June 5, 2020

ATTORNEY GENERAL RAOUL FIGHTS FOR ABORTION ACCESS DURING CORONAVIRUS PANDEMIC

Raoul, Coalition Take Legal Action to Remove Barriers to Women Accessing Abortion Pill

Chicago — Attorney General Kwame Raoul has joined a coalition of 23 attorneys general in taking legal action against the Food and Drug Administration (FDA) and the U.S. Department of Health and Human Services (HHS) for increasing the risk that women nationwide will contract COVID-19 as they seek abortions in their states.

In an amicus brief, Raoul and the coalition support the request for a preliminary injunction to halt 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 or for miscarriage care. The coalition argues that the drug should be readily accessible via telehealth, so as to not potentially expose women to COVID-19 by requiring unnecessary travel.

"Throughout this crisis, millions of Americans have received medical care through telehealth services," Raoul said. "At a time when social distancing requirements have decreased the spread of COVID-19, women should not have to travel to receive vital medical care if it can be provided remotely."

Since the widespread onset of COVID-19 across the United States in March, nearly 1.9 million Americans have contracted the disease, including more than 125,000 infections in Illinois. In response, officials across the nation have been instituting various emergency measures to slow the spread of the virus. The FDA's current policy requiring patients to appear in person in a clinical setting to receive mifepristone heightens the risk of contracting and transmitting COVID-19 for patients and health care providers. Forcing women to travel at a time when many states and the federal government are urging people to stay home is shortsighted, putting women and their close contacts across the country in harm's way. Further, this policy undermines different states' ability to effectively manage the pandemic.

In the brief, Raoul and the coalition specifically 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." Additionally, forcing women in higher density cities to travel to a clinical setting for mifepristone would further burden health care systems already strained by COVID-19 patients. Raoul and the coalition argue that the counseling required prior to a medication abortion is already available through telehealth and that using measures like telehealth to reduce person-to-person contact could protect patients and health care workers by slowing the rate of infection.

Another division of HHS and one of the FDA's sister agencies — the Centers for Disease Control and Prevention — has advocated for telehealth, stating, "[l]everaging telemedicine whenever possible is the best way to protect patients and staff from COVID-19." The American College of Obstetricians and Gynecologists has likewise championed telehealth as an effective substitute for in-clinic dispensing of mifepristone that can improve patient safety and outcomes during the COVID-19 public health crisis. And even before the pandemic in 2018, the American Medical Association passed a resolution urging the FDA to lift the requirement because it "impedes the provision of" mifepristone and has no "demonstrated or even reasonably likely advantage."

In March, Raoul and the coalition called on the federal government to waive or utilize its discretion not to enforce this mifepristone requirement because it dictates and subsequently impedes women's access to a

medication abortion. The coalition stressed the states’ need to ensure that women across the country have access to critical health care, including access to abortion services, without forcing them to travel and risk the spread of COVID-19.

Joining Raoul in filing the 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.

UNITED STATES DISTRICT COURT
DISTRICT OF MARYLAND

AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS et al.,

Plaintiffs,

No. 8:20-cv-01320

v

UNITED STATES FOOD AND DRUG ADMINISTRATION et al.,

Defendants.

BRIEF FOR THE STATES OF NEW YORK, MARYLAND, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, HAWAI‘I, ILLINOIS, MAINE, 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 SUPPORT OF PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

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INTEREST OF THE AMICI

The States of New York, Maryland, California, Colorado, Connecticut, Delaware, Hawai'i, Illinois, Maine, Massachusetts, Michigan, Minnesota, Nevada, New Jersey, New Mexico, North Carolina, Oregon, Pennsylvania, Rhode Island, Vermont, Virginia, and Washington, and the District of Columbia file this amicus brief in support of plaintiffs' request for a preliminary injunction prohibiting defendants from enforcing—during the ongoing public health crisis—a U.S. Food and Drug Administration (FDA) requirement that patients appear in person in a clinical setting to fill a prescription for mifepristone, a single-dose oral medication used for early-term abortions and miscarriage management. Amici submit this brief to offer the perspective and experience of twenty-three States that are managing the pandemic caused by the 2019 coronavirus and the resulting disease (COVID-19).

