No. 25A1208

In the Supreme Court of the United States

GENBIOPRO, INC., APPLICANT,

v.

STATE OF LOUISIANA, BY & THROUGH ITS ATTORNEY GENERAL, LIZ MURRILL, ET AL.

REPLY IN SUPPORT OF EMERGENCY APPLICATION TO VACATE STAY PENDING APPEAL

JOHN ADCOCK
ADCOCK LAW LLC
8131 Oak Street, Suite 100
New Orleans, LA 70118
(504) 233-3125

JOHN P. ELWOOD
Counsel of Record
DAPHNE O'CONNOR
ROBERT J. KATERBERG
BONNIE E. DEVANY
ARNOLD & PORTER KAYE SCHOLER LLP
601 Massachusetts Avenue, NW
Washington, DC 20001
(202) 942-5000
john.elwood@arnoldporter.com

MAY 8, 2026

TABLE OF CONTENTS

INTRODUCTION

Louisiana asks this Court to permit a single State to upend the nationwide status quo governing access to mifepristone, an FDA-approved medication with a twenty-five-year safety record available for lawful use in all 50 States. That request comes over the objection of amici representing over 20 States, 47 United States Senators, 212 Members of the House of Representatives, nine former FDA Commissioners, and pharmaceutical industry groups concerned about the implications of regulation by litigation. Those amici all urge the same: preserve the status quo that has governed mifepristone access for more than five years while this case proceeds and FDA completes the scientific review of the REMS Congress assigned solely to the agency.

The Fifth Circuit's order does the opposite. At the behest of a State that waited years to seek emergency relief, it reinstates a requirement FDA has not enforced since 2021: that mifepristone be dispensed in person at a hospital, clinic, medical office, or other healthcare setting. But that in-clinic dispensing requirement concerns only where a patient *receives* the medication, not where a patient *takes* mifepristone. Federal law permits patients to take mifepristone at home regardless of whether it is dispensed by mail, by a certified pharmacy, or in a healthcare setting. The order therefore does not restore a materially different model of care; it simply forces patients to make an unnecessary trip to obtain medication that they can take in the same place and manner as if it had been mailed.

The Fifth Circuit imposed that access barrier nationwide, years into a settled regulatory regime, without the benefit of an administrative record, and while FDA is actively collecting evidence and assessing whether any reasoned modification is warranted. Worse

still, the court's standing rationale turned on extra-record statements and two isolated Medicaid payments that Louisiana never linked to the challenged 2023 REMS feature—mail or pharmacy dispensing rather than in-clinic dispensing. Those payments come at the end of a long chain of independent third-party decisions that cannot establish standing. See *FDA* v. *Alliance for Hippocratic Medicine*, 602 U.S. 367 (2024).

Louisiana's sovereign-injury theory fares no better. Generalized statements by federal officials about reproductive rights do not transform FDA's drug-safety determination into regulation of Louisiana, much less give Louisiana standing to sue the federal government. At most, Louisiana claims that FDA's regulation of third parties makes state enforcement more difficult. Under this Court's straightforward analysis of State standing in *United States* v. *Texas*, 599 U.S. 670 (2023)—Louisiana's attempts to distinguish it notwithstanding, La. Opp. 32–34—that is not enough. Nor do Louisiana's invocations of state sovereignty change the result: a State cannot manufacture Article III standing to challenge federal regulation of third parties by pointing to alleged violations of state law by other third parties. And in an important case Louisiana barely addresses, the Ninth Circuit has rejected materially indistinguishable standing theories. *Washington* v. *FDA*, 108 F.4th 1163 (9th Cir. 2024).

Nor does FDA's current litigation posture or Louisiana's reliance on vacated Fifth Circuit opinions in *Alliance* change this Court's APA analysis. Indeed, Louisiana acknowledges that FDA is reviewing the 2023 REMS in response to "pressure from pro-life states and advocates," La. Opp. 12; having helped trigger the agency process Congress prescribed, Louisiana cannot use emergency litigation to short-circuit that process and

suspend the REMS Congress directed to remain in effect while FDA considers modification. Judicial review turns on the administrative record and the reasons FDA gave when it acted—not on a later administration's decision to revisit the REMS or decline to defend a prior agency action, and not on nonprecedential opinions vacated after this Court held the plaintiffs lacked Article III standing. FDA spent decades monitoring mifepristone across millions of patients and reasonably concluded that the in-person dispensing requirement was no longer necessary to ensure safe use—a judgment entitled to deference and reviewable only on the administrative record, which the Fifth Circuit never had before it. The question is whether the 2023 REMS was reasonably explained on the record before FDA, not whether FDA now chooses to collect additional data—especially when Congress requires that, during FDA's consideration of potential modification, the current REMS "remain[s] in effect." 21 U.S.C. § 355-1(g)(4)(B), (h)(2)(B).

