No. 25A1207

IN THE
Supreme Court of the United States

DANCO LABORATORIES, L.L.C.,

Applicant,

v.

THE STATE OF LOUISIANA, ET AL.,

Respondents.

On Application to Stay the Judgment of the United States Court of Appeals for the Fifth Circuit and Request for an Immediate Administrative Stay

AMICUS CURIAE BRIEF OF THE ASSOCIATION OF AMERICAN PHYSICIANS AND SURGEONS AND EAGLE FORUM EDUCATION & LEGAL DEFENSE FUND IN OPPOSITION TO THE APPLICATION

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INTEREST OF AMICUS CURIAE[1]

Amicus Association of American Physicians and Surgeons ("AAPS") is a national association of physicians, founded in 1943. AAPS is dedicated to protecting the patient-physician relationship, and has been a litigant in this Court and in other appellate courts. *See, e.g.*, *Ass'n of Am. Physicians & Surgs. v. Mathews*, 423 U.S. 975 (1975); *Ass'n of Am. Physicians & Surgs. v. Tex. Med. Bd.*, 627 F.3d 547 (5th Cir. 2010). AAPS's *amicus* briefs have been cited by justices of this Court. *See, e.g.*, *District of Columbia v. Heller*, 554 U.S. 570, 704 (2008) (Breyer, J., dissenting).

As a group of physicians, AAPS has strong interests in defending and restoring informed consent by patients, which is allowed and facilitated by requiring an in-person visit with a physician before taking a life-changing medication such as mifepristone.

Eagle Forum Education & Legal Defense Fund ("Eagle Forum ELDF") was founded in 1981 by Phyllis Schlafly, and has consistently defended federalism while supporting states' autonomy from federal actions that have the effect of increasing abortions. Eagle Forum ELDF has a longstanding interest in protecting unborn life, and has a direct and vital interest in the issues before this Court.

[1] Pursuant to Rule 37.6, counsel for *amicus curiae* authored this brief in whole, no counsel for a party authored this brief in whole or in part, and no such counsel or a party made a monetary contribution intended to fund the preparation or submission of this brief. No person or entity – other than *amicus*, its members, and its counsel – contributed monetarily to the preparation or submission of this brief.

SUMMARY OF ARGUMENT

The application to reinstate use of mifepristone without in-person dispensing is tantamount to demanding a revival of *Roe v. Wade*, 410 U.S. 113 (1973). As the Fifth Circuit explained and properly enjoined, the Food and Drug Administration (FDA) under the Biden Administration flouted this Court's reversal of *Roe v. Wade* by removing the in-person requirements for mifepristone. *See Louisiana v. FDA*, No. 26-30203, Slip op. 2 (5th Cir. May 1, 2026) (citing *Dobbs v. Jackson Women's Health Org.,* 597 U.S. 215, 292 (2022)). The FDA lacks medical expertise, cannot lawfully practice medicine, and cannot properly override state policy concerning abortion as the FDA attempts to do by mandating unlimited access to mifepristone.

The result of this politically motivated action by Biden's FDA has been a significant increase in abortions in the United States. *See, e.g.*, Guttmacher Institute, *Abortion in the United States* (March 2026).[2] Due to removal of the in-person requirements, more abortions are performed today without informed consent. Abortion pills are obtained and distributed to teenagers who consume them without even a prescription. Mifepristone-induced abortions rapidly increased to 65% of abortions by 2023, a percentage that is likely higher today; this reported increase does not even include the chemical abortions from "community networks" as facilitated by the FDA's policy.[3] The FDA's authorization of mifepristone without in-person dispensing

[2] https://www.guttmacher.org/fact-sheet/induced-abortion-united-states (viewed May 3, 2026). The Guttmacher Institute is a widely cited authority on abortion rates.
[3] *Id.*

circumvents laws that this Court held in *Dobbs* are left to the states to enact and enforce. *See Dobbs,* 597 U.S. at 292.

Dobbs means very little if a few federal bureaucrats at the FDA, acting under the direction of the pro-abortion Biden Administration, can override fundamental state laws concerning abortion. "It is time to heed the Constitution and return the issue of abortion to the people's elected representatives." *Id.* at 232. Mandating that abortion may be performed by handing out mifepristone without in-person requirements, as the FDA has done for political purposes, negates *Dobbs.*

Federalism is undermined, even imperiled, by allowing a few unelected federal subagency employees to transform American culture in defiance of state laws. *See, e.g.*, *GenBioPro, Inc. v. Raynes*, 144 F.4th 258, 266 (4th Cir. 2025) (Wilkinson, J.) ("For us to once again federalize the issue of abortion without a clear directive from Congress, right on the heels of *Dobbs*, would leave us one small step short of defiance."). State legislative hearings should be held, and those who advocate that mifepristone is safe should answer questions by elected officials and respond to many women who regret taking the drug. Redacted data concerning the harm caused by the drug must be publicly disclosed and analyzed. The emotional and psychological harm caused by the visual impact on a mother of having to see her own deceased unborn child should be addressed,[4] which Danco fails to do in its application here.

