid costs. *Id.* at 391. Here, Louisiana showed that they do. Unlike the doctors in *Alliance III*, Louisiana provided hard evidence linking thousands of dollars in Medicaid costs to care stemming from out-of-state mifepristone. As the district court correctly held, that “alone [is] sufficient to establish Louisiana’s standing.”

* * *

In sum, on either theory Louisiana has shown it has standing to challenge the 2023 REMS.⁶

C

We turn to the § 705 factors.

1

First, likelihood of success on the merits. *Nken v. Holder*, 556 U.S. 418, 434 (2009). Louisiana must make a strong showing that the 2023 REMS was not “reasonable” or “reasonably explained.” *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021).

⁶ We therefore need not consider whether Markezich also has standing. *See Biden v. Nebraska*, 600 U.S. 477, 489 (2023) (“If at least one plaintiff has standing, the suit may proceed.”).

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This factor plainly favors Louisiana and FDA does not contest it. To the contrary, as the district court explained, the agency “essentially acknowledged APA procedural deficits with respect to mifepristone” by “stating that [its] intention to review the mifepristone regulatory framework was precipitated by ‘the lack of adequate consideration underlying the prior REMS approvals.’”

Based on the same defects, our court has previously concluded that FDA’s actions here were likely unlawful. *See Alliance II*, 78 F.4th at 249–51; *Alliance I*, 2023 WL 2913725, at *16–18. That reasoning squarely applies to the 2023 REMS and we briefly summarize it.

First, in relaxing mifepristone’s in-person dispensing requirement, FDA gave “dispositive weight” to the lack of adverse-event data in a reporting system (known as “FAERS”). *Alliance II*, 78 F.4th at 249. The problem? FDA had previously eliminated the requirement to report mifepristone’s adverse events to FAERS. *Ibid.* Obviously, “[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.” *Ibid.* (quoting *Alliance I*, 2023 WL 2913725, at *17).⁷

Second, FDA “relied on various literature relating to remote prescription of mifepristone—despite FDA’s admission that the literature did not affirmatively support its position.” *Alliance II*, 78 F.4th at 250. The

⁷ Danco points out that federal law requires manufacturers report to FDA known adverse events. *See* 21 U.S.C. § 355(k)(1); 21 C.F.R. §§ 314.80, 314.81. We rejected this argument in *Alliance II*. *See* 78 F.4th at 247, 249–50. In short, Danco’s reporting requirements are “significantly different than the ones that were removed,” insofar as Danco “had no direct relationship with Mifeprex patients and little ability to track [adverse] events.” *Id.* at 247. As *Alliance II* concluded, “Danco’s residual reporting requirements do not cure this APA violation.” *Ibid.*; *see also id.* at 250 (explaining that “Danco’s data was exactly the same as the data FDA obtained from FAERS”).

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agency explained the literature was “not adequate on [its] own to establish the safety of the model of dispensing mifepristone by mail.” *Ibid.* (quotation omitted). This is a textbook example of arbitrary and capricious agency action. *See, e.g., Motor Vehicle Mfrs. Ass’n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 52 (1983) (“The agency must explain the evidence which is available, and must offer a ‘rational connection between the facts found and the choice made.’” (quoting *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168 (1962))).

Accordingly, like the district court, we conclude Louisiana has strongly shown a likelihood of winning its APA challenge to the 2023 REMS.

2

Second, irreparable harm. *See Nken*, 556 U.S. at 434; *Louisiana v. Biden*, 55 F.4th 1017, 1033–34 (5th Cir. 2022).

We agree 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.

As discussed, 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. Both injuries are irreparable.

Every abortion facilitated by FDA’s action cancels Louisiana’s ban on medical abortions and undermines its policy that “every unborn child is human being from the moment of conception and is, therefore, a legal person.” LA. STAT. ANN. § 40:1061.1(A)(1) (2022). Once lost, that sovereign prerogative of protecting unborn life cannot be regained by legal

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remedy. And because FDA “is entitled to sovereign immunity,” *Alliance II*, 78 F.4th at 251, Louisiana’s financial harms are also irreparable.

