September 8, 2020

ATTORNEY GENERAL RAOUL FILES SUPREME COURT BRIEF TO MAINTAIN ACCESS TO REPRODUCTIVE HEALTH CARE

Chicago — Attorney General Kwame Raoul today joined a multistate coalition of 23 attorneys general in filing a brief supporting a lawsuit against the Food and Drug Administration (FDA) and the U.S. Department of Health and Human Services (HHS) over a requirement that restricts access to medication abortions. The attorneys general point out that the agencies' requirement would increase the risk that women nationwide will contract COVID-19 as they seek abortions in their state.

Raoul and the coalition filed an amicus brief in support of the plaintiffs in FDA et al. v. American College of Obstetricians and Gynecologists et al. that is pending with the U.S. Supreme Court. In the brief, Raoul and the coalition encourage the court to reject the federal government's request to halt a preliminary injunction issued by a district court in July, and thereby reinstate an FDA requirement that forces women to appear in person in a clinical setting to receive a drug known as mifepristone for an early abortion. Raoul and the coalition have argued in the past — and continue to argue in today's amicus brief — that the drug should be readily accessible via telehealth and mail delivery, so as to not potentially expose women to COVID-19 by requiring unnecessary travel.

"At a time when social distancing requirements have helped to slow the spread of COVID-19, the federal government should not require women to travel to receive vital health care when it can be provided remotely," Raoul said. "I will continue to oppose any effort to use the coronavirus pandemic as an opportunity for the government to deny women the ability to make health care decisions for themselves."

Since the widespread onset of COVID-19 across the United States in March, more than 6.1 million Americans, including more than 252,000 in Illinois, have contracted the disease, resulting in more than 187,000 deaths – more than 8,100 in Illinois alone. In response, legislators, elected officials, and agencies across the nation have been instituting various emergency measures to slow the spread of the virus. States have limited face-to-face contact and reduced in-person social gatherings, closed schools and required all nonessential employees to work from home, as limiting interpersonal contact is central to the ability of states to control the spread of the virus.

The FDA's requirements force patients to appear in person in a clinical setting to receive mifepristone and heighten the risk of contracting and transmitting COVID-19 for everyone involved, including patients and health care providers. Before the pandemic, patients seeking medication abortions represented nearly 40 percent of all abortion patients in the U.S. in 2017. Forcing these women to travel at a time when many states are urging people to limit in-person contacts to curb the spread of COVID-19 is shortsighted, not only putting women across the country and their close contacts in harm's way, but also harming the public health more generally.

In today's brief, Raoul and the coalition specifically argue that reinstating and enforcing the FDA requirements during the current public health crisis will harm patient safety and the public interest by: conditioning access to essential reproductive health care on an increased risk of virus infection and transmission, and by undermining the states' ongoing efforts to manage the crisis through measures limiting unnecessary in-person contacts, such as stay-at-home orders, stay-safe orders, and telehealth. States have already effectively utilized such measures to control the spread of the virus, and these measures remain necessary to safely reopen communities, allow for essential in-person activities, and maintain health care capacity during the upcoming flu season.

Additionally, Raoul and the coalition argue that many women will need to travel long distances in order to reach a clinic that dispenses mifepristone, especially if they reside in rural and medically underserved locations, therefore increasing the likelihood of coming into contact with an individual who has contracted COVID-19.

Raoul and the coalition assert that by using measures like telehealth to reduce unnecessary person-to-person contacts, states can decrease their infection rate even as the pandemic continues. Raoul and the coalition also highlight that their states have already taken numerous steps to expand the use of telehealth during the current public health crisis, including the suspension of existing statutes and regulations that limit the use of telehealth in order to allow the delivery of regulated services through telehealth to additional patient populations, including especially vulnerable ones. These suspension orders expand the types of practitioners who can use telehealth, the settings in which it can be provided, the modalities that can be used to deliver telehealth services, and the circumstances under which telehealth can be initiated. Further, many states have also suspended rules that prohibit telehealth in the absence of an existing patient-provider relationship so that patients can receive care from new providers.

Today's amicus brief follows two previous amicus briefs filed in this case by Raoul and a coalition of attorneys general in the U.S. District Court for the District for Maryland and the U.S. Court of Appeals for the 4th Circuit, asking the district court to issue a preliminary injunction of the FDA requirements for mifepristone, and asking the circuit court to deny the federal government's efforts to stay the preliminary injunction. The courts have continued to rule in favor of the plaintiffs and the coalition of attorneys general.

