Nos. 25A1207 & 25A1208

In The
Supreme Court of the United States

DANCO LABORATORIES, LLC,
Applicant,
v.
State of LOUISIANA, et al.,
Respondents.

GENBIOPRO, INC.,
Applicant,
v.
State of LOUISIANA, et al.,
Respondents.

BRIEF FOR STATES OF NEW YORK, ARIZONA, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, HAWAI'I, ILLINOIS, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, NEVADA, NEW JERSEY, NEW MEXICO, NORTH CAROLINA, OREGON, RHODE ISLAND, VERMONT, VIRGINIA, WASHINGTON, AND THE DISTRICT OF COLUMBIA, AND THE GOVERNOR OF PENNSYLVANIA AS AMICI CURIAE IN SUPPORT OF APPLICANTS FOR A STAY

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Dated: May 4, 2026

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INTRODUCTION AND INTERESTS OF AMICI

In 2023, following extensive study, the U.S. Food and Drug Administration (FDA) eliminated the in-person dispensing requirement for the drug mifepristone as medically unnecessary. Several years later, plaintiffs (the State of Louisiana and a single individual) filed this suit seeking to compel the FDA to reinstate the requirement. The U.S. District Court for the Western District of Louisiana (Joseph, J.) denied plaintiffs' motion for preliminary relief without prejudice, and upon the request of the FDA and without objection from applicants, stayed the action pending resolution of the FDA's ongoing regulatory review of exactly the same requirement challenged in this case. Plaintiffs appealed, and the U.S. Court of Appeals for the Fifth Circuit issued an order "staying" the 2023 regulatory change pending appeal pursuant to section 705 of the Administrative Procedure Act. The Fifth Circuit's ruling is legally erroneous, creates regulatory and administrative chaos nationwide, and undermines the ability of millions of people to access lawful medical care.

Amici States of New York, Arizona, California, Colorado, Connecticut, Delaware, Hawai'i, Illinois, Maryland, Massachusetts, Michigan, Minnesota, Nevada, New Jersey, New Mexico, North Carolina, Oregon, Rhode Island, Vermont, Virginia, Washington, and the District of Columbia, and the Governor of Pennsylvania submit this brief in support of applicants' emergency requests for a stay of the Fifth Circuit's ruling. Mifepristone has been widely and safely used for more than two decades in the United States and across the world for termination of early pregnancies and management of early pregnancy loss. The regulatory removal of unnecessary restric-

tions on mifepristone, including the in-person dispensing requirement, has proven crucial to amici in improving abortion access for their residents, particularly in low-income, underserved, and rural communities, which experience higher rates of birth-related mortality and morbidity, and where access to health care is generally far more limited.

Amici States therefore have a strong interest in preserving the availability of access to mifepristone by telemedicine (also known as telehealth) specifically, and in ensuring high-quality, science-driven patient care within their borders more generally. Many amici operate public hospitals, clinics, and other facilities that provide health care and pharmaceutical services and public universities that provide health care services to their employees and students. Through their elected officials, amici also act to protect and promote the health, safety, and welfare of their residents. The continued availability of mifepristone, in accordance with sound medical guidelines, is therefore critical to safeguarding amici's important interest in protecting the health, safety, and rights of their residents to access essential reproductive health care, and the right of the professionals employed in their health care facilities to provide it.

Plaintiffs' request for preliminary relief in the Fifth Circuit was chiefly predicated on their disagreement with the legislative and policy judgments of States that have chosen to expand rather than to restrict access to abortion following the Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization*, 597 U.S. 215 (2022). After *Dobbs*, many States, including several amici, enacted constitutional and

statutory measures codifying the right to abortion under state law, directed funding toward expanding capacity and upgrading facilities to meet increased demand, and passed laws intended to support persons seeking and providing abortion care within their jurisdictions. Several such initiatives have focused specifically on increasing access to medication abortion, in light of its unique benefits and accessibility. The enactment and implementation of such state laws is beyond the regulatory authority of the FDA; by statute, the agency's authority is limited to evaluating the safety and efficacy of medications. The mere fact that some States have chosen to promote, rather than to restrict, access to abortion, does not justify judicial relief against the FDA.

