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

LETITIA JAMES
Attorney General
State of New York
BARBARA D. UNDERWOOD*
Solicitor General
ESTER MURDUKHAYEVA
Deputy Solicitor General
GALEN SHERWIN
Special Counsel for Reproductive Justice

28 Liberty Street
New York, New York 10005
(212) 416-8016
barbara.underwood@ag.ny.gov
**Counsel of Record*

(*Counsel listing continues on signature pages.*)

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INTRODUCTION AND INTERESTS OF AMICI CURIAE

Amici States of New York, Arizona, California, Colorado, Connecticut, Delaware, Hawai'i, Illinois, Maine, Maryland, Massachusetts, Michigan, Minnesota, Nevada, New Jersey, New Mexico, North Carolina, Oregon, Pennsylvania, Rhode Island, Vermont, Washington, and Wisconsin, and the District of Columbia submit this brief in support of petitioners United States Food and Drug Administration (FDA) and Danco Laboratories, LLC and reversal of the decision by the U.S. Court of Appeals for the Fifth Circuit purporting to retroactively "stay" regulatory actions taken by the FDA since 2016 relating to prescribing and dispensing the medication mifepristone. Amici agree with petitioners that the "stay" entered by the district court and modified by the Fifth Circuit is erroneous for many reasons. In this brief, however, amici offer their unique perspective on the harmful consequences to our residents if the Fifth Circuit's decision is allowed to take effect,[1] and explain how these concerns should inform the Court's analysis of the equitable considerations underlying requests for injunctive relief.

When used in combination with the drug misoprostol, mifepristone is the only drug approved for termination of pregnancy. Mifepristone has been widely and safely used in the Unites States and internationally for

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

more than two decades. Medication abortion now accounts for a majority of first-trimester abortions performed in the United States, and mifepristone is also a preferred method for managing early pregnancy loss.

Amici States have a strong interest in preserving the availability of mifepristone specifically, and in ensuring high-quality, science-driven patient care within their borders more generally. Many amici operate public hospitals, clinics, and other facilities that provide health care and pharmaceutical services and run public universities that provide health care services to their employees and students. Through their elected officials, amici States also act to protect and promote the health, safety, and welfare of their residents. In all these activities, amici rely on the availability of mifepristone.

The FDA's removal of unnecessary restrictions on mifepristone have proven crucial to amici in improving abortion access, particularly in low-income, underserved, and rural communities, which experience higher rates of birth-related mortality and morbidity, and where nonmedication abortion procedures (i.e., "procedural abortions") may be unavailable. The continued availability of mifepristone, in accordance with sound medical guidelines, is therefore critical to safeguarding amici States' important interest in protecting the health, safety, and rights of their residents to access essential reproductive health care.

If permitted to take effect, the Fifth Circuit's poorly reasoned decision reinstating unnecessary restrictions and outdated labeling for mifepristone would effectively turn back the clock to a time when medication abortion was significantly more difficult to access than

procedural abortion, with widespread adverse implications for individuals and the health care system as a whole. Among other things, the ruling could drive many individuals to undergo unwanted procedural abortions; push abortion procedures to later in pregnancy; sharply increase risks, costs, and delays; and deprive many individuals of access to abortion care altogether. Further, the decision below would lead to regulatory chaos, requiring confusing and medically inaccurate labeling and destabilizing the established drug approval process. Such an outcome could jeopardize the availability of countless drugs on which amici States and their residents depend.

The Fifth Circuit's unfounded decision would also gravely undermine the legislative and policy judgments of States that have chosen to expand rather than to restrict access to abortion at a watershed moment for reproductive health care in America. Following the overturning of *Roe v. Wade*, many States, including many amici, took steps to safeguard the right to abortion and promote widespread access to care within their borders. Several States enacted constitutional and statutory measures codifying the right to abortion, directed funding toward expanding capacity and upgrading facilities to meet increased demand, and passed laws intended to protect and support persons seeking and providing abortion care within their jurisdictions. Several such initiatives have focused specifically on increasing access to medication abortion, in light of its unique benefits and accessibility.

The policy choices described above are entirely consistent with this Court's recognition in *Dobbs v. Jackson Women's Health Organization*, 597 U.S. 215 (2022), that "the people of the various States may evaluate" the interests of a woman who wants an abor-

tion and the interests in fetal life differently, *id.* at 256, and the Court's determination to "return the issue of abortion to the people's elected representatives," *id.* at 232. Amici's efforts to protect and expand access to abortion more generally, and to medication abortion specifically, are a result of the "constitutional processes of democratic self-government," *id.* at 346 (Kavanaugh, J., concurring). Ultimately, such laws and policies represent a value judgment that the privacy, bodily autonomy, and dignity of all pregnant people includes the ability to decide whether to continue or terminate a pregnancy free from government interference. If allowed to take effect, the Fifth Circuit's erroneous and overreaching ruling could trammel these state legislative and policy judgments and harm our residents.

SUMMARY OF ARGUMENT

Mifepristone has been used safely and effectively for decades and has become an increasingly essential component of reproductive health care in amici States. The FDA's post-2016 actions in approving a modified label and relaxing the conditions for prescribing were supported by robust safety data and informed by the agency's statutory mandate to balance any restrictions on the availability of a drug with burdens on access, particularly for the underserved. These changes have proven particularly valuable in reaching rural and low-income communities where abortion care would otherwise be unavailable or extremely difficult to access.