The consequences of the Fifth Circuit's § 705 order are concrete and immediate. It would sow nationwide regulatory confusion, disrupt the sovereign interests of over 20 States that have structured their health systems around the current REMS, harm patients and providers, destabilize FDA's drug-regulatory framework, and irreparably injure GenBioPro. Louisiana's speculative injuries—traceable not to FDA but to the independent choices of out-of-state actors Louisiana cannot reach—do not justify that disruption. The Court should vacate the nationwide stay and preserve the status quo.

ARGUMENT

To vacate the Fifth Circuit's § 705 stay, GenBioPro must show a reasonable probability of certiorari, a fair prospect of reversal, a likelihood of irreparable harm absent relief,

and that the equities and public interest favor vacatur. *Hollingsworth* v. *Perry*, 558 U.S. 183, 190 (2010). All four factors are satisfied.

I. Louisiana's Speculative Injury Theories Cannot Support the Extraordinary Relief of a Nationwide Stay

Louisiana asks this Court to uphold extraordinary nationwide emergency relief that would strip patients across the country of mail and pharmacy access to mifepristone—including in States whose elected representatives have lawfully chosen to protect access to abortion care. To justify that extraordinary relief, Louisiana relies on two isolated Medicaid payments involving patients who allegedly received mifepristone from out of state. But Louisiana does not show that those payments had anything to do with the challenged feature of the 2023 REMS: mail or pharmacy dispensing rather than in-clinic dispensing. Louisiana's own opposition confirms that both its sovereign injury and economic standing theories rely on a multi-step chain of independent third-party choices that cannot establish the traceable, concrete harm that Article III requires, which it describes as "external forces combin[ing] to thwart" its law, or "a cabal of third parties." La. Opp. 25, 29. That is not the traceable, concrete injury Article III requires.

The cases Louisiana cites for the proposition that courts may consider foreseeable third-party conduct involved nothing like the cascade of independent choices by multiple third parties at issue here. They all involved well-documented reactions by single actors flowing directly and immediately from one government action directed at the party suing. See *Dep't of Commerce*, 588 U.S. at 768; *First Choice Women's Resource Centers*, 2026 WL 1153029, at *8; *Diamond Alternative Energy, LLC* v. *EPA*, 606 U.S. 100, 116–17 (2025). Louisiana cannot escape the fact that the Ninth Circuit considered and rejected the very

same standing theories—creating a circuit split that will merit this Court's review. Contrary to Louisiana's claims (at 37), the Ninth Circuit found standing lacking not only because of the speculative nature of the states' allegations (and Louisiana's allegations are just as speculative), but because "standing based on the alleged costs" to a State under the very same theory involves a "causal chain [that] is too attenuated." *Washington*, 108 F.4th at 1176–77. And that court specifically concluded that a "cognizable interest in the preservation of sovereign authority … does not convey standing to challenge federal action that affects state law enforcement indirectly, by making violations of state law more difficult or costly to detect." *Id.* at 1176. Holding otherwise would be antithetical to Article III, "greatly expand[ing] state standing to challenge any federal action that allegedly increases crime or disorder, or imposes indirect compliance costs for state law enforcement." *Id.* at 1177.

1. Louisiana's response expressly confirms that the State is trying to pass off policy objections as a pocketbook injury, and to judicially short-circuit the FDA's statutorily required process for a review of the REMS because Louisiana is unhappy with its pace (at 13). Louisiana never argues that the 2023 REMS will cause an overall increase in the State's Medicaid spending. Louisiana points to two isolated Medicaid payments allegedly associated with emergency care following use of "mifepristone mailed into Louisiana." La. Opp. 15, 26–27. But those isolated expenditures show nothing about whether Louisiana spent more because the 2023 REMS permits dispensing by mail than it would have spent if in-clinic dispensing were required. As amici FemInEM, a nonprofit organization focused on improving reproductive care in emergency departments, and mail-order pharmacy

Honeybee Health, Inc., explain, complications are rare, but may occur regardless of how mifepristone is dispensed—with no "measurable increase" in "serious adverse events" in patients who received mifepristone via telehealth. FemInEM Br. 21; see Honeybee Health Br. 11. And, importantly, mifepristone is associated with significantly fewer, and less severe, complications than full-term pregnancy. D. Ct. Dkt. 231-3 at 14–15. Louisiana does not estimate what Medicaid costs would have been had those same patients obtained mifepristone outside Louisiana or through another channel; elected to use a different method for pregnancy termination; or carried the pregnancy to term. Without evidence showing the net economic effect traceable to the challenged REMS change, Louisiana's claimed fiscal injury is pure speculation. "The causation requirement precludes speculative links." *Alliance*, 602 U.S. at 383. What remains is not an economic injury but a policy objection to spending any Medicaid funding on anything related to abortion care.