More fundamentally, the Fifth Circuit's order runs roughshod over the Supreme Court's recognition in *Dobbs* that "the people of the various States may evaluate" the interests of a woman who wants an abortion and the interests in fetal life differently, 597 U.S. at 256, and the Court's determination to "return the issue of abortion to the people's elected representatives," *id.* at 232. Amici's efforts to protect and expand access to abortion more generally, and to medication abortion specifically, are a result of the "constitutional processes of democratic self-government," *id.* at 346 (Kavanaugh, J., concurring). Ultimately, such laws and policies represent a value judgment that the privacy, bodily autonomy, and dignity of all pregnant people include the ability to decide whether to continue or terminate a pregnancy free from government interference. The Fifth Circuit has placed a federal thumb on the scale in favor of States that have made contrary policy choices, but that is the exact opposite of what this Court directed in *Dobbs*.

ARGUMENT

POINT I

MEDICATION ABORTION IS A SAFE AND EFFECTIVE METHOD FOR TERMINATING PREGNANCIES

By the age of forty-five, approximately one in four women in the United States will have had an abortion and at least as many will have had a miscarriage.[1] Mifepristone, in a regimen with misoprostol, is the standard method to terminate a pregnancy through ten weeks' gestation,[2] and it is commonly used by physicians to complete the termination of a pregnancy once a miscarriage has begun.[3] Although both procedural abortion and medication abortion are extremely safe, and individuals may choose one or the other option for different reasons, medication abortion offers significant benefits in terms of flexibility, privacy, and accessibility. Among other benefits, medication abortion promotes access to abortion as early as possible, when it is safest and least

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[1] Jessica Beaman et al., *Medication to Manage Abortion and Miscarriage*, 35 J. Gen. Internal Med. 2398, 2398 (2020); *see* Am. Coll. of Obstetricians & Gynecologists, *Early Pregnancy Loss: Frequently Asked Questions* (last updated Sept. 2024) ("How common is early pregnancy loss?").

[2] *See* U.S. Food & Drug Admin., *Information About Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation* (last updated Jan. 17, 2025).

[3] Courtney A. Schreiber et al., *Mifepristone Pretreatment for the Medical Management of Early Pregnancy Loss*, 378 N. Engl. J. Med. 2161, 2169 (2018); Justin J. Chu et al., *Mifepristone and Misoprostol Versus Misoprostol Alone for the Management of Missed Miscarriage (MifeMiso): A Randomised, Double-Blind, Placebo-Controlled Trial*, 396 Lancet 770, 777 (2020).

expensive, and has contributed to an increase in the proportion of pregnancy terminations taking place earlier than six weeks gestation.[4]

Since its approval in 2000, an estimated 7.5 million people in the U.S. have used mifepristone to terminate a pregnancy,[5] and medication abortion now accounts for 63% of all abortions performed in the formal U.S. health system nationwide.[6] In many States, including in several amici States, the use of medication abortion is even higher. For instance, in 2023, approximately 64% of the abortions performed in Massachusetts and 71% of the abortions performed in California were done by medication.[7]

The extensive experience of many of the amici States confirms what numerous scientific studies have demonstrated: mifepristone is extraordinarily safe and effective and an integral component of reproductive health care. A comprehensive survey of abortion care in the U.S. by the National Academies of Sciences, Engineering, and Medicine in 2018 concluded that medication abortion involving mifepristone is 96.7% effective and that complications are rare, i.e., "occurring in no more than a fraction of

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[4] *See* Nat'l Acads. of Scis., Eng'g & Med. (NASEM), *The Safety and Quality of Abortion Care in the United States* 5, 28-29 (2018).

[5] *See* U.S. Food & Drug Admin., *Mifepristone U.S. Post-Marketing Adverse Events Summary Through 12/31/2024* (n.d.).

[6] Rachel K. Jones et al., Guttmacher Inst., *Medication Abortion Accounted for 63% of All US Abortions in 2023—An Increase from 53% in 2020* (Mar. 19, 2024).