Permitting the Fifth Circuit's decision to take effect, and thus reinstating the pre-2016 restrictions, could severely limit the availability of medication abortion nationwide, including in amici States where abortion remains legal, consequently making all forms

of abortion more difficult to access. Curtailing access to the safest and most common method used for first-trimester abortion would exacerbate the extreme disruptions in delivery of reproductive health care across large swaths of the country in the wake of *Dobbs*. Reinstating these obstacles to obtaining medication abortion could result in more unwanted surgical procedures, increase travel and waiting times to obtain care, and push abortions to later in pregnancy, driving up both costs and medical risks. These obstacles would in turn lead to worse health outcomes across the entire health system and compound existing racial and economic disparities. Such outcomes are flatly contrary to the public interest.

Furthermore, the Fifth Circuit's ruling would create widespread confusion among health care providers, pharmacies, and patients because it would require reversion to a prior version of the drug label that contains medically inaccurate information and outdated standards for dosing and the safe period for use. Reverting to an inaccurate label contravenes the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq. (FDCA), and undermines the integrity of the drug approval process, radically destabilizing the pharmaceutical industry and jeopardizing the development and approval of thousands of innovative drugs on which amici States and their residents rely.

ARGUMENT

I. MEDICATION ABORTION IS A SAFE, RELIABLE, AND ESSENTIAL COMPONENT OF REPRODUCTIVE HEALTH CARE.

A. Medication Abortion Has Been Used Safely and Effectively in Amici States for Decades.

The experience of many of the amici States confirms what numerous scientific studies have demonstrated: mifepristone is extraordinarily safe and effective and an integral component of reproductive health care. Since its approval in 2000, an estimated 5.9 million people in the U.S. have used mifepristone to terminate a pregnancy,[2] and medication abortion now accounts for more than half of all abortions performed nationwide.[3]

The FDA's determination that mifepristone is safe and effective is consistent with scientifically rigorous evidence gleaned from more than a quarter century of clinical research and practice in the U.S. and globally.[4]

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[2] *See* U.S. Food & Drug Admin., *Mifepristone U.S. Post-Marketing Adverse Events Summary Through 12/31/2022* (n.d.). (For sources available on the internet, full URLs appear in the Table of Authorities.)

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

[4] *See* U.S. Food & Drug Admin., *Questions and Answers on Mifepristone for Medical Termination of Pregnancy through Ten Weeks Gestation* (last updated Sept. 1, 2023); U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Rsch., *Risk Evaluation and Mitigation Strategy (REMS) Memorandum: REMS Modification*

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For example, a recent comprehensive survey of abortion care in the U.S. by the National Academies of Sciences, Engineering, and Medicine concluded that medication abortion involving mifepristone is 96.7% effective and that complications are rare, i.e., "occurring in no more than a fraction of a percent of patients."[5] The World Health Organization includes the mifepristone/misoprostol regimen in its guidelines for abortion care,[6] and has long included the combination regimen in its Model List of Essential Medicines—i.e., those medicines "that satisfy the priority health care needs of a population" and "are intended to be available in functioning health systems at all times."[7] Indeed, mifepristone's safety record is so conclusive that leading medical associations, as well as several amici, have advocated that the FDA's Risk Evaluation and Mitigation Strategy (REMS) designation for the drug be eliminated altogether, viewing it as "outdated" and medically unjustified.[8]

(Mar. 29, 2016); *see also* U.S. Gov't Accountability Off., *Food and Drug Administration: Information on Mifeprex Labeling Changes and Ongoing Monitoring Efforts* (2018).

[5] Nat'l Acads. of Scis., Eng'g & Med. (NASEM), *The Safety and Quality of Abortion Care in the United States* 53, 55 (2018); *accord* Mary Gatter et al., *Efficacy and Safety of Medical Abortion Using Mifepristone and Buccal Misoprostol Through 63 Days*, 91 Contraception 269, 270 (2015).

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

[7] World Health Org., *Model List of Essential Medicines, 22nd List, 2021*, at 50 (Sept. 30, 2021).

[8] *See* Am. Coll. of Obstetrics & Gynecology, *Improving Access to Mifepristone for Reproductive Health Indications* (Mar. 2021); Letter from Michael L. Munger, Bd. Chair, Am. Acad. of Fam.

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Although both procedural abortion and medication abortion are extremely safe, and individuals may choose one or the other option for different reasons, medication abortion offers significant benefits in terms of flexibility, privacy, and accessibility. Medication abortion promotes access to abortion as early as possible, when it is safest and least expensive, and has contributed to an increase in the proportion of pregnancy terminations taking place earlier than six weeks gestation.[9] In addition, years of clinical use have shown that mifepristone can safely be provided in a variety of contexts and practice areas, including, for example, in a private physician's office, an ob-gyn or family practice setting, or at home under appropriate medical supervision, offering added flexibility, privacy, and security for both patients and providers.[10]

Given its numerous benefits, medication abortion has become an increasingly central component of reproductive health care. Between 2017 and 2020, the number of medication abortions in nonhospital facilities increased by 45 percent, and now constitute a majority

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Physicians, to Norman Sharpless, Acting Comm'r, U.S. Food & Drug Admin. (June 20, 2019). Many amici States are also plaintiffs in a lawsuit asserting the FDA's decision in 2023 to retain certain aspects of the REMS was arbitrary and capricious because it singles out an exceptionally safe drug for uniquely burdensome restrictions. *See* Am. Compl. at 3-4 ¶ 5, *Washington v. FDA*, No. 23-cv-03026 (E.D. Wash. Mar. 9, 2023), ECF No. 35; Order Granting in Part Pls.' Mot. for Prelim. Inj. 30 (E.D. Wash. Apr. 7, 2023), ECF No. 80.

