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 Petitions for a Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

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BRIEF OF OVER 600 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 600 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,* 142 S. Ct. 2228 (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. While many do not agree 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 the 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. Counsel of record for all parties received notice at least 10 days before the due date of the intention to file this brief.

expand abortion access consistent with the FDA's scientific judgment and approval processes. Amici ask this Court to grant certiorari to take up and overturn that legally erroneous and factually and scientifically unsound 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*.

There, the 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[.]" *Dobbs*, 142 S. Ct. at 2305 (Kavanaugh, J., concurring). State legislatures and the legislators elected to them, including many elected based on platforms that advocated for expanded abortion access, took up the mantle given them by the Court. Many states have since passed legislation addressing abortion—including legislation regulating medication abortion.

The Fifth Circuit's decision purporting to stay the FDA's 2016 and 2021 REMS modification decisions—and thereby limit access to medication abortion nationwide—comes like the proverbial bull in the china shop. It cannot be squared with the federalism principles that this Court articulated as the basis for its decision in *Dobbs*. In the guise of overseeing the FDA's exercise of routine regulatory authority over pharmaceuticals, the Fifth Circuit

wrests the power to decide abortion access issues back out of the hands of state legislators.

The Fifth Circuit's decision also disrupts the delicate balance between the FDA's authority to approve a drug using rigorous scientific standards, and 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.

State legislators also rely on the FDA's determination of whether a pharmaceutical drug is approved for distribution in the United States, and then regulate from that baseline to make healthcare accessible based on their constituents' needs and preferences. By second-guessing the FDA's actions modifying the baseline requirements for safe distribution and use of mifepristone, the Fifth Circuit has disrupted the state-level democratic processes to address abortion access set in motion by *Dobbs*.

For these reasons, the Court should grant the petitions for a writ of certiorari and overturn the Fifth Circuit's decision—reaffirming state legislators' authority over abortion access issues, consistent with this Court's stated intention in *Dobbs*.

BACKGROUND

Some background on the division of authority over medication approval and access between the FDA and states may be helpful as the Court considers the decision below, and what it means for states' ability to legislatively decide abortion access issues.

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. Commonwealth of 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] In fact, 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 consider and address local equity needs and disparities.[4]

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[2] Jennifer L. Pomeranz, *The Unique Authority of State and Local Health Departments to Address Obesity*, 101 AM. J. PUB. HEALTH 1192, 1192–97 (2011); INSTITUTE OF MEDICINE (US) COMMITTEE FOR THE STUDY OF THE FUTURE OF PUBLIC HEALTH, THE FUTURE OF PUBLIC HEALTH App'x A - Summary of the Public Health System in the United States (National Academies Press (US) 1988), https://www.ncbi.nlm.nih.gov/books/NBK218212/ doi: 10.17226/1091("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).

[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.1; Gulzar H. Shah and John P. Sheahan, *Local Health Departments' Activities to Address Health Disparities and Inequities: Are We Moving in the Right*

States have broad authority to legislate and regulate in furtherance of the health and welfare of their citizens.[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] Additionally, states have authority to declare public health emergencies, and to enact legislation that enables the provision and coverage of telehealth services, directly improving access to health care services for many residents.[9] State laws also seek 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

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Direction?, 13 INT'L. J. ENV'T. RES. PUB. HEALTH 44 (Jan. 2016), 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.

[6] Federation of State Medical Boards, *supra* n.4.

[7] *Id.*

[8] *Id.*

[9] *See, e.g.*, OR. REV. STAT. ANN. § 743A.058.

[10] *See, e.g.*, KAN. STAT. ANN. § 65-2886.

environments for residents.[11] 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.[12]

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 be distributed within their jurisdiction."[13] Some states have exercised this authority by passing legislation to foster access to mifepristone, including by eliminating physician-only prescriber requirements.[14]

States also "are primarily responsible for regulating pharmacists' practices, including the dispensing of medication."[15] When it comes to the delivery and availability of medication, states thus work in tandem with national regulators like FDA.

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[11] *See e.g.*, MISS. CODE. ANN. § 41-88-3 (West); IDAHO CODE ANN. § 39-4803.

[12] *See, e.g.*, ME. REV. STAT. ANN. tit. 22, § 1598(3); WASH. REV. ANN. CODE § 9.02.110.