[7] *See* Mass. Dep't Public Health, *Massachusetts Induced Termination of Pregnancy 2023*, at 5 (Nov. 2024); KFF, *California Abortion Data* (n.d.).

a percent of patients."[8] The World Health Organization includes the mifepristone/misoprostol regimen in its guidelines for abortion care,[9] and has long included the combination regimen in its Model List of Essential Medicines—i.e., those medicines "that satisfy the priority health care needs of a population" and "are intended to be available in functioning health systems at all times."[10]

Mifepristone's safety record is so conclusive that leading medical associations, as well as several amici, have advocated that the FDA's Risk Evaluation and Mitigation Strategy (REMS) designation for the drug be eliminated altogether, viewing it as outdated and medically unjustified.[11] And in October 2025, a federal district court in Hawai'i held that the FDA's decision to retain certain prescribing and dispensation restrictions on mifepristone was arbitrary and capricious because of the overwhelming record of the drug's safety and efficacy, and remanded to the agency without vacatur for a new analysis. *See Purcell v. Kennedy*, No. 1:17-cv-493, 2025 WL 3101785, at *2 (D. Haw. Oct. 30, 2025).

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[8] *See* NASEM, *supra*, at 53, 55; *accord* Mary Gatter et al., *Efficacy and Safety of Medical Abortion Using Mifepristone and Buccal Misoprostol Through 63 Days*, 91 Contraception 269, 270 (2015).

[9] *See* World Health Org., *Abortion Care Guideline* xxix, 16-17, 67-68 (2022).

[10] World Health Org., *WHO Model List of Essential Medicines - 22nd List, 2021* (Sept. 30, 2021).

[11] *See, e.g.*, Pet. of Am. Coll. of Obstetricians & Gynecologists et al. 2 (Jan. 31, 2025), FDA-2025-P-0377; Pet. of Andrea Joy Campbell, Att'y Gen. of Mass., et al. 2 (June 5, 2025), FDA-2025-P-1576-0001; Pet. of Nick Brown, Att'y Gen. of Wash., et al. 2 (Aug. 20, 2025), FDA-2025-P-3287-0001; *see also* Am. Coll. of Obstetricians & Gynecologists, *Leading Medical Organizations Reaffirm the Safety of Mifepristone* (May 22, 2025).

Years of clinical use have also shown that mifepristone can safely be provided in a variety of contexts and practice areas, including, for example, in a private physician's office, an obstetrician-gynecologist or family practice setting, or at home under appropriate medical supervision, offering added flexibility, privacy, and security for both patients and providers.[12] As the FDA observed, mifepristone's safety record is "well-characterized" and "has not changed over the period of surveillance."[13]

POINT II

THE ELIMINATION OF THE IN-PERSON DISPENSING REQUIREMENT IS CLINICALLY SUPPORTED AND HAS SUBSTANTIAL BENEFITS

The FDA's decision to remove the in-person dispensing requirement was amply supported by scientific data and consistent with the agency's statutory obligation to remove unnecessary barriers to medication access. *See* 21 U.S.C. § 355-1(f)(2). The decision was backed by an extensive literature review,[14] as well as mifepristone's stable safety record during the COVID-19 pandemic when the agency forbore from enforcing the in-person dispensing requirement. Subsequent research has shown no change in mifepristone's safety profile following changes to mifepristone's labeling,

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[12] *See* NASEM, *supra*, at 10, 58.

[13] U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Research, *REMS Modification Rationale Review* 15 (Dec. 16, 2021); *see also* Letter from Ctr. for Drug Evaluation & Research, U.S. Food & Drug Admin., to Am. Ass'n of Pro-Life Obstetricians & Gynecologists & Am. Coll. of Pediatricians at 20 (Dec. 16, 2021).

[14] U.S. Food & Drug Admin., *REMS Modification Rationale Review*, *supra*, at 24-36 (discussing studies).

prescribing, and dispensing requirements, including the elimination of the in-person dispensing requirement.