FDA’s only response is that Louisiana cannot prevail on this factor because it lacks any “Article III injury.” We have already rejected that argument, however.⁸

Accordingly, like the district court, we conclude that Louisiana has shown that it is irreparably harmed without a stay.

3

We turn to the balance-of-harms and public interest factors. *Nken*, 556 U.S. at 434. These factors “merge when the government opposes” a stay. *Airlines for Am. v. Dep’t of Transp.*, 110 F.4th 672, 677 (5th Cir. 2024) (quotation omitted).

Louisiana argues the district court erred by finding its irreparable harms are outweighed by FDA’s interest in continuing its review and Danco’s financial interests in selling mifepristone. We agree.

Once again, our court has spoken persuasively to this point before. “[N]either the FDA nor the public has any interest in enforcing a regulation that violates federal law.” *Alliance II*, 78 F.4th at 251 (citing *Louisiana*, 55 F.4th at 1035). We have now three times found that the agency’s progressive relaxation of mifepristone’s guardrails likely lacked a basis in data and scientific literature. FDA itself now concedes the regulations were marred by “procedural deficits” and a “lack of adequate consideration.” The public

⁸ Danco argues Louisiana waited too long to sue and seek a stay. That is beside the point. Louisiana has shown the 2023 REMS causes it daily irreparable harm by undermining its laws and costing it irreparable Medicaid funds. “Those costs are ongoing . . . and more than sufficient to satisfy the irreparable harm standard in this circuit.” *Career Colleges & Schs. of Tex. v. Dep’t of Educ.*, 98 F.4th 220, 237 (5th Cir. 2024).

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interest is not served by perpetuating a medical practice whose safety the agency admits was inadequately studied. Indeed, the public interest demands the opposite. *See Alliance II*, 78 F.4th at 253 (explaining “the public interest is disserved by a drug that does not afford adequate protections to its users”); *see also Hill Dermaceuticals, Inc. v. FDA*, 524 F. Supp. 2d 5, 12 (D.D.C. 2007) (“[T]he public interest weighs strongly in favor of preventing unsafe drugs from entering the market.”).

For its part, Danco points to a stay’s effect on its compliance costs and mifepristone profits. While we acknowledge a stay would impose costs on Danco, *cf. Alliance II*, 78 F.4th at 252, the company exaggerates by predicting a stay would destroy any “valid legal framework for distributing” the drug. To the contrary, a stay would only pause a method of prescribing mifepristone that began five years ago and was formally approved only three years ago. *Cf. Alliance I*, 2023 WL 2913725, at *20 (doubting that post-2016 deregulation was “so critical to the public given that the Nation operated—and mifepristone was administered to millions of women—without them for sixteen years following the 2000 Approval”). And, in any event, Danco’s potential financial losses 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.

The district court raised various concerns about the equities and public interest. We do not find that any of them tip the balance against Louisiana, however.

First, the district court cautioned it was “not a forum for resolving moral or policy disagreements” nor for adjudicating “scientific and medical judgments committed by Congress to an agency with specialized knowledge.” All quite true. This case, however, does not ask courts to resolve such matters. Despite dealing with the charged subject of abortion, at

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bottom the case is an APA challenge to a regulation, a task courts routinely undertake. *See, e.g., Sm. Elec. Power Co. v. EPA*, 920 F.3d 999, 1013 (5th Cir. 2019) (explaining that, while courts may not second-guess an agency’s “evaluation of complex scientific data,” they must “ensure that the agency examined the relevant data and articulated a satisfactory explanation for its action” (quotations omitted)).

Second, the district court emphasized the importance of FDA’s being able to “complete a fulsome review” and “proper science-driven evaluation” of mifepristone protocols. Again, quite true. However, this challenge involves the existing 2023 REMS, not FDA’s ongoing review. Granting a stay would do nothing to prevent FDA from completing its review of mifepristone’s safety protocols.