Many of amici are also part of a coalition of twenty-one States whose attorneys general requested, on March 30, 2020, that the FDA and U.S. Department of Health and Human Services (HHS) waive or suspend enforcement of the in-clinic dispensing requirement for mifepristone in order that States could safely ensure access to essential reproductive health care during the public health emergency. The coalition letter stressed the States' "need to ensure that women across the country have access to critical healthcare services" without forcing them "to travel at a time when many States and the federal government are urging people to stay home to curb the spread of COVID-19."[1]

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[1] 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.)

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. As of May 27, 2020, the country had 1.6 million confirmed infections, and more than 100,000 deaths from COVID-19.[2] In response, legislators, officials, and agencies in the amici States have been instituting various emergency measures to slow the spread of the virus by limiting face-to-face contact and reducing in-person social gatherings, such as by closing schools and requiring all nonessential employees to work from home.

Limiting interpersonal contact is central to amici's ability to control the spread of the virus. Accordingly, amici are encouraging the replacement of traditional in-person medical visits with remote telehealth visits, which connect patients to health care providers through telephonic and electronic platforms to deliver medical services consistent with patient safety. Amici have a strong interest in ensuring safe access to essential reproductive health care through telehealth services whenever telehealth is appropriate in the health care provider's judgment, and consistent with standards of care.

Amici's experiences show that telehealth can safely expand access to health care services, including essential reproductive health care, while limiting the spread of COVID-19. Amici's experiences also confirm that imposing and enforcing an in-person clinic dispensing requirement during the current pandemic harms patient safety and the public interest in at least two ways: *first*, by conditioning access to essential reproductive health care on increased risk of virus infection and transmission; *second*, by undermining the ongoing efforts of amici to manage the public health crisis through measures that limit unnecessary in-person contacts, such as stay-at-home orders,

[2] *Four Months After First Case, U.S. Death Toll Passes 100,000*, N.Y. Times (updated May 28, 2020) (internet).

stay-safe orders, and the promotion of telehealth. Through these measures, amici hope to limit the spread of the virus to a point where amici can safely lift their more onerous emergency measures and reopen their communities.

ARGUMENT

REQUIRING IN-CLINIC DISPENSING OF MIFEPRISTONE FOR ESSENTIAL REPRODUCTIVE HEALTH CARE HARMS AMICI'S EFFORTS TO MINIMIZE TRANSMISSION OF COVID-19 WHILE ALLOWING ACCESS TO ESSENTIAL CARE

A. Minimizing In-Person Contact Has Been and Remains Critical to Amici's Ability to Manage the COVID-19 Pandemic and to Safely Reopen.

Self-isolation and social distancing are some of the most effective means of reducing the spread of the virus that causes COVID-19. *See* Decl. of Arthur L. Reingold, M.D., in Supp. of Pls.' Mot. for Prelim. Inj. (Reingold Decl.) ¶¶ 15, 16, 19, 21 (May 22, 2020), ECF No. 11-4. Experts in infectious disease control and public health have advised that mitigating the spread of the virus 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.[3] *See id.* To limit social contacts, the amici States previously issued stay-at-home orders that directed residents to confine themselves to their homes except when necessary for essential matters.[4]

As these efforts have proved effective in reducing virus transmission and slowing the spread, many amici have begun to reopen their States by allowing increased business and

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[3] *See* Centers for Disease Control & Prevention (CDC), *Coronavirus Disease 2019 (COVID-19): Social Distancing* (last updated May 6, 2020) (internet).