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

[10] *See id.* at 10, 58.

of abortions performed.[11] The availability of medication abortion within mainstream medical settings and via telemedicine has doubtless contributed to its increasing popularity.[12] By 2020, medication abortion represented a large majority of abortions offered in private physicians' offices and nonspecialized clinics, at 70% and 64% respectively, up from 44% and 51%, respectively, in 2017.[13] And between 25%-30% of all nonhospital facilities (including physicians' offices) and specialized clinics provided medication abortion exclusively.[14] Between 2020 and 2022, the number of facilities offering telemedicine abortion has risen by 190%, and the number of facilities offering only medication abortion went from 0 to 69, more than doubling between 2021 and 2022.[15]

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[11] Rachel K. Jones et al., *Abortion Incidence and Service Availability in the United States, 2020*, 54 Persps. on Sexual & Reprod. Health 128, 136 (2022).

[12] *See* Rachel K. Jones et al., Guttmacher Inst., *Medication Abortion Now Accounts for More Than Half of All US Abortions* (updated Dec. 1, 2022). Such benefits are particularly critical given the historical stigmatization of abortion and the persistent and escalating violence at abortion clinics. *See* Nat'l Abortion Fed'n, *2021 Violence and Disruption Report* (June 24, 2022).

[13] Jones et al., *Abortion Incidence*, *supra*, at 136.

[14] *See id*.

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

B. The Lifting of Restrictions on Mifepristone Was Supported by Clinical Data and Has Allowed Greater Access, Particularly in Rural and Underserved Areas.

The post-2016 regulatory actions at issue in this case were supported by robust clinical data and prevailing medical standards[16] and comport with amici States' experience of the safe use of the medication by millions of people within our borders. The FDA's lifting of medically unnecessary restrictions has enabled many amici States to promote access to medication abortion in previously underserved areas, greatly benefitting their residents, reducing costs and strains on health systems, and furthering health equity goals.

First, the FDA's expansion of the approved period of use from seven to ten weeks of pregnancy allows more patients to access and benefit from medication abortion. Extensive research supports the use of mifepristone at up to ten weeks of pregnancy, and the FDA's approach is more conservative than the 12-week threshold accepted by the World Health Organization.[17]

Second, the FDA's revision of the dosing regimen for mifepristone was based on extensive clinical research demonstrating increased effectiveness and reflects the agency's expert determination that dosing

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[16] *See* U.S. Gov't Accountability Off., *supra*.

[17] *See* NASEM, *Safety and Quality of Abortion Care*, *supra*, at 51; World Health Org., *Medical Management of Abortion* 24 (2018).

changes are clinically warranted.[18] *See* Br. for Danco Lab'ys, LLC at 6-8; *cf. Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1686 (2019) (Alito, J., concurring in the judgment, joined by Roberts, C.J., and Kavanaugh, J.) (FDA's decision not to require label change in light of new information received indicated the agency's determination that such change was not warranted).

Third, the FDA's elimination of the requirement that mifepristone be dispensed in-person and followed by two additional in-person visits was similarly well reasoned. The changes to these dispensation requirements were made gradually: in 2016, the agency eliminated the required follow-up appointment to administer misoprostol; then, it lifted the mandate for in-person dispensing of mifepristone, first temporarily as a matter of enforcement discretion due to the COVID-19 pandemic, and then permanently.[19]

The conclusion that medication abortion can be provided safely outside of a brick-and-mortar setting has been repeatedly endorsed by clinical research and leading medical associations and reinforced by practice experience during the pandemic.[20] *See Food & Drug*

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[18] NASEM, *Safety and Quality of Abortion Care*, *supra*, at 51.

[19] FDA, *Questions and Answers*, *supra*; FDA, *Risk Evaluation and Mitigation Strategy (REMS): Single Shared System for Mifepristone 200 MG* (Jan. 2023); Letter from Patrizia Cavazzoni, Dir., Ctr. for Drug Evaluation & Rsch., to Graham Chelius, Soc'y of Fam. Plan., Cal. Acad. of Fam. Physicians (Dec. 16, 2021).

[20] *See* NASEM, *Safety and Quality of Abortion Care*, *supra*, at 57-58; Erica Chong et al., *Expansion of a Direct-to-Patient Telemedicine Abortion Service in the United States and Experience*

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Admin. v. American Coll. of Obstetricians & Gynecologists, 141 S. Ct. 578, 579 (2021) (Mem.) (Roberts., C.J., concurring in grant of application for stay). And significantly, lifting these restrictions has freed clinicians to offer medication abortion services remotely, where otherwise lawful, by conducting patient intake, examination, and follow-up via telephone or videoconference and enabling patients to obtain the medication through certified mail-order or certified retail pharmacies.[21]

During the COVID-19 Pandemic, 104 Contraception 43, 44 (2021); Ellen R. Wiebe et al., *Comparing Telemedicine to In-Clinic Medication Abortions Induced with Mifepristone and Misoprostol*, 2 Contraception X no. 100023 (2020); Daniel Grossman et al., *Effectiveness and Acceptability of Medical Abortion Provided Through Telemedicine*, 118 Obstetrics & Gynecology 296 (2011); Daniel Grossman & Kate Grindlay, *Safety of Medical Abortion Provided Through Telemedicine Compared with In Person*, 130 Obstetrics & Gynecology 778 (2017).

