Nos. 23-235, 23-236

IN THE

Supreme Court of the United States

FOOD AND DRUG ADMINISTRATION, ET AL.,
Petitioners,

v.

ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.,
Respondents.

DANCO LABORATORIES, L.L.C.,
Petitioner,

v.

ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.,
Respondents.

On Writs of Certiorari to the United States Court of Appeals for the Fifth Circuit

BRIEF OF REPRODUCTIVE FREEDOM ALLIANCE AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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INTEREST OF THE *AMICUS CURIAE*[1]

The Reproductive Freedom Alliance is a non-partisan coalition of 22 Governors who are committed to protecting and expanding reproductive freedom in their respective jurisdictions: Arizona Governor Katie Hobbs, California Governor Gavin Newsom, Colorado Governor Jared Polis, Connecticut Governor Ned Lamont, Delaware Governor John Carney, Guam Governor Lou Leon Guerrero, Hawai'i Governor Josh Green, Illinois Governor JB Pritzker, Maine Governor Janet Mills, Maryland Governor Wes Moore, Massachusetts Governor Maura Healey, Michigan Governor Gretchen Whitmer, Minnesota Governor Tim Walz, New Jersey Governor Phil Murphy, New Mexico Governor Michelle Lujan Grisham, New York Governor Kathy Hochul, North Carolina Governor Roy Cooper, Oregon Governor Tina Kotek, Pennsylvania Governor Josh Shapiro, Rhode Island Governor Daniel McKee, Washington Governor Jay Inslee, and Wisconsin Governor Tony Evers.

Governors formed the Reproductive Freedom Alliance in February 2023 to work together to strengthen reproductive rights and freedom. States, territories, and reproductive healthcare providers have all been forced to adapt their practices to comply with a shifting legal landscape. Those in states where reproductive freedom is protected are grappling with a surge of out-of-state patients and the challenges of helping people access basic health care far from their homes.

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[1] No counsel for any party authored this brief in whole or in part, and no party, counsel, or person other than *amici*, their members, and their counsel contributed money to fund the preparation or submission of this brief.

And those in states where reproductive freedom is limited are working to ensure that their constituents have access to the medical care they need. To address these challenges, Reproductive Freedom Alliance Governors share best practices, engage experts and on-the-ground reproductive healthcare providers, and work together to fight for and protect providers, patients, and all who are affected by efforts to diminish reproductive rights across the country.

Since its creation, Reproductive Freedom Alliance Governors coordinated to stockpile abortion medication to protect access in their states, increased Medicaid reimbursement rates for reproductive services to make these services more affordable, and made contraception more accessible. Reproductive Freedom Alliance Governors have also signed legislation to protect patients and providers, set up information hubs for those seeking care, and signed legislation to protect consumer and medical data related to abortion care.

Given its mandate, the Reproductive Freedom Alliance has a significant interest in ensuring that litigants in one judicial district who are morally opposed to a particular type of prescription-drug product are not permitted to dismantle patient access to that product nationwide. The Reproductive Freedom Alliance is participating in this important case to provide the Court with critical information about the extraordinarily disruptive impacts that affirmance would have on the ability of Governors to protect the health and well-being of their constituents.

SUMMARY OF THE ARGUMENT

The World Health Organization recognizes the medications used for medication abortion as "'core' essential medications for basic healthcare systems, a category comprised of 'the most efficacious, safe, and cost-effective medicines.'"[2] In the United States, medication abortion accounts for more than half of all abortions,[3] and has been repeatedly proven to be a safe and effective method for abortion and miscarriage management.[4] Indeed, these FDA-approved medications are safer than many commonly used over-the-counter and prescription medications, such as penicillin, Tylenol, and Viagra.[5]

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[2] Gilda Sedgh & Irum Taqi, Guttmacher Inst., *Mifepristone for Abortion in a Global Context: Safe, Effective and Approved in Nearly 100 Countries* (July 2023), https://www.guttmacher.org/2023/07/mifepristone-abortion-global-context-safe-effective-and-approved-nearly-100-countries (citation omitted).

[3] Rachel K. Jones et al., Guttmacher Inst., *Medication Abortion Now Accounts for More Than Half of All US Abortions* (Dec. 2022), https://www.guttmacher.org/article/2022/02/medication-abortion-now-accounts-more-half-all-us-abortions.

[4] *See, e.g.*, Luu Doan Ireland et al., *Medical Compared With Surgical Abortion for Effective Pregnancy Termination in the First Trimester*, 126 Obstetrics & Gynecology 22, 25-27 (2015), https://pubmed.ncbi.nlm.nih.gov/26241252/; Elizabeth G. Raymond et al., *First-Trimester Medical Abortion with Mifepristone 200 Mg and Misoprostol: A Systematic Review*, 87 Contraception 26, 30-32 (2013), https://pubmed.ncbi.nlm.nih.gov/22898359/; U.S. Food & Drug Admin., *Mifepristone U.S. Post-Marketing Adverse Events Summary Through 12/31/2022*, https://www.fda.gov/media/164331/download.

[5] Advancing New Standards in Reprod. Health, *Analysis of Medication Abortion Risk and the FDA Report "Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2018,"*

Medication abortion is highly effective and only rarely results in complications that require follow-up treatment.[6] That is why, as access to medication abortion has increased over the past decade or so, most patients increasingly prefer medication abortion when they have a choice between that option and procedural abortion.[7] This is well illustrated by data from North Carolina, where medication abortion accounted for just 23.4% of all abortions in 2011 but 59.1% of all abortions by 2020.[8] And in New Mexico, medication abortion accounted for more than 80% of all abortions covered by Medicaid in 2023.[9] Medication abortion is also more cost effective than procedural abortion, saving patients, insurers, and states (all of whom can be

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at 3 (2022), https://www.ansirh.org/sites/default/files/2022-11/mifepristone_safety_11-15-22_Updated_0.pdf.

[6] Mary Gatter et al., *Efficacy and Safety of Medical Abortion Using Mifepristone and Buccal Misoprostol Through 63 Days*, 91 Contraception 269, 269, 271-272 (2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4373977/; Ushma D. Upadhyay et al., *Incidence of Emergency Department Visits and Complications After Abortion*, 125 Obstetrics & Gynecology 175, 179 tbl. 3 (2015), https://pubmed.ncbi.nlm.nih.gov/25560122/.

[7] Daniel Grossman et al., *Effectiveness and Acceptability of Medical Abortion Provided Through Telemedicine*, 118 Obstetrics & Gynecology 296, 300 (2011), https://pubmed.ncbi.nlm.nih.gov/21775845/ (reporting over 70% of study participants said they strongly preferred medication abortion).

[8] State Ctr. for Health Stats., N.C. Dep't of Health & Human Servs., *NC Resident Abortions: Characteristics of Women Receiving Abortions North Carolina Residents, 2011-2020*, (2020), https://schs.dph.ncdhhs.gov/data/vital/pregnancies/2020/abortioncharacteristics.pdf.