And consider what spurred that review: the agency’s concession that its prior evaluation of mifepristone—including the 2023 REMS—was marred by “procedural deficits” and a “lack of adequate consideration.” As Louisiana points out, it “makes no sense to deny preliminary relief on the grounds that agency action is so unlawful that the agency openly concedes a review is necessary.” That would mean an agency could forestall judicial review of admittedly unlawful regulations merely by promising to review them in the future. And here FDA cannot even say when its review will conclude—perhaps over a year from now because it has not finished collecting data.⁹

Finally, the district court was concerned that, because “this case arises amid multiple parallel lawsuits across the country,” there is “a

⁹ *See Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, FDA, <https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation>.

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substantial risk of inconsistent judicial outcomes on a question of nationwide importance.” That risk is inevitable in such litigation, however. *See, e.g., BST Holdings, L.L.C. v. OSHA*, 17 F.4th 604, 610 (5th Cir. 2021) (observing OSHA’s covid vaccine mandate was challenged “in federal courts of appeals across the nation”). It does not absolve courts from deciding the cases before them. If disagreement emerges, we have a Supreme Court. *See NFIB v. OSHA*, 595 U.S. 109, 117 (2022) (agreeing with us that “the Secretary lacked authority to impose the [covid vaccine] mandate”).

It is true, as the district court noted, that a § 705 stay “would, as a practical matter, have a nationwide effect.” *See Alliance II*, 78 F.4th at 254 (explaining “a stay [under § 705] temporarily voids the challenged authority”).¹⁰ We do not agree, however, that this result is somehow in tension with *Trump v. CASA*, 606 U.S. 831 (2025), as the district court suggested. In *CASA*, the Supreme Court plainly said it was addressing only equitable relief and not remedies under the APA. *See id.* at 846 n.10 (“Nothing we say today resolves the distinct question whether the [APA] authorizes federal courts to vacate federal agency action.”).

In sum, we conclude that the balance of equities and public interest weigh in Louisiana’s favor.

IV

Accordingly, IT IS ORDERED that the motion to stay the 2023 REMS under 5 U.S.C. § 705 pending appeal is GRANTED.

IT IS FURTHER ORDERED that the alternative motion for injunction pending appeal is DENIED AS MOOT.

¹⁰ *See also Career Colleges*, 98 F.4th at 255 (“Nothing in the text of Section 705, nor of Section 706, suggests that either preliminary or ultimate relief under the APA needs to be limited to [parties].”).

Tab 7

THOMAS, J., dissenting

SUPREME COURT OF THE UNITED STATES

No. 25A1207

DANCO LABORATORIES, LLC *v.* LOUISIANA, ET AL.

ON APPLICATION FOR STAY

No. 25A1208

GENBIOPRO, INC. *v.* LOUISIANA, ET AL.

ON APPLICATION FOR STAY

[May 14, 2026]

The applications for stay presented to JUSTICE ALITO and by him referred to the Court are granted. The May 1, 2026 order of the United States Court of Appeals for the Fifth Circuit, case No. 26–30203, is stayed pending disposition of the appeal in the United States Court of Appeals for the Fifth Circuit and disposition of a petition for a writ of certiorari, if such a writ is timely sought. Should certiorari be denied, this stay shall terminate automatically. In the event certiorari is granted, the stay shall terminate upon the sending down of the judgment of this Court.

JUSTICE THOMAS, dissenting.

Applicants are manufacturers and distributors of mifepristone, a drug that is primarily designed to cause abortion. They complain that the Fifth Circuit’s order would reduce profits they derive from selling mifepristone. I would deny their applications because they have not satisfied their burden for securing interim relief.