[4] Sarah Mervosh et al., *See Which States and Cities Have Told Residents to Stay at Home*, N.Y. Times (updated April 20, 2020) (internet); *see, e.g.,* N.Y. Office of the Governor, Exec. Order No. 202.8, 9 N.Y.C.R.R. § 8.202.8 (2020) (requiring all nonessential businesses in New York to reduce workforce at work locations by 100%).

community activities, but have emphasized that safe reopening requires that residents continue to minimize in-person contacts.[5] Continuing to limit social interactions is critical to maintaining health and safety and preventing a surge in infection rates. Thus, while more activity is permitted, it is important for residents to avoid unnecessary travel and in-person contacts.

B. Telehealth Is Central to Amici's Ability to Provide Essential Health Care While Minimizing the Spread of COVID-19.

The amici States have recognized that telehealth is an "invaluable tool in slowing the spread of COVID-19"[6] and is "crucial" in providing residents with needed health care during the public health crisis.[7] Amici have thus emphasized that telehealth should 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 health care staff.[8]

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[5] *See, e.g.*, N.Y. Office of the Governor, *Reopening New York: Curbside and In-Store Pickup Retail Guidelines for Employers and Employees* (internet) (requiring six feet of distance between personnel, limiting occupancy to 50%, prohibiting more than one person in confined spaces, etc.); *see also* Sarah Mervosh et al., *See How All 50 States Are Reopening*, N.Y. Times (updated June 3, 2020) (internet).

[6] D.C. Health Reg. & Licensing Admin., *Guidance on Use of Telehealth in the Dist. of Columbia* 1 (Mar. 12, 2020) (internet).

[7] 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) (quotation marks omitted) (internet).

[8] Cal. Exec. Dep't, Exec. Order N-43-20, at 1 (Apr. 3, 2020) (internet); *see also* Minn. Office of the Governor, Emergency Exec. Order 20-51, at 3 (May 6, 2020) (internet) (strongly encouraging the use of telehealth "whenever possible"); Cal. Dep't of Public Health, *Resuming California's Deferred and Preventive Health Care* (Apr. 27, 2020) (internet) (encouraging "as many [medical] services as possible and appropriate be delivered by telehealth/telephonic even after loosening of the Stay-at-Home restrictions to protect patients and health care workers").

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-clinic interactions. Decl. of Allison Bryant Mantha, M.D., M.P.H., FACOG, in Supp. of Pls.' Mot. for Prelim. Inj. ¶ 31 (May 26, 2020), ECF No. 11-3. In some cases, clinics also may be able to use telehealth when conducting the required assessment of a patient's suitability for medication abortion. *Id.* ¶ 30.

When telehealth is appropriate in the judgment of the medical provider and consistent with standards of care, it can be used to provide medical care in a manner that avoids unnecessary travel and visits to health care facilities—thus reducing the participants' contact with other people and with high touch surfaces, and promoting the health and safety of both patients and health care workers.[10] Reingold Decl. ¶¶ 9, 36, 38. The Centers for Disease Control and Prevention advises health care practitioners that "[l]everaging telemedicine whenever possible is the best way to protect patients and staff from COVID-19."[11]

In addition, telehealth helps to conserve and expand health care resources that can then be used to address the pandemic. Telehealth decreases local health care workers' risk of infection and

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[9] A variation of telehealth, which involves a patient visiting a local clinic and using a video connection to meet with a certified provider who is located at a distant clinic and who dispenses mifepristone remotely, has proven to be an effective and acceptable method of obtaining medication abortion. *See* Daniel Grossman et al., *Effectiveness and Acceptability of Medical Abortion Provided Through Telemedicine*, 118 Obstetrics and Gynecology 296 (Aug. 2011) (internet).

[10] CDC, *Coronavirus Disease 2019 (COVID-19): Travel in the US* (last updated May 28, 2020) (internet).

[11] CDC, *Coronavirus Disease 2019 (COVID-19): Print Resources* (last updated Mar. 31, 2020) (internet).

subsequent need to stop working in order to self-quarantine, and increases the number of available medical professionals to include those who are located farther away but can provide services remotely. These benefits are particularly important for underserved areas, such as remote rural communities with limited medical resources, and more populous communities whose health care systems are strained by COVID-19 patients.[12] Telehealth also accommodates individuals who need timely medical care but are self-isolating or subject to quarantine, thereby facilitating adherence to stay-at-home and safer-at-home orders.[13]

In view of these advantages, the 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 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.[14] Many amici have

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[12] *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).