[13] Catherine M. Sharkey, STATES V. FDA, 83 Geo. Wash. L. Rev. 1609, 1615 (Sept. 2015).

[14] *See, e.g.*, CAL. BUS. & PROF. CODE § 2253 (b)(2); N.Y. PUB. HEALTH LAW § 2599-bb.

[15] Sharkey, *supra* n.12, at 1615.

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

State authority over healthcare does not, however, 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 the 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 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 the 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 the FDA's scientific process that millions of Americans (like the 5.9 million women in the country who have used mifepristone to terminate their pregnancies) access life-saving—and life-changing— medications.[20]

As part of FDA's authority to manage drug risks, the agency sometimes may require a Risk Evaluation and Mitigation Strategy ("REMS").[21] REMS may include elements to assure safe use if the drug has

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[16] U.S. FOOD & DRUG ADMINISTRATION, DEVELOPMENT & APPROVAL PROCESS (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.

[20] *See id.*

[21] *Id.* at 5.

demonstrated efficacy but requires certain guardrails based on risk data available at the time.[22]

Fundamental to FDA's consideration is the potential burden of a REMS on healthcare delivery systems and patient access to drugs.[23] For example, before and after the approval of a REMS, the FDA must consider "how patients for whom the drug is indicated currently access health care (such as whether patients are in rural or medically underserved areas) and whether the REMS may impose additional access difficulties."[24] If, based on periodic assessment or other information, the FDA determines that REMS are no longer necessary to ensure a medication's benefits outweigh its risks, as FDA did in the case of mifepristone, REMS may be modified or removed.[25] Further, by congressional mandate, FDA may not impose REMS that are "unduly burdensome on patient access to the drug, considering in particular . . . patients who have difficulty accessing health care (such as patients in rural or medically underserved areas)." 21 U.S.C. § 355-1(f)(2)(C)(ii).

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[22] U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION, REMS: FDA'S APPLICATION OF STATUTORY FACTORS IN DETERMINING WHEN A REMS IS NECESSARY, GUIDANCE FOR INDUSTRY 9 (Apr. 2019), https://www.fda.gov/media/100307/download.

[23] *Id.*

[24] *Id.*

[25] U.S. FOOD & DRUG ADMINISTRATION, FREQUENTLY ASKED QUESTIONS (FAQS) ABOUT REMS (Jan. 26, 2018), https://www.fda.gov/drugs/risk-evaluation-and-mitigation-strategies-rems/frequently-asked-questions-faqs-about-rems.

Importantly from the perspective of state legislators, the FDA's approval of a drug addresses an area—the determination of whether a drug is safe—that most states would never have the resources to address themselves. State legislators thus depend on the FDA's process to approve medications as safe for distribution and use across the nation, so that they can then take action to ensure that all citizens can access the care that they and their healthcare providers determine is appropriate.

ARGUMENT

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

There is a delicate balance between the FDA's authority over the approval of drugs and states' authority to legislate regarding healthcare and medication access. The Fifth Circuit's decision suspending FDA's 2016 and 2021 mifepristone REMS modifications injects that court into this federal/state partnership. This is inappropriate and problematic, from both practical and legal perspectives. And critically, it is contrary to this Court's holding in *Dobbs*, "return[ing]" the issue of abortion "to the people and their elected representatives." 142 S. Ct. at 2284 (2022). This Court should grant the petition for certiorari to protect the right of states to determine how citizens may access abortion—including through medication procedures that the FDA has approved as safe and effective.

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 2283–84 (citations 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.* at 2284; *see also id.* at 2241 (criticizing *Roe* for ending the "political process" despite one-third of states "liberalizing" 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). Yet the Fifth Circuit's decision overturning the FDA's actions allowing expanded access to mifepristone takes state legislators back out of the policymaking equation.

State legislators have taken *Dobbs'* federalism premise at face value, exercising their authority to regulate abortion access based on their views of what is best for their states and what the constituents who elected them want them to do. For example, just this spring, North Carolina legislators introduced Senate Bill 353 to overturn many of the state's onerous abortion restrictions.[26] 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 young people, people of color and those with disabilities, individuals with low incomes, and those who live in rural areas or are undocumented[.]"[27] Also consistent

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

[27] *Id.*

with *Dobbs*, state populations have democratically voted to decide issues of abortion access.

