Nos. 20-1784, 20-1824, 20-1970

United States Court of Appeals for the Fourth Circuit

AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, on behalf of its members and members' patients, et al.,

Plaintiffs-Appellees / Cross-Appellants,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, et al.,

Defendants-Appellants / Cross-Appellees,

and

STATE OF IDAHO, et al.,

Intervenors-Appellants.

On Appeal from the United States District Court
for the District of Maryland

BRIEF FOR STATES OF NEW YORK, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, HAWAI'I, ILLINOIS, MAINE, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, NEVADA, NEW JERSEY, NEW MEXICO, NORTH CAROLINA, OREGON, PENNSYLVANIA, RHODE ISLAND, VERMONT, VIRIGINIA, AND WASHINGTON, AND THE DISTRICT OF COLUMBIA, AS *AMICI CURIAE* IN SUPPORT OF PLAINTIFFS-APPELLEES/CROSS-APPELLANTS

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INTRODUCTION AND INTERESTS OF AMICI STATES

The States of New York, California, Colorado, Connecticut, Delaware, Hawai'i, Illinois, Maine, Maryland, Massachusetts, Michigan, Minnesota, Nevada, New Jersey, New Mexico, North Carolina, Oregon, Pennsylvania, Rhode Island, Vermont, Virginia, and Washington, and the District of Columbia submit this brief as amici curiae supporting the plaintiffs-cross-appellants. The amici States are striving to protect their residents from COVID-19 while also ensuring that their residents can continue to safely access essential healthcare. The district court's preliminary injunction facilitates those efforts by providing safe access to abortion care during the pandemic through means that avoid unnecessary in-person contacts—thus reducing the risk of virus transmission for patients, providers, and the public. Amici submit this brief to support the existing preliminary injunction and to explain that the same public health interests support suspending in-person dispensing of mifepristone for miscarriage treatment.

The preliminary injunction partially prohibits enforcement, during the ongoing public health crisis, of U.S. Food and Drug Administration (FDA) requirements mandating in-person dispensing of mifepristone: a

single-dose oral medication used for early-term abortions and miscarriage management. The FDA requires that patients seeking mifepristone for pregnancy-related care appear in person in a clinical setting to sign an acknowledgment form and fill their mifepristone prescription. The district court concluded that these requirements impose an undue burden on access to abortion during the pandemic.

Amici States' experiences confirm the correctness of the district court's finding that mifepristone can be safely dispensed without unnecessary travel and interpersonal contacts, through remote medical consultations via video or phone (telehealth), a remote acknowledgement, and delivery of mifepristone to patients' homes by or under the supervision of a certified provider. Anticipating the obstacles that the in-person dispensing requirements would impose during the COVID-19 crisis, many of amici States' attorneys general asked defendants-appellants in March 2020 to suspend the enforcement of these requirements during the pandemic and permit the use of telehealth as a substitute.[1] At the same

[1] *See* Letter from Att'ys Gen. to Alex M. Azar II, Sec'y, HHS, and Stephen Hahn, Comm'r, FDA, at 1 (Mar. 30, 2020) (internet). (For authorities available on the internet, full URLs are listed in the table of authorities.)

time, amici States began to loosen their own telehealth restrictions and to affirmatively encourage the use of telehealth during the pandemic as a safe way to provide needed medical services while limiting interpersonal contacts—with beneficial results for patients, providers, and their communities.

Amici States have a strong interest in ensuring access to telehealth for essential healthcare whenever telehealth is appropriate in the provider's judgment and consistent with standards of care. As the district court found, and as amici's experiences confirm, enforcing the in-person requirements during the current public health crisis will harm patient safety and the public interest in at least two ways: *first*, by conditioning access to essential reproductive healthcare on an increased risk of virus infection; and *second*, by undermining amici's ongoing efforts to slow the spread of the virus through measures that limit unnecessary interpersonal contacts. Those measures, which include telehealth, are critical to amici's ability to permit essential in-person activities, maintain healthcare capacity, and save lives—particularly as new and much more contagious variants of the virus begin to spread across the country.

STATEMENT

A. The COVID-19 Pandemic

The spread of COVID-19, which can cause severe and life-threatening illness, has thrown the amici States and the country at large into an unprecedented crisis with devastating consequences for public health. At the end of January 2021, the country had nearly twenty-six million confirmed infections and more than 436,000 deaths from COVID-19.[2] The past month has seen the highest number of infections yet, with daily infections more than three times higher than during the last major surge of infections in July 2020.[3] Hospitalizations are at unprecedented levels in a majority of the States, with more than forty percent of Americans living in areas that are running out of beds in intensive care units.[4] The death rate from COVID-19 has also spiked,

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[2] John Hopkins University of Medicine, Coronavirus Resource Center, *New Cases of COVID-19 in World Countries* (updated Jan. 31, 2021) (internet).

[3] *See id.* (showing persistently high infection rates in forty States); Jordan Allen et al., *Coronavirus in the U.S.: Latest Map and Case Count*, N.Y. Times (updated Feb. 12, 2021) (internet).