[21] Respondents asserted below that the federal Comstock Act prohibits the distribution of mifepristone by mail because the statute purportedly "prohibits the mailing or delivery of '[e]very article or thing designed, adapted, or intended for producing abortion.'" *See* Br. for Appellees at 58-63 (May 8, 2023), ECF 380 (quoting 18 U.S.C. §§ 1461-1462)). Judge Ho's concurring opinion reached a similar conclusion. *See* Pet. App. 98a-104a. Although a discussion of the Comstock Act is beyond the scope of this brief, amici States note that respondents' interpretation of the Comstock Act has been expressly rejected as having potentially boundless effects on medical care delivery, ostensibly preventing distribution of a host of devices, surgical instruments, and equipment used in obstetrics and gynecology and beyond, as well as numerous drugs routinely used to treat countless diseases and conditions. *See, e.g.*, *Youngs Rubber Corp. v. C.I. Lee & Co.*, 45 F.2d 103, 108 (2d Cir. 1930). Moreover, the U.S. Department of Justice's Office of Legal Counsel has concluded that the Comstock Act restricts only the

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Fourth, the FDA's elimination of the requirement that mifepristone be prescribed only by a physician allows advanced practice clinicians such as nurse practitioners and physician assistants to prescribe mifepristone where otherwise authorized by law. Studies have routinely shown that trained advanced practice clinicians are well-equipped to provide abortion care and enjoy a record of safety and satisfaction comparable to physicians.[22] Accordingly, major medical associations support policies authorizing advanced practice clinicians to prescribe medication abortion,[23] and many amici States permit this practice. *See* Br. Amici Curiae Nat'l Ass'n of Nurse Practitioners in Women's Health et al. in Supp. of Pet. for Writ of Certiorari 10-17, 24 (Oct. 12, 2023).[24]

Finally, the FDA's elimination of the requirement that prescribers report adverse events to the drug manufacturer was based upon 15 years of data that

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sending of items intended for use in unlawful abortions. *See* Application of the Comstock Act to the Mailing of Prescription Drugs That Can Be Used for Abortions, 46 Op. O.L.C., slip op. at 1-2 (Dec. 23, 2022).

[22] *See* NASEM, *Safety and Quality of Abortion Care*, *supra*, at 102 (summarizing research).

[23] *See*, *e.g.*, Am. Coll. of Obstetrics & Gynecology, Comm. on Health Care for Underserved Women, Comm. Op. No. 815, *Increasing Access to Abortion*, 136 Obstetrics & Gynecology e107 (2020); Am. Pub. Health Ass'n, Pol'y No. 20112, *Provision of Abortion Care by Advanced Practice Nurses and Physician Assistants* (Nov. 1, 2011); NASEM, *Safety and Quality of Abortion Care*, *supra*, at 102.

[24] *See* AP Toolkit, *State Abortion Laws and Their Relationship to Scope of Practice* (n.d.).

"the safety profile . . . is well-characterized, that no new safety concerns have arisen in recent years, and that the known serious risks occur rarely." Jt. App. 426. This determination merely brought the conditions for dispensing mifepristone more closely in line with countless other drugs and medications with a similar, or even higher, risk profile. *See* Br. for Food and Drug Law Scholars as Amicus Curiae in Supp. of Pet'rs. for Writ of Certiorari 14-15 (Oct. 12, 2023).

In addition, the challenged agency actions were informed by Congress's direction that the FDA ensure that any restrictions on approved medications impose minimal burdens on access, particularly for those patients "who have difficulty accessing health care (such as patients in rural or medically underserved areas)," and on the health care delivery system as a whole. *See* 21 U.S.C. § 355-1(f)(2). Removal of the in-person dispensing requirement and the need for multiple follow-up visits has enabled the expansion of telemedicine, virtually eliminating the need for travel to obtain medication abortion care in amici States. Similarly, allowing clinicians other than physicians to prescribe mifepristone where otherwise authorized has eased the acute shortage of abortion providers, extending access into previously underserved areas and freeing physicians to focus on more complex cases, without compromising patient health.[25]

Removal of medically unnecessary restrictions on mifepristone has been particularly critical in reaching

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[25] *See* Am. Pub. Health Ass'n, Pol'y No. 20112, *supra*; AP Toolkit, *State Abortion Laws*, *supra*.

rural and underserved communities where barriers to abortion access are most acute. According to 2020 data, 89% of U.S. counties, predominantly in rural areas, had no abortion clinic and 38% of women of reproductive age resided in such a county.[26] Patients in rural areas were eight times as likely as urban patients to travel more than 100 miles for abortion care.[27] And the many practical and cost barriers that can make it difficult to obtain an abortion—including childcare needs, missed work and resulting lost income, lack of insurance coverage, and travel costs and logistics—increase with distance traveled.[28] Such barriers are steepest for low-income people and people of color, and for many, place abortion out of reach altogether.[29]

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[26] Jones et al., *Abortion Incidence and Service Availability*, *supra*, at 134.

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

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

[29] *See* Jill Barr-Walker, *Experiences of Women Who Travel for Abortion: A Mixed Methods Systematic Review*, 14 PLOS ONE e0209991, at 19-21 (Apr. 9, 2019); Elizabeth A. Pleasants et al., *Association Between Distance to an Abortion Facility and Abortion or Pregnancy Outcome Among a Prospective Cohort of People Seeking Abortion Online*, 5 JAMA Network Open e2212065, at 10 (May 13, 2022).

The challenged FDA actions significantly reduced many of these obstacles and expanded access to critical health care. For example, 69 virtual clinics in 23 States and the District of Columbia currently offer medication abortion via telemedicine.[30] And many state and local governments have expended substantial resources to increase access to mifepristone, both through in-person care and via telemedicine. In Maine, which has among the highest rates of rural residents in the U.S., a major clinic chain has made medication abortion available at its 16 health centers via telemedicine.[31] New York City recently announced it will offer free medication abortion at four public health clinics serving primarily low-income New Yorkers.[32] And several amici States, including Massachusetts, New York, and California, have taken steps to extend access to public university students by making medication abortion available through campus health centers.[33]

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[30] *See* ANSIRH, *Availability of Telehealth Services for Medication Abortion*, *supra*.

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

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

[33] *See* N.Y. Educ. Law § 6438-b (effective Aug. 1, 2023); Mass. Gen. Laws ch. 15A, § 46 (effective July 29, 2022); Cal. Educ. Code § 99251 (effective Jan. 1, 2020).

