Nos. 23-235, 23-236

IN THE

# Supreme Court of the United States

FOOD AND DRUG ADMINISTRATION, et al.,
*Petitioners*,
v.
ALLIANCE FOR HIPPOCRATIC MEDICINE, et al.,
*Respondents*.

DANCO LABORATORIES, L.L.C.,
*Petitioner*,
v.
ALLIANCE FOR HIPPOCRATIC MEDICINE, et al.,
*Respondents*.

**ON PETITIONS FOR WRITS OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT**

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


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## INTRODUCTION AND INTERESTS OF AMICI CURIAE

Amici States of New York, Arizona, California, Colorado, Connecticut, Delaware, Hawai'i, Illinois, Maine, Maryland, Massachusetts, Michigan, Minnesota, Nevada, New Jersey, New Mexico, North Carolina, Oregon, Pennsylvania, Rhode Island, Vermont, Washington, and Wisconsin, and the District of Columbia submit this brief in support of petitioners United States Food and Drug Administration (FDA) and Danco Laboratories, Inc. and urge this Court to grant the petitions for a writ of certiorari.[1] The petitions ask this Court to review a decision of the U.S. Court of Appeals for the Fifth Circuit purporting to retroactively "stay" various regulatory decisions made by the FDA to eliminate medically unnecessary restrictions on the dispensation of mifepristone, which, in combination with the drug misopristol, is the only drug approved by the FDA for medication abortion.

Amici States have a strong interest in the meaningful availability of mifepristone specifically, and in ensuring high-quality, science-driven patient care within their borders more generally. Amici operate public hospitals and other facilities that provide health care and pharmaceutical services, run public universities that provide health care services to their employees and students, and otherwise act in numerous ways to protect the health, safety, and welfare of their residents. In all these activities, amici rely on the availability of mifepristone, which is an essential component of comprehensive reproductive health care, accounting for

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[1] Amici timely notified counsel of record of their intent to file this brief. *See* Sup. Ct. Rule 37.2(a).

a majority of first-trimester abortions performed in the United States and also representing the recommended treatment for early pregnancy loss. The availability of mifepristone has proven critical to amici in improving abortion access, particularly in low-income, underserved, and rural communities, which experience higher rates of birth-related mortality and morbidity, and where nonmedication abortion procedures (i.e., "procedural abortions") may be unavailable. Accordingly, the continued availability of mifepristone in accordance with sound scientific guidelines is critical to safeguarding amici States' important interest in protecting the health, safety, and rights of their residents to access essential reproductive health care.

If permitted to take effect,[2] the Fifth Circuit's poorly reasoned decision regarding the appropriate labeling and dispensation requirements for mifepristone could disrupt access to the most common method of abortion, harming countless individuals in need of abortion care or management of pregnancy loss, with widespread implications for the health care system. Among other things, the ruling could lead many individuals to undergo unwanted procedural abortions; push abortion procedures to later in pregnancy; drive up risks, costs, and delays; and deprive many individuals of access to reproductive health care altogether. The ruling would also create widespread confusion among providers, distributers, and pharmacies, and radically destabilize the regulatory process for drug approvals, stifling scientific innovation and imperiling the development and availability of thousands of drugs nationwide.

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[2] The decision is currently stayed by order of this Court. *See Danco Lab'ys, LLC v. Alliance for Hippocractic Med.*, 143 S. Ct. 1075 (Mem) (Apr. 21, 2023).

The harms from the Fifth Circuit's unfounded decision would gravely undermine the sovereign legislative and policy judgments of those States, including many amici, that have chosen to expand rather than to restrict access to abortion in the wake of *Dobbs v. Jackson Women's Health Organization*, 142 S. Ct. 2228 (2022). Such choices by many amici States—to, for example, implement constitutional and statutory measures to safeguard the right to abortion care, improve abortion access within their borders including to medication abortion, provide additional funding to increase capacity, upgrade facilities to meet increased demand, and support out-of-state travel—are entirely consistent with this 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, *id.* at 2257, and the Court's determination to "return the issue of abortion to the people's elected representatives," *id.* at 2243. If allowed to take effect, the Fifth Circuit's erroneous and overreaching ruling could trammel these state legislative and policy judgments and harm our residents.