The breadth of Louisiana's theory underscores its flaw. On Louisiana's view, any State could challenge any FDA decision by pointing to a Medicaid claim involving a patient who used a regulated drug and asserting that a more or less restrictive federal regime might have prevented the expense. That is the same limitless theory this Court rejected in *Alliance*: because "virtually all drugs come with complications, risks, and side effects," accepting downstream treatment costs as sufficient for standing would allow regulated-drug challenges whenever someone might later seek reimbursable medical care. 602 U.S. at 391–92. Louisiana strains to avoid this Court's on-point precedent (at 33-34), but Article III bars States from turning disagreement with agency regulation of third parties into standing by recasting the dispute as a fiscal injury. See *Texas*, 599 U.S. at 680 n.3.

Article III similarly precludes Louisiana's attempt to establish standing by citing a few thousand dollars in investigatory costs. While this Court has sometimes found standing on behalf of private litigants who incurred preventive costs to avoid a "substantial risk" of harm, see *Bost* v. *Ill. State Bd. of Elections*, 146 S. Ct. 513, 524 (2026) (Barrett, J., concurring in the judgment) (citing *Monsanto Co.* v. *Geertson Seed Farms*, 561 U.S. 139, 153–55 (2010)), it has never extended that principle to find that States have standing merely because they incurred costs in the ordinary course of enforcing State law. For good reason: if a State had standing anytime it spent money in response to a federal policy, any State could challenge virtually any policy with which it disagreed.

2. Louisiana's theory of harm to sovereign interests fares no better. Louisiana says it is injured whenever a third party uses an FDA-regulated drug in a way Louisiana believes violates state law. But Article III standing turns on what FDA did to Louisiana—not what independent third parties did after FDA regulated others. The 2023 REMS does not regulate Louisiana or prevent Louisiana from imposing abortion restrictions. It is a safety-and-access regulation that sets federal conditions for dispensing mifepristone. And Louisiana does not ban mifepristone outright; it prohibits administering or prescribing drugs with the specific intent to terminate a pregnancy,[1] and mifepristone has lawful uses in the State. See La. Rev. Stat. Ann. § 14:87.1(1)(b)(ii), (2)(a). At most, then, Louisiana claims that FDA's regulation of third parties makes state enforcement more difficult. But Article

[1] Louisiana law excludes from its definition of "abortion" procedures necessary to prevent a patient's death (or substantial risk of death), to prevent the serious, permanent impairment of a life-sustaining organ, or to terminate certain "medically futile" pregnancies. La. Rev. Stat. Ann. § 14:87.1(1)(b); see id. § 40:1061(F).

III does not recognize sovereign injury merely because a federal policy increases the practical burdens of enforcing state law. See *Texas*, 599 U.S. at 680 n.3.

Nor would the Fifth Circuit's order redress Louisiana's asserted sovereign injury. The § 705 stay does not order any third party to comply with Louisiana law or resolve Louisiana's disputes with other States' shield laws. It would simply replace one federal distribution rule for regulated third parties with another. Louisiana's injury, by its own account, comes not from FDA, but from "the indiscriminate, nationwide attacks from prescribers and activists in proabortion states." La. Opp. 55. If Louisiana's theory is that those third parties would predictably change their conduct if the federal REMS changed, that only underscores the attenuated nature of the claim: Louisiana's sovereign-injury theory depends on speculation about how independent actors not before the Court will respond to interim relief, not on any legal constraint FDA has imposed on Louisiana.