[4] *See* Carla K. Johnson & Nicky Forster, *2 in 5 Americans Live Where COVID-19 Strains Hospital ICUs*, A.P. News (Jan. 24, 2021) (internet).

with a new record of over 80,000 deaths in January 2021, and over 4,400 deaths on January 12 alone.[5] According to the Centers for Disease Control and Prevention (CDC), the total death count is expected to reach half a million in the next two weeks.[6]

Experts at the CDC have advised that the virus "spread[s] mainly through close contact from person-to-person," and that "[t]he best way to prevent illness is to avoid being exposed to this virus."[7] Limiting in-person contacts "whenever possible" is "very important in preventing the spread of COVID-19."[8] (*See also* Joint Appendix (J.A.) 1492.)

Accordingly, since March 2020, amici States have been instituting emergency measures to slow the virus's spread by limiting face-to-face contacts and in-person gatherings. When necessary to curb rising

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[5] *See* Alexa Lardieri, *CDC: 100K Projected to Die of Coronavirus in Biden's First Month in Office*, U.S. News & World Report (Jan. 27, 2021) (internet); Apoorva Mandavilli et al., *C.D.C. Warns the New Virus Variant Could Fuel Huge Spikes in Covid-19 Cases*, N.Y. Times (updated Jan. 19, 2021) (internet).

[6] Alexa Lardieri, *supra*.

[7] CDC, *COVID-19: How COVID-19 Spreads* (updated Oct. 28, 2020) (internet).

[8] *Id.*

infection rates, amici States have closed schools, required nonessential employees to work from home, and directed residents to confine themselves to their homes except for essential matters. (*See* J.A. 1429.)

As these efforts proved effective in reducing virus transmission, many amici began to allow increased business and community activities, and some have permitted in-person instruction at schools.[9] But amici States have emphasized that safe reopening requires residents to minimize in-person contacts in order to keep infection rates under control.[10] In light of the unremitting surge of infections and hospitalizations, limiting unnecessary in-person contacts is critical to amici's ability to slow the spread of the virus, maintain hospital capacity, and save lives while avoiding the reimplementation of more restrictive measures.[11]

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[9] *See* Jasmine C. Lee et al., *See How All 50 States Are Reopening (and Closing Again)*, N.Y. Times (updated Sept. 4, 2020) (internet); *Where Schools Are Reopening in the US*, CNN.com (updated Aug. 31, 2020) (internet).

[10] *See, e.g.*, N.Y. Office of the Governor, Reopening New York: Curbside and In-Store Pickup Retail Guidelines for Employers and Employees (n.d.) (internet) (e.g., requiring six feet between personnel, limiting occupancy to 50%, limiting confined spaces to one person).

[11] *See Read the Latest Federal Report on States' Response to the Virus*, N.Y. Times (July 28, 2020) (internet) (White House Coronavirus Task Force report identifying high-infection areas where strict protective

Public health experts expect the rate of infections and deaths to increase even more in the next several months due to several newly identified variants of the coronavirus that are much more contagious than the current prevailing strain in the U.S.[12] One new variant, which is 50% more infectious than the current prevailing strain, is expected to become the dominant strain in the U.S. by March 2021.[13] As compared to the current prevailing strain, this new variant could result in twice as many infections and deaths over a two-week period, and four or five times

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measures are recommended); *see also, e.g.*, Laurel Wamsley and Scott Neuman, *6 Million Coronavirus Infections Now Confirmed in U.S., a Country in Limbo*, National Public Radio (Aug. 31, 2020) (internet) (individual colleges reporting several hundred to a thousand new cases in the first two weeks after in-person reopening).

[12] *See* CDC, *COVID-19*, *Emerging SARS-CoV-2 Variants* (Jan. 28, 2021) (internet); Nick Evershed, *New UK and South Africa Covid Variants May Spread More Easily, So What Does This Mean for the Fight Against Coronavirus?*, The Guardian (Jan. 24, 2021) (internet); Brian Resnick, *Why Epidemiologists Are So Worried About the New Covid-19 Variants, in 2 Charts*, Vox (Jan. 8, 2021) (internet).

[13] *See* Evershed, *supra*; Mandavilli, *supra*; Nicole L. Washington et al., *Genomic Epidemiology Identifies Emergence and Rapid Transmission of SARS-CoV-2 B.1.1.7 in the United States* 3 (Feb. 7, 2021) (internet).

as many infections and deaths over a month.[14] The CDC has warned that the additional demand for healthcare resources and hospital capacity associated with the accelerated surge of infections may further increase death rates.[15] The potency and anticipated spread of these new variants underscores the importance of amici States' efforts to minimize unnecessary in-person contacts in order to limit virus transmission, maintain hospital capacity, and save lives.

