No. 20-1824

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, et al.,
Plaintiffs-Appellees,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, et al.,
Defendants-Appellants.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MARYLAND

BRIEF OF *AMICI CURIAE* MEDICAL ASSOCIATIONS IN SUPPORT OF PLAINTIFFS-APPELLEES

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UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

DISCLOSURE STATEMENT

- In civil, agency, bankruptcy, and mandamus cases, a disclosure statement must be filed by **all** parties, with the following exceptions: (1) the United States is not required to file a disclosure statement; (2) an indigent party is not required to file a disclosure statement; and (3) a state or local government is not required to file a disclosure statement in pro se cases. (All parties to the action in the district court are considered parties to a mandamus case.)
- In criminal and post-conviction cases, a corporate defendant must file a disclosure statement.
- In criminal cases, the United States must file a disclosure statement if there was an organizational victim of the alleged criminal activity. (See question 7.)
- Any corporate amicus curiae must file a disclosure statement.
- Counsel has a continuing duty to update the disclosure statement.

No. 20-1824 Caption: American College of Obstetricians and Gynecologists et al. v. FDA

Pursuant to FRAP 26.1 and Local Rule 26.1,

American Medical Association, American Academy of Family Physicians,
(name of party/amicus)

American Academy of Pediatrics, Abortion Care Network, American College of Nurse-Midwives, (cont.)

who is amicus curiae, makes the following disclosure:
(appellant/appellee/petitioner/respondent/amicus/intervenor)

1. Is party/amicus a publicly held corporation or other publicly held entity? ☐ YES ☑ NO

2. Does party/amicus have any parent corporations? ☐ YES ☑ NO
If yes, identify all parent corporations, including all generations of parent corporations:

3. Is 10% or more of the stock of a party/amicus owned by a publicly held corporation or other publicly held entity? ☐ YES ☑ NO
If yes, identify all such owners:

4. Is there any other publicly held corporation or other publicly held entity that has a direct financial interest in the outcome of the litigation? ☐YES ☑NO
If yes, identify entity and nature of interest:

5. Is party a trade association? (amici curiae do not complete this question) ☐YES ☑NO
If yes, identify any publicly held member whose stock or equity value could be affected substantially by the outcome of the proceeding or whose claims the trade association is pursuing in a representative capacity, or state that there is no such member:

6. Does this case arise out of a bankruptcy proceeding? ☐YES ☑NO
If yes, the debtor, the trustee, or the appellant (if neither the debtor nor the trustee is a party) must list (1) the members of any creditors' committee, (2) each debtor (if not in the caption), and (3) if a debtor is a corporation, the parent corporation and any publicly held corporation that owns 10% or more of the stock of the debtor.

7. Is this a criminal case in which there was an organizational victim? ☐YES ☑NO
If yes, the United States, absent good cause shown, must list (1) each organizational victim of the criminal activity and (2) if an organizational victim is a corporation, the parent corporation and any publicly held corporation that owns 10% or more of the stock of victim, to the extent that information can be obtained through due diligence.

Signature: /s/ Kimberly Parker Date: 2/12/2021

Counsel for: Amici Curiae (above)

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Appendix A

Name of party/amicus, cont.: American College of Osteopathic Obstetricians and Gynecologists, American Gynecological and Obstetrical Society, American Society for Reproductive Medicine, National Abortion Federation, North American Society for Pediatric and Adolescent Gynecology, National Association of Nurse Practitioners in Women's Health, Planned Parenthood Federation of America, Reproductive Health Access Project, Society of Family Planning, Society of General Internal Medicine, Society of Ob/Gyn Hospitalists, Society of Gynecologic Surgeons, and Society for Maternal-Fetal Medicine.

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Amici American Medical Association ("AMA"), American Academy of Family Physicians ("AAFP"), American Academy of Pediatrics ("AAP"), Abortion Care Network ("ACN"), 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 Abortion Federation ("NAF"), North American Society for Pediatric and Adolescent Gynecology ("NASPAG"), National Association of Nurse Practitioners in Women's Health ("NPWH"), Planned Parenthood Federation of America ("Planned Parenthood"), Reproductive Health Access Project ("RHAP"), Society of Family Planning ("SFP"), Society of General Internal Medicine ("SGIM"), Society of Gynecologic Surgeons ("SGS"), Society of Ob/Gyn Hospitalists ("SOGH"), and Society for Maternal-Fetal Medicine ("SMFM") are medical and public health associations that are familiar with the clinical use of mifepristone (brand name Mifeprex®) for reproductive health care and how medical practice has adapted in response to the unique conditions created by the COVID-19 pandemic.[1]

[1] Pursuant to Federal Rule of Appellate Procedure 29, *amici* certify that all parties have consented to the filing of this brief. No party's counsel, nor any person other than *amici*, authored or funded this brief.

