Nos. 23-235, 23-236

IN THE

Supreme Court of the United States

U.S. 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 Writs of Certiorari to the United States Court of Appeals for the Fifth Circuit

BRIEF OF OVER 640 STATE LEGISLATORS AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

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INTERESTS OF *AMICI CURIAE*

Amici curiae[1] State Senator Erin Maye Quade of Minnesota and State Representative Julie von Haefen of North Carolina *et al.* are over 640 state legislators from across the United States, including both Senators and Representatives. Amici represent their constituents in both "red" and "blue" states and districts, and they hold a range of views on abortion access and reproductive health. Some ran on platforms that called for legislative changes to the state's abortion laws and regulations, including those addressing medication abortion access. A full list of state legislator amici is provided in Appendix A.

Since this Court's decision in *Dobbs v. Jackson Women's Health Organization*, 597 U.S. 215 (2022), overturning *Roe v. Wade*, 410 U.S. 113 (1973), amici have been legislating to address abortion access issues in their Legislatures and General Assemblies. Regardless of whether state legislators agree or disagree with *Dobbs*, they have taken seriously the Court's mandate, absent federal congressional action protecting the right to abortion, to address abortion access on a state-by-state basis, based on the needs, values, and desires of the constituents they were elected to represent.

The Fifth Circuit's decision staying FDA's 2016 and 2021 mifepristone "REMS" modifications improperly undermines state legislatures' ability to

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[1] Pursuant to Rule 37.6, amici affirm that no counsel for a party authored this brief in whole or in part and that no person or entity other than amici or their counsel made a monetary contribution to its preparation or submission.

decide whether to expand or restrict abortion access, taking regulatory choices away from legislators and their constituents. Amici ask this Court to overturn that decision, and thereby maintain states' authority over abortion access, consistent with *Dobbs*.

INTRODUCTION AND SUMMARY OF ARGUMENT

The Fifth Circuit's decision finding likely unlawful and staying two FDA actions modifying the conditions under which mifepristone can be prescribed for abortion cannot be reconciled with the federalism principles underlying *Dobbs*.

In *Dobbs*, this Court overturned *Roe*, "leav[ing] the issue for the people and their elected representatives to resolve through the democratic process in the States or Congress[.]" 597 U.S. at 338 (Kavanaugh, J., concurring). State legislatures and the legislators elected to them, including many elected based on platforms that advocated for expanded or restricted abortion access, took up the mantle given them by the Court. Many states have since passed legislation addressing abortion—including legislation regulating medication abortion. Some have chosen to expand access to abortion, including by explicitly allowing medication abortion and enacting measures to make that form of abortion more accessible to their constituents, such as expanding provision of the medication by advanced practice clinicians like nurse practitioners. Other states have chosen to limit abortion access, whether temporally or by restricting access to certain forms of abortion care, such as medication abortion.

But under the guise of overseeing FDA's exercise of routine regulatory authority over pharmaceuticals, the Fifth Circuit now seeks to wrest the power to decide abortion access issues back out of the hands of state legislators. That court's decision staying FDA's 2016 and 2021 REMS modification decisions—which, if it entered into effect, would limit access to medication abortion—does not square with the federalism principles that this Court articulated as the basis for its decision in *Dobbs*.

The Fifth Circuit's decision also undermines states' longstanding authority to regulate healthcare access and delivery. States have long enjoyed the right to enable easier access to FDA-approved medications when legislators determine appropriate, so long as their actions do not contravene FDA's approval and distribution decisions. Some states have accordingly taken legislative action, after *Dobbs*, to liberalize access to medication abortion based on FDA's conclusions, in 2016 and 2021, that mifepristone can safely be prescribed and used in a broad range of circumstances. The Fifth Circuit's decision pulls the rug out from under states that have made such legislative choices, potentially forcing legislators back to the drawing board.

The Fifth Circuit decision also ignores that state legislators regulate access to FDA-approved medications in light of their constituents' particular circumstances, including disparities in access to healthcare and approved pharmaceutical products, whether because they are located in rural communities or from historically underserved or disadvantaged populations. Courts of appeals are not well positioned to consider such local issues.

In short, by second guessing FDA's actions modifying the baseline requirements for safe distribution and use of mifepristone, the Fifth Circuit has wrongly restricted state legislators' regulatory choices, disrupting the state-level democratic processes *Dobbs* set in motion. This Court should overturn the Fifth Circuit's decision enjoining FDA's recent actions expanding mifepristone access and thereby reaffirm state legislators' authority over abortion access issues, consistent with *Dobbs*.

BACKGROUND

Some background on state authority over healthcare access, FDA's complementary role in approving medications and guiding their safe use, and state legislators' responses to *Dobbs* may be helpful as the Court considers the appropriate balance between the courts and state legislators when it comes to abortion regulation.

I. State legislators' authority over the delivery of healthcare to their constituents, including medication access.

There is a longstanding history and deeply-rooted tradition of state authority in health law and regulation. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996). Since at least 1905, this Court has

> distinctly recognized the authority of a state to enact . . . 'health laws of every description;' indeed, all laws that relate to matters completely within its territory. . . . [T]he police power of a state must be held to embrace, at least, such reasonable regulations established directly by

> legislative enactment as will protect the public health[.]

Jacobson v. Massachusetts, 197 U.S. 11, 25 (1905). State legislators' authority to ensure effective healthcare delivery to their constituents based on local need is thus deeply ingrained in the fabric of the United States' healthcare system.

Fifty state departments of health (plus the District of Columbia) and five territories exercise their authority to promote and protect community health.[2] Health care is one of the largest expenditures of state and local governments, accounting for about 10% of direct general spending.[3] State and territorial health departments engage in rulemaking to fulfill their health obligations, address health care and public health costs, and address specific health needs of their residents. State and local health and welfare departments can be beacons of innovation and healthcare improvement based on their ability to

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[2] Jennifer L. Pomeranz, *The Unique Authority of State and Local Health Departments to Address Obesity*, Am. J. Pub. Health 101(7), 1192–97 (July 2011); Institute of Medicine (US) Committee for the Study of the Future of Public Health, *The Future of Public Health*, *Appendix A - Summary of the Public Health System in the United States* (National Academies Press (US) 1988), https://www.ncbi.nlm.nih.gov/books/NBK218212 ("States are the principal governmental entity responsible for protecting the public's health in the United States.").