## STATEMENT

The experience of many of the amici States confirms what numerous studies have demonstrated: mifepristone is extraordinarily safe and effective and an integral component of reproductive health care. Since its approval in 2000, an estimated 5.6 million women in the U.S. have used mifepristone to terminate a pregnancy,[3] and

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[3] *See* U.S. Food & Drug Admin., *Mifepristone U.S. Post-Marketing Adverse Events Summary through 06/30/2022* (n.d.).

medication abortion now accounts for more than half of all abortions performed nationwide.[4]

The FDA's determination that mifepristone is safe and effective is based on ample, high-quality evidence gleaned from more than a quarter century of clinical research and practice in the U.S. and globally.[5] For example, a recent comprehensive survey of abortion care in the U.S. by the National Academies of Sciences, Engineering, and Medicine concluded that medication abortion using mifepristone is 96.7% effective and that complications are rare, i.e., "occurring in no more than a fraction of a percent of patients."[6] The World Health Organization includes the mifepristone/misoprostol regimen in its guidelines for abortion care,[7] and has long included the combination regimen in its Model List of Essential Medicines.[8]

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[4] Rachel K. Jones et al., Guttmacher Inst., *Medication Abortion Now Accounts for More than Half of All US Abortions* (last updated Dec. 1, 2022).

[5] *See* U.S. Food & Drug Admin., *Questions and Answers on Mifepristone for Medical Termination of Pregnancy through Ten Weeks Gestation* (last updated Sept. 1, 2023); U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Rsch., *Risk Evaluation and Mitigation Strategy (REMS) Memorandum: REMS Modification* (Mar. 29, 2016); *see also* U.S. Gov't Accountability Off., *Food and Drug Administration: Information on Mifeprex Labeling Changes and Ongoing Monitoring Efforts* (2018).

[6] Nat'l Acads. of Scis., Eng'g & Med., *The Safety and Quality of Abortion Care in the United States* 10, 55 (2018) (hereinafter "NASEM, *Safety and Quality of Abortion Care*"); *accord* Mary Gatter et al., *Efficacy and Safety of Medical Abortion Using Mifepristone and Buccal Misoprostol Through 63 Days*, 91 Contraception 269, 270 (2015).

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

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

Since 2016, the FDA has taken steps to align mifepristone's Risk Evaluation and Mitigation Strategy (REMS) and labeling more closely with clinical protocols and eliminate medically unnecessary barriers to access. In addition to approving the generic version of the drug,[9] the FDA expanded the approved period of use from seven to ten weeks of pregnancy, eliminated the requirement that it be dispensed only by physicians, lifted the requirement for multiple follow-up visits, and eliminated the in-person dispensing requirement—first, on an emergency basis due to the Covid-19 pandemic, and then, as a final determination.[10] These actions comport with amici States' experience of the safe use of the medication by millions of women within their borders, and with medical evidence showing that medication abortion can safely be provided in a variety of contexts and practice areas, including, for example, in a private physician's office, an ob-gyn or family practice setting, or at home under appropriate medical supervision.[11] Indeed, mifepristone's safety record is so conclusive that major medical associations, as well as several amici States, have advocated that the REMS

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[9] The FDA's approval of the generic version of mifepristone in 2019 rested on the same body of evidence, supplemented with additional safety data gleaned from nearly two additional decades of use. *See* FDA, *Questions & Answers*, *supra*; *see also* U.S. Food & Drug Admin., *Abbreviated New Drug Application Approval Letter for Mifepristone Tablets, 200 mg*, ANDA No. 091178 (Apr. 11, 2019). The Fifth Circuit reversed the district court's stay of the approval of the generic drug. *See* Pet. App. 4a, 43a.