Indeed, numerous studies have further confirmed that medication abortion care provided by telehealth is highly safe and effective,[15] and that patients are highly satisfied with telehealth medication abortion care.[16] For example, one study of nearly 3,800 patients who received medication abortion either in-person or through telehealth "found high effectiveness and safety rates" overall, with "similarly high effectiveness and safety rates comparing patients who received medications in-person vs by mail."[17] Another study of over 6,000 patients who obtained medication abortion via telehealth between April 2021 to January 2022 found an overall effectiveness rate

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[15] *See, e.g.*, Jane W. Seymour et al., *Potential Impact of Telemedicine for Medication Abortion Policy and Programming Changes on Abortion Accessibility in the United States*, 112 Am. J. Pub. Health 1202 (2022); Samantha P. Ruggiero et al., *Patient and Provider Experiences Using a Site-to-Site Telehealth Model for Medication Abortion*, 8 Health 32 (2022); Abigail R.A. Aiken et al., *Safety and Effectiveness of Self-Managed Medication Abortion Provided Using Online Telemedicine in the United States: A Population Based Study*, 10 Lancet Reg'l Health - Americas, no. 100200 (2022); Ushma D. Upadhyay et al., *Outcomes and Safety of History-Based Screening for Medication Abortion: A Retrospective Multicenter Cohort Study*, 182 JAMA Intern. Med. 482, 488-89 (2022); Ushma D. Upadhyay et al., *Safety and Efficacy of Telehealth Medication Abortions in the US During the COVID-19 Pandemic*, 4 JAMA Netw. Open, no. e2122320, at 1-2 (2021).

[16] *See, e.g.*, Courtney Kerestes et al., *Person-Centered, High-Quality Care from a Distance: A Qualitative Study of Patient Experiences of TelAbortion, a Model for Direct-to-Patient Medication Abortion by Mail in the United States*, 54 Persps. on Sexual & Reprod. Health 177 (2022); Leah R. Koenig et al., *Mailing Abortion Pills Does Not Delay Care: A Cohort Study Comparing Mailed to In-Person Dispensing of Abortion Medications in the United States*, 121 Contraception, no. 109962 (2023).

[17] Upadhyay et al., *Outcomes and Safety of History-Based Screening for Medication Abortion*, *supra,* at 488-89; *see also* Lauren J. Ralph et al., *Comparison of No-Test Telehealth and In-Person Medication Abortion*, 332 JAMA 898 (2024).

of 97.7% and an overall safety rate of 99.7%.[18] A 2024 study likewise concluded that telehealth medication abortion is "as effective, timelier, and potentially more accessible than in-clinic care."[19] Given this overwhelming weight of evidence, numerous medical organizations including the National Abortion Federation, the American College of Obstetricians and Gynecologists, and the Society of Family Planning have issued clinical practice guidelines supporting the provision of telehealth medication abortion care.[20] While a majority of abortions in the U.S. health system still occur in person, a growing number—27% in 2025 as compared to 5% in 2022—now take place via telemedicine.[21]

The FDA's elimination of the in-person dispensing requirement was also consistent with the agency's statutory obligation to ensure that any restrictions on approved medications impose minimal burdens on access, particularly for those patients "who have difficulty accessing health care (such as patients in rural or

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[18] Ushma D. Upadhyay et al., *Effectiveness and Safety of Telehealth Medication Abortion in the USA*, 30 Nature Med. 1191 (2024).

[19] Silpa Srinivasulu et al., *Telehealth Medication Abortion in Primary Care: A Comparison to Usual in-Clinic Care*, 37 J. Am. Bd. Fam. Med. 295, 299 (2024).

[20] Nat'l Abortion Fed'n, *2024 Clinical Policy Guidelines for Abortion Care* 1 (2024) (explaining that "[t]elemedicine can be safely used to provide abortion care, including medication abortion provision, informed consent, and follow-up"); Am. Coll. of Obstetricians & Gynecologists & Soc'y of Fam. Plan., Prac. Bull. No. 225, *Medication Abortion Up to 70 Days of Gestation*, 136 Obstetrics & Gynecology e31, e35 (2020, reaff'd 2023) ("Medication abortion can be provided safely and effectively by telemedicine with a high level of patient satisfaction, and telemedicine improves access to early abortion care, particularly in areas that lack a health care practitioner.").