[3] Urban Institute, *State and Local Backgrounders – Health and Hospital Expenditures*, https://www.urban.org/policy-centers/cross-center-initiatives/state-and-local-finance-initiative/state-and-local-backgrounders/health-and-hospital-expenditures (citing data from 2020) (last visited Jan. 26, 2024).

consider and address local equity needs and disparities.[4]

States have broad authority to legislate and regulate in furtherance of the health and welfare of their residents.[5] For example, since at least 1859, state legislators have regulated the practice of medicine within their state's borders through state medical boards.[6] These medical boards are designed to protect constituents against unprofessional and incompetent medical practice.[7] They also conduct fundamental functions such as licensing medical practitioners, establishing qualifications and standards for the practice of medicine in a particular state, and adopting policies to ensure the delivery of safe and quality healthcare.[8]

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[4] National Academy for State Health Policy, *State Policy and Program Strategies to Advance Health and Racial Equity* (Feb. 12, 2021), https://nashp.org/state-policy-and-program-strategies-to-advance-health-and-racial-equity/; The Future of Public Health, *supra* n.2; Gulzar H. Shah and John P. Sheahan, *Local Health Departments' Activities to Address Health Disparities and Inequities: Are We Moving in the Right Direction?*, 13 Int. J. Environ. Res. Public Health 44 (Dec. 23, 2015), https://doi.org/10.3390/ijerph13010044.

[5] *See* U.S. Const. amend. X; Federation of State Medical Boards, *Understanding Medical Regulation in the United States*, https://www.fsmb.org/siteassets/education/pdf/best-module-text-intro-to-medical-regulation.pdf (last visited Jan. 26, 2024).

[6] Federation of State Medical Boards, *supra* n.5.

[7] *Id.*

[8] *Id.*

State laws addressing healthcare and medication access go well beyond regulation of the practice of medicine, however. States can declare public health emergencies.[9] They can enact laws aiming to control the prevention and spread of contagious and infectious disease,[10] and regulate childhood immunization administration and reporting to ensure safe and healthy school environments for residents.[11]

States also have authority to enact legislation that enables the provision and coverage of telehealth services, directly improving access to health care services for many residents.[12] As yet another example of states exercising their long-standing authority over healthcare access and administration, state legislators have passed laws to permit advanced practice providers, such as Nurse Practitioners and Physician Assistants, to provide healthcare, thereby increasing accessibility and reducing disparities.[13]

State oversight of the practice of medicine and pharmacies grants legislators some purview over pharmaceutical drugs dispensed within their states. For example, "states are responsible for determining how and under what conditions [approved drugs] will

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[9] Lainie Rutkow, *An Analysis of State Public Health Emergency Declarations*, Am. J. Pub. Health 104(9), 1601–05 (Sept. 2014).

[10] *See, e.g.*, Kan. Stat. Ann. § 65-2886.

[11] *See, e.g.*, Miss. Code Ann. § 41-88-3; Idaho Code Ann. § 39-4803.

[12] *See, e.g.*, Or. Rev. Stat. Ann. § 743A.058 (2021).

[13] *See, e.g.*, Me. Rev. Stat. Ann. tit. 22, § 1598(3) (2023); Wash. Rev. Code Ann. § 9.02.110 (2022).

be distributed within their jurisdiction."[14] States also "are primarily responsible for regulating pharmacists' practices, including the dispensing of medication."[15] Thus, when it comes to addressing public health issues, access to and safe provision of health care services, and ensuring the availability of prescription medications, states have a primary role and work in tandem with national regulators like FDA.

II. FDA's authority to determine whether medications are safe and under what conditions they may be used.

While states have significant authority to regulate the healthcare sector, state authority over healthcare does not extend to the drug approval process. Congress has charged FDA with the mandate and authority to ensure the safety and effectiveness of pharmaceuticals before they come to market. 21 U.S.C. §§ 321(p), 355, 393(b)(2)(B).

Enacted in 1938, the Food, Drug, and Cosmetic Act ("FDCA"), delegates oversight of new drug approval to FDA. The process for such approval is rigorous and evidence based, and state legislators and their constituents have depended on that scientifically based process for many years. *See id.* § 355(d); 21 C.F.R. §§ 314.50, 314.105(c). The application process for a new FDA approved drug is extensive, and rooted in science. *See* 21 U.S.C. § 355(d) (outlining conditions for approving or denying a new drug application, including requiring analysis of supporting safety and efficacy studies). Under the

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[14] Catherine M. Sharkey, *States vs. FDA*, 83 Geo. Wash. L. Rev. 1609, 1615 (Sept. 2015).

[15] *Id.*

authority granted by Congress, FDA also enacts regulations regarding what constitutes an "adequate and well-controlled" study to confirm the safety and effectiveness of a new drug. 21 C.F.R. § 314.126.

Within FDA, the Center for Drug Evaluation and Research ("CDER"), which is comprised of highly trained scientists (including physicians, pharmacologists, chemists, and statisticians), analyzes pharmaceutical data and proposed drug labels.[16] CDER's review is independent and aims to confirm that drugs are safe and effective for consumer use, weighing the drug's benefits against its risks within the context of the condition that the drug is used to treat.[17] FDA also assesses "benefits and risks from clinical data" and "strategies for managing risks," which exist for all drugs.[18]

To be sure, the "FDA's determination that a drug is safe does not signify an absence of risk but rather that the drug's clinical benefits outweigh its known and potential risks."[19] But it is through FDA's scientific process that millions of Americans (like the 5.9 million people in the country who have used

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[16] U.S. Food & Drug Administration, *Development & Approval Process / Drugs* (Aug. 8, 2022), https://www.fda.gov/drugs/development-approval-process-drugs.

[17] *Id.*

[18] *Id.*

[19] Congressional Research Service, *FDA Risk Evaluation and Mitigation Strategies (REMS): Description and Effect on Generic Drug Development* (Mar. 16, 2018), https://crsreports.congress.gov/product/pdf/R/R44810/5.

mifepristone to terminate their pregnancies) access life-saving—and life changing—medications.[20]

Importantly from the perspective of state legislators, FDA's approval of a drug addresses an area—the determination of whether a drug is safe and effective based on scientific data—that most states do not have the resources to address. State legislators thus depend on FDA's science-based processes to approve medications as safe and effective for distribution and use across the nation, so that they can then legislate to ensure that all the residents of their state can access the medical care (including medications) that they and their healthcare providers determine is appropriate. And as discussed below (Arg. § II), state legislators consider the unique attributes of and challenges faced by the communities they serve when doing so.