[10] FDA, *Questions and Answers*, *supra*; FDA, *Risk Evaluation and Mitigation Strategy*, *supra*; Letter from Patrizia Cavazzoni, Dir., Ctr. for Drug Evaluation & Rsch., to Graham Chelius, Soc'y of Fam. Plan., Cal. Acad. of Fam. Physicians (Dec. 16, 2021).

[11] *See* NASEM, *Safety and Quality of Abortion Care*, *supra*, at 10.

designation be eliminated altogether, viewing it as "outdated" and medically unjustified.[12]

In amici States' experience, the FDA's actions in lifting these unnecessary restrictions have greatly benefitted their residents, the health care system, and the public fisc. Medication abortion promotes access to abortion as early as possible, when it is safest and least expensive, and has contributed to an increase in the proportion of pregnancy terminations taking place at less than six weeks gestation, when risks are lowest.[13] Mifepristone is also critical to managing early pregnancy loss.[14] Moreover, the availability of medication abortion within mainstream medical settings offers added privacy and security for both patients and providers—benefits that are particularly critical given persistent and escalating violence at abortion clinics.[15]

Furthermore, promoting availability of medication abortion has been a key strategy to improve access in rural and underserved communities where barriers to

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[12] *See* Letter from Michael L. Munger, Bd. Chair, Am. Acad. of Fam. Physicians, to Norman Sharpless, Acting Comm'r, U.S. Food & Drug Admin. (June 20, 2019); Am. Coll. of Obstetrics & Gynecology, *Position Statement: Improving Access to Mifepristone for Reproductive Health Indications* (Mar. 2021). Seventeen amici States are also plaintiffs in a lawsuit asserting the FDA's decision in 2023 to retain certain aspects of the REMS was arbitrary and capricious because it singles out an exceptionally safe drug for uniquely burdensome restrictions. *See* Am. Compl. at 4 ¶ 5, *Washington v. FDA*, No. 23-cv-03026 (E.D. Wash. Mar. 9, 2023), ECF No. 35.

[13] *See* NASEM, *Safety and Quality of Abortion Care*, *supra*, at 5, 28-29.

[14] Kurt Barnhart, *Medical Management of Miscarriage with Mifepristone*, 396 Lancet 737 (2020).

[15] *See* Nat'l Abortion Fed'n, *2021 Violence and Disruption Report* (June 24, 2022).

abortion access are most acute.[16] According to 2020 data, 89% of U.S. counties, predominantly in rural areas, had no abortion clinic and 38% of women of reproductive age resided in such a county.[17] Patients in rural areas were eight times as likely as urban patients to travel more than 100 miles for abortion care.[18] Removal of the requirements for in-person dispensing and multiple follow-up visits, where otherwise lawful, has permitted clinicians to offer medication abortion services entirely remotely, by conducting patient intake, examination, and follow-up via telephone or videoconference and enabling patients to obtain the medication through properly certified mail-order or retail pharmacies.[19]

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[16] *See* Liza Fuentes, Guttmacher Inst., *Inequity in US Abortion Rights and Access: The End of* Roe *Is Deepening Existing Divides* (Jan. 17, 2023).

[17] Rachel K. Jones et al., *Abortion Incidence and Service Availability in the United States, 2020*, 54 Perspectives in Sexual & Reprod. Health 125, 134 (2022).

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

[19] Respondents asserted below that the federal Comstock Act prohibits the distribution of mifepristone by mail because the statute purportedly "prohibits the mailing or delivery of '[e]very article or thing designed, adapted, or intended for producing abortion.'" *See* Br. for Appellees at 58-63 (May 8, 2023), ECF 380 (quoting 18 U.S.C. §§ 1461-1462)). The U.S. Department of Justice's Office of Legal Counsel disagrees and has concluded that the Comstock Act restricts only the sending of items intended for use in unlawful abortions. *See* Application of the Comstock Act to the Mailing of Prescription Drugs That Can Be Used for Abortions, 46 Op. O.L.C. __, pp. 1-2 (Dec. 23, 2022). Although a discussion of the Comstock Act is beyond the scope of this brief, amici States note that respondents' interpretation of the Comstock Act has been

(*continues on next page*)