[9] Data obtained from New Mexico Human Services Department (on file with Reproductive Freedom Alliance).

payors) hundreds or even thousands of dollars in per-patient medical costs.[10]

It is therefore no surprise that the availability of safe, effective, and FDA-approved medication abortion is a critical component of the reproductive healthcare regime in states in which abortion is legal, including Reproductive Freedom Alliance member states. Physician shortages, insufficient resources, and rural communities without enough clinics to serve the local populations (known as maternal health deserts) all create enormous challenges for Governors when confronting one of their most important roles—protecting public health. And that is particularly true with respect to reproductive healthcare, given the changing legal landscape over the past several years.

In the wake of this Court's decision in *Dobbs*, Governors took action to increase access to reproductive healthcare services and to ensure that the state's reproductive healthcare resources are sufficient to meet the demand, including in rural areas. In doing so, and even before *Dobbs*, Reproductive Freedom Alliance Governors built their reproductive healthcare infrastructures around, and in reliance on, the stability of the existing FDA framework. Most state executive branches simply do not have the resources, expertise,

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[10] Saeed Husseini Barghazan et al., *Economic Evaluation of Medical Versus Surgical Strategies for First Trimester Therapeutic Abortion: A Systematic Review*, 11 J. Educ. & Health Promotion 184, 5 (2022), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9393924/; Rosalyn Schroeder et al., *Advancing New Standards in Reprod. Health, Trends in Abortion Care in the United States*, 2017-2021 14 (2022), https://www.ansirh.org/sites/default/files/2022-06/Trends%20in%20Abortion%20Care%20in%20the%20United%20States%2C%202017-2021.pdf.

or authority to serve as mini-FDAs.[11] Governors therefore rely heavily on the federal/state division of authority, which tasks FDA with studying the safety and effectiveness of prescription drugs and making approval decisions based on its knowledge and expertise, and tasks Governors with developing and executing solutions in reliance on FDA's approval decisions and expert judgment.

Nothing about this framework contemplates litigants outside of Reproductive Freedom Alliance states who morally disapprove of a particular drug using out-of-state federal courts to invalidate FDA's expert judgment nationwide based on a flimsy APA challenge. This strategy, if successful, would have an enormously disruptive impact on state governance and hamstring Governors' ability to fulfill their mandate of protecting public health and safety in the reproductive healthcare context and beyond. This Court should reject that outcome and reverse the judgment below.

ARGUMENT

I. Governors addressing public-health challenges necessarily rely on FDA determinations to meet the needs of those seeking healthcare in their states.

Governors have an obligation to protect and promote the health and well-being of their constituents. For Reproductive Freedom Alliance Governors, that

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[11] As of 2018, FDA employed approximately 18,000 people, including over 5,000 focused on drug evaluation and research alone. *See* FDA, *Detail of Full-Time Equivalents*, https://www.fda.gov/media/132813/download?attachment (last visited Jan. 24, 2024).

responsibility includes protecting and promoting the right to bodily autonomy and equitable access to reproductive healthcare. This Court's decision in *Dobbs v. Jackson Women's Health Organization*, 597 U.S. 215 (2022), removed federal constitutional protection for abortion and placed the responsibility for safeguarding reproductive rights and ensuring access to reproductive healthcare in the hands of state governments. While Reproductive Freedom Alliance Governors do not agree with that decision, they have responded to the challenges created and exacerbated by that decision with the utmost urgency. They have done so in reliance on FDA's expert determinations regarding the safety and efficacy of medication abortion, which promised not only the continued availability of mifepristone, but also flexibility in the way it is prescribed given variable needs and accessibility challenges faced by many states.

A. In the wake of this Court's decision in *Dobbs* (and even before then, in the months leading up to the issuance of that decision), Reproductive Freedom Alliance Governors took action to protect reproductive rights and increase access to reproductive healthcare.

For example, Maine Governor Janet Mills, New Mexico Governor Michelle Lujan Grisham, Michigan Governor Gretchen Whitmer, and Minnesota Governor Tim Walz issued executive orders directing their state agencies to develop and implement strategies to expand access to reproductive healthcare, including medication abortion, in underserved areas.[12] New

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[12] Me. Exec. Order No. 4 (July 5, 2022), https://www.maine.gov/governor/mills/index.php/official_documents/executive-orders/2022-07-executive-order-4-order-protecting-access-reproductive; N.M. Exec. Order No. 2022-107 (June 27, 2022),

York Governor Kathy Hochul created a $35 million fund to directly support abortion providers in her state, and signed legislation that provided abortion providers with increased protections.[13] Illinois Governor JB Pritzker increased Medicaid reimbursement rates for reproductive healthcare services and expanded Title X funding through the Illinois Department of Public Health for family planning and reproductive healthcare service providers across the state.[14]

Massachusetts Governor Maura Healey issued an executive order to protect access to medication

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https://www.governor.state.nm.us/wp-content/uploads/2022/06/Executive-Order-2022-107.pdf; Mich. Exec. Order No. 2022-5 (May 25, 2022), https://www.michigan.gov/whitmer/-/media/Project/Websites/Whitmer/Documents/Exec-Directives/ED-20225-Reproductive-Rights-in-Michigan-with-signature.pdf; Minn. Exec. Order No. 22-16, 46 Minn. Reg. 1532 (June 27, 2022), https://mn.gov/admin/assets/SR46_52%20-%20Accessible_tcm36-532112.pdf.

[13] Off. of Governor Kathy Hochul, *Governor Hochul Announces Nation-Leading $35 Million Investment to Support Abortion Providers in New York* (May 10, 2022), https://www.governor.ny.gov/news/governor-hochul-announces-nation-leading-35-million-investment-support-abortion-providers-new; Off. of Governor Kathy Hochul, *Governor Hochul Signs Nation-Leading Legislative Package to Protect Abortion and Reproductive Rights for All* (May 10, 2022), https://www.governor.ny.gov/news/governor-hochul-signs-nation-leading-legislative-package-protect-abortion-and-reproductive.