III. State legislation addressing abortion, including medication abortion, after *Dobbs*.[21]

Since the Supreme Court's decision in *Dobbs*, states have exercised their authority to legislate to either expand or limit abortion-related healthcare access. As shown below, over the past year-and-a-half a majority of state legislatures have enacted laws addressing whether, when, and how their constituents may access abortion care, including medication abortion. The list below is non-exhaustive,

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[20] *See id.*

[21] Some laws below are currently being challenged, but that is beyond the scope of this brief.

but provides illustrative examples of state legislators' and voters' responses to *Dobbs*.

Arizona: In 2022, Arizona banned abortion after fifteen weeks' gestation except in cases of medical emergency for which physicians must file a report with the Department of Health Services concerning the date, method, and justification for performing an abortion.[22] Arizona's statute expressly prohibits the use of telehealth to provide abortions.[23]

California: In November 2022, Californians approved Prop 1, which explicitly adds abortion and contraception rights to the state constitution.[24] Also in 2022, California enacted laws to protect providers, patients, and individuals who assist others in accessing abortions.[25]

Colorado: In 2022, Colorado enacted a statutory protection for abortion as a fundamental right.[26] In 2023, Colorado enacted a law that protects providers from criminal, civil, licensure and insurance consequences based on providing abortion care.[27]

Connecticut: In 2022, Connecticut enacted prohibitions against disclosure of information and

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[22] Ariz. Rev. Stat. Ann. § 36-2322 (2022).

[23] Ariz. Rev. Stat. Ann. § 36-3604 (2021).

[24] Cal. Const. art. 1, § 1.1 (2022).

[25] 2022 Cal. Legis. Serv. Ch. 42 (A.B. 1666) (codified at Cal. Health & Safety Code § 123467.5).

[26] Colo. Rev. Stat. Ann. § 25-6-403 (2022).

[27] 2023 Colo. Legis. Serv. Ch. 68 (S.B. 23-188) (codified at Colo. Rev. Stat. § 12-30-121 *et seq*.).

communications related to patient reproductive healthcare services permitted under Connecticut law.[28]

Delaware: In 2022, Delaware enacted a law to protect providers who assist in providing reproductive healthcare services permitted under Delaware law from investigations and civil actions, and to prohibit the disclosure of communications and records related to reproductive health services by healthcare providers.[29]

Florida: In 2023, Florida prohibited physicians from performing or inducing termination of pregnancy if the physician determines that the gestational age of the fetus is more than six weeks.[30] Florida also expressly prohibits physicians from using telehealth to perform an abortion, including, but not limited to, a medication-induced abortion.[31] The statute further provides that any medication intended for use in a medication abortion must be dispensed in person by a physician and may not be dispensed through a shipping service.[32]

Hawaii: In 2023, Hawaii enacted a law to prohibit healthcare providers from disclosing information related to reproductive healthcare services, and to protect providers and individuals who

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[28] H.B. 5414, 2022 Leg., Reg. Sess. (Conn. 2022).

[29] H.B. 455, 151st Gen. Assemb., Reg. Sess. (Del. 2022).

[30] Fla. Stat. Ann. § 390.0111 (2023).

[31] *Id.*

[32] *Id.*

assist with lawful abortion access from out-of-state investigations and legal action.[33]

Idaho: In 2023, Idaho modified its existing abortion ban that had few exceptions by narrowing the law's exception for survivors of rape and incest to only allow abortion in the first trimester of pregnancy.[34]

Illinois: In January 2023, Illinois enacted a law to protect health care professionals, medical institutions, and patients from legal claims when abortion is permitted under Illinois law.[35]

Indiana: In 2022, Indiana enacted a law to prohibit abortion except to protect the life or physical health of the pregnant person, in cases where a pregnancy is the result of rape or incest, or in cases of lethal fetal anomaly.[36] Indiana's statute also provides that telehealth may not be used to provide an abortion, including the writing or filling of a prescription intended to result in an abortion.[37]

Iowa: In July 2023, Iowa enacted a new law to prohibit abortions after the gestational age of 6 weeks except in cases of rape, incest, fetal abnormality that a doctor reasonably believes to be incompatible with

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[33] S.B. 1, 32nd Leg., Reg. Sess. (Haw. 2023).

[34] H.B. 374, 67th Leg., Reg. Sess. (Idaho. 2023) (codified at Idaho Code §§ 18-604, 18-622).

[35] H.B. 4664, 102nd Gen. Assemb., Reg. Sess. (Ill. 2023).

[36] S.B. 1, 122nd Leg., 1st Spec. Sess. (Ind. 2022).

[37] Ind. Code Ann. § 16-34-2-1 (2022).

life, or if continuing the pregnancy would result in irreversible harm to the pregnant person.[38]

Kentucky: In November 2022, Kentucky voters rejected Proposition 2, which would have specified that the state constitution does not protect abortion rights.[39]

Maine: In 2023, Maine expanded legal abortion care to include abortion post viability when necessary in the professional judgment of a licensed physician.[40]

Maryland: In 2022, Maryland enacted a law that allows nurse practitioners, nurse midwives, licensed midwives, and physician assistants to provide abortion care in addition to physicians.[41] And, in 2023, Maryland enacted a law to protect health care providers and patients from out-of-state investigations and legal action related to legally protected healthcare.[42]

Massachusetts: In 2022, Massachusetts enacted a law to protect providers, patients, pharmacists, and people who help others access abortion from professional licensure consequences

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[38] S.F. 579, 90th Gen. Assemb., Spec. Sess. (Iowa 2023).

[39] Act proposing an amend. to the Const. of Ky. relating to abortion, Ch. 174 (2021), apps.legislature.ky.gov/law/acts/21RS/documents/0174.pdf.

[40] Me. Rev. Stat. Ann. tit. 22, § 1598 (2023).

[41] H.B. 937, 444th Leg., Reg. Sess. (Md. 2022).

[42] S.B. 859, 445th Leg., Reg. Sess. (Md. 2023).

arising from out-of-state investigations and legal actions.[43]

Michigan: In 2022, Michiganders approved Proposition 3, which enshrines reproductive freedom in the Michigan constitution.[44] In 2023, Michigan enacted a law protecting abortion as a fundamental right and prohibiting the state from taking adverse action against someone for helping a pregnant person access lawful abortion care.[45] Also in 2023, Michigan repealed two laws that criminalized medication abortion and advertising or selling medication used in medication abortion.[46]

Minnesota: In 2023, the state legislature created a statutory right to reproductive freedom.[47]

Montana: In November 2022, voters rejected LR-131, a referendum that could have criminalized medical professionals for providing abortions.[48] In 2023, there have been several bills in Montana restricting abortion access, including ones that required patients to undergo an ultrasound before getting an abortion and prohibited the use of dilation and evacuation abortions.[49]

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[43] H.B. 5090, 192nd Gen. Ct., Reg. Sess. (Mass. 2022).