Similarly, the extension of prescription authority to clinicians other than physicians has eased the acute shortage of providers in States authorizing advanced practice clinicians such as nurse practitioners and physician assistants to offer abortion services, extending care to underserved areas and freeing physicians to focus on more complex cases and other critical services without compromising patient health.[20]

In reliance on the FDA's regulatory actions, many state and local governments have expended substantial resources in expanding access to mifepristone. For example, in Maine, which has among the highest rates of rural residents in the U.S., a major clinic chain has since 2016 made medication abortion available at its 16 health centers via telemedicine.[21] New York City recently announced it will offer free medication abortion at four public health clinics.[22] And several amici States, including Massachusetts, New York, and California, have taken steps to extend access to public university students by making medication abortion available at

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expressly rejected by courts 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).

[20] Am. Pub. Health Ass'n, Pol'y No. 20112, *Provision of Abortion Care by Advanced Practice Nurses and Physician Assistants* (Nov. 1, 2011); AP Toolkit, *State Abortion Laws and Their Relationship to Scope of Practice* (n.d.).

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

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

campus health centers.[23] The FDA's actions since 2016 have significantly eased constraints on dispensing the medication and allowed amici States to promote access more broadly—efforts to provide health care to our residents that are gravely threatened by the decision below.

## SUMMARY OF ARGUMENT

The petitions raise questions of profound national importance meriting this Court's immediate review. The Fifth Circuit's determination to stay the FDA's post-2016 REMS and labeling decisions could severely limit the availability of medication abortion nationwide, including in amici States where abortion remains legal, consequently making all forms of abortion more difficult to access. Curtailing access to the safest and most common method used for first-trimester abortion would result in more unwanted and costly surgical procedures, increase travel and waiting time to obtain care, and push abortions to later in pregnancy, driving up both costs and medical risks. The resulting obstacles could ultimately deprive numerous people of access to care altogether and increase strain on an already stretched health care system, leading to worse health outcomes across the entire system and compounding existing disparities.

Furthermore, the Fifth Circuit's ruling could foment confusion among providers, distributers, and amici States by reinstating medically unnecessary and outdated protocols. In this case, the Fifth Circuit

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[23] *See* Ch. 129, § 1, 2023 N.Y. Laws (eff. Aug. 1, 2023) (codified at N.Y. Educ. Law § 6438-b); Ch. 127, § 6, 2022 Mass. Acts 740, 743 (eff. July 29, 2022) (codified at Mass. Gen. Laws ch. 15A, § 46); Ch. 740, § 2, 2019 Cal. Stat. 6200, 6202 (eff. Jan. 1, 2020) (codified at Cal. Educ. Code § 99251).

impermissibly overrode the FDA's determinations in defiance of scientific evidence and in a manner that unduly burdens rather than assures safe access to medication. The decision contravenes the mandate of the FDA and undermines the integrity of the FDA-approval process, radically destabilizing the pharmaceutical industry and jeopardizing the development and approval of thousands of innovative drugs and treatments on which amici States and their residents depend to prevent and treat a host of conditions and diseases.

## REASONS FOR GRANTING THE PETITION

### I. The Fifth Circuit's Ruling Could Cause Devastating Harms to Patients and Health Care Systems.

The cumulative consequences of reinstating the medically unnecessary requirements eliminated by the FDA since 2016 could (i) nullify many benefits of mifepristone's availability, particularly in rural and underserved communities; (ii) result in increased delays and denials of abortion care; and (iii) disrupt the delivery of health care nationwide.[24] The FDA's elimination of

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[24] The Fifth Circuit acknowledged that disrupting access to mifepristone would harm patients and burden state and local health care systems—concerns the court recognized were "not insignificant." Pet. App. 68a. Yet the court dismissed these concerns as "apply[ing] primarily (if not wholly) to the challenge to the 2000 Approval." Pet. App. 68a. The court failed to address the extensive evidence of specific harms associated with nullifying the FDA's post-2016 determinations. *See, e.g.*, Br. for State of New York et al. as Amici Curiae at 22-27, *Alliance for Hippocratic Med. v. FDA*, No. 23-10362 (5th Cir. May 4, 2023), ECF 356; *see also* Br. for Amici Curiae the City of New York et al. at 6-8, *Alliance* (May 4, 2023), ECF No. 349.

unnecessary restraints on mifepristone's use and distribution have enabled amici States to vastly improve access to abortion care and further their broader health equity goals. The Fifth Circuit's ruling would undo these gains and, beyond that, pose grave harms to patients and health care systems across the country.