Louisiana cannot cure that defect by invoking political statements from Biden Administration officials. Those statements do not show that FDA adopted the 2023 REMS to evade state law. FDA stopped enforcing the in-clinic requirement in the 2021 REMS, years before *Dobbs*. *Alliance*, 602 U.S. at 376. Louisiana does not contend that the officials who made the statements were the FDA decisionmakers responsible for the 2023 REMS. Louisiana's theory depends on isolating snippets from their context. Each statement Louisiana quotes was directed not at FDA but at HHS, and each directed only that HHS *identify* or *study* potential actions in light of the FDA's own safety determination—not that it dictate the REMS outcome. The "by mail" language appeared in a White House fact sheet discussing access to FDA-approved medication "in light of the FDA's determination that the drug

is safe and effective," not as a pledge to circumvent state law. La. App. 242. That same statement recognized that nationwide abortion access would require "*Congress* to restore the protections of *Roe* as federal law." La. App. 241 (emphases added). The April 2023 fact sheet post-dated the 2023 REMS and described FDA's action as "independent" and "evidence-based." La. App. 414. The Executive Orders Louisiana cites directed HHS to study or identify potential actions; they did not dictate FDA's REMS decision. La. App. 232-239. While *Department of Commerce* v. *New York* permits courts to consider predictable third-party responses to government action for traceability, 588 U.S. 752, 768 (2019), it does not permit inferring an agency's purpose from extra-record political statements and manufacturing sovereign standing based on innuendo.

The cases Louisiana invokes involving the United States as sovereign do not establish that a State may sue the federal government whenever federal regulation allegedly makes state law harder to enforce. In our federal system, the national and state governments each act directly on the people "within their respective spheres." *Printz* v. *United States*, 521 U.S. 898, 920 (1997) (citation omitted). That structure is inconsistent with treating every downstream effect of federal regulation—repackaged as a violation of state law—as a judicially cognizable injury to state sovereignty.

The consequences of Louisiana's theory confirm why Article III forbids it. If accepted, any State could challenge FDA's regulation of opioids, contraceptives, vaccines, controlled substances, or any other medication—or, for that matter, other federal agencies' regulations of guns, automobiles, or artificial intelligence products—by alleging that someone might use the product in violation of state law and thereby make enforcement harder.

As this Court explained in *United States* v. *Texas*, such sweeping conceptions of state standing would run roughshod over our federal system and find no support in Article III.

II. Louisiana Fails to Establish that the 2023 REMS is Arbitrary and Capricious

Louisiana does not show that FDA ignored the statutory REMS criteria or failed to provide a reasoned safety-and-access judgment. Instead, it asks this Court—at an emergency stage, before the administrative record has been filed—to fault FDA for not satisfying Louisiana's heightened evidentiary demands, to treat FDA's ongoing review as a concession of error, and to defer to two vacated Fifth Circuit panel opinions in *Alliance* that this Court reversed on standing grounds. None of Louisiana's theories establishes that the 2023 REMS is arbitrary and capricious, much less justifies a nationwide stay. And even though FDA reconsidered the 2023 REMS "[u]nder pressure from pro-life states and advocates," La. Opp. 12, FDA assured the public at the outset of that process that mifepristone remains "safe when used as indicated and directed and consistent with the Mifepristone [REMS] Program." FAQ #4, https://perma.cc/Z5TD-MHL7.

A. The 2023 REMS Reflects FDA's Lawful and Reasoned Scientific Judgment

Mifepristone is safe, effective, and exceptionally well studied. FDA has regulated the drug for more than twenty-five years, continually monitored its safety, and repeatedly concluded that its risks are exceedingly rare. Consistent with its statutory mandate not to "unduly burden[]" patient access while ensuring patient safety, 21 U.S.C. § 355-1(f)(2)(C), in 2021, FDA removed a single access burden: the requirement that the drug be dispensed in person even though patients could (and often would) take it elsewhere.

FDA formalized that decision in the 2023 REMS, reasonably concluding, based on decades of experience, adverse-event data, REMS assessments, and published studies of

mail and pharmacy dispensing, that the in-clinic dispensing requirement was no longer necessary to ensure safe use. But it did not eliminate the REMS framework or leave distribution unregulated. It replaced the in-clinic dispensing requirement with a pharmacy-certification requirement, while preserving the REMS's other core safeguards, including prescriber certification and the Patient Agreement Form. FDA Scholars Br. 2, 15. That measured approach reduced an unnecessary patient-access burden while maintaining controls designed to ensure safe use.

The APA does not require FDA to prove safety beyond a shadow of a doubt, as Louisiana wishes it would. It requires reasoned decisionmaking. See *FCC* v. *Prometheus Radio Project*, 592 U.S. 414, 423, 427 (2021). And the FDCA does not direct FDA to preserve REMS restrictions unless every conceivable uncertainty has been eliminated. It directs FDA to ensure that REMS elements are necessary, commensurate with the drug's risks, not "unduly burdensome on patient access," and minimally burdensome on the healthcare system. 21 U.S.C. § 355-1(f)(2)(C)–(D). FDA did exactly that.