SUMMARY OF ARGUMENT

As the Court is well-aware, the country is facing an unprecedented public health crisis. While the number of lives lost due to SARS-CoV-2 approaches 480,000 and new cases continue to rise,[2] health care professionals, including *amici* and their members, are working around the clock to combat its spread. As part of that effort, consistent 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 person-to-person interactions and leverage telemedicine whenever medically appropriate.

The Food and Drug Administration ("FDA") has been part of that effort, relaxing in-person treatment requirements for certain medications so that practitioners, using their clinical judgment, may prescribe necessary medications via telemedicine. Telemedicine allows patients to stay home and avoid travel and interactions that would put them, as well as practitioners, at risk of infection. Yet, without any medical basis, the FDA has refused to do the same for mifepristone.

Mifepristone, in combination with misoprostol, has been approved by the FDA for 20 years to safely treat individuals seeking early pregnancy termination. More than 4 million people in the U.S. have safely used mifepristone to terminate a

[2] *See* Coronavirus Resources Center, Johns Hopkins, https://coronavirus.jhu.edu/ (visited Feb. 10, 2020).

pregnancy.[3] It is also used for miscarriage care. However, unlike medications with a similar safety profile, the FDA has placed a number of requirements on the distribution and provision of mifepristone. Two of those requirements -- that mifepristone be dispensed in person in a healthcare setting and that the patient sign the Patient Agreement Form in the presence of the clinician (the "in-person requirements") -- are the subject of this lawsuit.

Based on clear-cut medical evidence, a federal district court preliminarily enjoined the in-person requirements only during the COVID-19 pandemic to promote patient safety during this unprecedented time. As the court properly found, the in-person requirements result in unnecessary risk for patients during the current pandemic by requiring them to travel even when not medically necessary. This travel will not only require patients to interact with staff at the clinician's office, but also often will require interacting with others along the way and/or with others needed for the patient to be away from home, such as childcare providers.

The in-person requirements particularly harm low-income patients and patients of color. Patients of color are more likely than white patients to contract SARS-CoV-2, and upon contracting the disease they face a greater likelihood of

[3] Danco, *Mifeprex in the United States*, https://www.earlyoptionpill.com/what-is-mifeprex/mifeprex-in-the-united-states/ (visited Feb. 3, 2020).

hospitalization and death.[4] Low-income patients and patients of color are also more likely to use public transportation than Americans overall.[5] Due to lack of private transportation, insufficient funds, and lack of reliable childcare, these vulnerable populations are particularly likely to be exposed to unnecessary risks from the in-person requirements during the pandemic, or to have these risks prevent them from being able to access abortion at all. Injunctive relief is critical to protect patients and clinicians against these risks while still ensuring safe use of mifepristone during the remainder of this public health crisis.

Amici, leading professional medical groups with expertise in the safe use of mifepristone as well as the appropriate use of telemedicine, therefore, urge this Court to affirm the District Court's grant of a preliminary injunction on Plaintiffs' due process claim and reverse its ruling denying relief on Plaintiffs' equal protection claim.

ARGUMENT

Medication abortion involves two FDA-approved prescription medications: mifepristone and misoprostol, which, in combination, cause pregnancy termination in a predictable time and manner. Sixty percent of abortions performed up to 10

[4] *CDC, COVID-19 Hospitalization and Death by Race/Ethnicity* (Nov. 30, 2020), https://www.cdc.gov/coronavirus/2019-ncov/covid-data/investigations-discovery/hospitalization-death-by-race-ethnicity.html.

