IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, *et al.*, Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al.*, Defendants.	CIV. NO. 20-1320

BRIEF OF *AMICI CURIAE* MEDICAL ASSOCIATIONS IN SUPPORT OF PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

HOWARD M. SHAPIRO (D. Md. Bar No. 14731)
Howard.Shapiro@wilmerhale.com
KIMBERLY A. PARKER
Kimberly.Parker@wilmerhale.com
LESLEY R. FREDIN
Lesley.Fredin@wilmerhale.com
ANYA C. OLSEN
Anya.Olsen@wilmerhale.com
AYANA D. WILLIAMS
Ayana.Williams@wilmerhale.com
WILMER CUTLER PICKERING
HALE AND DORR LLP
1875 Pennsylvania Ave., N.W.
Washington, D.C. 20006
(202) 663-6000 (t)
(202) 663-6363 (f)

Counsel for Amici Curiae

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

OTHER AUTHORITIES

INTERESTS OF AMICI CURIAE

Amici the American Medical Association ("AMA"), American Academy of Family Physicians ("AAFP"), American Academy of Pediatrics ("AAP"), American College of Nurse-Midwives ("ACNM"), American College of Osteopathic Obstetricians and Gynecologists ("ACOOG"), American Gynecological and Obstetrical Society ("AGOS"), American Society for Reproductive Medicine ("ASRM"), National Association of Nurse Practitioners in Women's Health ("NPWH"), North American Society for Pediatric and Adolescent Gynecology ("NASPAG"), Planned Parenthood Federation of America ("Planned Parenthood"), Society for Maternal-Fetal Medicine ("SMFM"), Society of Family Planning ("SFP"), Society of Gynecologic Oncology ("SGO"), Society of Gynecologic Surgeons ("SGS"), and Society of Ob/Gyn Hospitalists ("SGOH") are medical and public health associations that are familiar with the clinical use of mifepristone (brand name Mifeprex®) for reproductive healthcare as well as how medical practice has adapted in response to the unique conditions created by the COVID-19 pandemic.

SUMMARY OF ARGUMENT

Amici ask this Court to grant Plaintiffs' motion for a preliminary injunction to enjoin the enforcement, operation, and execution of the mifepristone in-person dispensing requirement for the duration of the COVID-19 pandemic. Mifepristone, in combination with misoprostol, is used to safely and predictably treat women seeking pregnancy termination or miscarriage care. The Food and Drug Administration ("FDA") requirement that mifepristone be dispensed in person is both medically unnecessary and burdensome to patients. While the FDA has relaxed certain in-

person requirements for access to other drugs in response to the COVID-19 pandemic and instead empowered clinicians to use their medical judgment, it has not done so for mifepristone.

In keeping with guidance from the Centers for Disease Control and Prevention ("CDC") and the Department of Health and Human Services ("HHS"), health care professionals are attempting to limit certain person-to-person interactions and leverage telemedicine when, in the judgment of the clinician, it is medically appropriate to do so. Implicit in this guidance from the CDC and HHS is the recognition that physicians are best suited to determine when telehealth visits may be appropriate and when a patient requires an additional in-person visit. The in-person dispensing requirement prevents clinicians from using their judgment to determine how best to protect and treat their patients when providing abortion and miscarriage care. This results in unnecessary risk for patients in the midst of the current pandemic.

As the country works to contain the spread of SARS-CoV-2, the in-person dispensing requirement subjects patients to unnecessary risk by requiring them to travel even when not medically necessary, often interacting with others along the way to the clinician's office. Due to lack of transportation, insufficient funds, and lack of childcare, low-income patients and patients of color are particularly likely to be exposed to unnecessary risks from the in-person dispensing requirement during the pandemic. Clinicians' inability to exercise their judgment when providing miscarriage and abortion care thus particularly harms these populations. For these and the reasons set forth below, *amici* urge this Court to grant Plaintiffs' motion for a preliminary injunction.

ARGUMENT

Medication abortion involves two FDA-approved prescription medications: mifepristone and misoprostol, which in combination, cause pregnancy termination in a predictable time and

manner. In the two decades since its FDA approval, mifepristone has been safely and widely used to treat patients who seek abortion; more recently, in accordance with high-quality evidence, it has also been used to improve the efficacy and safety of miscarriage care.[1] The FDA has noted that major adverse events from the use of mifepristone, such as hospitalization, serious infection, and ectopic pregnancies, are "exceedingly rare, generally far below 0.1% for any individual adverse event."[2]

Since 2000, under its authority to issue Risk Evaluation and Mitigation Strategies ("REMS"), the FDA has required that Mifeprex® and its generic mifepristone ("mifepristone")[3] be dispensed in person, necessitating that a patient eligible for a medication abortion visit a prescriber's hospital, clinic, or medical office to receive the medication, even if the patient will later take it at home (as the FDA permits). This is true even if the initial medical consultation was done through telehealth and the patient is otherwise not obtaining in-person services.

