

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

AMERICAN COLLEGE OF OBSTETRICIANS AND
GYNECOLOGISTS, on behalf of its members and members' patients;
COUNCIL OF UNIVERSITY CHAIRS OF OBSTETRICS AND
GYNECOLOGY; NEW YORK STATE ACADEMY OF FAMILY
PHYSICIANS, on behalf of its members and members' patients;
SISTERSONG WOMEN OF COLOR REPRODUCTIVE JUSTICE
COLLECTIVE, on behalf of its members and members' patients; and
HONOR MACNAUGHTON, M.D.,

Plaintiffs-Appellees,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION;
STEPHEN HAHN, M.D., in his official capacity of Commissioner of
Food and Drugs, and his employees, agents and successors in office;
UNITED STATES DEPARTMENT OF HEALTH & HUMAN
SERVICES; and ALEX AZAR, in his official capacity of Secretary,
United States Department of Health and Human Services, and his
employees, agents and successors in office,

Defendants-Appellants.

**Motion of 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 to
Submit a Brief as *Amici Curiae* in Support of Appellees and in
Opposition to Appellants' Application for a Stay**

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 opposition to appellants' application for a stay pending appeal of the district court's July 13, 2020 preliminary injunction order.¹ Counsel for all parties to this appeal have been informed of this motion, and have consented to the filing of the amicus brief. *See* Fourth Cir. Rule 27(a).

The amicus brief includes material that is "relevant to the disposition" of the stay application, and which would be "desirable" for the Court to consider. Fed. R. App. P. 29(a)(3)(B). The brief describes, through amici's own experiences, how mifepristone can be safely and effectively dispensed during the public health crisis without requiring

¹ While a State is permitted to file an amicus brief without the parties' consent or permission of the Court during the "consideration of a case on the merits," Fed. R. App. P. 29(a)(1)-(2), that Rule does not expressly permit a State to file an amicus brief during the Court's consideration of a motion. Accordingly, in an abundance of caution, amici States move for leave to file an amicus brief in opposition to appellants' stay request.

travel that places patients and their communities at risk. Amici explain how they have been able to safely and effectively deliver medical services, including counseling, through remote telehealth options, which minimizes the risk of COVID-19 infection and transmission. These aspects of amici's experiences help illuminate why the preliminary injunction will not result in irreparable harm to patients seeking medication abortions.

Amici's 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's ongoing efforts to manage the current public health crisis through measures limiting unnecessary in-person contacts, such as stay-at-home orders, stay-safe orders, and the promotion of 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 proposed brief complies with the type-volume limitations for an amicus brief on a motion because it uses fewer than half of the 5,200 words permitted for a motion or response. *See* Fed. R. App. P. 27(d)(2(A), 29(a)(5).

CONCLUSION

The Court should grant amici curiae leave to file the enclosed brief in support of plaintiffs-appellees and in opposition to defendants-appellants' stay application.

Dated: New York, New York
August 4, 2020

/s/ Anisha S. Dasgupta
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20-1824

**United States Court of Appeals
for the Fourth Circuit**

AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, on behalf of its members and members' patients; COUNCIL OF UNIVERSITY CHAIRS OF OBSTETRICS AND GYNECOLOGY; NEW YORK STATE ACADEMY OF FAMILY PHYSICIANS, on behalf of its members and members' patients; SISTERSONG WOMEN OF COLOR REPRODUCTIVE JUSTICE COLLECTIVE, on behalf of its members and members' patients;
HONOR MACNAUGHTON, M.D.,

Plaintiffs-Appellees,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION; STEPHEN HAHN, M.D., in his official capacity of Commissioner of Food and Drugs, and his employees, agents and successors in office; UNITED STATES DEPARTMENT OF HEALTH & HUMAN SERVICES; ALEX AZAR, in his official capacity of Secretary, United States Department of Health and Human Services, and his employees, agents and successors in office,

Defendants-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, WASHINGTON, AND THE
DISTRICT OF COLUMBIA AS *AMICI CURIAE* IN SUPPORT OF
APPELLEES AND IN OPPOSITION TO APPELLANTS' APPLICATION
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INTERESTS OF AMICI

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, Washington, and the District of Columbia—are striving to protect their residents from the 2019 coronavirus and resulting disease (COVID-19), while continuing to ensure access to essential reproductive health care. Staying the district court’s preliminary injunction will irreparably harm amici’s efforts.