I write separately to note that, as Louisiana argued below, it is a criminal offense to ship mifepristone for use in abortions. The Comstock Act bans using “the mails” to ship

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any “drug . . . for producing abortion.” 18 U. S. C. §1461. A neighboring provision makes it a felony to use “any express company or other common carrier or interactive computer service” to ship “any drug . . . designed, adapted, or intended for producing abortion.” §1462(c). Applicants “[s]hip mifepristone . . . to certified pharmacies,” which, in turn, must “ship mifepristone using a shipping service” to users. FDA, Risk Evaluation and Mitigation Strategy (REMS) Single Shared System for Mifepristone 200 MG, pp. 3, 4 (Jan. 2023), https://www.accessdata.fda.gov/drugsatfda_docs/remis/Mifepristone_2023_01_03_REMS_Full.pdf (archived at <https://perma.cc/T7D6-QZ5R>). As relevant to this case, mifepristone shipped to Louisiana, which bans abortion, causes nearly 1,000 abortions per month. “All of this violates the Comstock Act.” *Alliance for Hippocratic Medicine v. FDA*, 78 F. 4th 210, 268 (CA5 2023) (Ho, J., concurring in part and dissenting in part), rev’d on other grounds, 602 U. S. 367 (2024).

Applicants are not entitled to a stay of an adverse court order based on lost profits from their criminal enterprise. They cannot, in any legally relevant sense, be irreparably harmed by a court order that makes it more difficult for them to commit crimes. And, whereas it would “serve the public interest” to “reduc[e]” applicants’ “opportunity to commit crimes,” *Zedner v. United States*, 547 U. S. 489, 501 (2006), a stay would have the opposite effect.

I respectfully dissent.

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SUPREME COURT OF THE UNITED STATES

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[May 14, 2026]

JUSTICE ALITO, dissenting.

The Court’s unreasoned order granting stays in this case is remarkable. What is at stake is the perpetration of a scheme to undermine our decision in *Dobbs v. Jackson Women’s Health Organization*, 597 U. S. 215 (2022), which restored the right of each State to decide how to regulate abortions within its borders. Some States responded to *Dobbs* by making it even easier to obtain an abortion than it was before, and that is their prerogative. Other States, including Louisiana, made abortion illegal except in narrow circumstances. See, *e.g.*, La. Rev. Stat. Ann. §40.1061 *et seq.* But Louisiana’s efforts have been thwarted by certain medical providers, private organizations, and States that abhor laws like Louisiana’s and seek to undermine their enforcement.

These medical providers and private organizations have developed an operation enabling women in Louisiana and other States that restrict abortions to place an online order for a pill called mifepristone that induces abortion. See, *e.g.*, Aid Access, Get Abortion Pill Online in Louisiana – Order Here, <https://aidaccess.org/en/page/2934664/where-can->

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i-buy-the-abortion-pill-online-in-louisiana (archived at <https://perma.cc/NW2Z-M4B9>). After an order is placed, the drug is mailed to women in Louisiana. The manufacturers of the drug, including Danco and GenBioPro, are obviously aware of what is going on yet nevertheless supply the drug and reap profits from its felonious use in Louisiana.

One might think that Louisiana could stop or impede this out-of-state interference in its law enforcement by bringing civil actions or criminal charges against the participants in this scheme. But States have effectively blocked these efforts by enacting so-called “shield laws,” which prevent Louisiana from visiting any adverse legal consequences on the perpetrators. See, *e.g.*, N. Y. Exec. Law §837-x (barring state officials from cooperating with other States’ efforts to take civil or criminal action relating to illegal abortions); N. Y. Educ. Law §6810.1-a (exempting mifepristone from the requirement that prescription labels bear the prescribing medical provider’s name); see also App. to Opposition to Applications for a Stay or Vacatur 462–463 (La. App.) (reporting that New York Governor Kathy Hochul has refused to extradite a doctor who allegedly prescribed and sent abortifacients into Louisiana). As a result, more abortions now occur each month in Louisiana than they did before *Dobbs*. La. App. 519. By one count, nearly 1,000 abortions occur there each month. *Ibid*.