B. Proceedings Below

Mifepristone is a single-dose oral medication used for early-term abortions and miscarriage management. As relevant here, the FDA requires patients seeking mifepristone for pregnancy-related care to appear in person at a hospital, clinic, or medical office to (1) sign a form acknowledging their receipt of counseling and information about mifepristone, and (2) fill their mifepristone prescription. (*See* J.A. 1425-1426.)

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[14] *See* Resnick, *supra*; *see also* Washington, *supra*, at 3, 5 (recent study finding new variant is doubling in relative frequency every ten days in the U.S.).

[15] *See* CDC, *New Variants of the Virus That Causes COVID-19* (updated Feb. 2, 2021) (internet).

In May 2020, respondents—who include national and statewide organizations representing 90% of the country's obstetric and gynecological physicians—sought declaratory and injunctive relief to prohibit enforcement of the two FDA requirements during the pandemic. Respondents requested a preliminary injunction allowing patients to sign the acknowledgment form and receive mifepristone for abortion care and miscarriage treatment without traveling to a clinical setting. (*See* J.A. 1436.)

After full briefing and a hearing, the district court preliminarily enjoined enforcement of the in-person requirements when mifepristone is being dispensed for a medication abortion. The court concluded that enforcing the in-person requirements during the pandemic created a substantial obstacle to abortion access and an undue burden for a large fraction of the women seeking a medication abortion during the pandemic—i.e., patients for whom a healthcare provider has determined that an in-person visit is not medically necessary. (*See* J.A. 1460-1470, 1482.) Based on expert evidence and the federal government's own actions during the pandemic, the court found that the in-person signature and dispensing requirements "do not advance general interests of patient

safety and thus constitute 'unnecessary health regulations.'" (J.A. 1471 (quoting *Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292, 2309 (2016)); *see also* J.A. 1463-1465.) The court found that healthcare providers could safely provide required counseling using telehealth, and safely and efficiently deliver the drug to patients by mail or courier. (*See* J.A. 1477-1479.)

Finally, the court found that the equities and public interest weighed in favor of the preliminary injunction, which "aligns with the public health guidance to eliminate unnecessary travel and in-person contact." (J.A. 1490-1492.) Although the court enjoined enforcement of the in-person requirements for medication abortions (J.A. 1504), the court declined to enjoin enforcement for miscarriage treatment (J.A. 1485-1488).

Defendants appealed the preliminary injunction order and asked the district court for a stay pending appeal. (J.A. 1512-1535.) After the district court denied the stay request (J.A. 1550-1551), defendants sought a stay from this Court, which also denied the request, *see American Coll. of Obstetricians & Gynecologists v. U.S. Food & Drug Admin.*, No. 20-1824, ECF 30 (4th Cir. Aug. 13, 2020). Defendants then sought a stay from the

Supreme Court, which held the application in abeyance pending further development in the district court of a supplemental record encompassing then-improving conditions in individual states in October and November 2020. *See Food & Drug Admin. v. American Coll. of Obstetricians & Gynecologists*, 141 S. Ct. 10, 10-11 (2020). Based on the supplemented record, the Supreme Court granted a stay of the preliminary injunction. *See Food & Drug Admin. v. American Coll. of Obstetricians & Gynecologists*, 141 S. Ct. 578, 578 (2021).

Presently before the Court is defendants' appeal of the preliminary injunction order, and plaintiffs' cross-appeal of the order insofar as it declined to enjoin the in-person requirements for miscarriage treatment. Separately, proposed intervenors Indiana and nine other States have appealed the district court's denial of their motion to intervene. (J.A. 1509-1510.)

SUMMARY OF ARGUMENT

The district court properly granted a preliminary injunction that suspends, during the current public health crisis, FDA requirements prohibiting the remote dispensing of mifepristone for abortion care. Under the injunction, telehealth may be used to complete provider counseling and the patient's written acknowledgment of information about mifepristone, and the drug may then be delivered by mail. The injunction currently covers the dispensing of mifepristone for medication abortions, and the same public health interests support suspending the in-person requirements for miscarriage management.

Amici's experiences confirm the record evidence establishing that the balance of equities and public interest tip heavily in favor of plaintiffs' requested injunction. Medical care—including reproductive healthcare—is being safely delivered through remote means during the pandemic. And providers can use a combination of telehealth and mail delivery of mifepristone to safely provide patients with abortion care and miscarriage treatment. Defendants, meanwhile, have presented no evidence of harm to patients.

Plaintiffs' requested injunction also reduces unnecessary in-person contacts, which is critical to amici States' ability to limit the spread of COVID-19 and protect the public health. Amici are currently encouraging the use of telehealth to limit in-person contacts, increase available providers, ensure safe access to essential healthcare, and maintain healthcare system capacity—all in the interest of saving lives and facilitating the safe reopening of businesses and community activities. Absent a preliminary injunction, the FDA's requirements will force patients to engage in unnecessary travel and in-person contacts to access essential reproductive care, risking their exposure to and spread of COVID-19 and thwarting amici's efforts to manage the crisis.