Joining Raoul in today's amicus brief are the attorneys general of California, Colorado, Connecticut, Delaware, the District of Columbia, Hawaii, Maine, Maryland, Massachusetts, Michigan, Minnesota, Nevada, New Jersey, New Mexico, New York, North Carolina, Oregon, Pennsylvania, Rhode Island, Vermont, Virginia, and Washington.

Nos. 20A34

In The
Supreme Court of the United States

FOOD AND DRUG ADMINISTRATION, et al.,

Applicants,

v.

AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, et al.,

Respondents.

MOTION FOR PERMISSION TO FILE AS AMICI CURIAE, AND BRIEF FOR 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 AS AMICI CURIAE IN OPPOSITION TO DEFENDANTS' APPLICATION FOR A STAY PENDING APPEAL TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT AND PENDING FURTHER PROCEEDINGS IN THIS COURT

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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, Washington, and the District of Columbia move this Court for leave to file the enclosed brief as amici curiae in support of respondents, and in opposition to the application for a stay, (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 expedited briefing schedule set by the Court, it was not feasible to give 10 days' notice. All parties have consented to the filing of the brief without such notice.

The undersigned amici States have a strong interest in the continuation of the district court's preliminary injunction, and thus in the outcome of this application to stay the preliminary injunction. The preliminary injunction prohibits enforcement, during the ongoing COVID-19 public health crisis, of U.S. Food and Drug Administration (FDA) requirements for in-person dispensing of mifepristone, a single-dose oral medication used for early-term abortions. Anticipating the obstacles that the in-person requirements would impose during the COVID-19 crisis, in March 2020 many of amici States' attorneys general asked applicants to suspend enforcement of these requirements during the pandemic and permit the use of telehealth as a substitute.

The amicus brief includes relevant material not brought to the attention of the Court by the parties. *See* Sup. Ct. R. 37.1. The brief describes how, during the pandemic, amici States have loosened their own telehealth restrictions to affirmatively encourage telehealth. By enabling this alternative to in-person medical visits, amici States have been able to limit interpersonal contacts while providing needed medical services during the pandemic—with beneficial results for patients and providers. Amici's experiences with the safe and effective delivery of medical services through remote telehealth options help illuminate why the preliminary injunction will not result in irreparable harm to patients seeking medication abortions.

Amici States' experiences also underscore the irreparable injuries that will result if the preliminary injunction is stayed. Amici's experiences confirm that requiring patients to travel to a clinic in order to access abortion services will harm patient safety and the public interest in at least two ways: *first*, by conditioning access to essential reproductive health care on an increased risk of virus infection and transmission; *second*, by undermining amici States' ongoing efforts to manage the crisis through measures limiting unnecessary in-person contacts, such as stay-at-home orders, stay-safe orders, and telehealth. Diminishing amici's ability to limit unnecessary in-person contacts that may spread the virus, will harm amici's efforts to safely lift more onerous emergency measures and reopen communities.

The undersigned amici States therefore seek to file this brief in order to support respondents' showing that denying applicants' requested stay will not result in irreparable harm, but granting a stay will harm patients and the public health.

CONCLUSION

The Court should grant amici curiae leave to file the enclosed brief in support of respondents and in opposition to the application for a stay.

Dated: New York, New York
September 8, 2020

Respectfully submitted,

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES ii

INTRODUCTION AND INTERESTS OF AMICI STATES 1

STATEMENT 3

A. The COVID-19 Pandemic 3

B. Proceedings Below 5

SUMMARY OF ARGUMENT 7

ARGUMENT 9

POINT I

THE PRELIMINARY INJUNCTION ENSURES SAFE ACCESS TO ESSENTIAL REPRODUCTIVE HEALTHCARE IN A WAY THAT MINIMIZES TRANSMISSION OF COVID-19 10

A. During the Pandemic, Telehealth Has Been Routinely Used to Deliver Essential Healthcare While Minimizing In-Person Contacts. 11

B. The Record Demonstrates That Telehealth Counseling and Mail Delivery Can Be Used to Safely Provide Mifepristone to Patients. 15

POINT II

AMICI STATES' EXPERIENCE CONFIRMS THAT A STAY WOULD HARM PATIENTS AND THE PUBLIC BY REQUIRING UNNECESSARY TRAVEL AND IN-PERSON CONTACTS DURING THE PANDEMIC 20

CONCLUSION 23

TABLE OF AUTHORITIES

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558 U.S. 183 (2010) 9

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INTRODUCTION AND INTERESTS OF AMICI STATES

Amici—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—are striving to protect their residents from COVID-19, while also ensuring safe access to essential reproductive healthcare. Amici's experiences underscore that no one will experience irreparable harm from the preliminary injunction at issue here, whereas the stay sought by the federal agencies and officials (applicants here) will cause irreparable harm, including to amici's public health efforts.