II. REVERTING TO THE PRE-2016 CONDITIONS FOR PRESCRIBING AND DISPENSING MIFEPRISTONE IS CONTRARY TO THE PUBLIC INTEREST.

1. The balance of equities in this case strongly weighs against the injunctive relief ordered by the Fifth Circuit. "A preliminary injunction is an extraordinary remedy never awarded as of right." *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 24 (2008). And "[i]n exercising their sound discretion, courts of equity should pay particular regard for the public consequences" of employing such remedy. *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 312 (1982). Here, those consequences would be far-reaching. Rather than preserving the status quo, the Fifth Circuit's "stay" of years-old regulatory actions would have a "needlessly chaotic and disruptive effect," *Benisek v. Lamone*, 138 S. Ct. 1942, 1945 (2018) (quotation marks omitted), upending the established method for prescribing mifepristone, harming patients and health systems, and radically destabilizing the established regulatory regime for drug approvals.

2. The conditions challenged here for prescribing mifepristone, many of which have been in place for close to a decade, have been critical in meeting the unprecedented demands of the post-*Roe* landscape. Abortion is currently unavailable in fourteen States where bans or near-total restrictions are in effect or subject to pending litigation, and is extremely limited in several more States.[34] States where abortion has

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[34] *See* Ctr. for Reprod. Rts., *After* Roe *Fell: Abortion Laws by State* (n.d.).

been banned or effectively banned are home to more than 22 million women of childbearing age, representing almost one third of the total population of women ages 15-49.[35] The number of reported abortions performed in States with bans in effect (or thought to be in effect subject to litigation) has dropped to zero or close to zero.[36] While estimates vary, tracking suggests that as many as 66 clinics may have shuttered since the end of June 2022.[37] And distances and travel time to obtain abortion care have spiked dramatically.[38] For example, between March 2022 and September 2023, the estimated average distance to the closest provider in Texas increased from 43 to 499 miles; in Idaho it increased from 40 to 235 miles.[39]

Many States have consequently experienced a steep rise in demand at clinics from out-of-state

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

[36] *See* Soc'y of Fam. Plan., *#WeCount Report April 2022 to June 2023*, at 9-10 tbl. 1 (Oct. 24, 2023); *see also* Guttmacher Inst., *Monthly Abortion Provision Study* (n.d.).

[37] See Kirstein et al., *100 Days Post*-Roe, *supra*; Caitlin Myers et al., *Abortion Access Dashboard* (last updated Sept. 1, 2023); Allison McCann & Amy Schoenfeld Walker, *One Year, 61 Clinics: How Dobbs Changed the Abortion Landscape*, N.Y. Times (June 22, 2023).

[38] *See* Myers et al., *Abortion Access Dashboard*, *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, 2043-45 (2022).

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

patients, with Illinois, Florida, North Carolina, California, and New Mexico experiencing among the greatest increases.[40] While providers have endeavored to meet the increased demand, the influx has stretched clinics past their already-strained capacity and has dramatically increased wait times for patients from both within and outside of their States.[41]

Reviving the pre-2016 restrictions on mifepristone would eliminate a crucial tool in meeting the public health challenges described above. Since 2016, numerous facilities have been established which offer medication abortion via telemedicine, and medication abortions at virtual clinics spiked dramatically in the first year after *Dobbs*.[42] Reinstating the requirements of in-person dispensing followed by two additional visits would effectively eliminate access via telemedicine, wiping virtual clinics off the map and reimposing

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

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

[42] *See* Amelia Thomson-DeVeaux, *Virtual Abortions Surged After* Roe *Was Overturned—But the Texas Ruling Could Change That*, FiveThirtyEight (Apr. 11, 2023); Soc'y of Fam. Plan., *#WeCount Report*, *supra*, at 18-20 tbl.4; (reporting data showing an increase of 111% in States that permit abortion between April 2022 and 2023, with a peak of 135% in December 2022); ANSIRH, *Availability of Telehealth Services for Medication Abortion*, *supra*.

travel-related costs and delays.[43] Similarly, restoring the physician-only requirement would burden facilities and hospital systems forced to divert provision of medication abortion from advanced practice clinicians back to increasingly overburdened doctors, increasing wait times for appointments and cutting off a critical pipeline to care in underserved areas.

3. With mifepristone access out of reach, many patients would likely seek procedural abortions—which, although safe, are unnecessarily invasive procedures for those for whom medication abortion would have been preferred and are generally more costly to provide and to obtain. *See, e.g.*, Br. for Amici Curiae City of New York et al. in Supp. Pet'rs 15 (Oct. 12, 2023) (estimating procedural abortion is five times more costly to provide than medication abortion). Others desperate for care may well seek abortion medications through online services or overseas pharmacies and self-manage their abortions outside of a mainstream medical setting.[44] And many will be denied access to abortion altogether and be forced to carry unwanted, and in some cases medically risky, pregnancies to term.

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[43] *See* Jerman et al., *Barriers to Abortion Care and Their Consequences*, *supra*.

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

Denial of abortion care is in turn associated with numerous harms, including poor birthing and infant health outcomes, higher rates of poverty, and lower educational attainment for both parents and children.[45] For example, because carrying a pregnancy to term is 14 times more risky than early abortion,[46] reinstating obstacles to accessing medication abortion would likely lead to a steep rise in birth-related mortality rates purely due to the increased risks associated with giving birth, worsening a crisis already disproportionately faced by Black women.[47]

These outcomes are no longer mere predictions. *See Dobbs*, 598 U.S. at 361-63, 407-08 (Breyer, J., dissenting). In States where total or near-total bans on abortion have been allowed to take effect (or thought to be in effect subject to litigation), resulting delays and

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[45] *See, e.g.*, Diana G. Foster, *The Turnaway Study* (2020); Diana G. Foster et al., *Effects of Carrying an Unwanted Pregnancy to Term on Women's Existing Children*, 205 J. Pediatrics 183 (2019); Heidi D. Nelson et al., *Associations of Unintended Pregnancy with Maternal and Infant Health Outcomes: A Systematic Review and Meta-Analysis*, 328 JAMA 1714 (2022).