[44] Mich. Const. art. 1, § 28 (2022).

[45] 2023 Mich. Legis. Serv. P.A. 286 (H.B. 4949).

[46] 2023 Mich. Legis. Serv. P.A. 11 (H.B. 4006).

[47] Minn. Stat. Ann. § 145.409 (2023).

[48] H.B. 167, 67th Leg., Reg. Sess. (Mont. 2021).

[49] H.B. 575, 721, 68th Leg., Reg. Sess. (Mont. 2023).

Nebraska: In 2023, Nebraska enacted a law prohibiting an abortion after twelve weeks of gestation, except in the cases of medical emergency or pregnancy resulting from rape or incest.[50]

Nevada: In 2023, Nevada enacted a law that protects providers from out-of-state investigations and legal actions arising from the lawful provision of abortion.[51] The law also directs state licensing boards to implement policies ensuring that no person will be subject to discipline or disqualified from licensure for providing or assisting with lawful provision of abortion care in Nevada.[52] Also in 2023, Nevada enacted a data privacy law that regulates the collection, usage, and sharing of consumer health data, including abortion care, and prohibits the use of a geofence within 1,750 feet of a medical facility that provides healthcare services.[53]

New Jersey: In 2022, New Jersey enacted a statute that protects abortion as a fundamental right.[54]

New Mexico: In 2023, New Mexico enacted a law to ensure access to abortion, including by prohibiting public bodies from restricting or interfering with abortion care, discriminating against people who use abortion services, and enforcing any

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[50] Neb. Rev. Stat. Ann. § 71-6915 (2023).

[51] 2023 Nevada Laws Ch. 82 (S.B. 131).

[52] *Id.*

[53] 2023 Nevada Laws Ch. 525 (S.B. 370).

[54] N.J. Stat. Ann. 10:7-2 (2022).

law or policy that restricts abortion care.[55] It also imposes civil penalties for violating the law.[56] And in 2023, New Mexico enacted a law prohibiting public bodies from cooperating with out-of-state investigations.[57]

New York: In 2022, New York enacted additional protections for abortion providers.[58]

North Carolina: North Carolina enacted a twelve-week abortion ban, plus additional restrictions, which took effect in mid-2023.[59]

North Dakota: In 2023, North Dakota prohibited abortion at all stages of pregnancy, except in the case of death or serious health risk.[60] Survivors and victims of rape and incest can obtain abortions up to six weeks gestation.[61]

Ohio: In 2023, voters in Ohio approved Issue 1, a constitutional amendment to protect reproductive decision making.[62] The amendment recognizes the right to abortion; prohibits the state from burdening,

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[55] N.M. Stat. Ann. § 24-34-3 (2023).

[56] *Id.*

[57] N.M. Stat. Ann. § 24-35-1 *et seq*.

[58] N.Y. Crim. Proc. Law § 570.17 (2023).

[59] N.C. Gen. Stat. Ann. § 90-21.81B (2023).

[60] S.B. 2150, 68th Leg. Sess., Reg. Sess. (N.D. 2023).

[61] *Id.*

[62] Ohio Sec'y of State. State Issues 1 and 2, www.ohiosos.gov/globalassets/elections/2023/gen/issuesreport.pdf (codified at Ohio Const. art. I, § 22; Ohio Const. art. II, § 1b).

penalizing, or prohibiting abortion before viability of the fetus; and grants the pregnant person's physician authority to determine viability and whether an abortion is necessary after viability.[63]

Oregon: In 2023, Oregon enacted a law protecting abortion as a fundamental right.[64] This law prohibits public bodies from restricting or interfering with the exercise of reproductive health rights.[65] The law protects providers, patients, and people who help others access abortion from civil or criminal liability, professional licensure consequences, and adverse actions by insurance carriers.[66] It also allows people under the age of 15, which is the age when young people can provide informed consent to medical procedures without parental involvement, to consent to abortion care under certain circumstances.[67]

Pennsylvania: In 2022, Pennsylvania passed a bill that, if passed again in the 2023 biennium, would put on the ballot a constitutional amendment clarifying that the Pennsylvania constitution does not grant a right to abortion.[68]

South Carolina: In 2023, South Carolina enacted a law prohibiting abortion after cardiac activity can be detected in a fetus, commonly around

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[63] *Id.*

[64] H.B. 2002, 82nd Leg., Reg. Sess. (Or. 2023).

[65] *Id.*

[66] *Id.*

[67] *Id.*

[68] S.B. 106, Sess. of 2021, Reg. Sess. (Pa. 2022).

six weeks of pregnancy, with exceptions in cases of medical emergencies, fatal fetal anomalies, and for victims of rape and incest until twelve weeks of pregnancy.[69]

South Dakota: Effective in 2022, medication abortion may only be taken up to nine weeks after conception.[70] Medication abortion must be prescribed and dispensed by a licensed physician in a licensed abortion facility, meaning that prescribing abortion-inducing medication via telehealth is prohibited.[71]

Texas: Texas is enforcing its pre-*Dobbs* trigger ban, which prohibits abortion in most circumstances and imposes criminal and civil penalties on those who perform, induce, or attempt an abortion.[72] There are narrow exceptions to the ban, including to save the life of a pregnant person or prevent substantial impairment of major bodily function.[73] In 2023, Texas enacted a law creating limited affirmative defenses to civil claims brought against physicians for treating ectopic pregnancies or providing miscarriage management.[74]

Utah: In 2023, Utah enacted a law prohibiting abortion clinics from operating in the state beginning January 1, 2024 or the last valid date of a license

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[69] S.C. Code Ann. § 44-41-630 (2023).

[70] S.D. Codified Laws § 36-4-47.

[71] *Id.*

[72] Tex. Health & Safety Code Ann. §§ 170A.001-7 (2022).

[73] *Id.* § 170A.002(b).