1. Louisiana's FAERS argument rests on a false premise and an unduly demanding view of APA review. Contrary to Louisiana's assertions, FDA did not give "dispositive weight" to silence in FAERS. La. Opp. 39. It considered FAERS for what FDA says it is: an "Adverse-Event Reporting Database" containing data drawn from adverse-event reports submitted to FDA and used to identify safety signals, trends, and emerging concerns. See FDA, *FAERS Public Dashboard FAQ*, https://fis.fda.gov/extensions/FPD-FAQ/FPD-FAQ.html; PhRMA Br. 14 (FDA uses FAERS data to "identify trends and emerging concerns" and "as the sole source of adverse event reporting for virtually all drugs"). FDA

compared FAERS data from periods when the in-clinic dispensing requirement was in effect with periods when it was not, and considered that evidence alongside REMS assessments, sponsor submissions, published literature, postmarketing experience, and other real-world evidence. That is not arbitrary decisionmaking.

Louisiana's attempt to distinguish "adverse event reports" from "FAERS data," La. Opp. 41, is a non sequitur: as the words that make up the acronym make clear, FAERS is a collection of adverse event reports. And contrary to Louisiana's suggestion, nothing in the REMS statute makes adverse-event data a one-way ratchet that FDA may consider only to impose restrictions, but not to modify or remove them. FDA must determine whether REMS elements remain necessary to ensure that a drug's benefits outweigh its risks, while also ensuring that those elements are not unduly burdensome on patient access and minimize burdens on the healthcare system. 21 U.S.C. § 355-1(f)(2)(C)–(D), (g), (h). The absence of a safety signal in FAERS is directly relevant to that safety-and-access judgment—not because FAERS establishes incidence rates, but because it helps FDA assess whether known or potential risks warrant continued regulatory burdens.

The APA question is not whether FAERS alone could establish incidence rates—it cannot, and FDA understood that—but whether FDA could consider FAERS for its ordinary safety-signal function as part of a broader predictive scientific judgment. Agencies may make reasonable predictive judgments from the evidence before them. *Prometheus*, 592 U.S. at 427. The APA does not demand "perfect empirical or statistical data." *Ibid.* Louisiana may disagree with FDA's weighing of the evidence, but that is not enough. A court may set aside agency action only if the agency failed to consider an important aspect

of the problem, relied on impermissible factors, contradicted the evidence before it, or failed to draw a rational connection between the facts found and the choice made. *Motor Vehicle Mfrs. Ass'n* v. *State Farm*, 463 U.S. 29, 43 (1983). And when an agency makes a "scientific determination" based on a prediction "within its area of special expertise," "a reviewing court must generally be at its most deferential." *Baltimore Gas & Elec. Co.* v. *Nat. Res. Def. Council, Inc.*, 462 U.S. 87, 103 (1983).

Moreover, FDA did not "eliminate[]" adverse-event reporting in 2016. La. Opp. 17. Manufacturers remain subject to mandatory adverse-event reporting obligations, and mifepristone retains a fatality-reporting requirement "more stringent than the requirements for most other drugs." *Alliance*, 602 U.S. at 376; PhRMA Br. 21–22. Indeed, physicians' FAERS reporting is voluntary for "virtually all of the 20,000 drugs approved by FDA." FDA Comm'rs Br. 13. That is the case for literally *hundreds* of drugs with boxed warnings, contrary to Louisiana's suggestion that mifepristone's treatment is extraordinary. See La. Opp. 41. If Louisiana's critique were accepted, FDA could not rely on FAERS in the ordinary way for most approved drugs—an approach that would upend the postmarketing safety system Congress and FDA have built. See FDA Comm'rs Br. 14-15; PhRMA Br. 8.

2. Louisiana's attack on FDA's review of the published literature fails for the same reason as its FAERS argument: it isolates limitations in individual evidence sources and then demands a level of certainty the APA does not require. Louisiana's literature argument is, at bottom, an effort to impose a new *mifepristone-specific* evidentiary rule: that FDA may only rely on literature that "affirmatively support[s] its position," La. Opp. 41, and only if those studies independently and conclusively establish the safety of the precise

dispensing model at issue. The APA contains no such requirement. Agencies may rely on multiple imperfect sources of evidence, acknowledge limitations in each, and make a reasoned predictive judgment based on the record as a whole. See *Prometheus*, 592 U.S. at 427. Indeed, even under substantial-evidence review, "the possibility of drawing two inconsistent conclusions from the evidence does not prevent an administrative agency's finding from being supported by substantial evidence." *Consolo* v. *Fed. Mar. Comm'n*, 383 U.S. 607, 620 (1966). That principle applies with particular force where FDA is weighing scientific literature because FDA "possesses the requisite know-how" to "weigh each conflicting study," *Henley* v. *FDA*, 77 F.3d 616, 621 (2d Cir. 1996), and its "judgments as to what is required to ascertain the safety and efficacy of drugs fall squarely within the ambit of the FDA's expertise and merit deference from us." *Schering Corp.* v. *FDA*, 51 F.3d 390, 399 (3d Cir.), cert. denied, 516 U.S. 907 (1995).