For example, reinstating the in-person dispensing requirement, along with the requirement of two in-person follow-up visits, would effectively eliminate the ability of patients to access mifepristone through telemedicine, thereby multiplying costs and delays.[25] And reviving the physician-only requirement would burden facilities and hospital systems forced to divert provision of medication abortion from advanced practice clinicians, who have been safely prescribing mifepristone for years, back to already-overburdened physicians.[26] These additional hurdles will ultimately result in more later-gestation procedures, increased health risks, and denials of care.[27]

With mifepristone access out of reach, many patients would likely seek procedural abortions—which, although safe, are unnecessarily invasive procedures for those for whom medication abortion would have been

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[25] *See* 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 (2017).

[26] *See* Br. for Amici Curiae City of New York et al., *supra*, at 6.

[27] *See* NASEM, *Safety and Quality of Abortion Care*, *supra*, at 116; Fuentes & Jerman, *Distance Traveled*, *supra*, at 1623; Jill Barr-Walker, *Experiences of Women Who Travel for Abortion: A Mixed Methods Systematic Review*, 14 PLOS ONE e0209991, at 17 (Apr. 9, 2019); Rachel K. Jones & Jenna Jerman, Guttmacher Inst., *Time to Appointment and Delays in Accessing Care Among U.S. Abortion Patients* (Aug. 2016).

recommended, and are generally more costly to provide and to obtain.[28] Others desperate for care will seek abortion medications through online services or overseas pharmacies and self-manage their abortions outside of a medical setting.[29] And many will be denied access to abortion altogether and be forced to carry unwanted pregnancies to term.

Restricting the availability of medication abortion would also exacerbate the drastic reduction in abortion access across large swaths of the country in the wake of *Dobbs*. Abortion is currently unavailable in fourteen States where bans or near-total restrictions are in effect or subject to pending litigation, and extremely limited in several more.[30] States where abortion has been banned or nearly banned since *Dobbs* are home to more than 22 million women of childbearing age, representing almost one third of the total population of women ages 15-49.[31] The number of reported abortions

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[28] *See, e.g.*, Br. for Amici Curiae City of New York et al., *supra*, at 31 (estimating procedural abortion costs five times as much as a medication abortion to provide).

[29] *See* Abigail R.A. Aiken et al., *Requests for Self-Managed Medication Abortion Provided Using Online Telemedicine in 30 US States Before and After the* Dobbs v. Jackson Women's Health Organization *Decision*, 328 JAMA 1768, 1768-70 (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 The Lancet Reg'l Health - Americas 4 (2022); Daniel Grossman & Nisha Verma, *Self-Managed Abortion in the US*, 328 JAMA 1693, 1693-94 (2022).

[30] *See* Ctr. for Reprod. Rts., *After* Roe *Fell: Abortion Laws by State* (n.d.). Numerous state bans or restrictions are subject to pending litigation.

[31] *See* Marielle Kirstein et al., Guttmacher Inst., *100 Days Post*-Roe*: At Least 66 Clinics across 15 US States Have Stopped Offering Abortion Care* (Oct. 6, 2022).

performed in States with bans in effect has dropped to zero or close to zero.[32] Dozens of clinics have been shuttered since the end of June 2022, and distances and travel time to obtain abortion have increased dramatically.[33] For example, between March 2022 and September 2023, the average distance to the closest provider in Texas increased from 43 to 499 miles; in Idaho it increased from 40 to 235 miles.[34] And studies tracking travel patterns for abortion suggest tens of thousands of pregnant people have been unable to obtain abortion care.[35]

Many amici States have experienced a steep rise in demand at clinics from out-of-state patients, with California, Colorado, Illinois, Maryland, New Mexico, and North Carolina experiencing among the greatest increases.[36] The influx has stretched providers past their already-strained capacity and dramatically increased wait times for patients from both within and

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[32] *See* Soc'y of Fam. Plan., *#WeCount Report April 2022 to March 2023*, at 9-10 tbl. 1 (June 15, 2023); *see also* Guttmacher Inst., *Monthly Abortion Provision Study* (n.d.).