[14] Press Release, Off. of Governor JB Pritzker, Gov. Pritzker Announces Medicaid Reimbursement Increases and Expanded Title X Funds for Reproductive Health Care Providers (Aug. 4, 2022), https://hfs.illinois.gov/content/dam/soi/en/web/hfs/sitecollectiondocuments/governorpritzkerannouncesmedicaidreimbursementincreasesforreproductivehealthcareproviders.pdf.

abortion in the state and to support public institutions of higher education in developing and implementing medication abortion readiness plans.[15] California Governor Gavin Newsom and Pennsylvania Governor Josh Shapiro each launched new websites offering reproductive healthcare resources in the wake of the lower court decisions in this case.[16] The Pennsylvania website includes an interactive map, search capabilities to find local providers, and information on seeking financial support for reproductive healthcare—offering crucial support in a state where over 55% of abortions occur through the medication method.[17]

North Carolina Governor Roy Cooper issued an executive order requiring all Executive Cabinet Agencies to coordinate to protect anyone providing, assisting, seeking, or obtaining lawful reproductive healthcare services in North Carolina, protecting access to and egress from healthcare facilities, and forbidding Cabinet Agencies from requiring pregnant employees to travel for work to a state that restricts access to reproductive healthcare that does not

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[15] Ma. Exec. Order No. 609 (Apr. 10, 2023), https://www.mass.gov/executive-orders/no-609-protecting-access-to-medication-abortion-services-in-the-commonwealth; Mollie Fairbanks, Guttmacher Inst., *How Governors Used Executive Orders to Protect Abortion Access in a Post-*Roe *United States*, (July 20, 2023), https://www.guttmacher.org/2023/07/governors-eo-analysis-appendix-table.

[16] *Accessing Abortion Care in Pennsylvania*, http://www.pa.gov/freedomtochoose (last visited Jan. 26, 2024); *California Abortion Access*, https://abortion.ca.gov/ (last visited Jan. 26, 2024)

[17] Pa. Dep't of Health, 2021 Abortion Statistics 8 (2022), https://www.health.pa.gov/topics/HealthStatistics/VitalStatistics/Documents/Pennsylvania_Annual_Abortion_Report_2021.pdf.

include an exception for the health of the pregnant person.[18]

Anticipating increased demand for abortion services from individuals living in states enacting or expecting to enact abortion bans or restrictions, Reproductive Freedom Alliance Governors also took action to ensure that the increased demand would not overwhelm the resources of in-state providers who offer not only abortion services, but other critical reproductive healthcare services like cancer screenings and pregnancy care. For instance, New Mexico Governor Michelle Lujan Grisham allocated $10 million in funding to a reproductive healthcare clinic.[19] New York Governor Kathy Hochul allocated $35 million from the health commissioner's emergency fund to expand provider capacity, increase abortion access, and enhance safety measures for abortion,[20] and subsequently promised $100.7 million more in new funding for abortion providers and reproductive healthcare clinics in 2024.[21] Oregon Governor Kate Brown established a

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[18] N.C. Exec. Order No. 263 (July 6, 2022), https://governor.nc.gov/executive-order-no-263.

[19] N.M. Exec. Order No. 2022-123 (Aug. 31, 2022), https://www.governor.state.nm.us/wp-content/uploads/2022/08/Executive-Order-2022-123.pdf.

[20] Kierra B. Jones, Ctr. for Am. Progress, *Expanding Access and Protections in States Where Abortion Is Legal* (July 25, 2022), https://www.americanprogress.org/article/expanding-access-and-protections-in-states-where-abortion-is-legal/ (Jones, *Expanding Access*).

[21] Off. of Governor Kathy Hochul, *Governor Hochul Announces Major Actions to Strengthen Abortion Protections and Access as Part of FY 2024 Budget* (May 3, 2023), https://www.governor.ny.gov/news/governor-hochul-announces-major-actions-strengthen-abortion-protections-and-access-part-fy (Hochul, *Major Actions*).

$15 million reproductive healthcare equity fund to expand provider network capacity and patient access.[22] Between 2022 and 2023, California allocated over $200 million to support abortion patients and providers.[23] This includes funding for the Abortion Practical Support Fund, which provides support for those seeking abortions; clinical infrastructure grants to assist with training providers, including advanced practice clinicians ("APCs"), on abortion-related care; and scholarships and loan repayments for healthcare workers committed to providing reproductive healthcare.[24] And immediately following *Dobbs*, Washington Governor Jay Inslee announced $1 million in emergency funds for reproductive healthcare clinics in the state.[25] In light of legal challenges, like respondents', that threaten the supply of mifepristone nationwide, several Reproductive Freedom Alliance Governors have also entered stock-up agreements with suppliers to protect the continued availability of these medications in their states.[26] Massachusetts, for example, purchased 15,000 doses for this purpose,

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[22] Jones, *Expanding Access*, *supra*.

[23] Data obtained from California Department of Health & Human Services (on file with Reproductive Freedom Alliance).

[24] Cal. Dep't of Health Care Access & Information, *Reproductive Health Care Access Initiative*, https://hcai.ca.gov/workforce/initiatives/reproductive-health-care-access-initiative/#:~:text=The%20Abortion%20Practical%20Support%20Fund,food%2C%20and%20other%20ancillary%20supports. (last visited Jan. 28, 2024).

[25] Jones, *Expanding Access.*

[26] *See, e.g.*, *id.*; Sarah McCammon, *With Abortion Pill Access Uncertain, States Strike Deals to Stock Up*, Nat'l Pub. Radio (April 11, 2023), https://www.npr.org/2023/04/10/1162182382/california-strikes-deal-to-stock-up-on-abortion-pills.

and Washington has stockpiled approximately three years' worth of anticipated mifepristone needs.[27]

These types of actions aren't merely policy preferences—many Governors are bound by state constitutions to uphold their constituents' right to abortion care.[28] In order to fulfill those mandates, Reproductive Freedom Alliance Governors depend on their ability to implement policies that accurately reflect the needs of those who seek reproductive healthcare in their states. And that ability relies on a consistent supply of FDA-approved medications, and on the stability of FDA approval decisions that allow for broad access to critical medication.

B. While the need for these types of gubernatorial actions is certainly new given the federal constitutional protections that had been recognized for 50 years before this Court's decision in *Dobbs*, the actions themselves were hardly unusual. Governors have long played an important role in improving health outcomes for those in their states—indeed, that is one of their most critical obligations in public service.[29] "With an emphasis on finding equitable solutions to

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[27] *Id.*

[28] *See* Martin K. Mayer et al., Dobbs, *American Federalism, and State Abortion Policymaking*, 53 Publius: J. Federalism 378, 383 (2023) (providing a survey of state constitutional provisions covering abortion and noting that the state constitutions of California, Michigan, and Vermont explicitly protect abortion, and fourteen other state constitutions have been interpreted by their high court as protecting at least some abortion rights).

[29] *See, e.g.*, Minn. Dep't of Health, *Government's Responsibility for Public Health*, https://www.health.state.mn.us/communities/practice/resources/chsadmin/mnsystem-responsibility.html (last updated May 3, 2023).

some of the most pressing public health issues, governors establish partnerships, utilize state resources, and work across multiple sectors and state agencies to develop and promote relationships to improve public health."[30] To achieve this goal, governors have a number of tools at their disposal, including signing (or vetoing) proposed legislation and issuing executive orders that address public health emergencies, establishing new programs or entities to study or tackle ongoing public health concerns, directing state agencies, and recommending (and implementing) state budgets.[31]

For example, Governors have long played a significant role in developing policies and promoting awareness surrounding childhood immunization, in order to prevent the spread of infectious disease.[32] All 50 states and the District of Columbia mandate some form of vaccination for children in public school.[33] But

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[30] Nat'l Governors Ass'n, *Public Health*, https://www.nga.org/bestpractices/public-health/ (last visited Jan. 11, 2024).