[21] Soc'y of Fam. Plan., *#WeCount Report, April 2022 to June 2025*, at 1 (Dec. 9, 2025).

medically underserved areas)," and on the health care delivery system as a whole. *See* 21 U.S.C. § 355-1(f)(2). Removal of the requirement has allowed clinicians to offer medication abortion services remotely, where otherwise lawful, by conducting patient intake, examination, and follow-up via telephone or videoconference and enabling patients to obtain the medication through certified mail-order or certified retail pharmacies.[22] Elimination of the in-person dispensing requirement has also enabled clinicians in brick-and-mortar clinics to prescribe the medication to patients in person for pick-up by the patient at a pharmacy, eliminating the need for health care providers to keep a supply of the medications on-site.

These changes have been critical to extending access for amici's residents in rural and underserved communities where barriers to abortion and other forms of health care are most acute.[23] The availability of abortion care by telehealth has reduced the impact of many practical and cost barriers that can make it difficult for many people to obtain an abortion—including childcare needs, missed work and resulting lost income, lack

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[22] Plaintiffs asserted below that the federal Comstock Act prohibits the distribution of mifepristone by mail. *See* Pls.' Mem. of Law in Support of Mot. for Prelim. Relief at 13-14 (W.D. La. Dec. 17, 2025), ECF No. 20-26. Although a discussion of the Comstock Act is beyond the scope of this brief, amici States note that plaintiffs' interpretation of the Comstock Act has been expressly rejected as having potentially boundless effects on medical care delivery, ostensibly preventing distribution of a host of devices, surgical instruments, and equipment used in obstetrics and gynecology and beyond, as well as numerous drugs routinely used to treat countless diseases and conditions. *See, e.g.*, *Youngs Rubber Corp. v. C. I. Lee & Co.*, 45 F.2d 103, 108 (2d Cir. 1930); Application of the Comstock Act to the Mailing of Prescription Drugs That Can Be Used for Abortions, 46 Op. O.L.C. (Dec. 23, 2022) (slip op. at 1-2).

[23] Liza Fuentes & Jenna Jerman, *Distance Traveled to Obtain Clinical Abortion Care in the United States and Reasons for Clinic Choice*, 28 J. Women's Health 1623, 1627 (2019).

of insurance coverage, and travel costs and logistics.[24] Telehealth is also generally less expensive than in-person care. As one study found, "[t]he median cost of a medication abortion offered in-person increased from $580 in 2021 to $600 by 2023," while "[t]he median price of a medication abortion offered by virtual clinics decreased from $239 in 2021 to $150 in 2023."[25]

Many state and local governments, including in many amici States, have expended substantial resources to increase access to mifepristone, both through in-person care and via telemedicine. In Maine, which has among the highest rates of rural residents in the U.S., a major clinic network has made medication abortion available at its health centers via telemedicine.[26] New York City offers free medication abortion at several public health clinics serving primarily low-income New Yorkers.[27] And several amici States, including Massachusetts, New York, and California, have taken steps to extend access to public university students by making medication

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[24] *See id.* at 1623-24; Sarah Varney, *Long Drives, Air Travel, Exhausting Waits: What Abortion Requires in the South*, KFF Health News (Aug. 3, 2021); Jenna Jerman et al., *Barriers to Abortion Care and Their Consequences for Patients Traveling for Services: Qualitative Findings from Two States*, 49 Persps. on Sexual & Reprod. Health 95, 98 (2017); Rachel K. Jones & Jenna Jerman, Guttmacher Inst., *Time to Appointment and Delays in Accessing Care Among U.S. Abortion Patients* (Aug. 2016).

[25] Ushma D. Upadhyay et al., *Pricing of Medication Abortion in the United States, 2021-2023*, 56 Persps. on Sexual & Reprod. Health 282, 282 (2024).

[26] *See* Kanya D'Almeida, *Telemedicine Abortion Care Is Coming to Maine*, Rewire News Grp. (Feb. 29, 2016).

[27] *See* Elizabeth Kim, *NYC Will Offer Free Abortion Pills at 4 City-Run Sexual Health Clinics*, Gothamist (Jan. 17, 2023).

abortion available through campus health centers.[28] In addition, nearly seventy virtual clinics in twenty-three States and the District of Columbia currently offer medication abortion via telemedicine.[29] Reinstating the in-person dispensing requirement for mifepristone would undermine the significant efforts to promote access within those States.