ARGUMENT

AMICI'S EXPERIENCES CONFIRM THE RECORD EVIDENCE SHOWING THAT THE EQUITIES AND THE PUBLIC INTEREST SUPPORT THE REQUESTED PRELIMINARY INJUNCTION

To obtain a preliminary injunction, plaintiffs must establish that they are likely to succeed on the merits, that they are likely to suffer irreparable harm in the absence of the preliminary injunction, that the balance of the equities tips in their favor, and that the injunction is in the public interest. *See Winter v. NRDC, Inc.*, 555 U.S. 7, 20 (2008); *Pashby v. Delia*, 709 F.3d 307, 321 (4th Cir. 2013). A district court's decision to grant a preliminary injunction is reviewed for an abuse of discretion. *Roe v. Department of Def.,* 947 F.3d 207, 219 (4th Cir. 2020). Under that "deferential standard," the injunction should be upheld "so long as the district court's account of the evidence is plausible in light of the record viewed in its entirety." *Id.* (quotation marks omitted).

Here, as amici's experiences confirm, the equities and the public interest tip heavily in favor of plaintiffs' requested preliminary injunction: i.e., in favor of suspending, during the pandemic, the FDA's requirement that patients receiving mifepristone for abortion care and miscarriage treatment appear in person in a clinical setting to sign a form

acknowledging receipt of counseling about mifepristone, and to fill their mifepristone prescription.[16] As the record demonstrates—and as amici's experiences confirm—remote counseling and signing of the form through telehealth, followed by mail delivery of the drug, provides safe access to essential reproductive healthcare for patients while avoiding in-person contacts that risk exposure to and spread of COVID-19.

A. Telehealth Followed by Remote Delivery of Mifepristone Provides Safe Access to Essential Reproductive Healthcare During the Pandemic.

Telehealth has proven to be a safe and effective method for the delivery of healthcare—including essential reproductive care—during the current public health crisis. The CDC has noted that telehealth can "improve patient health outcomes" and has approved of "policy changes

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[16] Plaintiffs' brief to this Court explains that the record evidence supports plaintiffs' likelihood of success on the merits of their substantive due process claim, and the likelihood of irreparable harm in the absence of an injunction that includes miscarriage treatment as well as abortion care. Pls.-Appellees/Cross-Appellants' Opening Br. at 36-52, 53, 60-72. Plaintiffs also explain their likelihood of success on their equal protection claim seeking suspension of the in-person requirements for both abortion care and miscarriage treatment, which implicate fundamental rights and sex-based discrimination. *See id.* at 65-66; *see also Grimm v. Gloucester Cnty. Sch. Bd.*, 972 F.3d 586, 607-08 (4th Cir. 2020).

during the COVID-19 pandemic [that] have reduced barriers to telehealth access and have promoted the use of telehealth as a way to deliver acute, chronic, primary and specialty care."[17]

The amici States' experiences confirm that telehealth can be used to safely deliver essential healthcare during the pandemic. Amici have encouraged telehealth use wherever consistent with standards of care and appropriate in the judgment of the provider; such telehealth use has been "crucial" to providing amici's residents with safe access to needed healthcare during the public health crisis.[18]

Many of the amici States have suspended statutes and regulations restricting telehealth, in order to permit safe delivery of services to additional patient populations, especially medically vulnerable people. These suspension orders expand the types of practitioners who can use telehealth, the settings in which telehealth can be provided, the types of

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[17] CDC, *COVID-19, Healthcare Workers*: *Using Telehealth to Expand Access to Essential Health Services during the COVID-19 Pandemic* (updated June 10, 2020) (internet).

[18] Press Release, N.J. Office of the Governor, Governor Murphy Signs Legislation to Expand Telehealth Access and Expedite Licensure of Out-of-State Professionals (Mar. 19, 2020) (internet) (quotation marks omitted).

modalities for delivering telehealth services, and the circumstances under which telehealth can be initiated.[19] To enable patients to receive care from new providers or for new conditions without an initial face-to-face appointment, amici have suspended rules that prohibit telehealth in the absence of an existing patient-provider relationship.[20]

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[19] *E.g.*, Cal. Exec. Dep't, Executive Order N-43-20 (Apr. 3, 2020) (internet); Cal. Dep't of Health Care Services, *Medicine: Telehealth* (updated Aug. 2020) (internet); Del. Office of the Governor, Second Modification: Declaration of a State of Emergency (Mar. 18, 2020) (internet); Haw. Office of the Governor, Exec. Order 20-02 (Mar. 29, 2020) (internet); Md. Dep't of Health, Bd. of Physicians, Notice (Mar. 20, 2020) (internet); Minn. Office of the Governor, Emergency Exec. Order 20-28 (April 6, 2020) (internet); Ch. 3, 2020 N.J. Laws (Mar. 19, 2020) (A3860); Letter from Judith M. Persichilli, Comm'r, N.J. Dep't of Health, to Adm'rs of Long-Term Care Facilities et al. (Apr. 17, 2020) (internet); N.Y. Office of the Governor, Exec. Order No. 202.1, 9 N.Y.C.R.R. § 8.202.1 (2020); N.Y. Office for People with Developmental Disabilities, *Interim Guidance Regarding the Use of Telehealth/COVID-19* (updated Apr. 10, 2020) (internet); R.I. Office of the Governor, Exec. Order 20-06 (Mar. 18, 2020) (internet); Vt. Exec. Dep't, Exec. Order No. 01-20 (internet); Act No. 91, 2020 Vt. Laws (Mar. 30, 2020) (H742); Va. Office of the Governor, Exec. Order No. 57 (Apr. 17, 2020) (internet).