[74] Tex. Civ. Prac. & Rem. Code Ann. § 74.552 (2023).

issued prior to May 2, 2023, and requiring abortion care to be provided in a hospital except in emergencies.[75]

Vermont: In November 2022, voters approved Proposal 5, which enshrines reproductive freedom in the Vermont constitution.[76] Also in 2023, Vermont enacted a law protecting providers, patients, and people who help others access abortion from out-of-state investigations and legal actions.[77] And the law prohibits public bodies from cooperating with any such out-of-state investigations and legal actions arising from legally protected health care activity.[78]

Washington: In 2022, Washington enacted a law prohibiting the state from denying or interfering with a pregnant person's right to have an abortion prior to viability of the fetus or to protect the pregnant person's life or health.[79] In 2023, Washington enacted a law protecting people from out-of-state civil and criminal actions and investigations that restrict or criminalize abortion care.[80] This law also creates a cause of action for interference with protected healthcare services such as abortion.[81]

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[75] Utah Code Ann. § 26B-2-204.

[76] Vt. Const. ch. I, art. 22 (2022).

[77] H.B. 89, 77th Gen. Assemb., Reg. Sess. (Vt. 2023).

[78] *Id.*

[79] Wash. Rev. Code § 9.02.110 (2022).

[80] Wash. Rev. Code § 18.130.450(1) (2023).

[81] Wash. Rev. Code § 7.115.040.

West Virginia: In September 2022, West Virginia enacted a near-total abortion ban, with exceptions for non-viable fetuses, ectopic pregnancy, and medical emergencies. Survivors and victims of sexual assault and incest can obtain abortions up to eight weeks of gestation (fourteen if they are a minor or an incompetent or incapacitated adult), but only if they report to law enforcement having jurisdiction to investigate the complaint first.[82]

Wyoming: In 2023, Wyoming banned medication abortion.[83]

These descriptions of states' post-*Dobbs* legislative initiatives show how active state legislatures have been and are in proposing abortion-related legislation.[84] And it shows how actively state legislators have taken up the mantle this Court handed them when it issued that decision.

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[82] W. Va. Code § 16-2R-3 (2022).

[83] H.B. 152, 67th Leg., Reg. Sess. (WY 2023).

[84] Indeed, there is pending legislation even now in states across the country aimed at further delineating when and how persons may access abortion care, including medication abortion. *E.g.*, H.B. 1541-FN, 2024 Sess. (N.H. 2024) ("requires an abortion performed after viability or 15 weeks gestation to be performed in a hospital with an intensive care unit and in the presence of a second physician"); S.B. 567, 2024 Sess. (N.H. 2024) (directing state health services agency to adopt measures to ensure access to medication abortion); H.B. 276 (Md. 2024) (requiring the Maryland Department of Health to report abortion data requested by the Centers for Disease Control and Prevention); L.B. 1109 (Neb. 2024) (proposing allowing abortions after 12 weeks for fetal anomalies); H.B. 1519 (Fla. 2024) (seeking to ban nearly all abortions).

State legislatures have also implemented *Dobbs'* directive by taking other actions (beyond directly authorizing or restricting abortion) to expand access to medication abortion. As of April 2023, at least 18 states, including California, Colorado, Connecticut, Delaware, Hawaii, Illinois, Maine, Maryland, Massachusetts, Minnesota, Montana, New Hampshire, New Jersey, New York, Oregon, Vermont, Virginia, and Washington, as well as the District of Columbia, have legislated to encourage advanced practice clinicians to become certified prescribers of medication abortion, as FDA's 2016 actions modifying the REMS for mifepristone permit.[85] States have also advanced legislation to ensure medication abortion access at public universities.[86]

Other states, however, have legislated to explicitly prohibit health care providers from prescribing abortion-inducing medication via telehealth services. For example, as described above, South Dakota, Florida, and Indiana have enacted such restrictions. And Alaska, Arizona, Utah, Nebraska, Kansas, Iowa, Wisconsin, Ohio, Florida, Georgia, South Carolina, and North Carolina have legislated to require at least one in-person trip to a clinic to receive mifepristone, functionally prohibiting

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[85] Kaiser Family Foundation, *The Availability and Use of Medication Abortion* (Sept. 28, 2023), https://www.kff.org/womens-health-policy/fact-sheet/the-availability-and-use-of-medication-abortion/.

[86] *E.g.*, A.B. A1395C, 2023-2024 Legis. Sess. (N.Y. 2023).

direct-to-patient telehealth prescription.[87] And even before *Dobbs*, Texas law did not allow for prescribing of abortion medications via telehealth.[88]

In short, since *Dobbs*, state legislators have legislated not only to address the lawfulness of abortion generally, but specifically to determine whether and how to enable access to medication abortion.

ARGUMENT

I. The Fifth Circuit's decision undermines state legislators' authority over abortion, contrary to the federalism principles invoked in *Dobbs*.

The Fifth Circuit's decision suspending FDA's 2016 and 2021 mifepristone REMS modifications improperly disrupts state legislators' ongoing efforts to regulate abortion access, including medication abortion, contrary to this Court's holding in *Dobbs*.

In *Dobbs*, this Court determined that the issue of abortion should be "return[ed] . . . to the people and their elected representatives." 597 U.S. at 302. As described above, state legislators have taken that directive seriously, proposing and enacting hundreds of initiatives that address abortion access, including many that address medication abortion. The Court should not allow the Fifth Circuit to interfere in those legislative processes by limiting access to medication abortion—particularly where FDA specifically has

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[87] *The Availability and Use of Medication Abortion*, *supra* n.85.

[88] Tex. Occ. Code Ann. § 111.005(c) (2021).

found, based on the available scientific evidence, the underlying products and practices are safe.

As this Court explained in *Dobbs*, "[s]tates may regulate abortion for legitimate reasons" and "courts cannot 'substitute their social and economic beliefs for the judgment of legislative bodies.'" *Id.* at 300 (citation omitted). This Court further explained "[t]hat respect for a legislature's judgment applies even when the laws at issue concern matters of great social significance and moral substance." *Id.*; *see also id.* at 228 (criticizing *Roe* for ending the "political process" despite one-third of states "liberaliz[ing]" their abortion laws prior to the decision). After *Dobbs*, "courts play only a modest and minor role" in the realm of abortion because it is "the people's representatives—not judges—[who] decide whether to allow . . . or regulate abortions." *Raidoo v. Moylan*, 75 F.4th 1115, 1118 (9th Cir. 2023).