The preliminary injunction prohibits enforcement, during the ongoing COVID-19 public health crisis, of U.S. Food and Drug Administration (FDA) requirements regarding in-person dispensing of mifepristone, a single-dose oral medication used for early-term abortions. The FDA requires that patients seeking a medication abortion appear in person in a clinical setting to sign an acknowledgment form and fill their mifepristone prescription. The U.S. District Court for the District of Maryland concluded that the in-person requirements impose an undue burden on access to abortion during the pandemic. The court also found that patients may safely access abortion services—while avoiding unnecessary travel and interpersonal contacts that could further the spread of COVID-19—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.

Amici States' experiences confirm the correctness of the district court's findings. Anticipating the obstacles that the in-person requirements would impose during the COVID-19 crisis, in March 2020 many of amici States' attorneys general asked applicants to suspend enforcement of these requirements during the pandemic and permit the use of telehealth as a substitute.[1] At the same time, amici States began to loosen their own telehealth restrictions and affirmatively encourage it during the pandemic.

By encouraging telehealth instead of in-person medical visits, amici States have been able to limit interpersonal contacts while providing needed medical services during the pandemic—with beneficial results for patients and providers. Amici States have a strong interest in ensuring access to essential reproductive healthcare through telehealth, whenever telehealth is appropriate in the provider's judgment and consistent with standards of care.

Amici States' experiences confirm that enforcing the FDA 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 transmission; *second*, by undermining amici's ongoing efforts to manage the crisis through measures limiting unnecessary in-person contacts, such as stay-at-home orders, stay-safe orders, and telehealth.[2] Amici

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[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.)

[2] For a recent example, see Honolulu Office of the Mayor, Emergency Order 2020-25 (Aug. 25, 2020) (internet).

have utilized such measures to control the spread of the virus, and these measures remain necessary to safely reopen communities, allow for essential in-person activities, and maintain healthcare capacity during the upcoming flu season.

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. By August 31, 2020, the country had more than six million confirmed infections and more than 180,000 deaths from COVID-19.[3] National infection rates persist at more than 40,000 cases daily, and continue to increase in certain areas of the country.[4]

Experts in infectious disease control and public health have advised that the virus "spread[s] mainly from person-to-person," and that "[t]he best way to prevent illness is to avoid being exposed to this virus."[5] Limiting in-person contacts is one of the most effective means of reducing the spread of COVID-19.[6] (*See also* App. 72a.)

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.

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[3] Laurel Wamsley & Scott Neuman, *6 Million Coronavirus Infections Now Confirmed in U.S., a Country in Limbo*, National Public Radio (Aug. 31, 2020) (internet).

[4] *See id.*; Lisa Shumaker & Maria Caspani, *COVID-19 Cases Spike in U.S. Midwest as Deaths Reach over 180,000*, Reuters (Aug. 27, 2020) (internet).

[5] *See* Ctrs. for Disease Control & Prevention (CDC), *Coronavirus Disease 2019 (COVID-19): How to Protect Yourself* (updated July 31, 2020) (internet).

[6] *See id.*

When necessary to curb rising 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* App. 9a.)

As these efforts have proved effective in reducing virus transmission, many amici have begun to allow increased business and community activities, and some have permitted in-person instruction at schools.[7] But amici States have emphasized that safe reopening requires residents to minimize in-person contacts in order to keep infection rates under control.[8] Continuing to limit unnecessary in-person contacts is critical to amici's ability to safely reopen while avoiding a surge in infections that might require the reimplementation of more restrictive measures.[9]

Public health experts have warned that States will experience COVID-19 and influenza simultaneously in the fall, potentially stressing hospital systems,[10] creating increased demand for COVID-19 testing, and causing testing delays.[11] Minimizing

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[7] *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).

[8] *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).

[9] *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 measures are recommended); *see also, e.g.*, Wamsley & Neuman, *supra* (individual colleges reporting several hundred to a thousand new cases in the first two weeks after in-person reopening).

