United States Court of Appeals for the Fifth Circuit

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, 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,

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.

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.

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.

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"

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

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.").

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.

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.

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[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).

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

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*

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.").

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").

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

remedy. And because FDA "is entitled to sovereign immunity," *Alliance II*, 78 F.4th at 251, Louisiana's financial harms are also irremediable.

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 F4th 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 irremediable 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).

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

bottom the case is an APA challenge to a regulation, a task courts routinely undertake. *See, e.g.*, *Sw. 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.

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.

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[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].").

United States Court of Appeals

FIFTH CIRCUIT
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May 01, 2026

MEMORANDUM TO COUNSEL OR PARTIES LISTED BELOW:

No. 26-30203 State of Louisiana v. FDA
USDC No. 6:25-CV-1491

Enclosed is the opinion entered in the case captioned above.

Sincerely,

LYLE W. CAYCE, Clerk

Christy Combel

By: _____
Christy M. Combel, Deputy Clerk
504-310-7651

Mr. John N. Adcock
Mr. Jorge Benjamin Aguinaga
Mr. Erik Baptist
Mr. Andrew Marshall Bernie
Ms. Julie Marie Blake
Ms. Jessica Lynn Ellsworth
Mr. John Patrick Elwood
Ms. Carrie Yvette Flaxman
Mr. Eugene M. Gelernter
Ms. Erin Morrow Hawley
Ms. Jillian Horowitz
Ms. Caitlin Ann Huettemann
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Mr. Robert J. Katerberg
Mr. Noah T. Katzen
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Ms. Gabriella McIntyre
Ms. Katherine McKay
Ms. Hilarie M. Meyers
Mr. William Brock Most
Ms. Lisa Newman
Ms. Daphne O'Connor
Ms. Dana A. Raphael
Ms. Jo-Ann Tamila Sagar
Ms. Clara Simone Spera
Ms. Danielle Desaulniers Stempel
Ms. Maria Michelle Uzeta
Mrs. Hadiya Williams
Mr. Daniel Winik
Mr. Daniel W. Wolff