[4] M. Antonia Biggs, *et al.*, "Women's Mental Health and Well-being 5 Years After Receiving or Being Denied an Abortion," 74 *JAMA Psychiatry* 169-78 (Feb. 2017) https://jamanetwork.com/journals/jamapsychiatry/fullarticle/2592320 (viewed May 3, 2026).

Louisiana properly objects to this exploitation of its residents by purveyors of mifepristone. Informed consent for the protection of the recipients of this drug requires the minimal protection of in-person dispensing. The irreparable harm is profound when consumers of mifepristone are not told, for example, that mifepristone is reversible. The American College of Obstetricians and Gynecology admits that "as many as half of women who take only [the first dose] mifepristone continue their pregnancies,"[5] yet many purchasers of mifepristone will not hear this in the absence of an in-person visit with a physician or from in-person dispensing. The public interest weighs in favor of policies that require in-person dispensing so that women can learn more information about this life-changing drug before taking it. The Fifth Circuit therefore properly stayed the FDA's removal of the in-person requirements, which was facilitating people to share the abortion pill with those not having prescriptions for it.

Applicant Danco Laboratories ("Danco"), in seeking an immediate stay, relies heavily on the decision by this Court in 2023 against legal standing by plaintiffs who opposed the FDA's authorization of mifepristone. *See FDA v. All. for Hippocratic Med.*, 602 U.S. 367 (2024) (cited by Danco Appl. 1, 18, 32) Since that decision was rendered, on jurisdictional grounds, more than two million unborn American children have been aborted through use of mifepristone. Many of these abortions occurred amid a misunderstanding about the reversibility of the decision after taking mifepristone,[6]

[5] ACOG, "Facts Are Important: Medication Abortion 'Reversal' Is Not Supported by Science," https://www.acog.org/advocacy/facts-are-important/medication-abortion-reversal-is-not-supported-by-science (viewed Feb. 4, 2026).
[6] "Abortion Pill Reversal," https://abortionpillreversal.com/ (viewed May 3, 2026).

which an in-person requirement can help correct. Danco's application to continue selling its drug without an in-person requirement should be denied.

ARGUMENT

I. Requiring In-Person Dispensing Is Beneficial to Patients, and Would Not Result in "Chaos" as Danco Pretends.

In its application, Danco resorts to hyperbole by predicting "Nationwide Chaos" if in-person dispensing is required. (Danco Appl. 39) But far from "immediate confusion and dramatic upheaval" (*id.* at 32), women would benefit from medical advice and information that are currently being withheld from them. With more advice and information, some women would decline to use Danco's abortion pill, but a decline in revenue to Danco is not irreparable harm. Danco's profitability is not a basis for overturning the well-reasoned judgment issued below. Having to visit in-person with a licensed practitioner before taking a life-changing abortion pill is not a hardship, but a benefit to the mother and father in making this momentous decision about aborting their child.

Yet notably absent from Danco's application (and from the similar application by GenBioPro) is any assurance that the consumers of mifepristone are informed about risks and harms from this product. For example, there is no mention of the 36 reported deaths after taking mifepristone, to which the FDA itself admits on its website despite being generally favorable about the product.[7] There is also no mention in these applications or by the FDA of the psychological scars left in many consumers of

[7] FDA, "Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation" (April 8, 2026), cited *infra* n.10.

mifepristone. *See, e.g.*, Pauline Slade, *et al.*, "Termination of pregnancy: Patient's perception of care," 27 *J. of Family Planning & Reproductive Health Care* 72-77 (2001) ("Seeing the foetus, in general, appears to be a difficult aspect of the medical termination process which can be distressing, bring home the reality of the event and may influence later emotional adaptation.").

Instead of addressing these substantive issues, much of Danco's application relies on the lack of standing by private plaintiffs found by this Court in *FDA v. All. for Hippocratic Med.*, under the theory that physicians and their association lack standing to assert claims on behalf of patients harmed by mifepristone. But if so, then Danco as a manufacturer certainly lacks standing to assert claims on behalf of its customers, as it implicitly attempts by its application. Danco itself faces nothing more than a speculative dip in revenue, which hardly commands the emergency attention of this Court.