[31] *See, e.g.*, Maxim Gakh et al., *Using Gubernatorial Executive Orders to Advance Public Health*, 128 Public Health Reps. 127, 127-130 (2013); Nat'l Governors Ass'n, *Powers and Authority*, https://www.nga.org/governors/powers-and-authority/ (last visited Jan. 25, 2024).

[32] *See, e.g.*, Off. of Governor Kathy Hochul, *To Mark National Immunization Awareness Month, Governor Hochul Encourages New Yorkers to Stay Up to Date on Vaccines as School Returns and Fall Nears*, (Aug. 11, 2023) https://www.governor.ny.gov/news/mark-national-immunization-awareness-month-governor-hochul-encourages-new-yorkers-stay-date.

[33] Drew DeSilver, Pew Research Ctr., *States Have Mandated Vaccinations Since Long Before COVID-19* (Oct. 8, 2021), https://www.pewresearch.org/short-reads/2021/10/08/states-have-mandated-vaccinations-since-long-before-covid-19/.

the extent to which each state requires childhood immunization varies, depending on the needs and values of state residents, as well as the threat of any unique public health emergencies.[34] When states mandate childhood immunization, they necessarily rely on decades of FDA research and evaluation, leading to expert determinations about the safety and efficacy of vaccines for children. If those types of critical determinations could easily be overturned through spurious APA challenges, it could render key vaccines unavailable for use in stopping the spread of preventable diseases.

C. Reproductive Freedom Alliance Governors now face serious challenges in the context of reproductive healthcare, due to the uncertainty surrounding the availability of mifepristone in the future. *Dobbs*, of course, permits states to restrict abortion. Following that decision, numerous states did exactly that.[35] In addition to making it impossible as a practical matter for many women to access abortion, post-*Dobbs* abortion restrictions have also forced women in many states to travel to obtain the reproductive healthcare they need. As a result, "[s]tates where abortion remained legal saw an average of 9,733 more abortions per month and a cumulative total of 116,790 more abortions in those states in the 12 months post

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[34] *Id.*; *see also* Julia Horowitz, *California Governor Signs Strict New Vaccination Law*, Associated Press (June 30, 2015), https://apnews.com/article/398c4096d34c42099ef5a5f5b8c96aea.

[35] Guttmacher Inst., *Interactive Map US Abortion Policies and Access After* Roe, https://states.guttmacher.org/policies/ (last visited Jan. 25, 2024).

Dobbs."[36] Indeed, approximately 92,100 people in the United States traveled out of state to receive abortions in the first half of 2023, more than double the number of patients who traveled out of state for an abortion in 2020, before *Dobbs* .[37] One study by the Guttmacher Institute found that nearly one in five abortion patients traveled out of state to obtain abortion care in the first six months of 2023, as compared with one in ten abortion patients during a similar period in 2020.[38]

These increases have been particularly evident in surge states—states that permit abortion and are geographically proximate to states that ban or severely restrict abortion.[39] Illinois, for example, saw abortions increase by 21,500 in the year following *Dobbs*; Florida, by 20,460; North Carolina, by 11,830;

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[36] Soc'y for Fam. Plan., *#WeCount Report, April 2022 to June 2023*, at 3, https://societyfp.org/wp-content/uploads/2023/10/WeCountReport_10.16.23.pdf (Oct. 24, 2023) (*#WeCount Report*).

[37] *Id.*

[38] Guttmacher Inst., *New Data Show That Interstate Travel for Abortion Care in the United States Has Doubled Since 2020* (Dec. 7, 2023), https://www.guttmacher.org/news-release/2023/new-data-show-interstate-travel-abortion-care-united-states-has-doubled-2020. Justice Kavanaugh's concurrence in *Dobbs* contemplated this exercise of patient choice in response to restrictive state abortion laws. *See Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215, 346 (2022) (Kavanaugh, J., concurring) ("[A]s I see it, some of the other abortion-related legal questions raised by today's decision are not especially difficult as a constitutional matter. For example, may a State bar a resident of that State from traveling to another State to obtain an abortion? In my view, the answer is no based on the constitutional right to interstate travel.").

[39] *#WeCount Report*, *supra*, at 4.

California, by 8,810; and New Mexico, by 8,640.[40] In Michigan, out-of-state patients seeking abortions from Planned Parenthood have more than tripled following *Dobbs*.[41] And 72% of all abortions performed in 2023 in New Mexico were for patients who traveled from Texas.[42] Even non-surge states, like Massachusetts, have seen increases.[43] Elizabeth Janiak of the Division of Family Planning at the Department of Obstetrics and Gynecology at Brigham and Women's Hospital in Massachusetts explained, "We've always had abortion travelers from New England," but since *Dobbs*, "we see that we have people coming from much farther away, like Texas, Louisiana, Florida, or Georgia."[44]

These increases in demand have serious impacts on patient access to medical care—and not just to abortion.[45] Healthcare providers in North Carolina

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[40] *Id.*

[41] Data obtained from Planned Parenthood of Michigan (on file with Reproductive Freedom Alliance).

[42] Data obtained from New Mexico Department of Health (on file with Reproductive Freedom Alliance).

[43] Brianna Keefe-Oates et al., *Use of Abortion Services in Massachusetts After the* Dobbs *Decision Among In-State vs Out-of-State Residents*, JAMA Netw. Open e2332400 (2023), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10483311/#:~:text=After%20Dobbs%2C%20there%20was%20a,estimated%20190%20additional%20abortions%20overall (reporting a 6.2% increase in the total number of abortions post-*Dobbs*).

[44] BWH Commc'ns, *Surge in 'Abortion Travelers' to Mass. Post-Dobbs*, Harvard Gazette (Sept. 6, 2023), https://news.harvard.edu/gazette/story/2023/09/massachusetts-sees-rise-in-out-of-state-abortion-patients-post-dobbs-since-roe-overturned/.

[45] Marisa Kendall, *Demand Has Quadrupled at Some California Abortion Clinics Since Roe Fell*, The Mercury News (Jan. 1,

have reported "seeing an influx of out-of-state patients" seeking abortion care, resulting in increases in wait times for abortion and other health services.[46] For example, in Asheville, North Carolina, wait times for medication abortion appointments have nearly doubled.[47]

Even prior to *Dobbs*, lean staffing and insufficient funding often left many facilities struggling to meet patient demand for the whole spectrum of reproductive healthcare, which encompasses not only abortion, but pregnancy care, cancer screenings, miscarriage management, and more. Many clinics that provide abortion care already served large, dispersed populations, resulting in long wait times for appointments. It was (and still is) particularly challenging to schedule appointments for treatments that require the presence of a doctor, due in large part to the nationwide shortage of physicians.[48]

2023), https://www.mercurynews.com/2023/01/01/demand-has-tripled-quadrupled-at-california-abortion-clinics-since-roe-fell/

[46] Decl. of Katherine Farris, M.D. in Support of Plaintiffs' Motion for a Partial Preliminary Injunction ¶ 54, *Planned Parenthood S. Atlantic v. Timothy K. Moore*, No. 20 CVS 500147 (N.C., General Court of Justice, Sup. Ct. Div.).