Louisiana identifies no study showing that dispensing mifepristone by mail or pharmacy reduces mifepristone's effectiveness or increases serious adverse events. FDA reviewed 15 studies addressing alternative dispensing models, including mail, courier, partner-entity, and pharmacy dispensing. Louisiana does not show that those studies, considered collectively with the rest of the record, failed to support FDA's judgment. Instead, Louisiana discusses claimed limitations in only a handful of studies, focusing principally on individual studies reflecting more frequent urgent-care or emergency-department visits among some patients using non-in-clinic dispensing. La. Opp. 43–44. But healthcare utilization is not the same thing as a serious adverse event. Patients may seek emergency or urgent care to confirm pregnancy termination, obtain treatment for expected symptoms

such as cramping or bleeding, ask questions, obtain reassurance, or because they lack convenient access to another provider—especially in rural or underserved areas. See FemInEM Br. 11, 14; ACOG & AMA Br. 12–13. FDA explicitly acknowledged that these visits frequently do not involve any serious adverse event or any medical treatment at all. See La. App. 178 ("half of the ED/urgent care visits did not entail any medical treatment."); 360 Reproductive Health Researchers Br. 14. Louisiana's reliance (at 41) on mifepristone's labeling does not change that point. Although the "Black Box" label reflects that some patients may visit an emergency room, that statistic does not correspond to serious adverse events, which the same label indicates occur at a far lower rate. FemInEM Br. 15–16. FDA reasonably distinguished healthcare utilization from safety outcomes and found that the evidence did not show that mail or pharmacy dispensing increased serious adverse events. La. App. 328.

Nor does FDA's acknowledgment of study limitations help Louisiana. That acknowledgment exemplifies objective, reasoned scientific decisionmaking. FDA did not claim that any single study was perfect or dispositive. It evaluated the literature together with adverse-event data, REMS assessments, sponsor submissions, and decades of postmarketing experience. Louisiana isolates FDA's statement that the literature was "not inconsistent with" its conclusion and treats that cautious scientific formulation as a concession that the evidence did not support the 2023 REMS. But the surrounding analysis shows the opposite: FDA reviewed the studies, acknowledged their limits, weighed them collectively with the rest of the record, and reasonably concluded that mifepristone would remain safe and effective without the in-clinic dispensing requirement. That is reasoned decisionmaking, not

a basis for emergency nationwide relief.

B. FDA's Ongoing Review Does Not Justify Suspension of the Operative REMS

Louisiana, like the court below, highlights a letter from the HHS Secretary and FDA Commissioner indicating that FDA's "prior REMS approvals" "lack[ed] adequate consideration" and stating that FDA would "conduct a study of the safety of the current REMS, in order to determine whether modifications are necessary." La. Opp. 12–14, 18, 45, 50–51; La. App. 478. Louisiana acts as though the letter conceded that the 2023 REMS is unlawful. It did not. The letter does not withdraw FDA's prior determination, identify any specific defect in the 2023 REMS, explain how FDA's prior reasoning was inadequate, or assert that mail or pharmacy dispensing is unsafe. It merely announced further data collection and review "in order to determine whether modifications are necessary," La. App. 478—the very process Congress prescribed for FDA to assess whether a REMS change may be warranted. See 21 U.S.C. § 355-1(g)(4), (h).

Louisiana counters that "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." La. Opp. 19. To the contrary, that is the process Congress has directed: Congress has dictated that while FDA considers a REMS modification, the existing REMS "remain[s] in effect." 21 U.S.C. § 355-1(h)(2)(B). And it bears repeating: FDA's public position is that mifepristone "is safe when used as indicated and directed and consistent with the Mifepristone [REMS] Program." FAQ #4, https://perma.cc/Z5TD-MHL7.