Danco complains that "Mifeprex [its brand name for mifepristone] is Danco's *only* product. Without a valid legal framework for distributing that product, Danco will lose its only source of revenue and may be unable to continue operating." (Danco Appl. 36, emphasis added). Courts are not here to make sure a company can stay in business, especially when its only purpose is selling a drug that kills unborn children. Danco's revenue may be of concern to Danco's owners, but not to the public or to the Court in allowing Louisiana to protect its residents against the sale of a harmful product within its borders. All states have increased the minimum age to purchase alcohol to age 21, which surely reduced revenue to alcohol companies and

may have driven some out of business, but those considerations do not undermine the legal validity of those and similar laws.

Louisiana increased the minimum age to 21 for playing video poker and buying lottery tickets, and that was properly sustained against legal challenge as "substantially related to the protection of the general welfare of this state." *Latour v. State*, 778 So. 2d 557, 566 (La. 2001). Nothing grants the FDA authority to override attempts by Louisiana to protect the general welfare of its residents, including those under the age of 21, from chemical abortion.

II. The Severe Interference with Federalism by the FDA Is Contrary to *Dobbs*, and Unsustainable for our Nation.

At least 20 states have disagreed with the FDA's approving and facilitating chemical abortion, and objected to the Biden Administration making it available by mail contrary to longstanding federal law. 18 U.S.C. § 1461 (banning the mailing of any "article or thing designed, adapted, or intended for producing abortion").

For example, 20 state Attorneys General signed and sent a remarkable letter to CVS pharmacy on Feb. 1, 2023, to tell CVS that President Biden is violating the law and that CVS should not provide mifepristone in their states. Their letter, a similar copy of which was also sent to Walgreens pharmacy, explains that:

> In December, the Biden administration's Office of Legal Counsel encouraged the U.S. Postal Service to disregard this plain text [of federal law]. … [T]he Biden administration's opinion [to broadly distribute mifepristone] fails to stand up even to the slightest amount of scrutiny.[8]

[8] Letter from Andrew Bailey, Attorney General of Missouri, to Tom Moriarty, General Counsel, CVS Health (Feb. 1, 2023) https://acrobat.adobe.com/link/review?uri=urn:aaid:scds:US:50ee3999-cf8d-4a26-9d4a-ec56c854e352 (viewed May 3, 2026).

This joint letter by 20 states explains further that:

> Abortion pills are far riskier than surgical abortions, according to established scientific consensus: "Medication abortions were 5.96 times as likely to result in a complication as first-trimester aspiration abortions." Abortion pills carry the added risk that when these heightened complications invariably occur, women suffer those harms at home, away from medical help. And finally, mail-order abortion pills also invite the horror of an increase in coerced abortions. When abortion drugs are mailed or consumed outside a regulated medical facility, the risk of coercion is much higher—indeed, guaranteed—because there is no oversight. Outside the regulated medical context, a person can obtain an abortion pill quite easily and then coerce a woman into taking it.[9]

By removing the requirement that the pill be obtained in-person, the FDA has increased the likelihood of pressure on teenagers to take this pill at a party or otherwise.[10] The FDA also expanded distribution of this pill to open it up to any retail pharmacy to seek certification to dispense it.[11] The FDA thereby acted in violation of the abortion policies in many states, and this Court should decide in favor of federalism rather than this abuse of federal administrative power.

It is well-established (but rarely disclosed) that carrying a pregnancy to term is beneficial to a woman's long-term health. "Women who gave birth to a child when they were younger than 24 years of age exhibit a decrease in their lifetime risk of

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[9] *Id.* (quoting Upadhyay, et al., "Incidence of Emergency Department Visits and Complications After Abortion," Obstet. Gynecol. 2015 Jan.; 125:175, 181, https://www.ansirh.org/sites/default/files/publications/files/upadhyay-jan15incidence_of_emergency_department_visits.pdf, parenthetical omitted).

[10] FDA, "Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation" (Jan. 4, 2023). https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation (FDA "removes the in-person dispensing requirement") (viewed May 3, 2026).