[47] *Id.* ¶ 62.

[48] Advisory Bd., *America Deliberately Limited Its Physician Supply—Now It's Facing a Shortage* (Feb. 16, 2022), https://www.advisory.com/daily-briefing/2022/02/16/physician-shortage; Mary Carmichael, *Primary-Care Doctor Shortage Hurts Our Health*, Newsweek (Feb. 25, 2010), https://www.newsweek.com/primary-care-doctor-shortage-hurts-our-health-75351; Elaine Howley, *The U.S. Physician Shortage Is Only Going to Get Worse. Here are Potential Solutions*, Time (Jul. 25, 2022), https://time.com/6199666/physician-shortage-challenges-solutions/.

In these states, a few clinics often serve as the only providers of medication abortion—or *any* reproductive healthcare—for large geographic areas.[49] This problem has only been made worse as more clinics that provide abortion care have closed following the *Dobbs* decision.[50] As of April 2023, one study found that 14% of the population is more than 200 miles from the nearest abortion facility, and the average American is 86 miles from a provider.[51]

Governors have sought to address these challenges in various ways, but these efforts have all been premised on FDA's expert judgments regarding safety and

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[49] *See, e.g.*, Liza Fuentes & Jenna Jerman, *Distance Traveled to Obtain Clinical Abortion Care in the United States and Reasons for Clinic Choice*, 28 J. Women's Health 1623, 1623 (2019), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6919239/ (finding that, as of 2014, nearly 35% of abortion patients traveled more than 25 miles one-way to access care, even though nearly half of abortion patients went to their nearest provider and 32% chose their facility because it was the closest); Teddy Rosenbluth, *New Abortion Law Drives Out NC's Scarce Supply of OB-GYNs & Primary Care Doctors*, News & Observer (Sept. 22, 2023), https://www.newsobserver.com/news/politics-government/article278503164.html.

[50] *See, e.g.*, Rosenbluth, *supra*; Benjamin Rader et al., *Estimated Travel Time and Spatial Access to Abortion Facilities in the US Before and After the Dobbs v Jackson Women's Health Decision*, 328 JAMA 2041, 2045-46 (Nov. 1, 2022), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9627517/#:~:text=In%20this%20repeated%20cross%2Dsectional,and%20100.4%20minutes%20in%20the.

[51] Selena Simmons-Duffin & Shelly Cheng, *How Many Miles Do You Have to Travel to Get Abortion Care? One Professor Maps It*, Nat'l Pub. Radio (June 21, 2023), https://www.npr.org/sections/health-shots/2023/06/21/1183248911/abortion-access-distance-to-care-travel-miles.

effectiveness—judgments that have been challenged in this litigation and displaced by the decision below. For example, some states have sought to meet patient demand by expanding the pool of available providers who could prescribe mifepristone based on FDA's evidence-based expert determination in 2016 that non-physician providers could safely and effectively prescribe and dispense the drug.[52] California, for instance, amended several statutes to make it easier for more practitioners to provide abortion care.[53] In contrast to the physician shortage, the number of APCs—which includes nurse practitioners, physician assistants, and certified nurse midwives—has increased, as many states have invested in more training programs and relaxed the rules governing the scope of practice and prescribing authority for qualified APCs.[54] To obtain an APC license, a clinician must meet rigorous educational, certification, and continuing education requirements.[55] APCs in every state

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[52] *See, e.g.*, Jones, *Expanding Access*, *supra*; Nicole Dube, Conn. Off. of Legis. Rsch., *States Allowing Non-Physicians to Provide Abortion Services* (July 29, 2022), https://www.cga.ct.gov/2022/rpt/pdf/2022-R-0167.pdf.

[53] *See, e.g.*, Cal. Bus. & Prof. Code § 870 (amended to accelerate the licensing process for health care professionals who come to California to perform abortions); Cal. Health & Safety Code §§ 128560-128564 (establishing the California Reproductive Health Scholarship Corps to recruit, train, and retain diverse reproductive healthcare professionals, including APCs, in underserved areas of the state).

[54] *See* Philip Zhang, *Practitioners and Prescriptive Authority*, StatPearls (Nov. 13, 2023), https://www.statpearls.com/point-of-care/131545.

[55] *See* Fed. Trade Comm'n, Policy Perspectives: Competition and the Regulation of Advanced Practice Nurses 7-8, 35 (Mar. 2014), https://www.ftc.gov/system/files/documents/reports/policy-persp

can legally prescribe controlled substances.[56] APCs also regularly and independently provide all elements of patient care before and after a medication abortion, including diagnosing and dating an intrauterine pregnancy, screening for contraindications, providing options counseling, providing follow-up care to ensure that the abortion was complete, and assessing and managing post-abortion complications.[57]

The "progressively increasing" practice scope and prescriptive authority of APCs has "occurred mainly through changing individual state laws," and states take different approaches to these regulations depending on the needs of their constituents.[58] Relying on APCs for treatments for which the presence of a physician is not medically necessary has been shown to significantly increase access to vital healthcare services, including reproductive healthcare, particularly in rural areas.[59] For example, in 2013, California

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ectives-competition-regulation-advanced-practice-nurses/140307aprnpolicypaper.pdf (FTC, Policy Perspectives).

[56] Kathryn Osborne, *Regulation of Controlled Substance Prescribing: An Overview for Certified Nurse-Midwives and Certified Midwives*, 62 J. Midwifery & Women's Health 341, 344 (2017), https://pubmed.ncbi.nlm.nih.gov/28544336/.

[57] *See, e.g.*, Planned Parenthood Cal. Cent. Coast, Job Description for Clinician Role 1, https://www.plannedparenthood.org/files/4314/7278/8320/Clinician.pdf (last visited Jan. 23, 2024) (describing essential functions of advanced practice clinician role); Marge Berer, *Provision of Abortion by Mid-Level Providers: International Policy, Practice, and Perspectives*, 87 Bull. World Health Org. 58, 59 (2009), https://pubmed.ncbi.nlm.nih.gov/19197405/.

[58] Zhang, *supra*.

