Nos. 22A901, 22A902

In The
Supreme Court of the United States

DANCO LABORATORIES, LLC, *Applicant*, v. ALLIANCE FOR HIPPOCRATIC MEDICINE, et al. *Respondents*.	FOOD AND DRUG ADMINISTRATION, et al., *Applicants*, v. ALLIANCE FOR HIPPOCRATIC MEDICINE, et al. *Respondents*.

MOTION FOR PERMISSION TO FILE AS AMICI CURIAE, AND BRIEF FOR THE STATES OF NEW YORK, ARIZONA, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, HAWAIʻI, 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 APPLICATIONS FOR A STAY PENDING APPEAL TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT AND PENDING FURTHER PROCEEDINGS IN THIS COURT

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Dated: April 14, 2023

The 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 move this Court for leave to file the enclosed brief as amicus curiae in support of the applications for a stay filed by the federal government and Danco Laboratories, LLC (i) without 10 days' advance notice to the parties of amici's intent to file as ordinarily required by Sup. Ct. R. 37.2(a), and (ii) in an unbound format on 8½-by-11-inch paper.

In light of the emergency nature of the applications, it was not feasible to give 10 days' notice. Specifically, the order at issue in these applications was issued by the district court on April 7, 2023, and was stayed for only seven days to allow defendants to seek appellate relief. Danco Laboratories, LLC, and respondents have consented to the filing of the brief without 10-day notice. The governmental applicants take no position on the request.

As set forth in the enclosed brief, the undersigned amici States have a strong interest in the subject of this litigation as well as the outcome of this stay application. As the brief explains, amici's experience confirms that mifepristone is a safe, reliable, and effective drug, and the availability of mifepristone has been critical to amici's efforts to provide access to reproductive health care, including in low-income, underserved, and rural communities. Amici's brief further explains how curtailing access to mifepristone could increase costs, medical risks, and burdens on already overtaxed health care systems. Finally, the brief argues that the lower courts' rulings

undermine amici's sovereign decisions to safeguard access to abortion for their residents by disrupting access to mifepristone in States where abortion is lawful.

The amici States thus have a distinct perspective on the harms threatened by the lower courts' rulings—and the need for a stay of those rulings—that may be of considerable assistance to the Court. The States have asserted and documented these harms in amicus curiae submissions made to the district court and the U.S. Court of Appeals for the Fifth Circuit.

Pursuant to Supreme Court Rule 37.1, the undersigned amici States therefore seek to file this brief in order to support applicants' requests for a stay.

CONCLUSION

The Court should grant amici curiae leave to file the enclosed brief in support of the applications for a stay.

Dated: New York, New York
April 14, 2023

Respectfully submitted,
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BRIEF FOR THE STATES OF NEW YORK, ARIZONA, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, HAWAIʻI, 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 APPLICATIONS FOR A STAY PENDING APPEAL TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT AND PENDING FURTHER PROCEEDINGS IN THIS COURT

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Dated: April 14, 2023

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INTRODUCTION AND INTERESTS OF AMICI

In 2000, the U.S. Food and Drug Administration (FDA) approved mifepristone as a single-dose oral medication used for early-term abortions. Plaintiffs (several anti-abortion organizations and physicians) filed this lawsuit and preliminary injunction motion challenging the FDA's initial approval and several subsequent regulatory actions pertaining to mifepristone. The U.S. District Court for the Northern District of Texas (Kacsmaryk, J.) granted plaintiffs' motion and stayed the effective date of the FDA's approval of mifepristone—more than twenty years after that date has passed. The U.S. Court of Appeals for the Fifth Circuit granted a stay pending appeal in part, acknowledging that plaintiffs' challenge to the original approval was likely time-barred but leaving in place portions of the district court's order that resurrected various restrictions on the use of mifepristone that the FDA determined are medically unnecessary and therefore eliminated. The Fifth Circuit's order also created uncertainty with respect to the status of the FDA's approval of the generic version of mifepristone, even though the only controversy between the parties in that regard was based on plaintiffs' rejected challenge to the 2000 approval of the branded drug. The lower courts' rulings are legally erroneous, undermine the regulatory scheme for drug approvals, and present devastating risks to millions of people across the country.