This scheme would not have been possible under FDA regulations had the federal government not taken steps in 2021 and 2023 to facilitate mail-order abortions. Since the FDA first approved mifepristone in 2000, the drug has been subject to “Risk Evaluation and Mitigation Strategies” (REMS) to ensure that its benefits outweigh its risks. See 21 U. S. C. §355–1. For two decades, REMS for mifepristone required that patients meet in person with a medical provider to administer the drug. *FDA v. Alliance for Hippocratic Medicine*, 602 U. S. 367, 375–376 (2024). In 2021,

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however, the FDA adopted a policy of nonenforcement as to the in-person-dispensing requirements. *Id.*, at 376.

The following year, after our decision in *Dobbs*, the Biden Administration announced that it would “use every lever” it had to “ensure every American has access to . . . medication abortion that has been approved by the FDA for over 20 years,” an obvious reference to mifepristone. La. App. 244. The FDA pulled one of those levers in 2023 when it formally eliminated the in-person-dispensing requirement in the mifepristone REMS, removing a significant regulatory barrier from schemes to undermine *Dobbs*.

Since then, the Secretary of Health and Human Services has admitted that the FDA gave inadequate consideration to patient safety when it approved the 2023 REMS. La. App. 478. Because concerns have arisen “about the safety of mifepristone as currently administered” under the 2023 REMS, the Secretary announced that the FDA would conduct a study to determine whether changes to the REMS are needed. *Ibid.* Nevertheless, the FDA has not yet acted, and the 2023 REMS remain in place.

In an effort to stop ongoing schemes to subvert its abortion laws, Louisiana sued the FDA under the Administrative Procedure Act. Citing the Secretary’s concerns about the 2023 REMS, the State challenges the removal of the in-person-dispensing requirement for mifepristone as arbitrary, capricious, and unlawful. La. App. 4, 46–50. The District Court denied Louisiana’s request for interim relief, but the Fifth Circuit suspended the 2023 changes pending appeal. *Louisiana v. FDA*, ___ F. 4th ___ (CA5 2026); see 5 U. S. C. §705. Danco and GenBioPro then filed these stay applications, and the FDA takes no position on this matter, even though it concerns the question whether an important rule that it has found to be flawed will remain in force for some unknown period of time.

I would deny the applications because, as things now stand, the manufacturers have failed to show that they face

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irreparable injury, without which this Court may not grant a stay. *Hollingsworth v. Perry*, 558 U. S. 183, 190 (2010) (*per curiam*). Unless the Fifth Circuit’s order spurs the FDA into moving on its safety review, there is no indication that the Fifth Circuit’s order will adversely affect the manufacturers whatsoever in the near future. All the evidence is to the contrary. In the two years before the 2023 REMS changes, the FDA declined to enforce the in-person-dispensing requirement, and the FDA seeks to maintain that status quo until it completes an internal safety review of the mifepristone REMS, which is unlikely to end this year. See Defendant’s Memorandum in Support of Motion to Stay the Case and in Response to Plaintiffs’ Motion for Preliminary Relief in *Louisiana v. FDA*, No. 6-25-cv-1491 (WD La.), ECF Doc. 51, pp. 4, 11–12. Indeed, there is evidence that FDA leadership has told agency officials to delay that safety review for at least six months. La. App. 556. So, at present, it is most unlikely that the manufacturers would be at all affected by the Fifth Circuit’s order for quite some time. That could conceivably change if the Fifth Circuit’s order were left in place and the FDA were spurred to speed up its safety review, but our disposition of this application cannot be predicated on the assumption that that will occur.