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

[47] *See, e.g.*, Elyssa Spitzer et al., Ctr. for Am. Progress, *Abortion Bans Will Result in More Women Dying* (Nov. 2, 2022); Amanda Jean Stevenson, *The Pregnancy-Related Mortality Impact of a Total Abortion Ban in the United States: A Research Note on Increased Deaths Due to Remaining Pregnant*, 58 Demography 2019 (2021) (estimating that birth-related mortality rates would rise by 21% overall should a total abortion ban go into effect nationwide, with Black women experiencing the highest estimated increase of 33%).

denials of care have already endangered the mental and physical health, future fertility, and lives of pregnant people.[48] Providers report that immediately following *Roe*'s reversal, patients considered desperate and unsafe measures to terminate pregnancies, and even threatened suicide.[49] Since then, such harms have continued to mount. Delays related to cross-state travel and increased wait-times for appointments have led to an increase in abortions occurring later in pregnancy, and thus to more complex, risky, and expensive procedures.[50] Those increased costs and delays have prevented numerous individuals from obtaining abor-

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[48] *See* Frances Stead Sellers & Fenit Nirappil, *Confusion Post-*Roe *Spurs Delays, Denials for Some Lifesaving Pregnancy Care*, Wash. Post (July 16, 2022); J. David Goodman & Azeen Ghorayshi, *Women Face Risks as Doctors Struggle with Medical Exceptions on Abortion*, N.Y. Times (July 20, 2022).

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

[50] *See, e.g.*, Kari White et al., Tex. Pol'y Evaluation Project, *Initial Impacts of Texas' Senate Bill 8 on Abortions in Texas and at Out-of-State Facilities* (Oct. 2021) (documenting increased wait-time at out-of-state clinics from July 2020 to July 2021); Advancing New Standards in Reprod. Health, Issue Brief, *Trends in Abortion Facility Gestational Limits Pre- and Post-*Dobbs (June 2023) (documenting nationwide increase in abortion facilities offering later-gestation procedures to meet increased demand following *Dobbs*); Kristen Schorsch, *Abortion Bans are Fueling a Rise in High-Risk Patients Heading to Chicago Hospitals*, WBEZ Chi. (June 28, 2023).

tion altogether.[51] Indeed, analysis of travel patterns suggests tens of thousands of pregnant people living in a State without abortion access have been unable to obtain a desired abortion.[52]

Emerging evidence from the medical field is demonstrating the myriad ways in which restrictions on abortion have harmed patient care. A majority (55%) of ob-gyns in States without abortion access report that those restrictions have compromised their ability to provide the standard of care, and around 40% report feeling constrained in their ability to manage miscarriage or to provide abortions in medical emergencies.[53] According to one study, the rate of serious morbidity in two Texas hospitals from implementing an "expectant management" protocol (57%) was *almost double* the rate that occurs when following the accepted protocol of terminating the pregnancy as soon as medically indicated (33%).[54]

Tragic scenarios are playing out every day in the lives of countless patients, including many with

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[51] *See* Daniel Grossman et al., *Care Post-Roe: Documenting Cases of Poor-Quality Care Since the Dobbs Decision* 15 (May 2023).

[52] Soc'y of Fam. Plan., #*WeCount Report*, *supra*, at 7-8; Maggie Koerth & Amelia Thomson-DeVeaux, *Over 66,000 People Couldn't Get an Abortion in Their Home State After Dobbs*, FiveThirtyEight (Apr. 11, 2023).

[53] *See* Brittni Frederiksen et al., KFF, *A National Survey of OBGYNs' Experiences After* Dobbs 12 (June 2023).

[54] *See* Anjali Nambiar et al., *Maternal Morbidity and Fetal Outcomes Among Pregnant Women at 22 Weeks' Gestation or Less with Complications in 2 Texas Hospitals After Legislation on Abortion*, 227 Am. J. Obstetrics & Gynecology 648, 649 (2022).

wanted pregnancies, who have been denied necessary abortions and turned away from medical care, some until they were near death. Women have been forced to forgo cancer treatment, left bleeding for days after incomplete miscarriage, allowed to develop sepsis requiring treatment in the intensive care unit, denied pain management during miscarriage, developed life-threatening hypertension, and endured risk of uterine rupture due to ectopic pregnancy.[55] Patients have been forced to continue carrying and deliver stillborn fetuses with lethal anomalies, been refused treatment during active miscarriage, and even been abandoned to deliver a stillbirth with no medical assistance.[56] Many have faced lifelong health consequences, including permanent organ damage and loss of future fertility.[57]

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[55] *See* Second Am. Verified Pet. for Decl. J. and Appl. for Temp. & Permanent Inj., *Zurawski v. State*, Cause No. D-1-GN-23-000968 (Tex. Dist. Ct. Travis County Nov. 14, 2023); Grossman et al., *Care Post-Roe*, *supra*, at 2; Eleanor Klibanoff, *Doctors Report Compromising Care out of Fear of Texas Abortion Law*, Texas Trib. (June 23, 2022).