Some examples of recent state laws[28] and popular initiatives both expanding and restricting abortion access include the below:

Arizona: In 2022, Arizona banned abortion after fifteen weeks' gestation.[29]

California: In November 2022, Californians approved Prop 1, which explicitly adds abortion and contraception rights to the state constitution.[30]

Colorado: In 2022, Colorado enacted a statutory protection for abortion as a fundamental right.[31]

Michigan: In 2022, Michiganders approved Proposition 3, which enshrines reproductive freedom in the Michigan constitution.[32]

Minnesota: In 2023, the state legislature created a statutory right to reproductive freedom.[33]

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[28] In other states, pre-existing "trigger bans" and limitations on abortion pre-dating *Dobbs* have since come into effect. For example, Texas' trigger ban, which outlaws abortion in the state, took effect August 25, 2022.

[29] ARIZ. REV. STAT. § 36-2322.

[30] CAL. CONST. art. 1, § 1.1.

[31] COLO. REV. STAT. ANN. § 25-6-403.

[32] MICH. CONST. art. 1, § 28.

[33] MINN. STAT. ANN. § 145.409.

Montana: In November 2022, voters rejected LR-131, a referendum that could have criminalized medical professionals for providing abortions.[34]

New York: In 2022, New York enacted additional protections for abortion providers.[35]

New Jersey: In 2022, New Jersey enacted a statutory protection for abortion as a fundamental right.[36]

North Carolina: North Carolina has enacted a twelve-week abortion ban, plus additional restrictions, which took effect July 1, 2023.[37]

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.[38]

Vermont: In November 2022, voters approved Proposal 5, which enshrines reproductive freedom in the Vermont constitution.[39]

State legislatures have also taken *Dobbs*' directive and expanded or restricted abortion access in other areas. As of April 2023, over 18 states,

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[34] H.B. 167, Reg. Sess. (Mont. 2021).

[35] N.Y. CRIM. PROC. L. § 570.17.

[36] N.J. STAT. ANN. 10:7-2.

[37] N.C. GEN. STAT. ANN. § 90-21.81B.

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

[39] VT. CONST. ch. I, art. 22.

including California, Colorado, Connecticut, Delaware, the District of Columbia, Hawaii, Maine, Maryland, Massachusetts, Minnesota, Montana, New Hampshire, New Jersey, New York, Oregon, Vermont, Virginia, and Washington, 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. Ohio, on the other hand, prohibits physician assistants and nurses from prescribing abortion medication.[40] Alaska, Arizona, Utah, Nebraska, Kansas, Iowa, Wisconsin, Ohio, Florida, Georgia, South Carolina, and North Carolina require at least one in-person trip to a clinic to receive mifepristone—functionally prohibiting direct-to-patient telehealth prescription.[41] And while 30 states have physician-only requirements for prescribing abortion medication despite FDA's REMS eliminating that requirement, the remaining 20 states do not.[42] Other states have advanced legislation with the aim of ensuring medication abortion access at public universities,[43] and revised public healthcare programs' guidelines on the provision of medication abortion to match updated science.[44]

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[40] OHIO REV. CODE ANN. §§ 4730.02(E), 4723.44(B)(6).

[41] Kaiser Family Foundation, *The Availability and Use of Medication Abortion* (June 1, 2023), https://www.kff.org/womens-health-policy/fact-sheet/the-availability-and-use-of-medication-abortion/.

[42] *Id.*

[43] A.B. A1395C, 2023-2024 Legis. Sess. (N.Y. 2023).

[44] A.B. 576, 2023-2024 Reg. Sess. (Cal. 2023).

In short, states legislators have taken up the mantle given to them by the *Dobbs* court to legislate to address abortion access issues—including questions regarding access to medication abortion. 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 provision to their constituents or otherwise makes access easier (so long as those measures are consistent with the baseline approval requirements set by the FDA).

The Fifth Circuit's decision staying the FDA's 2016 and 2021 REMS modifications also limits state legislators' ability to enact laws expanding telehealth care access. Citizens' use of telehealth-based abortion care has increased 137% nationally since the *Dobbs* decision.[45] Increasing access to telehealth appointments and mail-order pharmacies, as permitted by the FDA's 2016 and 2021 REMS, 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 costly abortion procedures. The Fifth Circuit's decision improperly removes such choices from state legislators, 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 representative—some of whom were elected

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

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. This Court should grant the FDA's petition for certiorari to correct the Fifth Circuit's overreach.