[59] *See, e.g.*, *id.*; *see also* Susan Yanow, *It Is Time to Integrate Abortion into Primary Care*, 103 Am. J. Pub. Health 14, 15 (2013),

enacted a law authorizing APCs to provide abortions.[60] As a result, "access to abortion care and the quality of care improved," and "[a]t some clinics, the presence of these abortion-trained personnel made the difference in being able to offer the service at all." [61]

FDA's REMS modification in 2016 reflecting its finding that mifepristone can be prescribed safely and effectively by APCs to the extent permitted by state law made it possible for reproductive healthcare facilities to increase their capacity by allowing APCs to independently prescribe mifepristone for abortion and miscarriage management. As of June 2023, twenty states have exercised the option to allow APCs to prescribe abortion medication.[62] Maryland even allocated $3.5 million toward the Abortion Care Clinical Training Program, which trains "clinical professionals on abortion care services, so that participating clinical care teams can increase the number of qualified professionals."[63]

Telehealth has likewise become a critical part of reproductive healthcare and has helped states cope with the surge in demand for abortion care and lack of

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https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3518342/; Howley, *supra*.

[60] A.B. 154, 2013 Leg., Reg. Sess. (Cal. 2013).

[61] Molly Battistelli et al., *Expanding the Abortion Provider Workforce: A Qualitative Study of Organizations Implementing a New California Policy*, 50 Persp. on Sexual & Reprod. Health 33, 34-35 (2018), https://pubmed.ncbi.nlm.nih.gov/29443434/.

[62] KFF, *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/.

[63] Jones, *Expanding Access*, *supra*.

access in healthcare deserts. FDA allowed mifepristone to be administered by telehealth and delivered via mail during the COVID-19 pandemic and made that determination permanent in 2021. Pet.App.11a, No. 23-235. Administration of mifepristone in this manner is "feasible, safe, and efficacious."[64] In light of FDA's expert determination that mifepristone can be prescribed safely and effectively without in-person visits, many states expanded access by opening new virtual clinics and enhancing telehealth services.[65] Doing so has allowed providers to treat more patients and reduced the amount of travel required to obtain medication abortion, which is particularly important for those who reside in rural areas.[66] Indeed, between April 2022 and June 2023 (the period between a few months prior to the *Dobbs* opinion and the one-year anniversary of its issuance), medication abortions via telehealth at virtual-only clinics jumped almost 90%.[67]

However, predictability of supply and certainty surrounding federal policy are vital to any state's ability to craft meaningful and effective solutions to the challenges facing reproductive healthcare. State

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[64] Ushma D. Upadhyay et al., *Safety and Efficacy of Telehealth Medication Abortions in the US During the COVID-19 Pandemic*, 4 JAMA Netw. Open e2122320 (2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8385590/ (Upadhyay, *Safety and Efficacy of Telehealth*).

[65] *#WeCount Report*, *supra*, at 7.

[66] Leah A. Koenig et al., *The Role of Telehealth in Promoting Equitable Abortion Access in the United States*, 9 JMIR Pub. Health & Surveillance e45671 (2023), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10664017/.

[67] *See id.* at 20.

governments generally do not have the resources to independently analyze the safety and efficacy of proposed drug treatments. They rely on FDA to make those assessments, approve medication regimens, and update REMS based on findings of what is medically or scientifically appropriate or necessary. In other words, when states make decisions about allocating funds, expanding telehealth, or allowing qualified practitioners to administer certain drugs, they do so in reliance on FDA's expert judgment—and with the understanding that FDA's expert judgment will not be easily displaced at the request of private litigants with moral qualms about particular drug treatments. Governors cannot effectively serve their vital role of protecting public health and safety if FDA judgments that have stood for years, or even decades, can suddenly be substituted for the moral judgments of private citizens in other states.

II. The decision below would have enormously disruptive consequences and undermine Governors' ability to protect public health and safety.

As noted above, demand for abortion care has not decreased since this Court's decision in *Dobbs*—but the provision of abortion has become concentrated in particular states and regions, including Reproductive Freedom Alliance member states. Although these dynamics have seriously strained healthcare resources in states that have seen a surge in demand for all reproductive healthcare services, Reproductive Freedom Alliance Governors have been able to take action to meet those needs in reliance on the FDA's 2016 and 2021 REMS modifications as noted above. However, if a single court can invalidate those FDA decisions

nationwide based on a flimsy challenge from a group of doctors who do not even prescribe mifepristone, the effect will be seismic—creating unprecedented public-health challenges that Reproductive Freedom Alliance Governors will have no realistic ability to address and that will harm doctors and patients across the country.

A. If Reproductive Freedom Alliance Governors are forced to squeeze their reproductive-health infrastructure into a pre-2016 regime, the consequences will be significant: increased strain on many healthcare providers and decreased patient access to both abortion and non-abortion healthcare. Even before the *Dobbs* decision, Governors faced serious public health challenges in ensuring adequate reproductive healthcare resources.[68] Prior to the 2021 REMS modifications, the constituents of many Reproductive Freedom Alliance member states had to travel long distances for one or more in-person appointments, often requiring them to coordinate childcare,[69] miss work, and expend resources that they did not have simply to take the mifepristone and misoprostol drug regimen.[70] Other constituents found themselves

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[68] *See* Jenna Jerman et al., *Barriers to Abortion Care and Their Consequences for Patients Traveling for Services: Qualitative Findings from Two States*, 49 Persps. on Sexual & Reprod. Health 95, 101 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5953191/.

[69] Most abortion patients are already parents. *See* Lawrence B. Finer, *Timing of Steps and Reasons for Delays in Obtaining Abortions in the United States*, 74 Contraception 334, 335 tbl. 1 (2006), https://pubmed.ncbi.nlm.nih.gov/16982236/.

[70] Fuentes & Jerman, *supra*, at 1629-30; Sarah Christopherson & Olivia Snavely, Nat'l Women's Health Network, *The FDA's Convoluted Stance on Abortion Pills Doesn't Protect Patients—It*

waiting weeks for an appointment to even become available, increasing the probability that they would need a procedural abortion rather than medication abortion.[71] And of course, the need for physician prescriptions significantly taxed the resources of healthcare providers and meant that many abortions had to occur through medical procedures rather than medication, if at all.

Returning to a world in which FDA's 2016 and 2021 REMS do not exist would not only restore these challenges but also exacerbate them—because it would occur in a post-*Dobbs* world in which many states have seen massive surges in demand and huge physician shortages. And those shortages are likely to only increase over time: the U.S. faces a projected physician shortage of between 37,800 and 124,000 physicians within the next decade.[72] While APCs are anticipated to generally play a "greater role in alleviating the effects of shortages and mitigating access problems,"[73] that will not be possible in the abortion context should the respondents' tactics prevail here. If APCs cannot independently prescribe medication abortion (including through telehealth-only

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Endangers Them (May 8, 2020), https://nwhn.org/the-fdas-convoluted-stance-on-abortion-pills-doesnt-protect-patients-it-endangers-them/.