[11] *Id.* ("The January 2023 modification to the Mifepristone REMS Program removed the requirement that did not allow mifepristone to be dispensed from retail pharmacies."). "REMS" stands for the mandatory Risk Evaluation and Mitigation Strategy implemented by the FDA to manage serious safety risks associated with mifepristone for medical abortion.

developing breast cancer, and additional pregnancies increase the protection." Jose Russo, et al., "The protective role of pregnancy in breast cancer," 7 BREAST CANCER RES 131-42 (2005).[12] The FDA's original approval of mifepristone in 2000 was based on a statutory provision expressly limited to drugs that were "studied for their safety and effectiveness in treating serious or life-threatening illnesses." 21 C.F.R. § 314.500. The FDA's continued authorization of mifepristone is based on the falsehood that it targets "serious or life-threatening illnesses." Pregnancy is not a "serious or life-threatening illness."

III. The FDA Has a History of Inflicting Harm on the Public, and Is Not Entitled to any Deference on the Issue of Abortion.

Put in perspective, the lack of judicial review of the FDA in the past is not anything to try to perpetuate. The FDA is widely perceived to be a highly politicized subagency that has a history of wrongly approving certain drugs.

Consider, for example, the medication diethylstilbestrol, abbreviated as DES. The FDA formally approved this medication in 1954 specifically for use by pregnant women, despite ample evidence that it caused harm in animal studies. The drug then caused decades of harm in unborn children as confirmed by numerous published studies, but the FDA did not revoke its approval until a half-century later, in 2000. The harm caused by DES included infertility in the unborn children of women who were misled into taking this medication, and also unusual cancers in their children, with some of the harm even extending to the third generation of

[12] https://pubmed.ncbi.nlm.nih.gov/15987443/ (viewed May 3, 2026).

children of mothers misled by the FDA into taking this medication.[13] In a more recent case of the FDA being too slow to withdraw an approval, it took 12 years and the withdrawal of the drug Makena (hydroxyprogesterone caproate) from the market by its manufacturer before the FDA corrected its own improper approval.[14]

The FDA does not have any expertise about the practice of medicine, such as whether in-person visits with a physician should be required for a medication, and thus has no justification overriding state pro-life policies about this. States, not the FDA, properly regulate the practice of medicine and the operation of pharmacies.

The medical societies that support mifepristone show their bias by opposing access by the public to an FDA-approved medication that reverses the abortion pill at issue in this case. In 2019 the American Medical Association ("AMA") filed a lawsuit in North Dakota "challenging two laws that required physicians to tell patients about abortion pill reversal and that abortion terminates 'the life of a whole, separate, unique, living human being.'"[15] The only consistency in the AMA's positions is that the AMA apparently sides with the abortion business every time, even when patient freedom is on the other side.

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[13] DES Action, "DES Timeline," https://desaction.org/des-timeline/ (viewed May 3, 2026).
[14] Robin Foster, "FDA withdraws approval of drug meant to prevent preterm births," *Medical Xpress* (Apr. 7, 2023) https://medicalxpress.com/news/2023-04-fda-drug-meant-preterm-births.html (viewed May 3, 2026).
[15] Claire Cleveland, "Colorado becomes the first state to ban controversial abortion pill reversals," *KFF Health News* (May 03, 2023) https://19thnews.org/2023/05/colorado-bans-abortion-pill-reversals/ (viewed May 3, 2026).

IV. Danco Fails to Satisfy the Standard for Staying the Judgment Below.

The proper standard of review is set forth in Justice Brennan's chambers opinion in the landmark *Rostker* v. *Goldberg* case:

> [A] four-part showing [must be] made. First, it must be established that there is a "reasonable probability" that four Justices will consider the issue sufficiently meritorious to grant certiorari or to note probable jurisdiction. Second, the applicant must persuade me that there is a fair prospect that a majority of the Court will conclude that the decision below was erroneous. … Third, there must be a demonstration that irreparable harm is likely to result from the denial of a stay. And fourth, in a close case it may be appropriate to "balance the equities" – to explore the relative harms to applicant and respondent, as well as the interests of the public at large.

Rostker v. Goldberg, 448 U.S. 1306, 1308 (1980) (Brennan, J., in chambers, inner citations omitted). *See also Hollingsworth v. Perry*, 558 U.S. 183, 190 (2010) (same).

Without speculating on whether the Court would ultimately grant certiorari in this case, Danco's application falls far short on each of the three other foregoing elements, which it alone bears the burden to satisfy. Danco has little chance of prevailing with a majority of the Justices on the merits, and Danco has not shown any irreparable harm from the judgment below. Balancing the equities and public interest both support ruling in favor of Louisiana's laws.

CONCLUSION

Due to grave issues of uninformed consent, often by teenagers, for the harmful and life-changing drug mifepristone, Danco is unjustified in seeking a stay of the judgment below. Danco's application should be denied.

Respectfully submitted,

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