[20] *See, e.g.*, Del. Office of the Governor, Eighth Modification: Declaration of a State of Emergency (Mar. 30, 2020) (internet); Haw. Office of the Governor, Exec. Order 20-02; Md. Office of the Governor, Order No. 20-04-01-01 (Apr. 1, 2020) (internet); Mass. Bd. of Registration in Med., Policy 2020-01, Policy on Telemedicine in the Commonwealth (June 25, 2020) (internet); N.J. Div. of Consumer Affairs, *Telehealth Services during the COVID-19 Pandemic: Frequently Asked Questions (FAQs)* (Oct. 30, 2020) (internet) (describing waivers).

Many amici have expanded the range of telehealth services covered under their state Medicaid programs, have required providers participating in state Medicaid programs to use telehealth whenever appropriate, and have allowed additional modalities of remote care such as audio-only connections.[21] Amici have also enabled the use of telehealth to prescribe certain regulated drugs by suspending penalty provisions and eliminating the requirement of written patient consents.[22]

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[21] *E.g.,* Cal. Dep't of Health Care Servs., Behavioral Health Information Notice No. 20-009 (updated May 20, 2020) (internet); Cal. Dep't of Health Care Servs., Supplement to All Plan Letter 19-009 (Mar. 18, 2020) (internet); D.C. Dep't of Health Care Fin., *Telemedicine Provider Guidance* (Mar. 19, 2020) (internet); Letter from Robert R. Neall, Secretary, Md. Dep't of Health, to All Medicaid Provider Types et al. (n.d.) (internet); Mass. Exec. Office of Health & Human Services, Office of Medicaid, All Provider Bulletin 289 (Mar. 2020) (internet); N.M. Human Servs. Dep't, *Medical Assistance Program Manual Supplement: Special COVID-19 Supplement #3* (Apr. 6, 2020) (internet); N.Y. Dep't of Health, *Comprehensive Guidance Regarding Use of Telehealth Including Telephonic Services During the COVID-19 State of Emergency* (last updated May 29, 2020) (internet); R.I. Office of the Governor, Exec. Order 20-06; Letter from Karen Kimsey, Dir., Va. Dep't of Med. Assistance Servs. (Mar. 19, 2020) (internet); Va. Dep't of Med. Assistance Servs., Medicaid Memo: New Administrative Provider Flexibilities Related to COVID-19 (May 15, 2020) (internet); *see also* Del. Office of the Governor, Tenth Modification: Declaration of a State of Emergency (Apr. 6, 2020) (internet) (allowing telephone use for telehealth generally).

[22] *See* Cal. Dep't of Health Care Servs., Behavioral Health Information Notice No. 20-009; Haw. Office of the Governor, Seventeenth

These experiences of the amici States are consistent with the district court's well-supported finding, based on the record below, that telehealth provides a medically safe and effective alternative to the FDA's in-person requirements. Plaintiffs' expert evidence showed that telehealth counseling and delivery of mifepristone through mail-order pharmacies is a safe and effective method for delivering reproductive healthcare. And medical studies confirm that telehealth can safely be used to provide essential reproductive care, including early abortions.[23] (*See* J.A. 152.)

During the COVID-19 pandemic, the counseling required prior to a medication abortion is routinely provided through telehealth in order to reduce in-person interactions, and telehealth can likewise be used to counsel miscarriage patients. (*See* J.A. 161-162, 263-264, 291, 1426-1427, 1475.) Consistent with established standards of care, clinics have safely

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Supplementary Proclamation Related to the COVID-19 Emergency (Dec. 16, 2020) (internet).

[23] *See* Daniel Grossman et al., *Effectiveness and Acceptability of Medical Abortion Provided Through Telemedicine*, 118 Obstetrics and Gynecology 296 (Aug. 2011) (internet) (studying outcomes where patients visit a local clinic and use a video connection to meet with certified providers located at distant clinics who dispense mifepristone remotely).

and effectively used telehealth to conduct the required assessment of a patient's suitability for miscarriage management or medication abortion. (*See* J.A. 263-264, 1471, 1476.)