We must instead proceed on the basis of what is known at present, and without any current indication that the FDA plans to resume enforcing the in-person-dispensing requirement, there is no reason to believe that the manufacturers could not continue their current distribution practices.*

* In that event, it would be unlikely that Louisiana (or anyone else) could force the FDA’s hand. The FDA would have a plausible argument that its nonenforcement reflects a decision “committed to agency discretion,” 5 U. S. C. §701(a)(2), and would thus be immune from judicial review under *Heckler v. Chaney*, 470 U. S. 821 (1985). In fact, the FDA previously made this very argument about its nonenforcement of the in-

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If the FDA were to execute an abrupt about-face and commence enforcement of the in-person-dispensing requirement, the manufacturers could promptly reapply for stays at that time. But even were that to happen, the manufacturers have not shown that they would suffer irreparable injury. The manufacturers spent just 3 of their 80-plus pages of applications trying to make this showing. See Application to Stay in No. 25A1207, pp. 35–36; Application to Stay in 25A1208, p. 35. To the extent that the manufacturers address this issue at all, they refer mostly to regulatory uncertainty that would result from a suspension of the 2023 REMS changes. Yet they fail to explain why the effect of the Fifth Circuit’s order is not simply to restore the pre-2023 REMS, under which the manufacturers successfully operated for years. As we have already explained in *FDA v. Alliance for Hippocratic Medicine*, 602 U. S. 367 (2024), a §705 order suspending the FDA’s changes to REMS allows a manufacturer to continue selling a drug subject to the previous set of regulatory requirements. 602 U. S., at 377.†

The manufacturers contend that resuming compliance with those requirements would involve inconvenient processes, such as updating prescriber agreements or adjusting pharmacy-distribution operations. But without any

person-dispensing requirement. See Defendants’ Opposition to Plaintiffs’ Motion for a Preliminary Injunction in *Alliance for Hypocritic Medicine v. FDA*, No. 2:22-cv-223 (ND Tex.) ECF Doc. 28, p. 20 (citing *Heckler*). For these reasons, the manufacturers have not shown that they face any imminent risk of irreparable harm.

† In arguing to the contrary, Danco relies on an FDA declaration in the *Alliance for Hippocratic Medicine* litigation. See Application to Stay in No. 25A1207, p. 35. But that declaration does not dispute that a §705 order causes the REMS “to revert to those in place prior to” the challenged amendments. App. to Application to Stay in *FDA v. Alliance for Hippocratic Medicine*, O. T. 2022, No. 22A902, p. 113a. Rather, the declaration simply explains that the manufacturers would need to take additional steps to come into compliance with the old rules. *Id.*, at 113a–116a.

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effort to show the extent of these burdens, such inconveniences are insufficient to constitute the requisite showing of irreparable harm.

GenBioPro makes a passing reference to the possibility of lost sales. See Application to Stay in 25A1208, p. 35. But lost sales in States where abortifacients are generally illegal are not “irreparable injuries” that can justify granting a stay. See *United States v. United Liquor Corporation*, 77 S. Ct. 208, 210 (1956) (Reed, J., in chambers) (denying a stay when the alleged irreparable injury was the defendant’s inability to engage in conduct that amounted to an unlawful conspiracy). Our decision to grant a stay is an exercise of equitable discretion, *Indiana State Police Pension Trust v. Chrysler LLC*, 556 U. S. 960, 961 (2009) (*per curiam*), and equity demands that profits from unlawful activity be surrendered, not protected, see *Liu v. SEC*, 591 U. S. 71, 79–80 (2020). As for States where abortion is legal, neither Danco nor GenBioPro explains why mifepristone sales would dry up if the in-person-dispensing requirement resumed. And even if the Fifth Circuit’s order affected sales in those States to some degree, the manufacturers do not establish that the lost profits would be so significant as to constitute irreparable injury. See *Wisconsin Gas Co. v. FERC*, 758 F. 2d 669, 674 (CAD 1985) (*per curiam*) (holding that a private party must show a threat to “the very existence of [its] business” to establish irreparable injury).

Because the manufacturers have not shown that they face any imminent risk of irreparable injury, the Court must deny these applications regardless of how they fare on the other stay factors. I therefore respectfully dissent. Cite as: ___ U. S. ___ (20__)

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[DISPOSITION]

Tab 8

CERTIFICATE OF SERVICE

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

/s/ J. Benjamin Aguiñaga
J. BENJAMIN AGUIÑAGA