APPENDIX

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 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 heads[1] (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]

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[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 Intervenors [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 Intervenors' primary contention – the threshold jurisdictional issue of the Plaintiffs' standing to bring this action. But because the Court grants the Governments motion to stay this case pending completion of FDA's mifepristone REMS review, the Court declines to substantively address the remaining issues raised by Intervenors at this time. Intervenors 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 refiling upon the Court lifting the stay. Likewise, the two Motions to Dismiss filed by Intervenors [Docs. 230, 232] are DENIED without prejudice to refiling 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 Mifepristone[4]

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.*

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[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'ys, 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.

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[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"); s*ee 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

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[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

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[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 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; s*ee 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'ys, 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

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[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

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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

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[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

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

THE STATE OF LOUISIANA, *et al.*, *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

DECLARATION OF EVAN MASINGILL

I, Evan Masingill, declare as follows:

1. I am the President and Chief Executive Officer of GenBioPro Inc. I make this declaration in support of GenBioPro's Motion to Intervene and its Opposition to Plaintiffs' Motion for Preliminary Relief under 5 U.S.C. § 705. If called to testify, I would testify competently to all of the statements in this Declaration.

2. GenBioPro is a privately held pharmaceutical company founded in 2011.

3. Between 2011 and 2019, GenBioPro invested several million dollars in working to bring to market a generic version of the drug mifepristone. That investment was necessary to satisfy requirements set by the U.S. Food and Drug Administration (FDA) for approval of an Abbreviated New Drug Application (ANDA) to sell a generic drug.

4. FDA approved GenBioPro's ANDA for generic mifepristone on April 11, 2019, and GenBioPro continues to hold that ANDA.

5. GenBioPro sells only generic mifepristone and misoprostol; it sells no other products. Sales of mifepristone account for the majority of GenBioPro's revenue.

6. GenBioPro currently manufactures and distributes mifepristone according to FDA's Risk Evaluation and Mitigation Strategy ("REMS"), which FDA updated in 2023. The 2023 REMS update, among other things, formally removed a requirement in the prior version of the REMS that mifepristone could be dispensed only in-person in certain healthcare settings, specifically clinics, medical offices, and hospitals. That in-person dispensing requirement, while it was in effect, meant that mifepristone could not be dispensed by pharmacies.

7. I understand that Plaintiffs in this case have asked the Court to suspend, vacate, or otherwise enjoin the 2023 REMS in a way that would reimpose the in-person dispensing requirement, including on a preliminary basis before any final rulings in the litigation. Doing so would have immediate and irreparable consequences for GenBioPro's business. Moreover, if the Court were to suspend the 2023 REMS, but that suspension were later lifted, modified, vacated, or or reversed (causing the 2023 REMS to go back into effect), GenBioPro would have no way to recover the revenue that it lost while the suspension was in effect.

8. In reliance on FDA's 2023 REMS, GenBioPro adapted its distribution model to incorporate a new system of pharmacy-based distribution.

9. GenBioPro's efforts toward adapting the pharmacy distribution model required hundreds (if not thousands) of internal staff hours over an 18-month period to redesign GenBioPro's supply chain and compliance operations. Those efforts included, among many other things, negotiating contracts with distributors, onboarding certified pharmacies, overhauling our information-technology and order-tracking systems, re-training the sales team, re-designing the company website and customer interface, and building new distribution and logistics frameworks.

The endeavor was so significant that we at GenBioPro considered the project to be a product "re-launch."

10. Currently, a significant portion of GenBioPro's total sales are to pharmacies. As such, a suspension of the 2023 REMS and reimposition of the in-person dispensing requirement would have an immediate effect of cutting off sales to pharmacies, and therefore cutting off a substantial portion of GenBioPro's total revenue.

11. Suspending the 2023 REMS would interfere with the entire market for mifepristone. For instance, in-person clinics would see a dramatic influx of patients who must travel to those clinics to obtain the medication in person. Given the inherent limitations on the capacity of the existing clinic network to serve patients in person, there is likely a ceiling on the amount of additional clinic sales that GenBioPro could make in response to a suspension of the 2023 REMS. Any additional sales to clinics could not offset lost pharmacy sales.

12. Any court-ordered suspension of the 2023 REMS would cause significant uncertainty about whether GenBioPro would be permitted to continue selling existing mifepristone stock pending FDA's issuance of new REMS and/or applicable guidance. Accordingly, the immediate impacts of a suspension could be disruptive nationwide.

13. A suspension of the 2023 REMS would also harm GenBioPro because the drop in sales may force GenBioPro to scale back procurement and other internal operations. If the suspension is later lifted and the 2023 REMS go back into effect, GenBioPro would need to incur many of the same costs that it previously expended to adapt to the 2023 REMS (as detailed in paragraph 9 above). In addition, GenBioPro would incur significant delays to ramp back up to the level of operations it was at pre-suspension.

14. A suspension of the 2023 REMS would be particularly disruptive and costly for the pharmacy-specific aspects of GenBioPro's operations. For instance, certain of GenBioPro's distribution contracts are specific to pharmacies, meaning they would need to be either cancelled or paused if pharmacy dispensing were suspended.

15. To the extent a suspension of the 2023 REMS requires changes to the REMS-related documents (such as prescriber and patient agreements), GenBioPro would need to expend time and resources updating those documents. And to the extent a suspension of the 2023 REMS requires changes to the product's labeling, GenBioPro will incur significant expense creating new labels for its product and potentially even re-labeling the inventory that it has already produced. All of these costs would be unnecessary and unrecoverable if the suspension of the 2023 REMS were later lifted, modified, vacated, or reversed (causing the 2023 REMS to go back into effect).

16. I understand that issues have been raised in this litigation about the reporting of adverse events to FDA. As an ANDA holder, GenBioPro is required to and does submit annual reports to FDA detailing all adverse event reports that it receives regarding mifepristone. GenBioPro also submits any serious and unexpected adverse drug experiences within 15 days of receipt. The first page of GenBioPro's mifepristone label also informs prescribers and patients how to report any negative side effects to GenBioPro or to FDA directly, consistent with federal law and regulations.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct to the best of my knowledge, information, and belief.

Dated: 03-Feb-26

Signed by Evan Masingill
Evan Masingill
I approve this document
03-Feb-26 | 3:38:05 PM PST
Evan Masingill
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