The Fifth Circuit's decision overturning FDA's actions allowing expanded access to mifepristone wrecks the balance the Court attempted to strike in *Dobbs*. It attempts to remove state legislators from the policymaking equation on key questions of medication abortion access. There is nothing "modest" or "minor" about the role the Fifth Circuit is attempting to play in second-guessing FDA's actions approving mifepristone based on science that bears out its safety and then relaxing restrictions that prevent access after decades of safe usage and scientific inquiry.

State legislators have taken *Dobbs'* federalism premise at face value, exercising their authority to legislate abortion access based on their views of what is best for their states and what the constituents who

elected them want them to do. To give just one example of the many identified above (Background § III), in 2023, Minnesota enacted the Protect Reproductive Options Act, which establishes an individual's fundamental right to make decisions about their reproductive health, including the right to continue a pregnancy or have an abortion.[89] To give another example: this past spring, North Carolina legislators introduced Senate Bill 353 to overturn many of the state's prior abortion restrictions.[90] And they did so in recognition that "the impact of abortion restrictions is predominantly felt by those who already experience systemic barriers to health care, including" those who live in rural areas, those with disabilities, individuals with low incomes, young people, and people of color.[91]

As also described above, states have not only enacted new legislation allowing or disallowing abortion in general, but many have specifically legislated to either expand or limit access to medication abortion. For example, Michigan recently repealed two laws that criminalized medication abortion.[92] Other states' legislators may yet determine that expanded access to mifepristone is appropriate given the particular needs and values of their constituents, and propose legislation that removes regulatory hurdles to mifepristone's

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[89] H.F. 1, 93rd Leg., Reg. Sess. (Minn. 2023).

[90] RBG Act, S.B. 353, 2023-2024 Sess. (N.C. 2023).

[91] *Id.*

[92] 2023 Mich. Legis. Serv. P.A. 11 (H.B. 4006).

provision to their constituents or otherwise makes access easier. Indeed, even now, legislators in New Hampshire are considering S.B. 567, which seeks to protect and enhance access to abortion medications in New Hampshire by directing the state's Department of Health and Human Services to enact measures to that end.[93] The Fifth Circuit should not be permitted to intervene in these democratic processes, which are precisely what this Court envisioned would follow when it decided *Dobbs*. 597 U.S. at 232 ("The permissibility of abortion, and the limitations, upon it, are to be resolved like most important questions in our democracy: by citizens trying to persuade one another and then voting.") (citation omitted).

The Fifth Circuit's decision staying FDA's 2016 and 2021 REMS modifications interferes with state-level democratic processes to address healthcare in another way: it limits state legislators' ability to enact laws expanding telehealth care access.

People's use of telehealth-based abortion care has increased 137% nationally since the *Dobbs* decision.[94] Increasing access to telehealth appointments and mail-order pharmacies, as permitted by FDA's 2021 REMS changes, may further some state legislators' goals of increasing and ensuring access to medication abortion in the earliest stages of pregnancy, and thereby limit the need for other, more invasive and

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[93] S.B. 567, 2024 Sess. (N.H. 2024).

[94] *See* Society of Family Planning, *#WeCount Report: April 2022 to December 2022*, at 2 (Apr. 11, 2023), https://doi.org/10.46621/143729dhcsyz.

costly abortion procedures. And while some states (*e.g.*, California, Colorado, and Nevada) permit certified abortion prescribers to undertake abortion care using telehealth technologies,[95] often in an effort to make such care more accessible for rural or disadvantaged populations, others (such as Florida and Indiana) have curtailed telehealth abortion. *See* Background § III. The Fifth Circuit's decision improperly limits state legislators' choices as they consider such potential legislative initiatives, disrupting the federal/state balance and undermining the federalism principles on which *Dobbs* is based.

Dobbs instructed that federal courts must respect the democratic decisions made by popularly-elected state representatives—some of whom were elected on platforms advocating for expanded abortion access. To allow the Fifth Circuit to limit state legislators' options as they consider action related to medication abortion access would undermine the very principle that the Court relied on to overturn *Roe*: federalism.

II. The Fifth Circuit's decision prevents state legislators from ensuring that the communities they serve can obtain reproductive healthcare despite access disparities.

State legislators, who routinely legislate on matters related to health care, are usually best placed to consider their constituents' healthcare needs, which vary by geography, socioeconomic status, and other demographic factors. Indeed, enabling state legislatures to consider the particular needs and

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[95] *The Availability and Use of Medication Abortion*, *supra* n.85.

desires or their populations was a core premise behind this Court's decision in *Dobbs*. 597 U.S. at 300 ("[C]ourts cannot 'substitute their social and economic beliefs for the judgment of legislative bodies.'") (citation omitted); *see id.* ("That respect for a legislature's judgment applies even when the laws at issue concern matters of great social significance and moral substance.").

By second-guessing FDA's decisions loosening restrictions on access to medication abortion, the Fifth Circuit jeopardizes state legislators' ability to consider and meet their constituents' needs, including by legislating to address disparities in access to healthcare (including reproductive care) that certain populations face. The Court should overturn that invasive decision, and thereby reaffirm states' oversight of health care delivery—and state legislators' authority to decide how best to regulate access to abortion, including medication abortion, based on the unique needs and attributes of their constituents.

A. Different state populations have different needs, which state legislators are best placed to consider when regulating to address abortion access.

The United States' decentralized and state-centric approach to healthcare oversight is deliberate. State demographics vary widely, requiring state legislators to consider their communities' unique healthcare challenges and other economic and social factors when legislating in regard to both abortion and medication access. Contrary to that scheme, the Fifth Circuit's decision improperly imposes a court's

view as to appropriate drug access policy across all 50 states for an FDA-approved prescription medication.

In addition to being inconsistent with *Dobbs*, there is a practical flaw in the Fifth Circuit's approach. Specifically, the Fifth Circuit's decision ignores that state legislators are usually better positioned to consider their constituents' needs and differences relevant to medication abortion access. Effective state healthcare governance is generally representative of, and more responsive to, constituent needs because it is more localized and considers barriers to healthcare access.[96]

An overview of the demographic and geographic-specific health disparities that state legislators' constituents may face, as well as legislators' attempts to redress such disparities, demonstrates the importance of localized governance.

1. Health disparities vary by social, demographic, and geographic factors.

"Health disparities—inequities in the quality of health, health care and health outcomes experienced by groups based on social, racial, ethnic, economic and environmental characteristics—persist across the nation."[97] Health disparities are driven and exacerbated by social determinants of health—the non-medical factors specific to the conditions of

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[96] The Future of Public Health, *supra* n.2 at App'x A.