I. The In-Person Dispensing Requirement to Obtain Mifepristone is not Medically Necessary.

Even before the SARS-CoV-2 pandemic, medical professionals deemed the in-person dispensing requirement for mifepristone outdated, medically unnecessary, and burdensome. In 2018, the AMA adopted a resolution urging the FDA to lift the REMS on mifepristone. This recommendation was based on testimony supporting a long history of safe mifepristone use, low rates of serious adverse events, a mortality rate fourteen times less than pregnancy-related death,

[1] Schreiber, et. al., *Mifepristone Pretreatment for the Medical Management of Early Pregnancy Loss*, New Eng. J. Med. (June 7, 2018), https://www.nejm.org/doi/full/10.1056/NEJMoa1715726.
[2] *See Medical Review, Application No. 020687Orig1s020* at 47, FDA Ctr. For Drug Evaluation & Research, (Mar. 29, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf
[3] The generic mifepristone has been available since 2019, and is subject to the in-person dispensing requirement.

and a showing that eliminating the mifepristone REMS would increase access to treatment.[4] The American Academy of Family Physicians ("AAFP") adopted a similar resolution in 2018.[5] Speaking in support of the resolution, AAFP delegates noted that "the mifepristone REMS classification is not founded in evidence."[6]

More recently, in 2019, AAFP urged the FDA to remove the REMS and Elements to Assure Safe Use ("ETASU") for mifepristone in order "to conform to current evidence."[7] AAFP explained that, at that time, nearly 3 million patients had used mifepristone since 2000, "with a high degree of effectiveness (over 97%) and minor complication risks (less than 1%)."[8]

In fact, the FDA has only imposed an in-person dispensing requirement on a small number of drugs, and mifepristone is unique among them. It is the only medication with an in-person dispensing requirement that a patient may take without clinical supervision in a place where she feels most comfortable.[9] Thus, even the FDA seems to agree with what the science shows: the in-person dispensing requirement does not contribute in any way to the drug's safety profile. Underscoring this point, when mifepristone is used for purposes other than abortion or miscarriage – to treat Cushing's syndrome – the same chemical compound is not subject to a

---

[4] *2008 Annual Meeting, Appendix 1 – Reference Reports*, American Medical Association, https://www.ama-assn.org/system/files/2018-11/a18-reference-committee-reports.pdf. *See also Improving Access to Mifepristone for Reproductive Health Indications,* ACOG (June 2018), https://www.acog.org/clinical-information/policy-and-position-statements/position-statements/2018/improving-access-to-mifepristone-for-reproductive-health-indications (Position Statement citing publications in medical journals to conclude that "[e]vidence regarding the safety of mifepristone for medication-induced abortion, used by over 3 million women in the U.S. since FDA approval in 2000, supports the removal of the REMS and ETASU" and urging that "mifepristone for reproductive health indications be made available in retail pharmacies like other prescription drugs and without unique provider certification or patient consent requirements.")

[5] Porter, *FPs Tackle Primary Care Spending, Other Weighty Topics*, American Academy of Family Physicians (Oct. 12, 2018), https://www.aafp.org/news/2018-congress-fmx/20181012cod-advocacy.html.

[6] *Id.*

[7] Letter from Michael Munger, Board Chair, American Academy of Family Physicians to Norman Sharpless, Acting Commissioner, FDA (June 20, 2019), https://www.aafp.org/dam/AAFP/documents/advocacy/prevention/women/LT-FDA-MifepristoneREMS-062019.pdf.

[8] *Id.*

[9] Decl. of Allison Bryant Mantha in Supp. of Pls.' Mot. for Prelim. Inj. ¶ 58, May 27, 2020 (Dkt. 11-3).

REMS and may be obtained from a mail-order pharmacy that delivers the drug to the patient's home.[10]

The evidence-based medical practice simply does not support the in-person dispensing requirement even in non-pandemic conditions. The REMS and ETASU are medically unnecessary and do not promote patient health.

II. Mandated In-Person Dispensing Is Inconsistent with Public Health Best Practices During the SARS-CoV-2 / COVID-19 Pandemic.