[13] *Id.*

[14] *See, e.g.*, Cal. Exec. Dep't, Exec. Order N-43-20, *supra*; Del. Office of the Governor, Second Modification: Declaration of a State of Emergency (Mar. 18, 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); Act of Mar. 19, 2020, ch. 3, 2020 N.J. Laws; Letter from Judith M. Persichilli, Comm'r, N.J. Dep't of Health, to Adm'rs of Long-Term Care Facilities, Assisted Living Facilities, Dementia Care Homes, and Residential Health Care Facilities (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

suspended existing 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.[15] In some instances, amici have also suspended penalties for unauthorized access or disclosure of health information during the provision of telehealth services when such lapses occur inadvertently and in good faith.[16]

Many of the amici States now require providers participating in state Medicaid programs to use telehealth whenever possible, and facilitate this by expanding covered telehealth services, including by allowing coverage for audio-only telehealth services to accommodate patients who lack access to video-communication equipment.[17] To encourage the use of telehealth for patients

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No. 01-20 (internet); H.742, No. 91, § 17, 2020 Vt. Laws; Va. Office of the Governor, Exec. Order No. 57 (Apr. 17, 2020) (internet).

[15] *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 (Mar. 29, 2020) (internet); Md. Office of the Governor, Order No. 20-04-01-01 (Apr. 1, 2020) (internet); Mass. Bd. of Registration in Med., Policy 2020-01 (Mar. 16, 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).

[16] Cal. Exec. Dep't, Exec. Order N-43-20, *supra*.

[17] *See, e.g.,* 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, Medicaid Managed Care Organizations, and Optum Behavioral Health ASO (internet); Mass. Exec. Office of Health & Human Servs., 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); Letter from Karen Kimsey, Dir., Va. Dep't of Med. Assistance Servs. (Mar. 19, 2020) (internet); Va. Dep't 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).

paying through private insurance, many of amici have required parity of coverage and/or reimbursement for services provided through telehealth, including services that were traditionally excluded from telehealth coverage.[18] Some States have prohibited co-pays, deductibles, and other patient out-of-pocket charges for telehealth services during the pandemic.[19]

To expand the use of telehealth for specific services, amici have suspended penalty provisions and eliminated the requirement of written patient consents to allow telehealth prescribing of certain regulated prescriptions,[20] and have developed special telehealth remote patient-monitoring programs for patients potentially infected with the coronavirus.[21] Amici have also expanded the use of telehealth in state programs that provide family planning services, and breast and cervical cancer screenings to low-income women.[22]

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[18] *See, 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); Act of Mar. 20, 2020, ch. 7, 2020 N.J. Laws (internet); 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*; H.742, No. 91, § 17, 2020 Vt. Laws; *see also* Cal. Dep't of Health Care Servs., Supplement to All Plan Letter, *supra* (requiring parity in Medi-Cal program).

[19] Ill. Office of the Governor, Exec. Order 2020-09, *supra*; Mass. Office of the Governor, Order Expanding Access to Telehealth Services and to Protect Health Care Providers, *supra*; Act of Mar. 20, 2020, ch. 7, 2020 N.J. Laws; N.Y. Codes, Rules & Regulations, Tit. 11, § 52.16(q).

[20] 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).

[21] Ill. Coronavirus (COVID-19) Resp., *Telehealth* (2020) (internet).

[22] *E.g.*, Cal. Dep't of Health Care Servs., *Update to Information on Coronavirus (COVID-19) for Family PACT* (Mar. 26, 2020) (internet); Cal. Dep't of Health Care Servs., *Every Woman Counts (EWC) Primary Care Provider (PCP) Information Notice: Program Update Regarding COVID-19 Public Health Emergency* (Apr. 2, 2020) (internet).