[33] *See* Caitlin Myers et al., *Abortion Access Dashboard* (last updated Sept. 1, 2023); Benjamin Rader et al., *Estimated Travel Time and Spatial Access to Abortion Facilities in the US Before and After the* Dobbs v Jackson Women's Health *Decision*, 328 JAMA 2041, 2043-45 (2022).

[34] *See* Caitlin Myers et al., *Abortion Access Dashboard*, *supra.*

[35] Soc'y of Fam. Plan., *#WeCount Report April 2022 to March 2023*, *supra*, at 6; Maggie Koerth & Amelia Thomson-DeVeaux, *Over 66,000 People Couldn't Get An Abortion In Their Home State After Dobbs*, FiveThirtyEight (Apr. 11, 2023).

[36] Soc'y of Fam. Plan., *#WeCount Report April 2022 to March 2023*, *supra*, at 6; Koerth & Thomson-DeVeaux, *Over 66,000 People*, *supra.*

outside of their States.[37] The availability of medication abortion has been a critical tool in meeting these challenges.[38]

Imposing medically unnecessary restraints on access to mifepristone could push providers to the breaking point and may leave many people without access to abortion care at all. Denial of abortion care is in turn associated with numerous harms, including poor birthing and infant health outcomes, higher rates of poverty, and lower educational attainment for both parents and children.[39] And because carrying a pregnancy to term is 14 times more risky than early abortion,[40] curtailing access to medication abortion would likely lead to a steep rise in birth-related mortality

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[37] *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*, Chi. Trib. (Aug. 2, 2022); Oriana Gonzalez & Nicole Cobler, *Influx of Out-of-State Patients Causes Abortion Delays*, Axios (Sept. 12, 2022).

[38] Amelia Thomson-DeVeaux, *Virtual Abortions Surged After* Roe *Was Overturned—But the Texas Ruling Could Change That*, FiveThirtyEight (Apr. 11, 2023).

[39] *See, e.g.*, Diana G. Foster, *The Turnaway Study: Ten Years, a Thousand Women, and the Consequences of Having—or Being Denied—an Abortion* (2021); Diana G. Foster et al., *Effects of Carrying an Unwanted Pregnancy to Term on Women's Existing Children*, 205 J. Pediatrics 183, 186-87 (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, 1714-29 (2022).

[40] Elizabeth G. Raymond & David A. Grimes, *The Comparative Safety of Legal Induced Abortion and Childbirth in the United States*, 119 Obstetrics & Gynecology 215, 216-18 (2012).

rates,[41] worsening a crisis already disproportionately faced by Black women.[42]

The dire outcomes resulting from denying abortion care are not hypothetical. In States where total or near-total bans on abortion have been enacted or are subject to litigation in the wake of *Dobbs*, resulting delays and denials of care have endangered the mental and physical health, future fertility, and lives of pregnant people.[43] Providers report that immediately following *Roe*'s reversal, patients considered desperate and unsafe measures to terminate pregnancies, and even threatened suicide.[44] Numerous pregnant people have faced potentially fatal risks from being denied emergency abortion care, including being forced to forgo cancer treatment, developing sepsis, being left bleeding for days after incomplete miscarriage, enduring risk of rupture due to ectopic pregnancy, and being forced to

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[41] *See, e.g.*, Amanda Jean Stevenson, *The Pregnancy-Related Mortality Impact of a Total Abortion Ban in the United States: A Research Note on Increased Deaths Due to Remaining Pregnant*, 58 Demography 2019, 2019-28 (2021).