[71] Amelia Thomson-DeVeaux et al., *It Can Already Take Weeks to Get an Abortion*, FiveThirtyEight (Apr. 18, 2022), https://fivethirtyeight.com/features/it-can-already-take-weeks-to-get-an-abortion/.

[72] HIS Markit Ltd., Ass'n of Am. Med. Colls., *The Complexities of Physician Supply and Demand: Projections From 2019 to 2034*, at 3 (June 2021), https://www.aamc.org/media/54681/download.

[73] FTC, Policy Perspectives, *supra*, at 25.

appointments), in states suffering from a physician shortage all in-person abortion and miscarriage-management care will fall to the already dwindling number of physicians—an unsustainable burden that will affect the ability of physicians to not only treat abortion patients, but also see and treat patients suffering from other conditions as well.[74] These resource constraints will almost certainly mean long wait times for cancer and STD screenings, pregnancy visits, and other healthcare needs.

Moreover, the resource constraints discussed above assume that a decision affirming the Fifth Circuit would have no impact on the supply of mifepristone. But in all likelihood, returning to the pre-2016 regulatory regime would prove to be even *more* disruptive because it would likely require suppliers of mifepristone to repackage and relabel the product before it could be sold, as the Fifth Circuit acknowledged.[75] Completing such changes will take time, and will likely interrupt the supply of mifepristone.

The consequences would be severe: Reproductive Freedom Alliance Governors would be deprived of the tools provided by the existing FDA framework that

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[74] Am. Coll. of Obstetricians and Gynecologists, *Issue Brief: Advanced Practice Clinicians and Abortion Care Provision* 1 (2023), https://www.acog.org/-/media/project/acog/acogorg/files/advocacy/issuebrief-advancedpractice-103123.pdf ("Even before *Roe v. Wade* was overturned, people in many regions of the United States did not have local access to a physician who provided abortion care, and travel for abortion care to neighboring counties or states was common. . . . Integrating advanced practice clinicians (APCs) . . . into abortion care can help expand and increase access to this essential care.").

[75] *See* Pet. App. 66a.

make it possible for them to fulfill their mandate of protecting public health, physicians and healthcare systems would be overwhelmed, and patients seeking abortions, suffering from early pregnancy losses, and attempting to obtain OB/GYN care more generally would be the ones to suffer the most[76]— low-income and rural women in particular.[77] Indeed, women with low incomes and who live in rural areas often face transportation limitations, such as lacking or sharing a car or having an unreliable vehicle, which makes it particularly difficult for them to travel long distances, especially for repeated in-person appointments.[78] As a result of these hardships, some women would have

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[76] *See generally* Silpa Srinivasulu et al., *US Clinicians Perspectives on How Mifepristone Regulations Affect Access to Medication Abortion and Early Pregnancy Loss Care in Primary Care*, 104 Contraception 92 (2021), https://pubmed.ncbi.nlm.nih.gov/33910031/ (documenting the physical, emotional, and financial harms suffered by patients in need of abortion or early pregnancy loss care when mifepristone is unavailable in primary care).

[77] *See* FTC, Policy Perspectives, *supra*, at 21; Sarah E. Baum et al., *Women's Experience Obtaining Abortion Care in Texas After Implementation of Restrictive Abortion Laws: A Qualitative Study*, 11 PLoS One e0165048, 5-14 (2016), https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0165048 (observing burdens women faced due to increased travel distances due to Texas abortion restrictions, including among women who strongly preferred medication abortion and women who obtained a procedural abortion though they preferred medication).

[78] Jerman et al., *supra*, at 11; Working Cars for Working Families, Nat'l Consumer Law Ctr., *Dangerous and Unreliable Vehicles*, http://www.workingcarsforworkingfamilies.org/promoting-improved-publicpolicy/dangerous-and-unreliable-vehicles (last visited Jan. 25, 2024); Elaine Murakami & Jennifer Young, Daily Travel by Persons with Low Income 6 (1997), https://rosap.ntl.bts.gov/view/dot/13239/dot_13239_DS1.pdf.

to wait weeks before they can access abortion care[79]—delays that can push a pregnant patient past the gestational age limit for medication abortion altogether.[80] For example, in Texas, as a result of the number of abortion providers dropping from 41 to 22 in 2013, there was a statistically significant increase in the proportion of abortions that occurred in the second trimester, suggesting that restrictions on abortion access delayed abortions from the first into the second trimester.[81]

Delays due to decreased access pose significant public-health problems. For many patients, medication abortion is the safest option. And for those who have experienced sexual assault, it can be a vastly preferred method over procedural abortion given the sexual trauma they have already endured. But if state healthcare systems are overwhelmed by the combination of abortion surges following *Dobbs* and the rollback of FDA's 2016 and 2021 REMS modifications, the form of abortion that medical consensus understands to be safe, effective, and often best practice in the first trimester[82] may have to be abandoned in favor of other

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[79] Daniel Grossman et al., *Change in Abortion Services After Implementation of a Restrictive Law in Texas*, 90 Contraception 496, 499-500 (2014), https://pubmed.ncbi.nlm.nih.gov/25128413/ (Grossman, *Change in Abortion Services*); Kari White et al., *Change in Second-Trimester Abortion After Implementation of a Restrictive State Law*, 133 Obstetrics & Gynecology 771, 771 (2019), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6435408.

[80] *Id.*

[81] Grossman, *Change in Abortion Services*, *supra*, at 499-500.

[82] Am. Coll. of Obstetricians & Gynecologists, ACOG Committee Opinion No. 815 (Dec. 2020), https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2020/12/increasing-acce

methods that, while exceedingly safe, are still more invasive, expensive, and could carry higher risks to patients.[83]

Furthermore, given the resource constraints women and providers will face if forced to return to a pre-2016 world, there is a very real risk that women may attempt to self-manage abortion without any interaction with the medical field at all, including through the purchase of products that have not been approved by FDA and have not been subject to the stringent safety and effectiveness testing that FDA-approved medications are required to go through.[84] Even pre-*Dobbs*, as access to legal abortion care decreased, healthcare providers reported caring for an increasing number of individuals who attempted a self-managed abortion.[85] Those occurrences may only

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ss-to-abortion; Upadhyay, *Safety and Efficacy of Telehealth*, *supra*.

[83] Schroeder, *supra*, at 14.

[84] Teresa A. Saultes et al., *The Back Alley Revisited: Sepsis After Attempted Self-Induced Abortion*, 10 W.J. of Emergency Med. 278, 278-280 (2009), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2791734/; Daniel Grossman et al., *The Public Health Threat of Anti-Abortion Legislation*, 89 Contraception 73, 73-74 (2014), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4418533/; Lauren Ralph et al., *Prevalence of Self-Managed Abortion Among Women of Reproductive Age in the United States*, 3 JAMA Netw. Open e2029245, 12 (2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7749440/; Usha Ranji et al., KFF, Key Facts on Abortion in the United States (Nov. 21, 2023), https://www.kff.org/womens-health-policy/issue-brief/key-facts-on-abortion-in-the-united-states/.