Indeed, even if the letter had confessed error—which it did not—that would not render the 2023 REMS unlawful and void. Of course agencies may change their positions,

including on complex scientific matters like drug safety, but they must do so through reasoned decisionmaking. An agency changing course must "display awareness that it is changing position," "provide [a] reasoned explanation," "show that there are good reasons for the new policy," and account for "reliance interests." *FCC* v. *Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009). To treat FDA's announcement of intent to reconsider the duly adopted REMS as an effective invalidation would allow agencies to evade their core administrative law obligations whenever a new Administration takes office. Neither the APA nor this Court's jurisprudence permit such an end-run.

Judicial review of the 2023 REMS can proceed only on the administrative record and FDA's contemporaneous reasoning contained therein. See *Dep't of Homeland Sec.* v. *Regents of the Univ. of Cal.*, 591 U.S. 1, 23–24 (2020). "It is a 'foundational principle of administrative law' that judicial review of agency action is limited to 'the grounds that the agency invoked when it took the action.'" *Id.* at 20 (quoting *Michigan* v. *EPA*, 576 U.S. 743, 758 (2015)). The lawfulness of the 2023 REMS must be judged only on "the reasons [FDA] gave when it acted," *id.* at 24, not new characterizations, litigation positions, or an announcement of an agency review.

But even if the letter were treated as an effective concession of arbitrary or capricious agency action in the 2023 REMS, Louisiana still would not be entitled to the extraordinary relief it obtained. The appropriate remedy would be remand for FDA to review and address any deficiency—leaving the existing REMS "in effect," 21 U.S.C. § 355-1(h)(2)(B)—not a universal stay that immediately and summarily overturns a nationwide regulatory regime. "Even when a court sets aside an unlawful agency action under the

APA, it is ordinarily 'the prerogative of the agency to decide in the first instance how best to provide relief.'" *Shands Jacksonville Med. Ctr., Inc.* v. *Azar*, 959 F.3d 1113, 1118 (D.C. Cir. 2020) (quoting *Bennett* v. *Donovan*, 703 F.3d 582, 589 (D.C. Cir. 2013)). And "[t]h[o]se principles apply with no less force when an agency voluntarily abandons its own action." *Ibid.* When that happens, courts routinely remand without vacatur to allow the agency to bring its expertise to bear. See, *e.g.*, *Clean Wisconsin* v. *EPA*, 964 F.3d 1145, 1175–76 (D.C. Cir. 2020); *Limnia, Inc.* v. *U.S. Dep't of Energy*, 857 F.3d 379, 386–87 (D.C. Cir. 2017). And remand without vacatur is virtually always best when, as here, "the disruptive consequences of vacating are substantial." *Apache Corp.* v. *FERC*, 627 F.3d 1220, 1223 (D.C. Cir. 2010) (Kavanaugh, J.) (quoting *Allied-Signal, Inc.* v. *U.S. Nuclear Regul. Comm'n*, 988 F.2d 146, 151 (D.C. Cir. 1993)).

Here, FDA is already doing what remand would require: determining whether a reasoned modification is warranted. If FDA ultimately determines that changes to the mifepristone REMS are in order, it must make that determination through lawful decisionmaking grounded in the required statutory criteria and the record before it. See D. Ct. Dkt. 250 at 3–4 (FDA acknowledging the mandatory agency procedures and the process due to drug sponsors if the agency determines the REMS must be modified). Until then, the mere announcement of further review provides no basis for Louisiana's claims and no justification for judicially suspending the operative REMS nationwide.

III. The Equities and Public Interest Overwhelmingly Favor Preserving the Five-Year Status Quo

Leaving the Fifth Circuit's § 705 stay intact would override coequal sovereigns' interests, disserve the public interest, and irreparably harm GenBioPro. And it would do so

through interim relief that upends a settled status quo. FDA has not enforced the in-clinic dispensing requirement for more than five years, and the 2023 REMS has governed for more than three. Louisiana could have sued at any point during that period. Against that backdrop, there was no equitable reason to impose a sweeping nationwide disruption now—before final judgment—rather than wait for FDA to issue its expert determination. If the Fifth Circuit's order takes effect and is later vacated, patients, prescribers, pharmacies, manufacturers, FDA, and States will be forced through regulatory whiplash: dismantling the current system only to rebuild it again.

This case does not present Louisiana's interests in isolation. On the other side are amici representing the interests of over 20 States and the District of Columbia, with equally weighty sovereign interests in protecting access to reproductive healthcare within their borders. Those States explain that reinstating the in-clinic dispensing requirement would disrupt their laws, their public-health systems, and their judgments about how best to safeguard the health, safety, and rights of their residents. New York, et al. Br. 2. *Dobbs* v. *Jackson Women's Health Org.* returned abortion policy to "the people and their elected representatives," 597 U.S. 215, 292 (2022); it did not empower one State to impose its policy judgments on its coequal sovereigns.