[56] *See* Pam Belluck, *They Had Miscarriages, and New Abortion Laws Obstructed Treatment*, N.Y. Times (July 17, 2022); Carrie Feibel, *Because of Texas' Abortion Law Her Wanted Pregnancy Became a Medical Nightmare*, NPR (July 26, 2022); Remy Tumin, *Ohio Woman Who Miscarried Faces Charge That She Abused Corpse*, N.Y. Times (Jan. 3, 2024).

[57] *See* Grossman et al., *Care Post-Roe*, *supra*, at 17; Temp. Inj. Order, *Zurawski* (Tex. Dist. Ct. Travis County, Aug. 4, 2023); Second Am. Verified Pet., *Zurawski*, *supra*; Pls.' Mot. for TRO & Prelim. Inj., *Preterm-Cleveland*, *supra*; Compl., *Adkins v. State*, No. CV01-23-14744 (Idaho 4th Jud. Dist., filed Sept. 11, 2023); First Am. Compl. for Declaratory J. & Permanent Inj., *Blackmon v. State*, No. 23-1196-I (Tenn. Ch. Ct. 20th Jud. Dist., Jan. 8, 2024).

Others have died of severe complications that could almost certainly have been prevented had they had the option to terminate their high-risk pregnancy.[58]

Still others have confronted the life-altering reality of being forced to continue their pregnancies and give birth against their wishes. One analysis showed that following *Dobbs*, the fertility rate in States without abortion access was 2.3% higher than in States in which abortion remains available, resulting in approximately 32,000 additional births.[59] According to news reports, those individuals include a 12-year-old in Mississippi raped in her backyard by a stranger, a 16-year-old Floridian in foster care denied a judicial bypass, and a 27-year-old mother of three in Texas fleeing domestic abuse, to name but a few.[60]

To be sure, practical and financial obstacles to obtaining abortion care have long been a reality.[61] But the threats to and ultimate loss of the legal right to abortion brought those inequities into sharper relief,

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[58] *See* Stephania Taladrid, *Did an Abortion Ban Cost a Young Texas Woman Her Life?* New Yorker (Jan. 8, 2024).

[59] Daniel Dench et al., *The Effects of the Dobbs Decision on Fertility* 15 (IZA Inst. of Lab. Econ. Discussion Paper No. 16608, Nov. 2023).

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

[61] *See* SisterSong, *Reproductive Justice* (n.d.); Andrea Miller, *I've Turned My Back on* Roe *to Fight for Abortion Equity*, Elle (June 21, 2023).

leading many amici States to reaffirm their commitments not only to safeguarding the right to abortion, but also to dismantling barriers to accessing essential reproductive health care.[62] Allowing unnecessary obstacles to medication abortion to once again take effect will frustrate those efforts and allow the harms associated with denial of abortion to proliferate nationwide, with the effects felt most acutely in amici States where abortion remains lawful.[63]

4. Reverting to the pre-2016 restrictions on mifepristone will also impede provision of other forms of critical health care. In many amici States, the same facilities providing abortion care also offer other essential services, such as pre- and post-natal care, family planning, cancer screening, testing and treatment for sexually transmitted infections and HIV, and other forms of necessary preventative health care. Increased demand for procedural abortions (in lieu of medication abortions) will obstruct access to all forms of care offered at those facilities, inevitably resulting in higher rates of unintended pregnancy and sexually transmit-

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[62] *See, e.g.*, Cal. Const. art. I, § 1.1; Cal. Health & Safety Code § 123453; 775 Ill. Comp. Stat. Ann. 55/1-1 et seq.; Me. Rev. Stat. Ann. tit. 22, § 1598; Act of July 29, 2022, Ch. 127, 2022 Mass. Acts 740; N.J. Stat. Ann. § 10:7-1; N.J. Stat. Ann. § 2A:160-14.1; N.Y. Pub. Health Law § 2599-AA; N.Y. Educ. Law § 6438-b; Vt. Stat. tit. 18, ch. 223.

[63] *See* Myers, *Abortion Access Dashboard*, *supra* (Medication Abortion Ban tab; estimating that States where the largest proportion of facilities would be affected should medication abortion be eliminated would be Maine (86%), California (60%), Connecticut (56%), Washington (51%), Vermont (50%), New Jersey (46%), and Oregon (46%)).

ted infections, barriers to early detection and treatment for breast, ovarian, and testicular cancers and chronic diseases, and worsened overall health outcomes.[64] Underserved groups, including women of color, low-income women, people with disabilities, and LGBTQ individuals, will be hardest hit.[65]

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

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

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

resulting from the challenged conditions for dispensing and use of mifepristone—harms that have never materialized, despite those conditions having been in effect for close to a decade.

By contrast, as detailed above, the dire outcomes resulting from denying access to abortion are already evident in States that severely restrict or ban abortion. By severely cutting off access to a major path to obtaining early abortion care, the Fifth Circuit's ruling would spread those harms nationwide, frustrating amici States' best efforts to safeguard and promote abortion access within our borders, increasing costs to health systems, and harming our residents.

6. The Fifth Circuit's ruling would also sow confusion and regulatory chaos for health care providers and drug manufacturers. Respondents have failed to allege, much less demonstrate, that the dosing changes reflected in the current label resulted in concrete or particularized harm to a single patient or objecting health care provider. Yet the Fifth Circuit's decision mandates reversion to the pre-2016 label. Under this ruling, the drug manufacturers would be forced to submit, and the FDA required to approve, a revised label with an archaic regimen directing providers to administer *three times the dose* for mifepristone and a less effective method of delivery of misoprostol than current data supports. *See* Br. for Danco Lab'ys, LLC at 6-8.