Limiting person-to-person interaction is critical to stopping the spread of SARS-CoV-2 and the disease it causes, COVID-19. For this reason, the AMA and other medical associations have advocated the use of telemedicine when appropriate and feasible and explained that "use of telemedicine and remote care services are critical to the safe management of the COVID-19 pandemic."[11] AAFP similarly has stated that: "Telemedicine and virtual care have quickly become important tools in caring for your patients while keeping yourself and your staff safe as the COVID-19 pandemic quickly evolves."[12] In light of the pandemic, in March 2020, the AMA, Physicians Foundation, Florida Medical Association, Massachusetts Medical Society, and Texas Medical Association announced the launch of a Telehealth Initiative to "help[] physicians implement telehealth services."[13] The AMA recognizes that the pandemic "reinforces the need

[10] *See generally Risk Assessment and Risk Mitigation Review(s)*, FDA Center for Drug Evaluation and Research (Jan. 12, 2007), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/202107Orig1s000RiskR.pdf.
[11] *AMA quick guide to telemedicine in practice*, American Medical Association (May 22, 2020), https://www.ama-assn.org/practice-management/digital/ama-quick-guide-telemedicine-practice.
[12] *Using Telehealth to Care for Patients During the COVID-19 Pandemic*, American Academy of Family Physicians (May 7, 2020), https://www.aafp.org/patient-care/emergency/2019-coronavirus/telehealth.html.
[13] *AMA supports Telehealth initiative to improve health care access*, American Medical Association (Mar. 19, 2020), https://www.ama-assn.org/press-center/press-releases/ama-supports-telehealth-initiative-improve-health-care-access.

for physician access to practical resources that will enable them to operate telehealth services efficiently while facilitating positive care team and patient experience."[14]

In the months since the SARS-CoV-2 public health crisis began, health care professionals and their practices have evolved to include the use of telemedicine where effective to treat patients for a variety of issues, including many that traditionally would have involved an in-person evaluation. Each clinician makes his or her own determination as to when telemedicine may be appropriate and effective considering factors such as the patient's medical history, the distance the patient would have to travel in order to obtain in-person care, precautions that may be taken to prevent the spread of the virus, and the patient's own condition and concerns. To give an example, AMA published a twenty-six page guide listing the telehealth services covered by Medicare, including those that are covered for the duration of the public health crisis caused by SARS-CoV-2.[15] Services covered include diabetes care, ventilation management, blood pressure management, and post-natal care.[16] Similarly, Planned Parenthood affiliates expanded their use of telehealth to offer telehealth services in all fifty states.[17] The U.S. Drug Enforcement Administration is also permitting physicians to "prescribe controlled substances based on telehealth visits" during the public health crisis.[18]

Physicians are best positioned to determine in what instances telehealth visits would be appropriate and when in-person visits would best serve the patient. In sum, health care professionals are following CDC guidance and safeguarding the health of their patients by using

---

[14] *Id.*
[15] *Telehealth Services Covered by Medicare and Included in CPT Code Set*, American Medical Association (May 1, 2020), https://www.ama-assn.org/system/files/2020-05/telehealth-services-covered-by-Medicare-and-included-in-CPT-code-set.pdf.
[16] *Id.*
[17] Felsenthal, *Front Line Workers Tell Their Own Stories in the New Issue of TIME*, TIME (April 9, 2020), https://time.com/5820326/planned-parenthood-telehealth-coronavirus/.
[18] *CARES Act: AMA COVID-19 pandemic telehealth fact sheet*, American Medical Association (April 27, 2020), https://www.ama-assn.org/delivering-care/public-health/cares-act-ama-covid-19-pandemic-telehealth-fact-sheet.

telemedicine when, in their professional judgment, it is medically appropriate and in the best interest of the patient to do so. A mandate for in-person dispensing of mifepristone, regardless of the patient's circumstances, is inconsistent with best practices for medical treatment under normal circumstances, and particularly during the pandemic when unnecessary travel to a health care facility carries a risk of exposure to a deadly virus.

The CDC has also urged people to stay home when possible and avoid travelling.[19] The administration has been supportive of the medical community's efforts to reduce the risk to patients and clinicians. The CDC issued guidance to health care professionals, advising that "[l]everaging telemedicine whenever possible is the best way to protect patients and staff from COVID-19."[20] Similarly, the CDC suggested using mail-order delivery to obtain medications, where possible, to mitigate risk. The FDA and HHS have also relaxed certain in-person requirements for access to regulated drugs. Specifically, the FDA announced that it would not enforce REMS requirements for laboratory testing or imaging before certain drugs can be prescribed as long as the "accommodations were made based on the judgment of a health care professional."[21] In this way, the FDA is empowering health care professionals to exercise their professional judgment to best protect their patients, staff, and themselves, while continuing to provide necessary medical care. In keeping with this guidance from the country's leading authority on preventing and controlling infectious diseases, telemedicine is being used where, in the judgment of the clinician, it is medically appropriate to do so.