POINT III

THE FIFTH CIRCUIT'S ORDER INTERFERES WITH AMICI STATES' SOVEREIGN AUTHORITY TO PROMOTE ACCESS TO REPRODUCTIVE HEALTH CARE FOR THEIR RESIDENTS

Absent immediate relief from this Court, the Fifth Circuit's nationwide "stay" of the FDA's elimination of an in-person dispensing requirement that has not been enforced since 2021 will have a "needlessly chaotic and disruptive effect," *Benisek v. Lamone*, 585 U.S. 155, 161 (2018) (quotation marks omitted), especially in amici States.

As explained above, over a quarter of abortions in the United States currently take place via telemedicine,[30] and many States and private providers have invested resources and established infrastructure to offer medication abortion via telemedi-

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[28] *See* N.Y. Educ. Law § 6438-b; Mass. Gen. Laws ch. 15A, § 46; Cal. Educ. Code § 99251.

[29] *See* Advancing New Standards in Reprod. Health (ANSIRH), Issue Brief, *Availability of Telehealth Services for Medication Abortion in the U.S., 2020-2022*, at 2 (June 2023).

[30] *See* Amelia Thomson-DeVeaux, *Virtual Abortions Surged After Roe Was Overturned—But the Texas Ruling Could Change That*, FiveThirtyEight (Apr. 11, 2023); Soc'y of Fam. Plan., *#WeCount Report*, *supra,* at 1; ANSIRH, *supra,* at 1-2.

cine. Reinstating the requirements of in-person dispensing for mifepristone would severely interfere with access to this crucial medication via telemedicine, reimposing unnecessary travel-related costs and delays on amici's residents forced to seek care in person. These burdens are especially notable for amici States, many of whom have experienced a steep rise in demand at clinics from out-of-state patients after *Dobbs*.[31] While providers have endeavored to meet the increased demand, the influx has stretched clinics past their already-strained capacity and has dramatically increased wait times for patients from both within and outside of their States.[32] Restricting access to medication abortion via telemedicine would hinder amici States' efforts to meet this demand.

To be sure, there have long been practical and financial obstacles to obtaining abortion care. But the threats to and ultimate loss of a federal constitutional right to abortion brought those inequities into sharper relief, leading many amici States to reaffirm their commitments not only to safeguarding the right to abortion, but also to dismantling barriers to accessing essential reproductive health care.[33] Denial of

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[31] *See* Soc'y of Fam. Plan., *#WeCount Report*, *supra*, at 3-4.

[32] *See* Margot Sanger-Katz et al., *Interstate Abortion Travel Is Already Straining Parts of the System*, N.Y. Times (July 23, 2022); Angie Leventis Lourgos, *Abortions in Illinois for Out-of-State Patients Have Skyrocketed. And Some Wait Times Are Exceeding Three Weeks*, Chi. Trib. (Aug. 2, 2022); Oriana González & Nicole Cobler, *Influx of Out-of-State Patients Causes Abortion Delays*, Axios (Sept. 12, 2022); Matt Bloom & Bente Berkland, *Wait Times at Colorado Clinics Hit Two Weeks as Out-of-State Patients Strain System*, KSUT (July 28, 2022).

[33] *See, e.g.*, Cal. Const. art. I, § 1.1; Cal. Health & Safety Code § 123453; 775 Ill. Comp. Stat. Ann. 55/1-1 et seq.; Me. Rev. Stat. Ann. tit. 22, § 1598; Act of July 29,

(*continued on the next page*)

abortion care is associated with numerous harms, including poor birthing and infant health outcomes, higher rates of poverty, and lower educational attainment for both parents and children.[34] Allowing an unnecessary obstacle to medication abortion to once again take effect will frustrate amici States' efforts to prevent these harms, allowing them to proliferate even in States where abortion remains lawful and protected.