[10] *Coronavirus in Context: CDC Director Discusses Next Steps in the War Against COVID*, WebMD (Aug. 12, 2020) (internet) (quoting CDC Director).

[11] Katherine J. Wu, *Flu Season Could Make Coronavirus Testing Delays Even Worse*, N.Y. Times (Aug. 25, 2020) (internet).

virus transmission is central to amici States' efforts to avoid what the Director of the Centers for Disease Control and Prevention (CDC) has warned may be "the worst fall from a public health perspective" that the country has "ever had."[12]

B. Proceedings Below

The FDA imposes special requirements for the dispensing of mifepristone, a single-dose oral medication used for early-term abortions. As relevant here, the FDA requires patients seeking a medication abortion to appear in person at a hospital, clinic, or medical office to (1) sign a form acknowledging their receipt of information about mifepristone, and (2) fill their mifepristone prescription. (*See* App. 5a-6a.)

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 receive mifepristone and sign the acknowledgment form without traveling to a clinical setting. (*See* App. 16a.) After full briefing and a hearing, the district court granted the preliminary injunction.

The court concluded that enforcing the in-person requirements during the pandemic created a substantial obstacle to abortion access that imposed an undue burden for a large fraction of the women affected by the requirements: namely, women seeking a medication abortion during the pandemic, for whom a healthcare

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[12] *Coronavirus in Context*, *supra*.

provider has determined an in-person visit was not medically necessary. (*See* App. 40a-50-a, 62a.) 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.'" (App. 52a (quoting *Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292, 2309 (2016)).) The court found healthcare providers could safely provide required counseling using telehealth, and safely and efficiently deliver the drug to patients by mail or courier. (*See* App. 57a-59a.)

The court specifically rejected applicants' reliance on a 2013 FDA analysis determining that the requirements provided an opportunity for in-person counseling and might avoid delays in dispensing. The court found the FDA had not considered telehealth counseling in either the 2013 analysis or a 2016 review of other modifications to the dispensing regime.[13] (App. 55a, 57a.) The court further found that any dispensing delays were unlikely under the terms of the preliminary injunction, because healthcare providers would retain control over dispensing and could select whatever method would be most efficient in a particular case: mail, courier, or in-person dispensing. (*See* App. 57a-58a.)

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." (App. 70a-72a.)

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[13] In 2016, the FDA allowed certified non-physician providers to dispense the drug, patients to take the drug at home, and providers to prescribe the drug up to ten weeks' gestation. (App. 4a-5a.)

Applicants appealed and asked the district court to stay the preliminary injunction pending appeal. (App. 83a-84a.) After the district court denied that request, applicants sought a stay from the Fourth Circuit, which unanimously denied a stay after full briefing. (App. 85a-86a.)

Meanwhile, respondents moved for clarification of the preliminary injunction order, noting a potential discrepancy between the court's decision and the order regarding permitted modes of delivering mifepristone. The court ruled that what controlled was the order that preliminarily enjoined the FDA requirements to the extent the requirements mandate "'that mifepristone be dispensed only in clinics, medical offices, or hospitals, rather than by mail or delivery service.'" (App. 89a (quoting preliminary injunction order).) The court clarified that "'[d]ispensing by mail or delivery service must still occur by or under the supervision of a certified healthcare provider.'" (App. 89a (quoting preliminary injunction order).) Thus, a mail-order pharmacy providing the drug would need to have a contract with the certified healthcare provider to stock the drug, and could mail it to a patient only at the provider's direction. (*See* App. 89a-90a.)

Applicants now ask this Court to stay the preliminary injunction.

SUMMARY OF ARGUMENT

The preliminary injunction allows provider counseling and patient acknowledgment of information about mifepristone to take place via telehealth, with mail delivery of the drug to follow. Denying applicants' requested stay will not result in irreparable harm, but granting it will harm patients and the public health.

As the district court found, and as amici's experiences confirm, telehealth has been used to safely provide essential reproductive healthcare—including early abortion care—during the current public health crisis. The record below shows telehealth can be used safely and effectively to assess a patient's suitability for medication abortion, identify patients who require an in-person visit, and provide required counseling. The district court thus correctly found that telehealth and mail delivery could be used to safely provide patients with mifepristone during the pandemic.