For example, for a medication abortion, the telehealth assessment is used to identify the subset of patients with risk factors who require a clinic visit—including any necessary ultrasound or blood work—in order to determine their suitability for a medication abortion. (*See* J.A. 1471; *see also* J.A. 145-146.) Contrary to the assertions of the proposed intervenor states (Intervenors-Appellants' Br. 43-44), neither the FDA nor the medical standard of care requires an in-person examination for every woman receiving a medication abortion (*see* J.A. 145-146, 151-152).

Nor does remote dispensing of mifepristone under the preliminary injunction adversely affect patient safety by causing significant delays in actual receipt of the drug after the required counseling. While defendants contend that delays could occur if a local pharmacy does not have the drug in stock (*see* Defs.-Appellants/Cross-Appellees' Opening Br. (Defs. Br.) 6, 33, 37-38, 42-43), that speculative concern has no basis in the record. As the district court made clear, the preliminary injunction requires direct delivery from the certified provider (e.g., by mail or courier) or from

specific mail-order pharmacies that stock the drug pursuant to a contract with the provider. (*See* J.A. 1478-1479, 1541-1542.) If immediate delivery is necessary for particular patients, providers may send the drug by same-day courier or even require the patient to come to the clinic. In any event, the FDA's current requirements do not ensure administration of the drug within a specific time period after counseling; rather, patients are permitted to take the drug at the time of their choosing after completing the counseling session. (*See* J.A. 1478-1479.)

Furthermore, defendants' own actions during the pandemic undermine their argument that the in-person requirements are necessary to protect patients here. The FDA has recognized as a general matter that enforcement of drug safety requirements applicable in normal times—including in-clinic dispensing, laboratory testing, and imaging—should be suspended during the pandemic in order to limit in-person contacts and virus transmission, and that dispensing decisions should be left to providers' best medical judgment.[24] Likewise, the Secretary of

[24] *See* FDA, Policy for Certain REMS Requirements During the COVID-19 Public Health Emergency: Guidance of Industry and Health Care Professionals 7 (Mar. 2020) (internet).

Health and Human Services has allowed telehealth to replace the required in-person evaluation for the prescribing of controlled substances during the public health emergency. (*See* J.A. 1430.) The FDA has provided no reasoned basis to retain the in-person requirements for mifepristone while suspending such requirements for other drugs, nor presented any evidence to rebut plaintiffs' showing that mifepristone can be safely prescribed using telehealth and delivered by courier or mail.

Finally, defendants miss the mark in criticizing the district court for having evaluated whether the in-person requirements were appropriate during the current pandemic. The court was not "second-guessing" the FDA's expertise. *See* Defs. Br. 42 (quotation marks omitted); *see also id.* at 35-40. To the contrary, the FDA declined multiple invitations to conduct this exact analysis itself (*see* J.A. 1473), and defendants have not identified any earlier FDA analysis considering the safety of telehealth counseling and mail delivery of mifepristone (*see* J.A. 1475, 1477). Therefore, while Chief Justice Roberts concurred in granting defendants a stay of the preliminary injunction on the ground that courts may "owe significant deference" to the determinations of "politically accountable entities" responding to the pandemic, *see Food & Drug Admin.*, 141 S. Ct.

at 579 (Roberts, C.J., concurring), the district court in fact owed no such deference here because the FDA did not make a determination of how to dispense mifepristone safely during the pandemic.[25]

Defendants therefore misplace their reliance on *South Bay United Pentecostal Church v. Newsom*, 140 S. Ct. 1613 (2020). *See* Defs. Br. 39-40. In that case, the Chief Justice explained that it was inappropriate for unelected federal judges to grant injunctive relief that would interfere with the judgment of politically accountable state officials managing a public health crisis. *South Bay*, 140 S. Ct. at 1613-14 (Roberts, C.J., concurring). In contrast, despite having ample opportunity during the preliminary injunction proceedings, defendants have never shown that federal officials made a considered judgment that the FDA requirements are necessary during the current public health crisis—as the district court correctly recognized (J.A. 1474-1475, 1477). Meanwhile, the FDA requirements actively interfere with the judgment of politically accountable

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[25] In any event, in granting defendants' stay application, the Supreme Court did not issue any majority opinion to guide or dictate the result of this appeal. *See, e.g.*, *Dodds v. U.S. Dep't of Educ.*, 845 F.3d 217, 221 (6th Cir. 2016). Moreover, the Supreme Court granted the stay based on a supplemented record that differs from the preliminary injunction record before this Court on appeal. *See Food & Drug Admin.*, 141 S. Ct. at 11.

officials in amici States, who are attempting to manage the pandemic by encouraging the widespread use of telehealth to safely provide essential healthcare. Under these circumstances, the district court properly declined to defer to the FDA's pre-pandemic assessment that the in-person requirements are necessary to protect patient safety.[26]

Defendants also misplace their reliance (Defs. Br. 42) on *South Bay* and *Maryland v. King*, 567 U.S. 1301 (2012) (Roberts, C.J., in chambers), in contending that the government necessarily suffers serious and irreparable harm any time government action is enjoined or invalidated. In *South Bay*, the Chief Justice declined to stay the Governor's Executive Order in large part because it was part of a statewide plan to begin lifting restrictions on particular social activities during the pandemic—"a dynamic and fact-intensive matter subject to reasonable disagreement" that was most appropriately left to the state officials charged with