As the amici in this case have cogently expressed, the patient and public-health harms are also concrete. PhRMA, the leading pharmaceutical trade association representing nearly three dozen manufacturers, explains that the order's consequences would extend across the pharmaceutical industry by allowing courts to second-guess FDA's ordinary use of adverse-event data and impose drug-specific evidentiary demands, which would

destabilize the regulatory system on which drug sponsors rely when developing, monitoring, and bringing medicines to market. PhRMA Br. 18–22. The Disability Rights Education & Defense Fund amici explain that mail and pharmacy dispensing are not just a convenience but often essential in the treatment of disabled patients. DREDF Br. 4, 11–22. Provider and telehealth amici explain that reinstating in-clinic dispensing would delay or deny time-sensitive care for patients facing barriers of distance, cost, privacy, safety, childcare, work, and domestic violence. See PRH Br. 2–4, 14–25; RHITES Br. 1–2. And former FDA Commissioners warn that the Fifth Circuit's order threatens the science-based drug-regulatory framework Congress entrusted to FDA. Former FDA Comm'rs Br. 2–5, 13–15.

The regulatory chaos is not simply that one access pathway is suspended; it is that the court's order purports to disable the operative 2023 regulatory regime on an interim basis without identifying what REMS, labeling, Patient Agreement, pharmacy certification, or dispensing infrastructure that governs in its place for manufacturers, prescribers, and patients who receive this medication every day. Whether or not as a matter of administrative law the previous regime "snapped back" upon the Fifth Circuit's order, that's not how FDA regulation of any drug works, let alone one with a REMS. The 2023 REMS is the current integrated framework under which certified prescribers ensure patients review and sign the operative Patient Agreement and certified pharmacies agree to comply with applicable REMS requirements. See App.58a–59a; Loc. Gov'ts Br. 13–15 (explaining that staying the 2023 REMS is "not as simple as returning to the drug-dispensing regime that existed five years ago" because "prescription, labeling, and dispensation practices have been built in reliance on the 2023 REMS"). Suspending that regime does not mechanically revive

superseded REMS materials. See 21 U.S.C. § 355-1(h)(2)(B). Instead, it leaves manufacturers, pharmacies, and prescribers uncertain whether existing REMS agreements remain valid, whether REMS documents and labeling must be changed, and whether product may be dispensed at all. See App.58a–59a.

GenBioPro's harms are equally immediate and concrete. Mifepristone accounts for the majority of GenBioPro's revenue, and pharmacy distribution is a substantial portion of that revenue—losses GenBioPro cannot recover if the Fifth Circuit's order is later vacated. App.57a–58a. In addition to the immediate regulatory uncertainty over existing REMS agreements, labeling, already-manufactured inventory, and supply arrangements generated by the Fifth Circuit's order, it forces GenBioPro to unwind on an emergency basis a distribution framework built over months in reliance on the 2023 REMS. App.57a–59a. Those unrecoverable financial, operational, and compliance harms are irreparable—and neither the Fifth Circuit nor Louisiana's response gave them meaningful weight.

Louisiana offers no comparable equitable showing. It seeks emergency relief from a years-old status quo based on speculative and attenuated injuries. Louisiana argues that the public-interest factor is settled by the proposition that "neither the FDA nor the public has any interest in enforcing a regulation that violates federal law," again quoting the now-vacated *Alliance II* panel. La. Opp. 50. But whether the 2023 REMS "violates federal law" is precisely the merits question the Fifth Circuit got wrong. The circular logic is not enough to justify the nationwide disruption—especially on an interim basis—to patients, providers, manufacturers, pharmacies, FDA's ongoing review, and the sovereign interests of States that have made different lawful choices.

CONCLUSION

The application should be granted and the Fifth Circuit's nationwide § 705 stay vacated.

Respectfully submitted.

JOHN ADCOCK
ADCOCK LAW LLC
8131 Oak Street, Suite 100
New Orleans, LA 70118
(504) 233-3125

JOHN P. ELWOOD
Counsel of Record
DAPHNE O'CONNOR
ROBERT J. KATERBERG
BONNIE E. DEVANY
ARNOLD & PORTER KAYE SCHOLER LLP
601 Massachusetts Avenue, NW
Washington, DC 20001
(202) 942-5000
john.elwood@arnoldporter.com

Counsel for Applicant GenBioPro, Inc.

MAY 8, 2026