[42] *See, e.g.*, Elyssa Spitzer et al., Ctr. for Am. Progress, *Abortion Bans Will Result in More Women Dying* (Nov. 2, 2022).

[43] *See* Frances Stead Sellers & Fenit Nirappil, *Confusion Post-*Roe *Spurs Delays, Denials for Some Lifesaving Pregnancy Care*, Wash. Post (July 16, 2022); J. David Goodman & Azeen Ghorayshi, *Women Face Risks as Doctors Struggle With Medical Exceptions on Abortion*, N.Y. Times (July 20, 2022); Anjali Nambiar et al., *Maternal Morbidity and Fetal Outcomes among Pregnant Women at 22 Weeks' Gestation or Less with Complications in 2 Texas Hospitals After Legislation on Abortion*, 227 Am. J. Obstetrics & Gynecology 648 (2022).

[44] *See* Pls.' Mot. for TRO and Prelim. Inj., *Preterm-Cleveland v. Yost*, No. A2203203 (Ohio C.P. Hamilton County Sept. 2, 2022); Jessica Valenti, *I Write About Post-*Roe *America Every Day. It's Worse than You Think*, N.Y. Times (Nov. 5, 2022).

continue carrying and deliver stillborn fetuses or fetuses with fatal anomalies.[45] And of course, many of those denied abortion have confronted the life-altering consequences of being forced to continue their pregnancies and give birth. These include a 12-year-old in Mississippi raped in her backyard by a stranger, a 16-year-old Floridian in foster care denied a judicial bypass, and a 27-year-old mother of three in Texas fleeing domestic abuse, to list just a few devastating examples.[46]

Limiting access to medication abortion would further cause harmful ripple effects across the entire health system. In many amici States, the same facilities providing abortion also offer other critical services, such as pre- and post-natal care, family planning, cancer screening, testing and treatment for sexually transmitted infections and HIV, and other critical forms of preventative health care. Delays resulting from increased demand for abortion procedures (in lieu of medication abortions) will obstruct 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

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[45] *See* Pls.' Appl. for Temporary Inj., *Zurawski v. State,* No. D-1-GN-23-000968 (Tex. Dist. Ct. Travis County May 22, 2023); Pls.' Mot. for TRO and Prelim. Inj., *Preterm-Cleveland*, No. A2203203; Compl., *Adkins v. State*, No. CV01-23-14744 (Idaho 4th Jud. Dist., filed Sept. 11, 2023); Compl., *Blackmon v. State* (Tenn. Ch. Ct. 20th Jud. Dist., filed Sept. 11, 2023).

[46] S*ee* Charlotte Alter, *She Wasn't Able to Get an Abortion. Now She's a Mom. Soon She'll Start 7th Grade*, Time (Aug. 14, 2023); Elizabeth Williamson, *Who Will Help Care for Texas' Post-Roe Babies*, N.Y. Times (Jun. 1, 2022); Brittany Shammas and Kim Bellware, *Florida Court Rules 16-Year-Old Is Not 'Sufficiently Mature' for Abortion*, Wash. Post (Aug. 17, 2022).

and chronic diseases, and worsened overall health outcomes.[47] Underserved groups, including women of color, low-income women, people with disabilities, and LGBTQ individuals, will be hardest hit.[48]

Such increasingly poor overall health outcomes will impose substantial costs on amici States and local governments.[49] By contrast, the purported health risks and strains on health care systems identified by respondents and accepted by the Fifth Circuit are entirely hypothetical.

## II. The Fifth Circuit's Ruling Will Result in Confusion and Regulatory Chaos.

This Court should grant review for the additional reason that the Fifth Circuit's ruling would sow confusion and regulatory chaos if allowed to take effect. For example, facilities offering medication abortion via telehealth or via advanced practice clinicians may face the prospect of canceling appointments and attempting to direct patients to alternate means of obtaining

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

[48] *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 Rimary, Ctr. for Am. Progress, *The Health Care System and Racial Disparities in Maternal Mortality* (May 10, 2018); Christine Dehlendorf et al., *Disparities in Family Planning*, 202 Am. J. Obstetrics & Gynecology 214 (2010).