[97] National Conference of State Legislatures, *Health Disparities Overview* (May 10, 2021), https://www.ncsl.org/health/health-disparities-overview.

individuals' daily lives and communities that impact health outcomes.[98] These determinants include where people live and work, as well as "economic policies and systems, development agendas, social norms, social policies, and political systems."[99]

Generally, factors causing healthcare access disparities include higher rates of employment in essential work settings with minimal or no paid sick days; increased likelihood of reliance on public transit; crowded housing situations; higher uninsured rates; and challenges navigating health care systems.[100] Existing inequities only compound obstacles to abortion and miscarriage care,[101] lack of access to which is itself a health disparity.[102]

Such disparities also exist "across socioeconomic strata, race, ethnicity, and geography in the United States" and "are well-documented in health statistics

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[98] *See* Centers for Disease Control & Prevention, *NCHHSTP Social Determinants of Health* (May 9, 2022), https://www.cdc.gov/nchhstp/socialdeterminants/index.html.

[99] *Id.*

[100] *Id.*

[101] Guttmacher Institute, *Inequity in US Abortion Rights and Access: The End of Roe is Deepening Existing Divides* (Jan. 17, 2023), https://www.guttmacher.org/2023/01/inequity-us-abortion-rights-and-access-end-roe-deepening-existing-divides.

[102] Katie Watson, *The Ethics of Access: Reframing the Need for Abortion Care as a Health Disparity*, 22 The Am. J. of Bioethics 22–30 (May 27, 2022), https://doi.org/10.1080/15265161.2022.2075976.

and the research literature."[103] They are most prevalent among "[c]ommunities of color, populations with a lower socioeconomic status, rural communities, people with cognitive and physical disabilities and individuals who identify as LGBTQ[.]"[104]

Some of the key differentials that state legislators consider when making abortion access decisions are described further below:

Geography. "Disparities in morbidity and mortality between urban and rural residents are well-documented and have been referred to as the 'rural mortality penalty.'"[105] This is because rural residents "have not seen the same health improvements as their urban counterparts," "have higher burdens of preventable conditions such as obesity, diabetes, cancer, and injury compared to urban populations", "are more likely to engage in risky behaviors such as substance use and smoking," and "exhibit lower levels of physical activity and consume lower nutrient and more calorically dense diets."[106]

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[103] Kelly D. Edmiston & Jordan AlZuBi, Center for Insurance Policy & Research, National Association of Insurance Commissioners, *Trends in Telehealth and Its Implications for Health Disparities* 3 (Mar. 2022), https://content.naic.org/sites/default/files/Telehealth%20and%20Health%20Disparities.pdf.

[104] National Conference of State Legislatures, *supra* n.97.

[105] Laura Richman, Jay Pearson, Cherry Beasley, & John Stanifer, *Addressing health inequalities in diverse, rural communities: An unmet need*, SSM Popul Health (Apr. 9, 2019), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6462771/.

[106] *Id.*

Indeed, "rural residents are more likely to be poor, lack health insurance, or rely substantially on Medicaid and Medicare," and "travel longer distances to receive care or to access a range of medical, dental, and mental health specialty services."[107] These barriers have obvious implications for access to reproductive care, including abortion where permitted by state law, that legislators may seek to address by expanding telehealth, authorizing nurse practitioners to prescribe medications (including mifepristone), or other legislative measures.

Race and Ethnicity. "[P]eople of color and those with lower income and less education fare worse across a wide range of health outcomes, including infant mortality, cancer incidence, and life expectancy."[108] For example, "Black women have the highest mortality rate of any group in the United States,"[109] while "Vietnamese-American women experience the highest incidence of cervical cancer in the United States, at rates nearly six times higher

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[107] The American College of Obstetricians and Gynecologists, *Health Disparities in Rural Women* (Feb. 2014), https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2014/02/health-disparities-in-rural-women.

[108] Christine Dehlendorf, Lisa H. Harris, and Tracy A. Weitz, *Disparities in Abortion Rates: A Public Health Approach*, Am. J. Pub. Health, 103(10): 1772-1779 (Oct. 2013), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3780732/.

[109] Center for Reproductive Rights, Comment on Notice of Proposed Rulemaking on HIPAA Privacy Rule to Support Reproductive Health Care Privacy (RIN 0945-AA20) (June 16, 2023).

than that of white women."[110] "These disparities are related to systemic hardships experienced by disadvantaged communities, including decreased access to health care, higher levels of stress, exposure to racial discrimination, and poorer living and working conditions,"[111] as well as lower likelihood of possessing health insurance and linguistic barriers.[112]

Additional causes of healthcare access disparities faced by racial and ethnic minorities include "economic disadvantage, neighborhood characteristics, lack of access to family planning, and mistrust in the medical system[.]"[113] Again, these disparities have obvious impacts on people's abilities to access abortion care to the full extent of state law, which state legislators may try to address by expanding access to mifepristone to the full extent of FDA's actions.

Gender Identity and Sexual Orientation. "People who identify as sexual and/or gender minority

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[110] Institute of Medicine (U.S.) Committee on Understanding and Eliminating Racial and Ethnic Disparities in Health Care (2003), *Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care*, https://www.ncbi.nlm.nih.gov/books/NBK220362/.

[111] Christine Dehlendorf, Lisa H. Harris, and Tracy A. Weitz, *supra* n.108.

[112] Institute of Medicine (U.S.) Committee on Understanding and Eliminating Racial and Ethnic Disparities in Health Care (2003), *supra* n.110.

[113] Christine Dehlendorf, Lisa H. Harris, and Tracy A. Weitz, *supra* n.108.

individuals face unique and challenging inequities in access to health care," including but not limited to reproductive healthcare.[114] Indeed, LGBTQ+ people are at higher risk of poor health outcomes compared to their heterosexual counterparts,[115] including sexually transmitted diseases, substance use disorders, and other conditions that can negatively impact pregnancy and fetal health.[116]

These disparities are driven largely from discrimination in accessing care, including difficulty or impossibility in finding a provider.[117] LGBTQ+ people also suffer increased risk of unintended pregnancy, compounded by barriers to sexual and reproductive health services, such as contraceptive counseling.[118]

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[114] Juan D. Salcedo-Betancourt, Samira S. Farouk, and Yuvaram N. V. Reddy, *Ensuring health equity for sexual and/or gender minority individuals* (June 2022), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9170236/#:~:text=People%20who%20identify%20as%20sexual,(including%20for%20kidney%20disease).