---

[19] *Coronavirus in the United States—Considerations for Travelers*, CDC, https://www.cdc.gov/coronavirus/2019-ncov/travelers/travel-in-the-us.html.
[20] *Prepare your practice for COVID-19*, CDC, https://www.cdc.gov/coronavirus/2019-ncov/hcp/preparedness-resources.html.
[21] *Policy for Certain REMS Requirements During the COVID-19 Public Health Emergency, Guidance for Industry and Health Care Professionals*, p. 7, FDA (Mar. 2020), https://www.fda.gov/media/136317/download.

III. The In-Person Dispensing Requirement Harms Clinicians and Patients.

The in-person dispensing requirement prevents clinicians from exercising their independent medical judgment when providing abortion and miscarriage care, resulting in medically unnecessary increased viral exposure for patients and practitioners. Medical ethics require medical professionals to provide the best possible care for patients. AMA policy provides that physicians individually and collectively share the obligation to ensure that the care patients receive is "safe, effective, patient centered, timely, efficient, and equitable."[22] Yet the REMS on mifepristone in the context of abortion and miscarriage care prevent physicians from carrying out this obligation. Rather than evaluating the concerns of each patient individually, clinicians are forced to schedule an in-person visit even when the clinician has determined that such a visit would be detrimental to the patient's health and well-being. Because of SARS-CoV-2, medically unnecessary in-person visits are particularly likely to negatively impact patients' health and well-being.

For these reasons, dozens of health care organizations and hundreds of medical professionals (including some *amici*) have urged the FDA to remove the REMS for mifepristone during the SARS-CoV-2 epidemic, warning that "[t]he in-person requirements in the Elements to Assure Safe Use (ETASU) of the REMS for mifepristone, is hindering access to medication abortion care" and by not allowing physicians to determine when in-person visits are necessary, risks "jeopardizing the health and safety of both patients and healthcare providers."[23] Medical associations have stressed that "[d]uring this public health crisis, it is imperative that patients, especially those who are vulnerable or who live in rural areas, can use telehealth services to

[22] *Code of Medical Ethics Opinion 1.1.6*, American Medical Association, https://www.ama-assn.org/delivering-care/ethics/quality.
[23] Letter from healthcare organizations and providers to Janet Woodcock, Director of the Center for Drug Evaluation and Research, FDA (Apr. 28, 2020).

access needed care without unnecessary restrictions, particularly for medications that do not pose a risk of abuse or overdose,"[24] and that "these antiquated and superfluous requirements put patients and their physicians at risk, with no demonstrated benefit."[25] Nevertheless, the FDA continues to maintain the restriction requiring an in-person visit during the public health crisis. Judicial intervention is thus necessary to ensure that patients seeking abortion and miscarriage care, like other patients, can access care in the safest manner – based on their clinicians' best medical judgment.

CONCLUSION

For the reasons stated above, *amici* urge this Court to grant the Plaintiffs' motion for a preliminary injunction.

[24] Letter from John Cullen, Board Chair, American Academy of Family Physicians to Stephen Hahn, Commissioner, FDA (Mar. 25, 2020).
[25] Letter from Maureen Phipps, CEO, American College of Obstetricians and Gynecologists, Judette Louis, President, Society for Maternal-Fetal Medicine, and Matt Granato, CEO, Society for Maternal-Fetal Medicine to Stephen Hahn, Commissioner, FDA (Apr. 20, 2020).

Dated: June 3, 2020

Respectfully submitted,

/s/ Howard M. Shapiro
HOWARD M. SHAPIRO (D. Md. Bar No. 14731)
Howard.Shapiro@wilmerhale.com
KIMBERLY A. PARKER
Kimberly.Parker@wilmerhale.com
LESLEY R. FREDIN
Lesley.Fredin@wilmerhale.com
ANYA C. OLSEN
Anya.Olsen@wilmerhale.com
AYANA D. WILLIAMS
Ayana.Williams@wilmerhale.com
WILMER CUTLER PICKERING
HALE AND DORR LLP
1875 Pennsylvania Ave., N.W.
Washington, D.C. 20006
(202) 663-6000 (t)
(202) 663-6363 (f)

Counsel for Amici Curiae