[49] *See* Br. for Amici Curiae the City of New York et al., *supra*, at 15-18.

care.[50] The need for a revised label and recertification of prescribers under preexisting REMS may create ambiguity regarding the legality of dispensing medication already on providers' shelves.[51] And providers will continue to struggle to understand the court's apparent endorsement of an archaic dosing and administration regimen in conflict with the current standard of care.

Adding to the confusion, the Fifth Circuit's decision appears to conflict with an order from the District of Washington, applicable to seventeen amici States, enjoining the FDA from altering the current version of the REMS.[52] It is unclear how the FDA could comply with the Washington order if the agency's actions from 2016 onward are "stayed" and thus deemed never to have taken effect. Nor is it clear how the Washington order affects Danco's regulatory obligations with respect to the distribution of mifepristone.[53]

Finally, the Fifth Circuit's decision risks upending the well-established regulatory framework for drug approvals and frustrates reliance interests in the stability of that system shared by amici States, manufacturers, patients, and providers alike. As industry

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[50] *See* Shannon Firth, *ACOG Responds to Clashing Abortion Pill Rulings*, MedPage Today (Apr. 10, 2023); Aaron Gregg & Christopher Rowland, *Abortion Pill Companies Struggle to Make Sense of Conflicting Court Rulings*, Wash. Post (Apr. 10, 2023); Celine Castronuovo, *Abortion Pill Prescribers Are Uncertain With New Court Order*, Bloomberg Law (Apr. 13, 2023).

[51] *See* Danco Lab'ys, L.L.C., Pet. 35 (No. 23-236) ("Danco Pet.").

[52] *See* Order Granting in Part Pls.' Mot. for Prelim. Inj. at 30, *Washington*, No. 23-cv-03026 (E.D. Wash. Apr. 7, 2023), ECF No. 80.

[53] *See* Danco Pet. 35.

leaders explained in amicus briefs filed before the Fifth Circuit, the market stability provided by the FDA's drug-approval regime is crucial to developing new drugs and maintaining ready access to available drugs.[54] Amici States in turn rely on the availability of such drugs and treatments to manage a range of medical conditions experienced by our residents, including asthma, HIV, infertility, heart disease, diabetes, and more. For each of these drugs, the FDA determined based on significant clinical data that the benefits of the drug outweighed any known and potential health risks. The instability resulting from the Fifth Circuit's ruling would inevitably chill research and development by disincentivizing drug developers from making the significant investments necessary to meet the agency's rigorous drug approval standards. And the threatened removal of other comparably essential, safe and effective drugs from the market could have catastrophic consequences for amici States and their residents.

The likelihood of these and other disruptions is readily demonstrated by the chaos experienced during earlier stages of this litigation, prior to this Court's stay of the district court's order. The district court decision, which purported to invalidate the FDA's approval of mifepristone, and the Fifth Circuit's ruling on petitioners' initial stay motions, which reinstated the post-2016 REMS and labeling conditions while purporting to invalidate the FDA's approval of generic mifepristone, created substantial uncertainty about access to mifepristone and confusion about the conditions under which it may be prescribed. Patients, providers, and

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[54] *See* Br. of Pharma. Rsch. Mfrs. of Am. et al. as Amici Curiae (May 2, 2023), ECF No. 312; Brief of Pharma. Cos., Execs., and Investors as Amici Curiae (May 2, 2023), ECF No. 309.

amici States grappled with the possibility that mifepristone could be removed from the market on a week's notice, while several States, including California, Illinois, Massachusetts, New York, and Washington took emergency measures to stockpile mifepristone or misoprostol.[55] Allowing the Fifth Circuit's merits ruling to take effect would almost certainly create additional rounds of confusion and disruption in the critical fields of health care delivery and pharmaceutical regulation.

## CONCLUSION

The petitions for a writ of certiorari should be granted.

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[55] *See* Sarah McCammon, *With Abortion Pill Access Uncertain, States Strike Deals to Stock Up*, NPR (Apr. 11, 2023).

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