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 applicants' emergency requests for a stay of the lower courts' rulings. The continued availability of mifepristone for medication abortions is critical to safeguarding amici States' important interest in protecting the health, safety, and rights of their residents, including an interest in ensuring safe access to essential reproductive health care.[1]

Mifepristone is proven to be a safe, reliable, and effective method for early pregnancy termination and, as part of a regimen taken in combination with the drug misoprostol, is the only drug approved by the FDA for medication abortion in the United States. The availability of mifepristone has been particularly critical in providing access to abortion in low-income, underserved, and rural communities where a nonmedication abortion procedure (or "procedural abortion") may be unavailable. And because medication abortion is the most common method used to terminate pregnancy during the first trimester, curtailing access to this method will result in more abortions taking place later in pregnancy, further increasing costs and medical risks.

Amici also have a strong interest in safeguarding their sovereign decisions to protect their residents' ability to obtain abortions in the wake of *Dobbs v. Jackson Women's Health Organization*, 142 S. Ct. 2228 (2022). Although this Court concluded that the U.S. Constitution does not protect the right to obtain an abortion, it

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[1] Several amici States are plaintiffs in *Washington v. U.S. Food & Drug Administration*, No. 23-cv-3026 (E.D. Wash.), which challenges certain restrictions on the use of mifepristone. The district court in that case has preliminarily enjoined the FDA from altering the status quo with respect to mifepristone in those States.

emphatically endorsed the States' authority to safeguard access to abortion for their residents, explaining that it was "return[ing] the issue of abortion to the people's elected representatives." *Id.* at 2243. The lower courts' rulings could eviscerate the sovereign decisions of many amici States by disrupting access to mifepristone in States where abortion is lawful.

ARGUMENT

POINT I

MEDICATION ABORTION IS SAFE AND EFFECTIVE AND INDISPENSABLE TO REPRODUCTIVE HEALTH CARE

The experience of many of the amici States confirms what numerous studies have demonstrated: medication abortion is safe and effective and an integral component of reproductive health care.

Since the FDA approved mifepristone in 2000, an estimated 5.6 million women in the U.S. have used this method to terminate a pregnancy.[2] According to current estimates, medication abortion now accounts for more than half—or 54%—of all abortions performed in the U.S."[3] A recent comprehensive survey of abortion care in the U.S. conducted by the National Academies of Sciences, Engineering, and Medicine concluded that medication abortion is safe and effective and that complications are

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[2] *See* U.S. Food & Drug Admin. (FDA), *Questions and Answers on Mifepristone for Medical Termination of Pregnancy through Ten Weeks Gestation* (last updated Jan. 4, 2023); U.S. Food & Drug Admin., *Mifepristone U.S. Post-Marketing Adverse Events Summary through 06/30/2022* (n.d.).

[3] Rachel K. Jones et al., *Medication Abortion Now Accounts for More than Half of All US Abortions*, Guttmacher Inst. (Feb. 24, 2022).

rare, i.e., "occurring in no more than a fraction of a percent of patients."[4] The World Health Organization authorizes use of medication abortion as safe through 12 weeks of pregnancy and has long included the mifepristone/misoprostol regimen in its Model List of Essential Medicines.[5]

Since 2016, the FDA has taken steps to eliminate medically unnecessary barriers to medication abortion access. Among other things, the FDA expanded the approved period of use for mifepristone from seven to ten weeks of pregnancy, eliminated the requirement that mifepristone be prescribed and dispensed by physicians, and eliminated the in-person dispensing requirement (first, on an emergency basis due to the Covid-19 pandemic, and then, as a final determination).[6] And in 2019, the FDA approved a generic version of mifepristone.[7] These changes, coupled with the growing adoption of telemedicine, have greatly increased access to reproductive health care, particularly for those living in low-income communities, communities of color, and

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[4] *See* National Acads. of Scis., Eng'g & Med., *The Safety and Quality of Abortion Care in the United States* 10, 55 (2018) (hereinafter "NASEM, *Safety and Quality of Abortion Care*").