The preliminary injunction prohibits appellants from enforcing—during the ongoing public health crisis—a U.S. Food and Drug Administration (FDA) requirement that patients seeking a medication abortion appear in person in a clinical setting to sign an acknowledgment form and fill a prescription for mifepristone, a single-dose oral medication used for early-term abortions. The district court concluded that the in-person dispensing requirement imposes an undue burden on access to abortion during the current pandemic. The court also found that a remote medical consultation via video or phone (telehealth), an electronic signature, and delivery of mifepristone to patients’ homes provides a safe

alternative way for patients to access abortion services, while avoiding unnecessary travel and interpersonal contacts that could further the spread of COVID-19.¹

Amici's experiences underscore that no one will experience irreparable harm from the preliminary injunction, whereas a stay of the preliminary injunction will cause irreparable harm. To limit interpersonal contact while ensuring the continued provision of needed medical services, amici have encouraged the replacement of in-person medical visits with remote telehealth visits—with beneficial results for patients and providers. Amici have a strong interest in the availability of safe access to essential reproductive health care through telehealth whenever telehealth is appropriate in the provider's judgment, and consistent with standards of care.

Amici's experiences also confirm that enforcing the FDA requirement during the current public health crisis will harm patient

¹ For these reasons, in March 2020, many of amici's attorneys general asked appellants to suspend enforcement of the FDA requirement during the pandemic. *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). (Full URLs for internet citations appear in the Table of Authorities.)

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’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. Amici have utilized such measures to control the spread of the virus, which is necessary to safely lift more onerous emergency measures and reopen communities.

ARGUMENT

The preliminary injunction that appellants seek to stay temporarily suspends—during the current public health emergency—enforcement of the FDA’s requirement that mifepristone be dispensed only at a clinic, hospital, or medical office. The preliminary injunction will not harm patients, but staying it will irreparably injure patients and public health conditions.

POINT I

NO-CONTACT DISPENSING OF MIFEPRISTONE MINIMIZES TRANSMISSION OF COVID-19 WHILE ENSURING SAFE ACCESS TO ESSENTIAL REPRODUCTIVE HEALTH CARE

As a threshold matter, appellants fail to establish that irreparable harm will result from the preliminary injunction. *See Nken v. Holder*, 556 U.S. 418, 434 (2009) (requiring more than a “possibility of irreparable injury” (quotation marks omitted)). The preliminary injunction permits the dispensing of mifepristone through safe and effective remote alternatives—namely, the use of telehealth to advise patients about the risks of the drug, followed by direct mailing or delivery of the drug.

a. Experts in infectious disease control and public health have advised that the virus “spread[s] mainly from person-to-person,” and “[t]he best way to prevent illness is to avoid being exposed to this virus.”² Social distancing and self-isolation to limit in-person contacts are some of the most effective means of reducing the spread of COVID-19. (*See* Appellants’ Addendum (Add.) 72.) When necessary to curb rising

² *See* Ctrs. for Disease Control & Prevention (CDC), *Coronavirus Disease 2019 (COVID-19): How to Protect Yourself* (updated July 31, 2020) (internet).

infection rates, amici States have issued stay-at-home orders that directed residents to confine themselves to their homes except for essential matters. (*See* Add. 9.)

As these efforts have proved effective in reducing virus transmission, many amici have begun to allow increased business and community activities.³ But amici have emphasized that safe reopening requires residents to minimize in-person contacts in order to keep infection rates under control.⁴ Continuing to limit in-person contacts is critical to maintaining health and safety and preventing a surge in infection rates that would require the reimplementing of more restrictive measures.⁵

³ *See* Sarah Mervosh et al., *See How All 50 States Are Reopening (and Closing Again)*, N.Y. Times (updated July 31, 2020) (internet).