In contrast, staying the preliminary injunction would irreparably harm patients and public health conditions generally. A stay would force women to undergo unnecessary travel and in-person contacts to access essential reproductive care, exposing them to the risk of contracting and spreading COVID-19. A stay would also inhibit amici States' ability to encourage the use of telehealth where appropriate, in order to reduce in-person contacts, increase available providers, ensure safe access to essential healthcare, and maintain healthcare system capacity—particularly as flu season arrives. As amici States' experience confirms, reducing in-person contacts is critical to keeping infection rates down, thereby saving lives and permitting the safe reopening of businesses and community activities.

ARGUMENT

A stay "is not a matter of right," and the party requesting it "bears the burden of showing that the circumstances justify an exercise of [judicial] discretion." *Nken v. Holder*, 556 U.S. 418, 433-34 (2009) (quotation marks omitted). Where applicants seek a stay on a matter pending before a federal court of appeals, applicants must demonstrate, at a minimum, (1) "a reasonable probability" that certiorari will be granted if the court of appeals affirms the preliminary injunction without modification, (2) "a fair prospect that a majority of the Court will vote to reverse" that preliminary injunction, and (3) "a likelihood that irreparable harm will result from the denial of a stay." *Hollingsworth v. Perry*, 558 U.S. 183, 190 (2010) (per curiam); *see also San Diegans for Mt. Soledad Nat'l War Memorial v. Paulson*, 548 U.S. 1301, 1302 (2006) (Kennedy, J., in chambers).

Even if all criteria are met, "the Circuit Justice or the Court will balance the equities and weigh the relative harms to the applicant and to the respondent." *Hollingsworth*, 558 U.S. at 190. The preliminary injunction here temporarily suspends, during the current COVID-19 crisis, enforcement of the FDA's requirements that patients seeking a medication abortion appear in person at a hospital, clinic, or medical office to (1) sign a form acknowledging receipt of information about mifepristone and (2) receive the drug.

Applicants are not entitled to a stay because—among other things—they fail to demonstrate that irreparable harm will likely occur if the preliminary injunction

continues, or that the equities weigh in their favor.[14] *See Rubin v. United States*, 524 U.S. 1301, 1301 (1998) (Rehnquist, C.J., in chambers) ("An applicant for a stay first must show irreparable harm if a stay is denied."). Applicants focus almost exclusively on the potential for a grant of certiorari and respondents' likelihood of success on the merits. *See* Application for Stay (Appl.) 10-32. For irreparable harm, they simply assert, without evidence, that the preliminary injunction will harm the government and could harm patients. *Id.* at 33. The record and amici's experiences show that the preliminary injunction will not harm patients, but staying it will irreparably injure patients and public health conditions.

POINT I

THE PRELIMINARY INJUNCTION ENSURES SAFE ACCESS TO ESSENTIAL REPRODUCTIVE HEALTHCARE IN A WAY THAT MINIMIZES TRANSMISSION OF COVID-19

Applicants fail to establish that irreparable harm will result from the preliminary injunction. *See Nken*, 556 U.S. at 434 (requiring more than a "possibility of irreparable injury" (quotation marks omitted)). They claim (Appl. 33) that the preliminary injunction harms the federal government and patients because the FDA previously concluded, in its last full review of mifepristone in 2013, that in-clinic dispensing "contributes to the patient's safe use of" the drug (s*ee* Dist. Ct. ECF No. 62-6, at image 17). But the preliminary injunction permits dispensing through safe and

[14] As respondents explain, applicants also cannot show the requisite likelihood that certiorari will be granted and the district court's preliminary injunction reversed.

effective remote alternatives not considered by the FDA in 2013—namely, using telehealth to counsel patients about mifepristone, and mail or courier to deliver the drug.

A. During the Pandemic, Telehealth Has Been Routinely Used to Deliver Essential Healthcare While Minimizing In-Person Contacts.

For amici States, telehealth has been an "invaluable tool in slowing the spread of COVID-19,"[15] and "crucial" in providing residents with needed healthcare during the public health crisis.[16] Amici have encouraged telehealth use wherever appropriate—even as phased reopenings of the States occur—because it "maximize[s] the number of capable health care workers" providing necessary medical treatment, while protecting patients and healthcare staff.[17]

Medical studies have confirmed that telehealth can safely be used to provide essential reproductive care, including early abortions.[18] During the COVID-19 pandemic, the counseling required prior to a medication abortion is routinely

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

[16] 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).

[17] Cal. Exec. Dep't, Exec. Order N-43-20 (Apr. 3, 2020) (internet); 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").