[5] World Health Org., *WHO Model List of Essential Medicines, 22nd List, 2021: Overview* (Sept. 30, 2021); *see* World Health Org., *Abortion Care Guideline* xxix, 16-17, 67-68 (2022). Mifepristone is also commonly used in treating early pregnancy loss. *See* Kurt Barnhart, *Medical Management of Miscarriage with Mifepristone*, 396 Lancet 737, 737-38 (2020).

[6] FDA, *Questions and Answers on Mifepristone*, *supra*; U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Rsch., *Risk Evaluation and Mitigation Strategy (REMS) Memorandum: REMS Modification* (Mar. 29, 2016); 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).

[7] FDA, *Questions and Answers on Mifepristone*, *supra*.

rural and underserved areas.[8] In amici States' experience, the FDA's actions in lifting these unnecessary restrictions, and the resulting increase in access to medication abortion, have greatly benefitted their residents, the health care system, and the public fisc.

The FDA's actions to increase access to mifepristone also comport with medical evidence, which shows that medication abortion can safely be provided in a variety of contexts and practice areas—for example, in a private physician's office, an ob-gyn or family practice setting, or at home with appropriate medical supervision.[9] The availability of medication abortion within mainstream medical settings not only lifts constraints on access but also offers added privacy and security for both patients and providers—benefits that are particularly critical given persistent and escalating violence at abortion clinics.[10] Medication abortion also promotes access to early abortion, when it is safest and least expensive, thereby reducing complication rates, decreasing costs, and easing burdens on the health care system overall.

Many amici States have therefore expended substantial resources in promoting access to medication abortion. For example, in Maine, which has among the highest rates of rural residents in the U.S., a major health clinic chain has made medication abortion available at its 16 health centers via telemedicine in order to

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[8] *See* Letter from Att'ys Gen. to Alex M. Azar II, Sec'y, U.S. Dep't of Health & Hum. Servs., and Stephen Hahn, Comm'r, FDA (Mar. 30, 2020).

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

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

provide access to residents who would otherwise have to travel long distances to urban centers.[11] New York City recently announced it will offer free medication abortion at four public health clinics.[12] And several amici States, including Massachusetts, New York, and California, have taken steps to extend access to public university students by making medication abortion available at campus health centers.[13]

The lower courts' rulings ignore the substantial investments made by amici States in reliance on the availability *and* accessibility of mifepristone. And the lower courts' unprecedented "stay" of the FDA's regulatory judgments undermines the integrity of the FDA-approval process not only for this drug but also for thousands of other FDA-approved drugs used by amici States' residents to treat or manage a range of medical conditions experienced by their residents, including asthma, HIV, infertility, heart disease, diabetes, and more. For each of these drugs, the FDA determined based on significant clinical data—just as it did with mifepristone—that the benefits of the drug outweighed any known and potential risks. If permitted to stand, the lower courts' rulings invite revisiting all these decisions.

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

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

[13] *See* Nadine El-Bawab, *Offering Abortion Pills on Campus Could Eliminate Boundaries to Access, Students Say*, ABC News (Oct. 15, 2022); Stephanie Hughes, *With* Roe v. Wade *Overturned, Colleges Prep to Provide Abortion Medication*, Marketplace (Oct. 10, 2022); Press Release, N.Y. Off. of the Governor, *Governor Hochul Announces Steps to Strengthen New York State's Safe Harbor for Abortion Care* (Jan. 10, 2023).

POINT II

ABSENT A STAY, THE LOWER COURTS' RULINGS WOULD HAVE DEVASTATING CONSEQUENCES

The Fifth Circuit's ruling—which left in place portions of the district court's order reinstating restrictions on the use of mifepristone that the FDA has deemed medically unnecessary, and cast unwarranted doubt on the availability of an approved generic medication—threatens devastating consequences nationwide, particularly in States that wish to protect rather than restrict abortion access. The Fifth Circuit erroneously concluded that the record supports a showing of irreparable harm concerning only the district court's stay of the FDA's original approval and incorrectly assumed that there is no evidence that turning the clock back on the FDA's post-2016 regulatory actions with respect to mifepristone "irreparably harms anyone." (CA5 Order at 37; *see also id.* at 39-40.) To the contrary, the practical effect of the Fifth Circuit's ruling is to make medication abortion substantially more difficult to access even than procedural abortion, thereby diminishing many of the benefits that medication abortion offers and imposing substantial burdens on already overtaxed health care systems. If the lower courts' rulings were to take effect nationwide, they could inflict massive harms on amici States and their residents.