II. State legislators rely on the FDA's process to ensure optimal medication access for their communities, which the Fifth Circuit's decision wrongly obstructs.

State legislators are best placed to consider their constituents' healthcare needs, whether they vary by socioeconomic status or even geographic location. But to legislate well, state legislators rely on FDA's expert drug approval processes. The Fifth Circuit's decision thus jeopardizes state legislators' ability to meet their constituents' needs. The Court should grant the FDA's petition to reaffirm state oversight of drug policy that complies with FDA's scientifically-based safety and efficacy minimums.

A. State populations have different drug access needs that state legislators are best placed to consider.

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 when legislating in regard to abortion access. The Fifth Circuit's decision, on the other hand, projects one view as to appropriate drug access policy—beyond FDA's baseline—across all 50 states for an FDA-approved prescription medication.

The Fifth Circuit's decision improperly interferes with states' authority to legislate in this area. State legislators are better positioned to consider their constituents' needs and differences relevant to medication abortion access. Effective state governance of health is representative of, and more responsive to, constituent needs because it is more localized and considers barriers to healthcare access.[46]

"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."[47] Such disparities exist "across socioeconomic strata, race, ethnicity, and geography in the United States" and "are well-documented in health statistics and the research literature."[48] 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[.]"[49]

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[46] THE FUTURE OF PUBLIC HEALTH, *supra* n.1 at App'x A.

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

[48] 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.

[49] National Conference of State Legislatures, *supra* n.46.

Factors causing 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.[50] Existing inequities only compound obstacles to abortion and miscarriage care,[51] lack of access to which is itself a health disparity.[52]

State legislators consider such disparities when enacting legislation. Between 2020 and 2021, at least 35 states enacted legislation addressing health disparities, including by expanding access to telehealth.[53] 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[.]"[54] This is particularly true for rural communities, many of whom may not otherwise access care due to distance.

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[50] *Id.*

[51] 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.

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

[53] National Conference of State Legislatures, *supra* n.46; National Conference of State Legislatures, *Health Disparities Legislation* (Feb. 21, 2022), https://www.ncsl.org/health/health-disparities-legislation.

[54] Edmiston & AlZubi, *supra* n.47, at 23.

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 several hours off work to attend an in-person doctor's appointment, that conflict with seeking care.[55]

FDA REMS modifications, adjusting requirements for the use of a medication based on data gathered after approval, have assisted state legislators in 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 abortion restrictions [could] access care."[56] FDA's removal of the in-person dispensing requirement and expansion of prescriber authority thus significantly increased access to mifepristone prescribers, the lack of which disproportionately impacts low-income, underserved, and rural communities.[57]

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[55] 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/.

[56] *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/.

[57] *See id.*

The 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.[58] State legislators may rightly opt to legislate to foster mifepristone access to minimize both risk and cost to their constituents from alternatives.

The Fifth Circuit's decision, which does not consider these state-specific interests, thus eliminates sensible policy options from state legislators' toolkits, disempowering them. And it does so despite scientific data showing that the extra protections removed by the 2016 and 2021 REMS modifications are no longer necessary to ensure mifepristone's benefits outweigh its risks. The Court should grant certiorari to return authority to state legislators, who are best placed to address medication abortion access issues based on their knowledge of the particular needs and problems of their constituents.

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[58] 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* 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.

B. State legislators rely on FDA's rigorous assessment of drug safety and effectiveness when setting medication access policy.

The Fifth Circuit's decision threatens to disrupt the delicate balance between, on one hand, the FDA's authority to approve medications, and on the other, states' important roles in ensuring medication access for their constituents.

As noted in an amicus brief filed by states before the Fifth Circuit, "[s]tates rely on the availability of thousands of FDA-approved drugs to treat or manage a range of medical conditions experienced by their residents[.]"[59] Unlike most states, FDA has the experts, resources, institutional capacity, and federal congressional directive at its back to thoroughly, and scientifically, assess drugs' safety and effectiveness. Allowing the Fifth Circuit to strip FDA's authority to weigh risks and set the baseline conditions for distribution of drugs after an extensive regulatory approval process would deprive state legislators of needed medical tools, and the guardrails for safe use of those tools.