[18] *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).

provided through telehealth in order to reduce in-person interactions. (*See* App. 6a-7a, 55a-56a.) Clinics have also safely and effectively used telehealth to conduct the required assessment of a patient's suitability for medication abortion, consistent with standards of care. (*See* App. 51a, 56a.) Among other things, 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* App. 51a; *see also* Decl. of Allison Bryant Mantha, M.D. in Supp. of Pls. (Bryant Decl.) ¶¶ 30-31 (May 27, 2020), Dist. Ct. ECF No. 11-3.) Contrary to the assertions of amici supporting applicants (Br. for Amicus Curiae States of Indiana et al. at 12), neither the FDA nor the medical standard of care requires an in-person examination for every woman receiving a medication abortion (*see* Bryant Decl. ¶¶ 30-31, 49-54).

When appropriate in the judgment of the provider and consistent with standards of care, telehealth can be used to provide care in a manner that avoids unnecessary travel to healthcare facilities—thus reducing the participants' contact with other people and promoting the health and safety of both patients and healthcare workers.[19] (*See* App. 44a-45a.) The CDC advises healthcare practitioners to use telehealth "'whenever possible' as 'the best way to protect patients and staff from COVID-19.'" (App. 11a (quoting CDC guidance).)

[19] *See* CDC, *Coronavirus Disease 2019 (COVID-19): Travel During the COVID-19 Pandemic* (updated Aug. 26, 2020) (internet).

In addition, telehealth helps conserve and expand healthcare resources needed to address the pandemic. Telehealth decreases local healthcare workers' risk of infection and subsequent need to stop working in order to self-quarantine, and increases the number of available medical professionals to include those located farther away who can provide services remotely.[20] As the White House has recently confirmed,[21] these telehealth benefits are particularly important for underserved areas, such as distant rural communities with limited medical resources, and more populous communities whose healthcare systems are strained by COVID-19 patients.[22] Telehealth also accommodates individuals who need timely medical care but are self-isolating or subject to quarantine, thereby facilitating adherence to stay-at-home orders.[23]

In view of these advantages, amici States have taken numerous steps to expand telehealth use during the current public health crisis, consistent with federal guidance. Many of the amici States have suspended existing statutes and regulations restricting telehealth to permit safe delivery of services to additional patient populations, especially medically vulnerable people. These suspension orders expand

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[20] *See* CDC, *Coronavirus Disease 2019 (COVID-19): Strategies to Mitigate Healthcare Personnel Staffing Shortages* (updated July 17, 2020) (internet).

[21] *See* Exec. Order 13941, Improving Rural Health and Telehealth Access, 2020 Daily Comp. Pres. Doc. 565 (Aug. 3, 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)).

[22] *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).

[23] *See id.*

the types of practitioners who can use telehealth, the settings in which telehealth can be provided, the types of modalities for delivering telehealth services, and the circumstances under which telehealth can be initiated.[24] Many amici have suspended rules prohibiting telehealth in the absence of an existing patient-provider relationship so that patients can receive care from new providers or for new conditions without an initial face-to-face appointment.[25] 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.[26]

Many of amici States now require providers participating in state Medicaid programs to use telehealth whenever appropriate, and have expanded covered telehealth services and allowed additional modalities, such as audio-only

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[24] *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).

[25] *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)* (Apr. 3, 2020) (internet) (describing waivers).

[26] *See* Cal. Dep't of Health Care Servs., Behavioral Health Information Notice No. 20-009 (updated May 20, 2020) (internet); Haw. Office of the Governor, Eighth Supplementary Proclamation Related to the COVID-19 Emergency (May 18, 2020) (internet).

connections.[27] To encourage telehealth for patients with private insurance, many of amici States have required parity of coverage or reimbursement for services provided through telehealth.[28] Some States have prohibited co-pays, deductibles, and other out-of-pocket charges for telehealth services during the pandemic.[29]

B. The Record Demonstrates That Telehealth Counseling and Mail Delivery Can Be Used to Safely Provide Mifepristone to Patients.

As the district court found, telehealth counseling and supervised delivery of mifepristone through mail-order pharmacies provides a safe alternative to the FDA's in-clinic requirements. Applicants' contentions that the preliminary injunction will

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[27] *E.g.,* Cal. Dep't of Health Care Servs., Behavioral Health Information Notice No. 20-009, *supra*; 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, *supra*; 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).

