SUPREME COURT OF THE UNITED STATES

No. 25A1207

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

ON APPLICATION FOR STAY

No. 25A1208

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

ON APPLICATION FOR STAY

[May 14, 2026]

JUSTICE ALITO, dissenting.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Because the manufacturers have not shown that they face any imminent risk of irreparable injury, the Court must deny these applications regardless of how they fare on the other stay factors. I therefore respectfully dissent.