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[26] *Roman Catholic Diocese of Brooklyn v. Cuomo*, 141 S. Ct. 63 (2020), is not to the contrary. There, the Court did not defer to the public health judgment of publicly-accountable officials because it concluded that the challenged restrictions were not neutral toward religion or narrowly tailored to protect religious interests, and therefore raised First Amendment concerns. *See id.* at 67-68; *see also South Bay United Pentecostal Church v. Newsom*, No. 20A136, 2021 WL 406258, at *1 (U.S. Feb. 5, 2020) (Roberts, C.J., concurring).

managing the pandemic in their State. 140 S. Ct. at 1613 (Roberts, C.J., concurring). The actual harm that could result from tinkering with that plan was the most significant pillar of his analysis. *See id.* at 1613-14. Likewise, in *King*, the Chief Justice granted a stay of a ruling in a criminal case that would have deprived state law enforcement officials of the ability to use, in the interest of public safety, an important and widely used investigative tool for identifying persons who committed violent crimes; that concrete harm to the State was an important basis for the stay, even though the Chief Justice also observed that States suffer harm when their laws are enjoined. *See* 567 U.S. at 1303-04.

Here, in contrast, defendants have not demonstrated any concrete harm caused by the preliminary injunction. And whatever amorphous harms are inflicted on the government by the bare act of enjoining the FDA requirements cannot outweigh the substantial, concrete harm of subjecting pregnant patients and others to unnecessary exposure to COVID-19 during the current public health crisis, restricting access to abortion services, and hampering amici States' ability to manage the pandemic.

B. Suspending the In-Person Requirements Protects the Public Health and Saves Lives by Limiting the Spread of the Virus.

The record here and amici's experiences show that reducing in-person contacts, such as through telehealth and remote delivery of medication, is critical to safeguarding the public health during the pandemic. Experts in infectious disease control and public health have advised that mitigating the spread of COVID-19 requires widespread adoption and enforcement of self-isolation and "social distancing": the practice of reducing in-person social contacts and avoiding crowded places as much as possible.[27] (*See* J.A. 191-193.) Amici have therefore implemented numerous measures to reduce in-person contacts. (J.A. 191-193.)

Telehealth, in particular, has been an "invaluable tool in slowing the spread of COVID-19" and permitting safe reopening of business and community activities in amici States.[28] Telehealth allows medical care to be provided without requiring travel to healthcare facilities—thus

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[27] *See* CDC, *Coronavirus Disease 2019 (COVID-19): Social Distancing* (last updated Nov. 17, 2020) (internet).

[28] D.C. Health Regul. & Licensing Admin., Guidance on Use of Telehealth in the District of Columbia (Mar. 12, 2020) (internet).

reducing in-person contacts and promoting the health and safety of patients, healthcare workers, and both parties' close contacts.[29] (*See* J.A. 1464-1465.) Widespread telehealth use has allowed the amici States to "maximize the number of capable health care workers" providing medical treatment, while protecting patients and healthcare staff.[30] Indeed, the CDC advises healthcare practitioners to use telehealth "'whenever possible' as 'the best way to protect patients and staff from COVID-19.'" (J.A. 1431 (quoting CDC guidance).)

Amici have also encouraged telehealth in order to conserve and expand healthcare resources, which is critically important to saving lives in amici States during the pandemic. (*See* J.A. 1462, 1466, 1492.) For example, telehealth decreases local healthcare workers' risk of infection and subsequent need to stop working in order to self-quarantine, and

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[29] *See* CDC, *COVID-19, Healthcare Workers*, *supra* ("Healthcare systems have had to adjust the way they triage, evaluate, and care for patients using methods that do not rely on in-person services.").

[30] Cal. Exec. Dep't, Exec. Order N-43-20; Cal. Dep't of Public Health, *Resuming California's Deferred and Preventive Health Care* (Apr. 27, 2020) (internet); *see also* Minn. Office of the Governor, Emergency Exec. Order 20-51 (May 6, 2020) (internet) (strongly encouraging the use of telehealth "whenever possible").

increases the number of available medical professionals to include those located farther away who can provide services remotely. (*See* J.A. 1431.)[31] As the White House has confirmed, telehealth is particularly helpful for underserved areas—such as distant rural communities with limited medical resources, or more populous communities whose healthcare systems are strained by COVID-19 patients.[32] Telehealth also enables individuals who need timely medical care to receive such care while self-isolating or subject to quarantine, thereby facilitating amici's efforts to limit the spread of the virus.[33]

The FDA in-person requirements thwart these efforts to manage the pandemic by forcing patients to undertake travel and in-person

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[31] *See also* CDC, *Coronavirus Disease 2019 (COVID-19): Strategies to Mitigate Healthcare Personnel Staffing Shortages* (updated Dec. 14, 2020) (internet).