C. As Amici's Experiences Show, the Balance of Equities and the Public Interest Support a Preliminary Injunction Halting the In-Clinic Dispensing Requirement During the Current Public Health Crisis.

Contrary to amici's goals of ensuring safe access to essential health care during the pandemic, the FDA has mandated that mifepristone be dispensed only by a certified provider at a clinic, hospital, or medical office when that drug is being used for early abortions and miscarriage treatment.[23] The FDA requirement in effect conditions such care on undertaking travel and in-person contacts at a time when those activities heighten the risk that a person will contract and transmit COVID-19. The heightened risk caused by the FDA's requirement harms women, their close contacts, and public health conditions in the amici States.

Travel to a clinic is a burden even in ordinary times, but 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: modes of transportation that expose the participants to increased risk of infection. Reingold Decl. ¶ 36. In addition, many women will need to travel long distances in order to reach a clinic that dispenses mifepristone—sometimes up to two-hundred miles—especially if they reside in rural and medically underserved locations.[24]

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[23] Many women are affected by the FDA requirement because patients seeking medication abortions represent approximately 39% of all abortion patients in the U.S. (or approximately 339,640 women in 2017). Rachel Jones et al., *Abortion Incidence and Service Availability in the United States, 2017*, Guttmacher Inst. (Sept. 2019) (internet). While the number of abortions in the U.S. has steadily declined, the percentage of medication abortions has consistently increased. *Id*.

[24] 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 &

The in-clinic requirement also thwarts the amici States' ability to encourage the use of telehealth for essential care when telehealth services are both 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 the amici States' health care systems, particularly in medically underserved and high-infection areas. See *supra* at 4-8. And 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. See *supra* at 3-4. By using measures like telehealth to reduce unnecessary person-to-person contacts, amici can decrease their infection rate, as required to safely commence reopening even as the pandemic continues.[25]

Experienced medical practitioners have concluded that the in-clinic dispensing requirement does not further patient health and safety—particularly during the current public health crisis. Dozens of professional associations and institutions, as well as hundreds of providers, have urged the FDA by letter to waive the in-clinic dispensing requirement during the COVID-19 pandemic, noting that the requirement "is hindering access to medication abortion care and jeopardizing the health and safety of both patients and healthcare providers" by "requiring patients, unnecessarily, to access medical services in-person, instead of using telemedicine and mail-order pharmacy options." Compl., Ex. 6, at 1 (Apr. 28, 2020), ECF No. 1-8; *see also* Pls.' Am. & Corrected Mem. of Law in Supp. of Mot. for Preliminary Injunction at 16 (May 27, 2020), ECF No. 12 (citing additional medical authorities). The American College of Obstetricians and Gynecologists has

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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).

[25] *See, e.g.*, N.Y. Forward, *Regional UnPause Dashboard* (June 1, 2020) (internet) (metrics based on guidance from CDC, World Health Organization, and U.S. Department of State, among others).

likewise sent a letter urging the FDA to lift the requirement, emphasizing that the requirement places patients and others at risk of contracting the virus, that in-clinic dispensing has not been shown to improve patient safety or outcomes, and that telehealth is an effective substitute for in-clinic dispensing. Compl., Ex. 5, at 1 (Apr. 20, 2020), ECF No. 1-7. Even before the pandemic in 2018, the American Medical Association passed a resolution urging the FDA to lift the requirement because it "impedes the provision of" mifepristone and has no "demonstrated or even reasonably likely advantage."[26] As those medical authorities have recognized, telehealth is readily available and well-suited to provide dispensing and counseling services when mifepristone is used for early abortions and miscarriage treatment.

The balance of equities therefore tips heavily in favor of an injunction halting enforcement of the FDA's in-clinic dispensing requirement during the public health crisis, and such relief is clearly warranted in the interest of protecting the health of women and the public.

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[26] Am. Med. Ass'n House of Delegates, *Resolution 504* 58 (Apr. 26, 2018) (internet).

CONCLUSION

For the reasons set forth above and in plaintiffs' motion, this Court should grant the preliminary injunction.

Dated: New York, New York
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