Such an absurd result is inconsistent with the text and purpose of the FDCA, which is intended to protect the public from harm and requires "substantial evidence" demonstrating that "adequate and well-controlled investigations" support the conditions of use in the proposed label. 21 U.S.C § 355(d). *Cf. United*

States v. Oakland Cannabis Buyers' Co-op., 532 U.S. 483, 498 (2001) (equitable remedies are constrained by statutory mandate). And while clinicians generally have latitude to prescribe medications "off label" in accordance with prevailing clinical protocols, the court-ordered reinstatement of an archaic dosing regimen could muddy the waters for providers as to which standard to follow and create unnecessary confusion for patients.

The likelihood of these and other disruptions is readily demonstrated by the chaos experienced during earlier stages of this litigation, prior to this Court's stay of the district court's order. Patients, providers, and amici States grappled with the possibility that a drug used by hundreds of thousands every year could, nearly overnight, be deemed "mislabeled" and removed from the market.[66] Allowing the Fifth Circuit's ruling to take effect would almost certainly create additional confusion and chaos at a time when the field of reproductive health care is already experiencing profound shock waves.

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

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

leaders have explained, the market stability provided by the FDA's drug-approval regime is crucial to developing new drugs and maintaining ready access to available drugs. *See* Br. for the Pharma. Rsch. Mfrs. of Am. as Amici Curiae in Supp. of Pet'rs (Oct. 12, 2023); Brief of Pharma. Cos., Execs., and Investors as Amici Curiae in Supp. of Pet'rs (Oct. 12, 2023). Overturning this regime would jeopardize the development and availability of drugs on which amici States and their residents depend to prevent and treat a host of conditions and diseases, including asthma, HIV, infertility, heart disease, diabetes, and more.

Yet the lower courts' poorly reasoned rulings set aside the FDA's determinations based upon respondents' anecdotal, generalized, and often second-hand assertions of harm and an irrational interpretation of the record. *Cf. Wyeth v. Levine*, 555 U.S. 555, 626 (2009) (Alito, J., dissenting) ("[T]he FDA has the benefit of 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 juries in all 50 States were free to contradict the FDA's expert determinations" (quotation and alteration marks omitted)). Sustaining the Fifth Circuit's ruling would open the door to additional challenges to drug approvals by aggrieved consumers or health care providers, based on their own individual adverse drug reactions or their personal objection to providing particular types of treatment. Inviting such novel litigation would inevitably chill research and development by disincentivizing drug developers from making the significant investments necessary to meet the agency's rigorous drug approval standards. And the threatened removal of other comparably essential, safe, and effective drugs from the market resulting

from challenges to FDA actions brought by other private actors could have catastrophic consequences for amici States and their residents.

CONCLUSION

For the foregoing reasons, the decision of the Fifth Circuit should be reversed.

Respectfully submitted,

LETITIA JAMES
Attorney General
State of New York
BARBARA D. UNDERWOOD*
Solicitor General
ESTER MURDUKHAYEVA
Deputy Solicitor General
GALEN SHERWIN
Special Counsel for Reproductive Justice
barbara.underwood@ag.ny.gov

January 2024

* *Counsel of Record*

(*Counsel listing continues on next page.*)

KRIS MAYES
Attorney General
State of Arizona
2005 N. Central Ave.
Phoenix, AZ 85004

ROB BONTA
Attorney General
State of California
1515 Clay St.
Oakland, CA 94612

PHILIP J. WEISER
Attorney General
State of Colorado
1300 Broadway
Denver, CO 80203

WILLIAM TONG
Attorney General
State of Connecticut
165 Capitol Ave.
Hartford, CT 06106

KATHLEEN JENNINGS
Attorney General
State of Delaware
820 N. French St.
Wilmington, DE 19801

ANNE E. LOPEZ
Attorney General
State of Hawai'i
425 Queen St.
Honolulu, HI 96813

KWAME RAOUL
Attorney General
State of Illinois
100 West Randolph St.
Chicago, IL 60601

AARON M. FREY
Attorney General
State of Maine
6 State House Station
Augusta, ME 04333

ANTHONY G. BROWN
Attorney General
State of Maryland
200 Saint Paul Pl.
Baltimore, MD 21202

ANDREA JOY CAMPBELL
Attorney General
Commonwealth of Massachusetts
One Ashburton Pl.
Boston, MA 02108

DANA NESSEL
Attorney General
State of Michigan
P.O. Box 30212
Lansing, MI 48909

KEITH ELLISON
Attorney General
State of Minnesota
75 Dr. Martin Luther King Jr. Blvd.
St. Paul, MN 55155

AARON D. FORD
Attorney General
State of Nevada
100 North Carson St.
Carson City, NV 89701

MATTHEW J. PLATKIN
Attorney General
State of New Jersey
25 Market St.
Trenton, NJ 08625

RAÚL TORREZ
Attorney General
State of New Mexico
P.O. Drawer 1508
Santa Fe, NM 87504

JOSHUA H. STEIN
Attorney General
State of North Carolina
114 W. Edenton St.
Raleigh, NC 27603

ELLEN F. ROSENBLUM
Attorney General
State of Oregon
1162 Court St. N.E.
Salem, OR 97301

MICHELLE A. HENRY
Attorney General
Commonwealth of Pennsylvania
Strawberry Square
Harrisburg, PA 17120

PETER F. NERONHA
Attorney General
State of Rhode Island
150 South Main St.
Providence, RI 02903

CHARITY R. CLARK
Attorney General
State of Vermont
109 State St.
Montpelier, VT 05609

ROBERT W. FERGUSON
Attorney General
State of Washington
P.O. Box 40100
Olympia, WA 98504

JOSHUA L. KAUL
Attorney General
State of Wisconsin
17 West Main St.
Madison, WI 53703

BRIAN L. SCHWALB
Attorney General
District of Columbia
400 6th St., NW
Washington, D.C. 20001