⁴ *See, e.g.*, NY-1 (requiring six feet between personnel, limiting occupancy to 50%, prohibiting more than one person in confined spaces, etc.). (Citations to numbered state authorities appear in the Addendum of State Authorities.)

⁵ *See* Ctr. for Pub. Integrity, *Exclusive: White House Document Shows 18 States in Coronavirus “Red Zone”* (updated July 17, 2020) (internet) (document prepared for White House Coronavirus Task Force recommending that “more than a dozen states” with increased infection rates “should revert to more stringent protective measures,” including limiting person-to-person contacts).

b. For amici States, telehealth has been an “invaluable tool in slowing the spread of COVID-19”⁶ and “crucial” in providing residents with needed health care during the public health crisis.⁷ Amici have encouraged telehealth to be used wherever possible—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 health care staff.⁸

Medical studies have confirmed that telehealth can safely be used to provide essential reproductive care including early abortions.⁹ 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. (See Add. 55-56.) Clinics have also safely and

⁶ DC-1.

⁷ NJ-1 (quotation marks omitted).

⁸ CA-1; CA-2; *see also* MN-1 (strongly encouraging the use of telehealth “whenever possible”).

⁹ *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 a patient visits a local clinic and uses a video connection to meet with a certified provider located at a distant clinic who dispenses mifepristone remotely).

effectively used telehealth to conduct the required assessment of a patient's suitability for medication abortion, consistent with standards of care. (*See* Add. 51, 56.) 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* Add. 51; *see also* Decl. of Allison Bryant Mantha, M.D. in Supp. of Pls. (Bryant Decl.) ¶¶ 30-31 (May 27, 2020), ECF No. 11-3.) Contrary to the assertions of amici supporting appellants (Br. of Amicus Curiae States of Indiana et al. at 9), and as the record here shows, the medical standard of care does *not* require an in-person examination for every woman receiving a medication abortion (*see* Bryant Decl. ¶¶ 30-31, 49-54).

When telehealth is appropriate in the judgment of the provider and consistent with standards of care, it can be used to provide medical care in a manner that avoids unnecessary travel to health care facilities—thus reducing the participants' contact with other people and promoting the health and safety of both patients and health care workers.¹⁰ (*See*

¹⁰ *See* CDC, *Coronavirus Disease 2019 (COVID-19): Travel during the COVID-19 Pandemic* (updated Aug. 3, 2020) (internet).

Add. 44-45.) The Centers for Disease Control and Prevention advises health care practitioners to use telehealth “‘whenever possible’ as ‘the best way to protect patients and staff from COVID-19.’” (Add. 11 (quoting CDC guidance).)

In addition, telehealth helps to conserve and expand health care resources needed to address the pandemic. Telehealth decreases local health care 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.¹¹ As the White House has recently confirmed,¹² these benefits are particularly important for underserved areas, such as distant rural communities with limited medical resources, and more populous communities whose health care systems are strained

¹¹ See CDC, *Coronavirus Disease 2019 (COVID-19): Mitigating Staff Shortages* (updated July 17, 2020) (internet).

¹² See Exec. Order on Improving Rural Health and Telehealth Access (Aug. 3, 2020) (internet); 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)).

by COVID-19 patients.¹³ 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.¹⁴

In view of these advantages, amici States have taken numerous steps to expand the use of telehealth during the current public health crisis. Many of the amici States have suspended existing statutes and regulations restricting telehealth in order to allow the 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 modalities that can be used to deliver telehealth services, and the circumstances under which telehealth can be initiated.¹⁵ Amici have also enabled the use of telehealth for the prescribing of certain regulated

¹³ 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).

¹⁴ See *id.*

¹⁵ *E.g.*, CA-1; CA-3; DE-1; DE-2; HI-1; MD-1; MA-1; MN-2; NJ-2; NJ-3; NJ-4; NY-2; NY-3; RI; VT-1; VT-2; VA-1.

prescriptions by suspending penalty provisions and eliminating the requirement of written patient consents.¹⁶

Many of the amici States now require providers participating in state Medicaid programs to use telehealth whenever possible, and have expanded covered telehealth services and allowed additional telehealth modalities, such as audio-only connections.¹⁷ To encourage the use of telehealth for patients with private insurance, many of amici have required parity of coverage and/or reimbursement for services provided through telehealth.¹⁸ Some States have prohibited co-pays, deductibles, and other out-of-pocket charges for telehealth services during the pandemic.¹⁹

c. Despite the demonstrated benefits of telehealth during the pandemic, appellants baldly assert that the preliminary injunction will impair the safe dispensing of mifepristone. *See* Mot. for Stay Pending

¹⁶ *See* CA-4; HI-2.