[32] *See* Exec. Order No. 13941, Improving Rural Health and Telehealth Access, 85 Fed. Reg. 47,881 (Aug. 6, 2020); *see also* Benedict Carey, *Birx Says U.S. Epidemic Is in a 'New Phase,'* N.Y. Times (Aug. 2, 2020) (internet) (federal public health officials warn of the virus's "'extraordinarily widespread'" reach "'into the rural [and] urban areas'" of the country (quoting Dr. Deborah Birx)).

[33] *See* Vivek Chauhan et al., *Novel Coronavirus (COVID-19): Leveraging Telemedicine to Optimize Care While Minimizing Exposures and Viral Transmission*, 13 J. of Emergencies, Trauma, and Shock (Mar. 19, 2020) (internet).

contacts—exposing them to a heightened risk of contracting and spreading COVID-19—in order to obtain abortion care or necessary miscarriage treatment during the pandemic. In the U.S., abortions are ordinarily provided either by medication with the mifepristone regimen (mifepristone followed by a second drug), or by a procedure performed in a medical setting.[34] (*See* J.A. 1422.) Thus, due to the FDA's in-person dispensing requirements for mifepristone, no patient seeking abortion care can avoid a clinic visit. Miscarriage is treated by expectant management (waiting to see if the uterine contents are expelled over time), the mifepristone regimen, or vacuum aspiration. (J.A. 144-145, 275.) Under the first two treatment options, patients may be forced to undertake an additional clinic visit in order to obtain mifepristone as a necessary part of their miscarriage treatment.[35]

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[34] Patients seeking medication abortions represented nearly 40% (approximately 339,640 women) of all abortion patients in the U.S. in 2017. Rachel Jones et al., *Abortion Incidence and Service Availability in the United States, 2017*, Guttmacher Inst. (Sept. 2019) (internet).

[35] Patients experiencing miscarriage are typically diagnosed at a clinic or emergency department, but mifepristone may not be dispensed at that visit. Patients, in consultation with providers, may decide on expectant management during the visit but later need or elect medication management to complete the miscarriage. (J.A. 275.) Additionally, patients may present at an emergency department that lacks capacity to treat

Travel to a clinic is a burden even in ordinary times, *see June Med. Servs. L.L.C. v. Russo*, 140 S. Ct. 2103, 2130 (2020) (plurality op.); *id.* at 2140 (Roberts, C.J., concurring), but currently imposes further harms to patients and public health conditions generally by exposing patients to increased risk of infection. Many patients, and particularly low-income patients, will need to use public transportation or ride-sharing, or borrow a car. (*See* J.A. 1434.) And many patients will need to travel long distances to reach a clinic that dispenses mifepristone—sometimes up to two-hundred miles—especially if they reside in rural and medically underserved locations.[36] That additional travel and person-to-person contact increases patients' risk of contracting COVID-19 and

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miscarriage patients or has no mifepristone-certified provider on site. (J.A. 161, 276.) In such cases, the FDA's requirements force miscarriage patients to undergo an additional in-person visit.

[36] Jill Barr-Walker et al., *Experiences of Women Who Travel for Abortion: A Mixed Methods Systematic Review*, PLOS ONE (Apr. 9, 2019) (internet). Women residing outside a metropolitan statistical area—as the U.S. Office of Management and Budget defines such areas—were four times more likely to travel 50-100 miles for abortion services and eight times more likely to travel more than 100 miles for such care. Liza Fuentes & Jenna Jerman, *Distance Traveled to Obtain Clinical Abortion Care in the United States and Reasons for Clinic Choice*, 28 J. of Women's Health 1623, 1626-27 (Dec. 2019) (internet).

transmitting it to their families and communities. (*See* J.A. 1462-1465, 1491-1492.)

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In sum, the district court correctly and properly found that the in-person requirements "provide 'no significant health-related benefit,' and are 'unnecessary regulations' under current circumstances." (J.A. 1479 (quoting *June Med. Servs.*, 140 S. Ct. at 2132; *Whole Woman's Health*, 136 S. Ct. at 2309).) Because the preliminary injunction requested by plaintiffs provides a safe means to deliver essential reproductive care while protecting patients, providers, and the public health more generally, the balance of the equities and the public interest weigh heavily in favor of that injunction.

CONCLUSION

The Court should affirm the district court's preliminary injunction order regarding the dispensing of mifepristone for abortion care and should modify the order to also cover the dispensing of mifepristone for miscarriage management.

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CERTIFICATE OF COMPLIANCE

Pursuant to Rule 32(a) of the Federal Rules of Appellate Procedure, William P. Ford, an employee in the Office of the Attorney General of the State of New York, hereby certifies that according to the word count feature of the word processing program used to prepare this brief, the brief contains 6,113 words and complies with the typeface requirements and length limits of Rule 32(a)(5)-(7).

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