[115] Chandra L. Jackson, Madina Agénor, Dayna A. Johnson, S. Bryn Austin, and Ichiro Kawachi, *Sexual orientation identity disparities in health behaviors, outcomes, and services use among men and women in the united states: a cross-sectional study* (Aug. 17, 2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4989521/.

[116] Juan D. Salcedo-Betancourt, Samira S. Farouk, and Yuvaram N. V. Reddy, *supra* n.114.

[117] Center for Reproductive Rights, *supra* n.109.

[118] Brittany M. Charlton et al., *Sexual orientation differences in pregnancy and abortion across the lifecourse* (Dec. 4, 2019), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7071993/.

In short, state legislators' constituents may face any number of healthcare access barriers and disparities. Each represented community is unique in this regard, and state and local legislators are most familiar with, and best positioned to, address the particular needs of and disparities faced by the residents they were elected to represent.

2. State legislators regularly pass measures to redress health disparities.

State legislators regularly consider healthcare access disparities when enacting legislation. Between 2020 and 2021, at least 35 states enacted legislation addressing health disparities, including by expanding access to telehealth.[119] State legislators have frequently turned to telehealth to address disparities in healthcare outcomes because "physical access to care [is] the most substantial and pervasive obstacle[.]"[120] This is particularly true for rural communities, many of whom may not otherwise access care due to distance. Telehealth also increases access for low-income and communities of color because it alleviates resource pressures, such as caretaking responsibilities or the inability to take

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[119] National Conference of State Legislatures, *supra* n.97; National Conference of State Legislatures, *Health Disparities Legislation* (Feb. 21, 2022), https://www.ncsl.org/health/health-disparities-legislation.

[120] Edmiston & AlZubi, *supra* n.103, at 23.

time off work to attend an in-person doctor's appointment.[121]

Examples of state legislative initiatives that address health disparities include the following:

Alabama: The governor of Alabama had temporarily expanded access to telehealth services in response to the COVID-19 public health emergency, authorizing Certified Registered Nurse Practitioners and Certified Midwives practicing pursuant to an Alabama collaborative practice agreement to provide all services within their scope of practice through telehealth services.[122] Also, the Alabama Administrative Code r. 540-X-9-.11, effective on September 14, 2023, recognizes that, in certain circumstances, physicians who have not personally examined patients may prescribe medicine.[123]

Alaska: In 2022, Alaska authorized health care providers' furnishing of care, and the prescribing, dispensing, and administering of prescriptions through telehealth services.[124]

California: Effective in 2023, federally qualified health centers and rural health centers in California may establish new patient relationships using audio-

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[121] Fabiola Carrión, Nat'l Health Law Program, *Will telehealth provide access or further inequities for communities of color?*, (Sept. 28, 2020), https://healthlaw.org/will-telehealth-provide-access-or-further-inequities-for-communities-of-color/.

[122] *See* 2020 Alabama Proclamation P20-05 (Apr. 2, 2020).

[123] Ala. Admin. Code r. 540-X-9-.11 (2023).

[124] Alaska Stat. Ann. § 08.02.130 (2022).

only synchronous interactions when the visit relates to certain sensitive services and when the patient requests audio-only modalities or attests that they do not have access to video.[125]

Missouri: Effective in August 2023, Advanced Practice Registered Nurses are authorized to use telehealth for the provision of services under collaborative practice arrangements to reach rural areas in need.[126]

North Dakota: Effective in August 2019, a physician, resident physician, or physician assistant licensed to practice in North Dakota who has performed a telemedicine examination or evaluation meeting certain requirements may prescribe medications according to the licensee's professional discretion and judgment.[127]

FDA's 2016 and 2021 actions to loosen the restrictions on mifepristone use, after years of safe use and based on data gathered after its approval and scientific analysis that further demonstrates its safety, have assisted state legislators in addressing the particular healthcare access disparities facing communities they represent—and thereby better serving their constituents. For example, under the pre-2021 REMS for mifepristone, "[o]nly people with the resources to take off work, arrange transportation, secure childcare, and navigate

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[125] Cal. Welf. & Inst. Code § 14132.100 (2023).

[126] Mo. Rev. Stat. § 335.175(1) (2023).

[127] N.D. Cent. Code Ann. § 43-17-45 (2019).

abortion restrictions [could] access care."[128] FDA's removal of the in-person dispensing requirement and expansion of eligible certified prescribers and prescriber authority thus enabled state legislators to better address the disparities and hurdles their constituents face, whether by applying preexisting telehealth initiatives to expand access to medication abortion or enacting new laws specifically to expand access to the full extent of FDA's approval actions.

Finally, FDA's elimination of scientifically unnecessary hurdles to mifepristone access also enables people to obtain abortions earlier in pregnancy, when it is safest and least expensive.[129] State legislators may rightly opt to legislate to foster mifepristone access to minimize both risk and cost to their constituents from alternatives, as well as costs to state health care programs that may otherwise be forced to pay for care needed as a result of

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[128] *See* Elizabeth B. Harned and Liza Fuentes, American Bar Association, *Abortion Out of Reach: The Exacerbation of Wealth Disparities After Dobbs v. Jackson Women's Health Organization* (Jan. 6, 2023), https://www.americanbar.org/groups/crsj/publications/human_rights_magazine_home/wealth-disparities-in-civil-rights/abortion-out-of-reach/.

[129] National Academies of Sciences, Engineering, and Medicine, *The Safety and Quality of Abortion Care in the United States* 5, 28-29 (National Academies Press, 2018), https://nap.nationalacademies.org/catalog/24950/the-safety-and-quality-of-abortion-care-in-the-united-states; *see also* UCSF, Advancing New Standards in Reprod. Health, *The average out-of-pocket cost for medication abortion is increasing, new study confirms* (Apr. 11, 2022), https://www.ansirh.org/research/research/average-out-pocket-cost-medication-abortion-increasing-new-study-confirms.

complications from more invasive procedures that may be necessary later in pregnancy.

The Fifth Circuit's decision eliminates such policy choices from state legislators' toolkits, disempowering them. The Court should overturn that decision and return authority over abortion care—including medication abortion—to state legislators, who are better placed to address the particular needs of the communities they serve.

CONCLUSION

This Court should overturn the Fifth Circuit's decision suspending FDA's 2016 and 2021 REMS modifications.

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APPENDIX

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Rep. Zack Fields	Alaska
Rep. Andy Josephson	Alaska
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