FDA relies on its vast expertise to determine whether a drug is safe and effective. By mandate,

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59 Brief for States of N.Y., Ariz., Cal., Colo., Conn., Del., Haw., Ill., Me., Md., Mass., Mich., Minn., Nev., N.J., N.M., N.C., Or., Pa., R.I., Vt., Wash., and Wis., and D.C. as Amicus Curiae, *Alliance for Hippocratic Medicine, et al., v. U.S. FDA, et al.*, 2022 WL 19795709, at *13 (5th Cir. 2022).

FDA assembles expert teams to weigh the evidence.[60] Its teams include "medical doctors, chemists, statisticians, microbiologists, pharmacologists, and other experts" charged with analyzing a drug application's supporting studies.[61] The reviewers consider weaknesses in drug safety and efficacy study designs and analyses and when they need it, the reviewers request additional evidence.[62] When appropriate, FDA also calls on advisory committees, "who provide FDA with independent opinions and recommendations from outside experts on applications to market new drugs, and on FDA policies."[63] States have no comparable dedicated teams to weigh drug safety and efficacy, nor could many states readily assemble such teams.

Throughout its processes, FDA is also able to take "the long view. Its drug-approval determinations consider the interests of all potential users of a drug, including 'those who would suffer without new medical [products]'" if disparate state actions were "free to contradict the FDA's expert determinations." *See Wyeth v. Levine*, 555 U.S. 555, 626 (2009) (Alito, J. dissenting) (discussing dangers of allowing state failure-to-warn claims against FDA-approved drugs despite FDA's labeling oversight) (internal citation omitted). And FDA conveys its warnings as to drugs "with one voice, rather than whipsawing the medical

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[60] U.S. FOOD AND DRUG ADMINISTRATION, FDA'S DRUG REVIEW PROCESS: CONTINUED (Aug. 24, 2015), https://www.fda.gov/drugs/information-consumers-and-patients-drugs/fdas-drug-review-process-continued.

[61] *Id.*

[62] *Id.*

[63] *Id.*

community with 50 (or more) potentially conflicting ones." *See id.* States can thus rightly look to FDA for informed, consistent guidance on drug safety and efficacy, as borne out by its decades of expertise monitoring drug performance throughout the United States and across varied populations.

State legislatures also do not have the resources or capacity to perform FDA's foundational work. FDA's Fiscal Year 2024 budget request totaled $7.2 billion,[64] over $2 billion of which is estimated for the Human Drugs Program.[65] The Human Drugs Program budget alone dwarfs both Minnesota's and North Carolina's Fiscal Year 2022 public health program budgets.[66] Also, as of Fiscal Year 2022, at least 13 states reduced their public health funding.[67] Thus, even if states could replace FDA's drug approval and distribution regulatory regime, budget constraints would prevent most states from doing so.

State legislators therefore have a strong interest in ensuring their constituents have continued access to drugs approved by the FDA based on its data-driven process. The Fifth Circuit's decision improperly obstructs legislators' ability to fulfill their

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[64] U.S. FOOD AND DRUG ADMINISTRATION, FY 2024 FDA BUDGET SUMMARY, https://www.fda.gov/media/166050/download.

[65] U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, FISCAL YEAR 2024: FOOD AND DRUG ADMINISTRATION JUSTIFICATION OF ESTIMATES FOR APPROPRIATIONS COMMITTEES at 72, https://www.fda.gov/media/166182/download?attachment.

[66] Trust for America's Health, *The Impact of Chronic Underfunding on America's Public Health System: Trends, Risks, and Recommendations* 30 (June 2023), https://www.tfah.org/report-details/funding-2023/.

[67] *Id.* at 6.

complementary role by legislating to expand or tailor their constituents' access to an FDA-approved medication. This Court should grant certiorari to protect state legislators' interests in addressing medication abortion access issues through tailored legislation, and overturn the Fifth Circuit's decision taking such authority away from state legislatures—and thereby undermining the democratic process and the federalism principles on which *Dobbs* was based.

CONCLUSION

The Court should grant certiorari to review the Fifth Circuit's decision suspending the FDA's 2016 and 2021 REMS modifications.

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APPENDIX

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Rep. Karlee R. Provenza, PhD	Wyoming
Rep. Mike Yin	Wyoming