[28] *E.g.,* Ill. Office of the Governor, Exec. Order 2020-09 (Mar. 19, 2020) (internet); Mass. Office of the Governor, Order Expanding Access to Telehealth Services and to Protect Health Care Providers (Mar. 15, 2020) (internet); Ch. 7, 2020 N.J. Laws (Mar. 20, 2020) (A3843); N.Y. Dep't of Fin. Servs., Insurance Circular Letter No. 6 (Mar. 15, 2020) (internet); R.I. Office of the Governor, Exec. Order 20-06, *supra*; Act No. 91, 2020 Vt. Laws; *see also* Cal. Dep't of Health Care Servs., Supplement to All Plan Letter 19-009, *supra* (parity in Medi-Cal program).

[29] *E.g.,* Ill. Office of the Governor, Exec. Order 2020-09, *supra*; Mass. Office of the Governor, Order Expanding Access to Telehealth Services, *supra*; Ch. 7, 2020 N.J. Laws; 11 N.Y.C.R.R. § 52.16(q) (eff. until Sept. 8, 2020).

harm patients and the federal government are not supported by the record or case law.

The district court concluded that telehealth is a safe and effective alternative for patients based on federal government's own actions encouraging the use of telehealth during the pandemic (App. 10a-12a, App. 43a-45a), and respondents' voluminous expert evidence (App. 51a-52a, 55a-56a). Like amici's experiences, this evidence demonstrates that telehealth can effectively be used to conduct safety assessments for a medication abortion—e.g., by assessing length of pregnancy, and identifying contraindications or an ectopic pregnancy—and to provide all necessary counseling and disclosure of risks. (App. 51a-52a, 55a-56a.)

The preliminary injunction preserves provider supervision over the dispensing of mifepristone by requiring direct delivery from the provider—e.g., by mail or courier—or through special relationships with mail-order pharmacies that stock the drug pursuant to a contract with the provider. (*See* App. 89a-90a, 93a.) The record does not support applicants' speculation that without in-clinic dispensing, delays may occur if local pharmacies do not have the drug in stock, and patients therefore may not take the drug immediately after the counseling session (*compare* Appl. 6, 21, 23, 33, *with* App. 58a-59a). 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, even under the FDA's regime, patients are permitted to take the drug at any time of their choosing, after completing the counseling session. (*See* App. 57a-59a.)

Contrary to applicants' assertions (Appl. 21-23), the district court properly declined to defer to the FDA's 2013 analysis of the benefits associated with in-person counseling at the time of dispensing. As the district court noted, that analysis was inapplicable and outdated here because the FDA has never required in-person counseling, and has never considered the use or effectiveness of telehealth counseling. (App. 55a-57a.) Moreover, applicants failed to present any evidence that in-person counseling at the time of dispensing is more effective than counseling via telehealth. (*See* App. 57a.) As for delays in taking the drug, the FDA's 2013 analysis considered simultaneous dispensing and administration, not the current regime allowing for home-administration at a time of the patient's choosing, because until 2016 the FDA required mifepristone to be administered in person by a physician. (App. 54a-55a.)

While applicants claim the district court usurped the FDA's role when evaluating the appropriateness of the in-clinic requirements during the pandemic (Appl. 25-26), the FDA declined multiple invitations to conduct this exact analysis itself (*see* App. 53a). *See also* Dist. Ct. ECF Nos. 1-5 to 1-8 (letters from medical and public health experts, healthcare institutions, clinicians, and researchers). And applicants had ample opportunity during the preliminary injunction proceedings to present any evidence demonstrating that telehealth and mail delivery are inadequate during the pandemic.

Applicants' own actions during the pandemic further undermine their argument for deference to the 2013 analysis. 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 transmission, and that dispensing decisions should be left to providers' best medical judgment.[30] Likewise, the Secretary of 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* App. 10a.)

Contrary to applicants' suggestion (Appl. 26), *South Bay United Pentecostal Church v. Newsom*, 140 S. Ct. 1613 (2020), does not support judicial deference to the FDA's requirements here. In *South Bay*, this Court declined to enjoin certain temporary restrictions on mass gatherings that were part of California's efforts to control the spread of COVID-19. The Chief Justice, concurring, explained 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. *Id.* at 1613 (Roberts, C.J., concurring). Here, the FDA's requirements are interfering with the judgment of politically accountable state officials managing a public health crisis, and a stay to preserve the FDA requirements would undermine the judgment of those officials. The FDA's expertise does not relate to the fraught issues of managing the current pandemic, and does not call for the deference that this Court gave to the California Executive Order at issue in *South Bay*.