First, patients who may no longer be able to access mifepristone due to the restoration of various dispensing requirements and potential confusion over whether the generic drug is approved will instead seek procedural abortions—which, although safe, would constitute an unnecessarily invasive procedure for those who would have preferred a medication abortion. Others may be required to travel long distances or

will seek abortion medications through online services or overseas pharmacies and self-manage their abortions outside of a medical setting.[14] Loss of access to medication abortion would also lead to more need for second-trimester abortions, with a resulting increase in health risks, costs, and delays.[15]

Second, many who are unable to afford the additional costs associated with or resulting from reinstating these unnecessary restrictions will be denied access to abortion altogether and be forced to carry unwanted pregnancies to term,[16] resulting in numerous harms, including poor birthing and infant health outcomes, higher rates of poverty, and lower educational attainment for both parents and children.[17] And because carrying a pregnancy to term is 14 times more risky than early abortion,[18] curtailing access to medication abortion would likely lead to a steep rise in birth-related

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[14] *See* Abigail R.A. Aiken et al., *Requests for Self-Managed Medication Abortion Provided Using Online Telemedicine in 30 US States Before and After the* Dobbs v. Jackson Women's Health Organization *Decision*, 328 JAMA 1768, 1768-70 (2022).

[15] *See* Liza Fuentes & Jenna Jerman, *Distance Traveled for Abortion in the United States and Reasons for Clinic Choice*, 28 J. Women's Health 1623, 1626 (2019).

[16] *See* Fuentes & Jerman, *supra*, at 1626; Kirsten M.J. Thompson et al., *Association of Travel Distance to Nearest Abortion Facility with Rates of Abortion*, JAMA Network Open 6-8 (July 6, 2021); Kristina Kimport, *Abortion After* Dobbs*: Defendants, Denials, and Delays*, 8 Sci. Advances (ade5327) 1-2 (Sept. 2022).

[17] *See, e.g.*, Diana G. Foster, *The Turnaway Study: Ten Years, a Thousand Women, and the Consequences of Having—or Being Denied—an Abortion* (2021).

[18] 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).

mortality rates,[19] worsening a crisis already disproportionately faced by Black women.[20]

Because severely restricting access to mifepristone could be tantamount to losing access to abortion for many people, the lower courts' rulings may exacerbate the many harms already associated with the drastic reduction in access to abortion care across large swaths of the country. Abortion is currently completely unavailable in the 13 States where bans or near-total restrictions are in effect or subject to pending litigation, and access is extremely limited in several more.[21] Those States are home to approximately 22 million women of childbearing age, representing almost one third of the total population of women ages 15-49.[22] If the lower courts' rulings take effect, access to abortion may be substantially reduced even in States where such care is legal, leaving many people with no access to abortion care at all.

The impacts on birth-related morbidity and mortality from being denied abortion are not hypothetical. In States without abortion access, resulting delays and denials of care have already led to dire health outcomes for women, including being forced to forgo cancer treatment, developing sepsis, being left bleeding for days after

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

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

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

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

incomplete miscarriage, enduring risk of rupture due to ectopic pregnancy, and being forced to continue carrying a fetus that was nonviable.[23] The brunt of these harms continues to disproportionately fall on communities of color.[24]

States where abortion remains legal and available, including many amici States, have already experienced a steep rise in demand at clinics as out-of-state patients flood into their States to receive necessary care.[25] The resulting "dramatic increases in caseloads mean clinic capacity and staff are stretched to their limits, resulting in longer wait times for appointments even for residents of states where abortion remains legal."[26]

The lower court's rulings are certain to exacerbate these problems. For example, the Fifth Circuit would require physicians to prescribe and dispense mifepristone even though the FDA (and many States) have determined that appropriately trained clinicians other than physicians are qualified to do so. Such a requirement would force an already limited pool of physician providers to shift critical resources

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[23] *See* Jessica Valenti, *I Write About Post-Roe America Every Day. It's Worse than You Think*, N.Y. Times (Nov. 5, 2022); Pl.'s Mot. for TRO and Prelim. Inj., *Preterm Cleveland v. Yost*, No. A2203203 (Ohio C.P. Hamilton County Sept. 2, 2022); Complaint, *Zurawski v. Texas*, No. D-1-GN-23-000968 (Dist. Ct. Travis County Mar. 6, 2023).