[85] Rachel K. Jones et al., *Abortion Incidence and Service Availability in the United States, 2020*, 54 Persps. on Sexual & Reprod. Health 128, 138 (2022), https://pubmed.ncbi.nlm.nih.gov/36404279/; Courtney A. Kerestes et al., *Abortion Providers'*

increase as women find themselves with fewer realistic options for obtaining an abortion through FDA-approved channels. Curtailment of access to mifepristone could thus lead to new public-health emergencies related to self-managed abortions, including the risk of fake or tainted drugs that could cause serious harm to women.[86] Governors have a substantial interest in preventing these outcomes in their important role of protecting the health and safety of their constituents by ensuring access to regulated reproductive healthcare, including treatments that have been evaluated by experts in drug research, including FDA, and are administered by qualified practitioners.

B. Suddenly returning to a world based on pre-2016 REMS is also likely to have a massive economic impact on many states in which abortion is legal. If the pre-2016 REMS are reinstated, the natural consequence will be higher per-patient costs for medication abortion (which will have to be prescribed by physicians and require in-person dispensing of mifepristone), and, as discussed above, greater use of procedural abortion rather than medication abortion. Consequently, healthcare costs for many states that are payors for abortion patients (through, for example, Medicaid funding) will skyrocket. The cost of a procedural abortion is, unsurprisingly, much higher than the cost of a medication abortion—hundreds or even

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Experiences and Views on Self-Managed Medication Abortion: an Exploratory Study, 100 Contraception 160, 162 (2019), https://pubmed.ncbi.nlm.nih.gov/31002777/.

[86] Anna North, *People Are Using Abortion Medication Later in Their Pregnancies*, Vox (June 18, 2023), https://www.vox.com/23755658/abortion-pill-second-trimester-mifepristone-misoprostol.

thousands of dollars more expensive.[87] In North Carolina, for example, the cost of a medication abortion using mifepristone is less than half of the cost of a procedural abortion.[88] In New York, the approximate Medicaid fee-for-service physician fee schedule reimbursement rate medication abortion is one-third the cost of procedural abortion.[89] In Maryland, the average cost difference between procedural and medical abortion is as high as $880 per patient.[90] And even where medication abortion remains an option, medication abortion under a prescribe-by-physician-only regime will dramatically increase the cost of even medication abortion care and will further strain reproductive healthcare facility capacity.

C. The lower courts' endorsement of the respondents' arguments also has enormously disruptive potential consequences outside of the reproductive healthcare sphere. Beyond the abortion context, Governors and state governments have to be able to rely on the safety and efficacy determinations made by

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[87] *See, e.g.*, Mary Rausch et al., *A Cost-Effectiveness Analysis of Surgical Versus Medical Management of Early Pregnancy Loss*, 97 Fertility & Sterility 355, 356-57 (2011), https://pubmed.ncbi.nlm.nih.gov/22192348/; Schroeder, *supra*, at 14 ("In 2021, the median self-pay cost for abortion services in the U.S. was $568 for medication abortion, $625 for first-trimester procedural abortion, and $775 for second-trimester abortion services.").

[88] Data obtained from NC Medicaid (on file with Reproductive Freedom Alliance).

[89] Data obtained from NY Medicaid (on file with Reproductive Freedom Alliance).

[90] Data obtained from Maryland Department of Public Health (on file with Reproductive Freedom Alliance).

FDA—they do not have the resources to duplicate FDA's work (and certainly private litigants are not doing so before they sue to enjoin the use of time-tested prescription drugs nationwide). If a doctor in another state can file a lawsuit and enjoin medication abortion from the market based on his moral convictions against the drug, that puts at risk Governors' abilities to deal with all types of public health emergencies and needs.

As just one example and as noted above, state and local governments may mandate vaccination requirements for enrolling children in public school systems based on guidance issued by the FDA and the CDC.[91] In fact, all 50 states and the District of Columbia mandate diphtheria, tetanus, pertussis, polio, measles, rubella, and chickenpox vaccinations for children in public school; 49 states mandate immunization against mumps, and most states require children to be vaccinated against hepatitis A and B.[92] Within these states, private citizens morally or ideologically opposed to vaccine mandates can (and do) lobby their state and local governments to remove these requirements, or to offer exemptions for their constituents.[93] But it would create an untenable public health emergency to allow private citizens with moral qualms about a vaccine to restrict or eliminate its availability *nationwide*—including in states that have created a years- or even decades-long strategy for controlling the spread of infectious disease *based on the availability of that vaccine*. That is, however, precisely the type

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[91] DeSilver, *supra*.

[92] *Id.*

[93] *Id.*

of lawsuit and outcome that the decision below invites. If endorsed by this Court, the approach taken by respondents could easily create *new* public health emergencies, including potential outbreaks of diseases in underserved communities.

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If the Court affirms the decision below, the upshot will be harm all around: harm to women, particularly rural and low-income women, who will be required to visit in-person clinics simply to take a prescription medication, or may not be able to access mifepristone for abortion or miscarriage management at all; harm to providers, clinics, and health systems, who will be overwhelmed with demand; harm to Governors, whose critical tools to safeguard public health will be unnecessarily curbed; and harm to the public fisc, which will bear the brunt of many of the economic costs of the decision.

And all of this harm for what benefit? FDA has determined that the additional burdens related to in-person abortion appointments, and physician prescriptions, neither necessary nor justified. Significantly reducing access to mifepristone will not make patients safer—it will only add extreme burdens to healthcare providers, patients, state medical systems, and those responsible for safeguarding public health and safety, including Governors, without any concomitant improvement in outcomes.

This perverse result is relevant to each of the questions presented—to the propriety of finding standing to seek nationwide relief based on speculative chains of inferences, to the readiness with which the courts below found arbitrary and capricious agency action

based on thin suppositions without even having the administrative record before them, and to the appropriateness of effectively enjoining FDA approval nationwide without adequately considering the public-interest factors. On each issue, the courts below favored the option that would cause profound disruption for those responsible for governing in states that have chosen to permit abortion—disruption that would affect only those falling outside of the jurisdiction of the district court presiding over this action.

Although members of the Reproductive Freedom Alliance disagree with *Dobbs*, they understand that it is the law of the land. And *Dobbs* itself promised an approach that would allow each state to meet the reproductive healthcare needs within the state. What the lower courts' decisions embraced here is exactly the opposite—one that would permit a single doctor in a single state to dictate what other states can and cannot do. Texas has already forbidden abortion within its own borders. Under *Dobbs*, it may have the right to do so. But its organizational citizens do not have the right to export that policy judgment nationwide to profoundly harm those living in states that have made different policy judgments.

CONCLUSION

The judgment below should be reversed.

Respectfully submitted.

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