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[30] *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).

Finally, applicants mistakenly rely (Appl. 32-34) on *South Bay* and *Maryland v. King*, 567 U.S. 1301, 1303 (2012) (Roberts, C.J., in chambers), for the proposition 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 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.* 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, although it was also supported by the general observation that States suffer harm when their laws are enjoined. *See* 567 U.S. at 1301. Here, in contrast, applicants 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 women 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.

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."[31] (App. 59a (quoting *June Med. Servs. L.L.C. v. Russo*, 140 S. Ct. 2103, 2132 (2020) (plurality op.); *Whole Woman's Health*, 136 S. Ct. at 2309).) There is thus no likelihood of irreparable harm from the denial of a stay.

POINT II

AMICI STATES' EXPERIENCE CONFIRMS THAT A STAY WOULD HARM PATIENTS AND THE PUBLIC BY REQUIRING UNNECESSARY TRAVEL AND IN-PERSON CONTACTS DURING THE PANDEMIC

The harms to patients and the public interest also weigh heavily against a stay here. *See Trump v. International Refugee Assistance Project*, 137 S. Ct. 2080, 2087 (2017). In the U.S., abortions are ordinarily provided either by medication (mifepristone followed by a second drug), or by a procedure performed in a medical setting.[32] (*See* App. 2a.) By mandating a clinic visit even for the medication option, the FDA requirements unnecessarily condition access to abortion on undertaking travel and in-person contacts at a time when those activities heighten the risk of

[31] Contrary to applicants' claim (Appl. 25), the district court found the in-person requirements imposed an undue burden during the current public health crisis—not that the requirements had underlying benefits that were simply outweighed by the risks of pandemic-associated harm. For example, the court found that applicants failed to demonstrate any benefit from the in-person dispensing requirements and that, during the pandemic, the in-person requirements could cause delays in patients' taking mifepristone. (App. 57a-58a.)

[32] 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).

contracting and spreading COVID-19. A stay would force women to engage in unnecessary travel and in-person contacts to access abortion services, contrary to amici's goals of ensuring safe access to essential healthcare during the pandemic.

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 it especially harms women during the current pandemic by exposing them and others 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* App. 14a.) 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.[33] That additional travel and person-to-person contact increases patients' risk of contracting COVID-19 and transmitting it to their families and communities. (*See* App. 42a-45a.)

The in-clinic requirements also thwart amici States' ability to encourage the use of telehealth for essential care whenever appropriate in the healthcare provider's judgment and consistent with standards of care. Providing essential care through telehealth limits the spread of COVID-19 and maintains capacity in amici's healthcare systems, particularly in medically underserved and high-infection areas,

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[33] 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).

and as seasonal respiratory infections like influenza rise in the fall. See *supra* at 4-5, 12-13. Reducing infections and maintaining healthcare capacity are critically important to saving lives in the amici States and to implementing amici's plans to safely reopen their communities for business and school activities. See *supra* at 3-4, 11-12. By using measures like telehealth to reduce unnecessary person-to-person contacts, amici can decrease infection rates, as required to safely continue phased-reopening of schools and businesses even as the pandemic continues.[34]

These harms to patients, their close contacts, and public health conditions weigh heavily against a stay—particularly in light of the lack of harm to applicants.

[34] *See, e.g.*, N.Y. Forward, *A Guide to Reopening New York and Building Back Better* 46-53 (May 2020) (internet) (reopening metrics based on CDC, World Health Organization, and New York State Department of Health guidance); *see also Read the Latest Federal Report, supra* (White House Coronavirus Task Force report recommending that counties with high infection rates encourage residents to reduce public interactions by 75%).

CONCLUSION

The stay application should be denied.

Dated: New York, New York
September 8, 2020

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Nos. 20A34

In The
Supreme Court of the United States

FOOD AND DRUG ADMINISTRATION, et al.,

Applicants,

v.

AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, et al.,

Respondents.

DECLARATION OF COMPLIANCE

I declare that, consistent with Supreme Court Rule 33.1(g)(x), governing a brief for an amicus curiae prior to the merits stage, the accompanying brief contains 5,930 words, excluding the parts of the document that are exempted by Supreme Court Rule 33.l(d).

I declare under penalty of perjury that the foregoing is true and correct.

Executed on September 8, 2020.

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