Reinstating an in-person dispensing requirement for mifepristone would also impede provision of other forms of critical health care in amici States. The same facilities that provide abortion care often offer other essential services, such as pre- and postnatal care, family planning, cancer screening, testing and treatment for sexually transmitted infections and HIV, and other forms of necessary preventative health care. Increased demand for in-person appointments for medication abortion and an increase in procedural abortions will likely delay access to all forms of care offered at those facilities, inevitably resulting in higher rates of unintended pregnancy and sexually transmitted infections, barriers to early detection and treatment for breast, ovarian, and testicular cancers and chronic diseases, and worsened overall health

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2022, Ch. 127, 2022 Mass. Acts 740; N.J. Stat. Ann. § 10:7-1; *id.* § 2A:160-14.1; N.Y. Pub. Health Law § 2599-aa; N.Y. Educ. Law § 6438-b; Vt. Stat. Ann. tit. 18, § 9493 et seq.

[34] *See, e.g.*, Diana G. Foster, *The Turnaway Study: Ten Years, a Thousand Women, and the Consequences of Having—or Being Denied—an Abortion* (2020); Diana G. Foster et al., *Effects of Carrying an Unwanted Pregnancy to Term on Women's Existing Children*, 205 J. Pediatrics 183, 187-88 (2019); Heidi D. Nelson et al., *Associations of Unintended Pregnancy with Maternal and Infant Health Outcomes: A Systematic Review and Meta-Analysis*, 328 JAMA 1714, 1727-29 (2022).

outcomes.[35] Underserved groups, including women of color, low-income women, people with disabilities, and LGBTQ+ individuals, will be hardest hit.[36]

The Fifth Circuit was mistaken for several reasons in asserting that reinstatement of the in-person dispensing requirement is necessary to protect the sovereign interests of States that have decided to restrict access to abortion (*see* CA5 Order at 14, 16). First, the FDA's role in determining whether and what REMS are appropriate is limited to whether a restriction "is necessary to ensure that the benefits of the drug outweigh the risks of the drug." 21 U.S.C. § 355-1(a)(1). The FDA decision to impose or eliminate an in-person dispensing requirement does not address the question of whether individual States may impose their own additional regulatory restrictions; the FDA REMS do not legalize or prohibit abortion in any jurisdiction.

Second, there is no indication that the FDA eliminated the in-person dispensing requirement for the purpose of frustrating state abortion prohibitions. The in-person dispensing requirement was first suspended by court order in 2020 during the COVID-19 pandemic and then through enforcement forbearance starting in 2021—all before *Dobbs* and before state abortion bans took effect. The FDA's 2021 review of mifepristone's REMS was likewise initiated prior to *Dobbs*, and there is no indication

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[35] *See* Julia Strasser et al., *Penalizing Abortion Providers Will Have Ripple Effects Across Pregnancy Care*, Health Affs. (May 3, 2022).

[36] *See* Liza Fuentes, Guttmacher Inst., *Inequity in US Abortion Rights and Access: The End of Roe Is Deepening Existing Divides* (Jan. 17, 2023); Theresa Chalhoub & Kelly Rimar, *The Health Care System and Racial Disparities in Maternal Mortality*, Ctr. for Am. Progress (May 10, 2018); Christine Dehlendorf et al., *Disparities in Family Planning*, 202 Am. J. Obstetrics & Gynecology 214, 215 (2010).

in the 2023 culmination of that review that the agency's evaluation of the in-person dispensing requirement was related to any state abortion bans.

Third, and most fundamentally, state laws protecting access to abortion in other States in no way preclude Louisiana or other similarly situated States from enforcing their own abortion laws. Plaintiffs chiefly complain about laws passed by certain States that prohibit state and local government officials and courts from enforcing out-of-state judgments for abortion care administered lawfully in the home State. Louisiana cannot complain that coequal sovereign States have declined to use their resources to facilitate the enforcement of Louisiana's abortion bans, because "each sovereignty is free to determine what conduct shall be proscribed within its jurisdiction," and "the wrong committed by violating such proscription" does not automatically cross state lines. *Farmland Dairies v. Barber*, 65 N.Y.2d 51, 56-57 (1985). In finding that nationwide preliminary relief was in the public interest, the Fifth Circuit improperly elevated the policy preferences of States that have banned or restricted abortion over the preferences of other States that have made the different but equally sovereign determinations to promote access to abortion care.

CONCLUSION

This Court should grant the applications for a stay.

Dated: New York, New York
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