[24] *See* Samantha Artiga et al., *What Are the Implications of the Overturning of* Roe v. Wade *for Racial Disparities?*, Kaiser Fam. Found. (July 15, 2022).

[25] *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); Matt Bloom & Bente Berkland, *Wait Times at Colorado Abortion Clinics Hit 2 Weeks as Out-of-State Patients Strain System*, KSUT (July 28, 2022).

[26] Kirstein et al., *100 Days Post*-Roe, *supra*.

and attention away from procedural abortion and other forms of reproductive health care.[27] And the Fifth Circuit imperils access to medication abortion through telemedicine, which has been critical to many amici States' ability to handle the influx of demand in the wake of post-*Dobbs* restrictions on abortion access.[28] In addition, the Fifth Circuit would require three in-person visits per patient to complete a medication abortion. If this order were to take effect nationwide, these dramatic changes would fundamentally alter the status quo and would leave providers in many amici States struggling to meet the additional spike in demand for abortion, from both state residents and persons travelling from other states to obtain treatment. The result would compound delays and place an untenable strain on an already overwhelmed system.

The harmful outcomes described above would cause ripple effects across the entire health care system. In many amici States, many of the same facilities providing abortion also offer other critical health care services, such as pre- and post-natal care, contraceptive care, cancer screening, and other critical forms of preventative health care. Delays resulting from increased demand for abortion procedures will obstruct access to other forms of care at those facilities, inevitably resulting in higher rates of unintended pregnancy and sexually transmitted infections, barriers to early detection and treatment for breast, ovarian, and testicular cancers, and worsened

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[27] *See* American Pub. Health Ass'n, Policy Number 20112, *Provision of Abortion Care by Advanced Practice Nurses and Physician Assistants* (Nov. 1, 2011).

[28] Amelia Thomson-DeVeaux, *Virtual Abortions Surged After* Roe *Was Overturned—But the Texas Ruling Could Change That*, FiveThirtyEight (Apr. 11, 2013).

health outcomes for patients' overall sexual and reproductive health and beyond.[29] Those harms will disproportionately impact groups already underserved by the health care system, including women of color, low-income women, people with disabilities, and LGBTQ individuals.[30] And in addition to jeopardizing the health of residents and deepening health care disparities, such outcomes would impose substantial costs on amici States and local governments. By contrast, in amici States' experience, strains on the health care system purportedly caused by the FDA's regulatory decisions since 2016, which the lower court decisions accepted as fact, have simply never materialized.

In finding that nationwide preliminary relief was in the public interest, the lower courts ignored the considerable harms identified by amici States, the federal government, medical practitioners, the pharmaceutical industry, and others. Instead, the lower courts elevated the policy preferences of plaintiffs and States that have banned or restricted abortion. (Op. & Order at 63; CA5 Order at 39-40.) But this Court recognized in *Dobbs* that "the people of the various States may evaluate" the interests of a woman who wants an abortion and the interests in fetal life differently, *Dobbs*, 142 S. Ct. at 2257, and mandated that "the authority to regulate abortion must be returned to the people and their elected representatives," *id.* at 2279. In this case, the

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[29] *See* Julia Strasser et al., *Penalizing Abortion Providers Will Have Ripple Effects across Pregnancy Care*, Health Affs. (May 3, 2022); Kirstein et al., *100 Days Post*-Roe, *supra*.

[30] *See, e.g.*, Strasser, *supra*; Theresa Chalhoub & Kelly Rimary, *The Health Care System and Racial Disparities in Maternal Mortality*, Ctr. for Am. Progress (May 10, 2018).

lower courts disregarded *Dobbs* by promoting the policy interests of one group of States over all others and ordering relief that could impose drastic consequences on States that have made the different but equally sovereign determinations to promote access to abortion care.

CONCLUSION

This Court should grant the applications for a stay.

Dated: New York, New York
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