¹⁷ *E.g.*, CA-4; CA-5; DC-2; MD-2; MA-2; NM; NY-4; RI; VA-2; VA-3; *see also* DE-3 (allowing telephone use for telehealth generally).

¹⁸ *E.g.*, IL; MA-3; NJ-5; NY-5; RI; VT-2; *see also* CA-5 (parity in Medi-Cal program).

¹⁹ *E.g.*, IL; MA-3; NJ-5; NY-6.

Appeal (Mot.) at 19. Appellants speculate that counseling about the risks of mifepristone via telehealth will not be as effective as in-person counseling at the time of dispensing. *See id.* at 15-16. The FDA requirements, however, do not mandate in-person counseling. (*See* Add. 56.) And appellants provide no evidence that in-person counseling at the time of dispensing is more effective than counseling via telehealth. (*See* Add. 57.) In contrast, appellees' expert evidence from numerous sources (Add. 51-52, 55-56), and federal action encouraging the use of telehealth during the pandemic (*see* Add. 10-12), show that telehealth is a safe and effective alternative in these circumstances.

Appellants also suggest that patients may be harmed if local pharmacies do not have the drug in stock or if the mail is delayed by a few days, and patients therefore do not take the drug immediately after the counseling session. *See* Mot. at 4-5, 14. But the FDA's requirements do not ensure immediate administration of the drug, as patients are permitted to take the drug at any time of their choosing after the counseling session. (Add. 58.) If immediate delivery is necessary for particular patients, providers may send the drug by same-day courier. (*See* Add. 58-59.)

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 Nken*, 556 U.S. at 426. In the U.S., abortions must occur either by taking medication (mifepristone followed by a second drug), or by undergoing a procedure in a medical setting.²⁰ (*See* Add. 2.) By mandating a clinic visit even for the medication option, the FDA requirement unnecessarily conditions access to abortion on undertaking travel and in-person contacts at a time when those activities heighten the risk of contracting and transmitting 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 health care during the pandemic.

Travel to a clinic is a burden even in ordinary times, *see June Med. Servs. LLC v. Russo*, 140 S. Ct. 2103, 2130 (2020) (plurality op.); *id.* at

²⁰ 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).

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, ride-sharing, or a borrowed car that exposes participants to increased risk of infection. (See Add. 14.) 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.²¹ That additional travel and person-to-person contact increases patients’ risk of contracting COVID-19 and transmitting it to their families and communities. (See Add. 42-45.)

The in-clinic requirement also thwarts the amici States’ ability to encourage widespread use of telehealth for essential care when telehealth

²¹ 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).

is appropriate in the health care 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 health care systems, particularly in medically underserved and high-infection areas. See *supra* at 8-9. Reducing infections and maintaining health care capacity are central to saving lives in the amici States and to amici's implementation of plans to safely reopen their communities. By using measures like telehealth to reduce unnecessary person-to-person contacts, amici can decrease their infection rate, as required to safely commence or continue phased-reopening even as the pandemic continues.²²

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 appellants.

²² See, e.g., NY-7 (reopening metrics based on guidance from CDC, World Health Organization, and U.S. Department of State).

CONCLUSION

This Court should deny appellants' motion for a stay.

Dated: New York, New York
August 4, 2020

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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 2,584 words and complies with the typeface requirements and length limits of Rule 32(a)(5)-(7).

/s/ William P. Ford

Addendum of State Authorities

ADDENDUM OF STATE AUTHORITIES

California

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CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing documents with the Court's CM/ECF system on August 4, 2020. I certify that all parties and counsel of record in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

Dated: August 4, 2020
New York, NY

/s/ Anisha S. Dasgupta