[5] *See* Anderson, *Who Relies on Public Transit in the U.S.*, Pew Research Center (Apr. 7, 2016), https://www.pewresearch.org/fact-tank/2016/04/07/who-relies-on-public-transit-in-the-u-s/.

weeks of pregnancy are medication abortions.[6] And a significant number of medical facilities that provide abortions only offer medication abortions.[7] Many patients prefer a medication abortion to a surgical abortion because it allows them to avoid an invasive procedure, including sedation, and because the medication can be ingested in the earliest weeks of pregnancy.[8] This is particularly the case for patients who have experienced rape or sexual abuse and who may strongly prefer medication abortion to avoid the trauma of having instruments inserted into their vagina.[9] For patients with certain medical conditions, medication abortion is their safest option.[10] In the two decades since its FDA approval, mifepristone has been safely and widely used to treat patients who seek abortion care (more than 4 million people); more recently, in accordance with evidence-based research, it has also been used to improve the efficacy and safety of miscarriage care.[11]

While Defendants and their *Amici* States attempt to suggest in the context of this litigation that mifepristone is a dangerous medication, in fact, the FDA has recognized that mifepristone's safety profile is "well-established" and that major

[6] Jones, et al., *Abortion Incidence and Service Availability in the United States, 2017*, Guttmacher Institute (Sept. 2019), https://www.guttmacher.org/report/abortion-incidence-service-availability-us-2017#.
[7] *Id.* (one-quarter of nonhospital abortion providers and one-third of clinic abortion providers offer only medication abortion).
[8] Medical Versus *Surgical Abortion*, University of California San Francisco Health, https://www.ucsfhealth.org/education/medical-versus-surgical-abortion (visited Sept. 7, 2020).
[9] *See* Sharkansky, *Sexual Trauma: Information for Women's Medical Providers*, U.S. Dep't of Veterans Affairs, https://www.ptsd.va.gov/professional/treat/type/sexual_trauma_women.asp (visited Feb. 9, 2021).
[10] *Medication Abortion up to 70 Days of Gestation*, Contraception Journal (Aug. 14, 2020), https://www.contraceptionjournal.org/article/S0010-7824(20)30301-2/fulltext.
[11] Schreiber, et. al., *Mifepristone Pretreatment for the Medical Management of Early Pregnancy Loss*, N. Eng. J. Med. (June 7, 2018), https://www.nejm.org/doi/full/10.1056/NEJMoa1715726.

adverse events from the use of mifepristone are "exceedingly rare, generally far below 0.1% for any individual adverse event."[12] A recent review by the National Academies of Sciences, Engineering, and Medicine ("National Academies"), an expert body established by Congress in 1863 to provide independent, objective expert analysis and advice to inform public policy, concluded that the "risks of medication abortion are similar in magnitude" to those of commonly prescribed and over-the-counter medications such as antibiotics and nonsteroidal anti-inflammatory drugs such as aspirin and ibuprofen.[13] The National Academies further reported that "telemedicine provision of medication abortion was not associated with a significantly higher prevalence of adverse events" than in person provision.[14] In other words, the available data shows that medication abortion can be provided via telemedicine without increased risk to patients. This is particularly critical in the context of the COVID-19 pandemic, where medical experts recommend that clinicians perform assessment, counseling, and consent for a medication abortion by video or telephone for medically eligible patients.[15]

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[12] *See* FDA Ctr. For Drug Eval. & Research, *Medical Review, Application No. 020687Orig1s020* at 8, 47, (Mar. 29, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf.
[13] Nat'l Acads. of Sci., Eng'g, & Med., *The Safety and Quality of Abortion Care in the United States* 79 (2018) ("NASEM Report"), http://nap.edu/24950.
[14] NASEM Report at 57-58.
[15] ACOG, *Physicians FAQs: COVID-19 FAQs for Obstetrician-Gynecologists, Gynecology* (2020), https://www.acog.org/en/clinical-information/physician-faqs/COVID19-FAQs-for-Ob-Gyns-Gynecology (explaining that "[p]atients can safely self-administer [mifepristone and misoprostol] at home" and "[f]ollow up after an uncomplicated medication abortion can be provided effectively by video or telephone . . . .").

Despite mifepristone's extremely strong safety profile, the FDA imposes a Risk Evaluation and Mitigation Strategy ("REMS") requiring, among other things, that mifepristone be dispensed in person in a healthcare setting and the patient sign the Patient Agreement in the presence of the clinician, 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 took place through telehealth and the patient is otherwise not obtaining in-person services. Notably, however, the REMS does not require an in-person evaluation. In fact, the REMS in-person requirements at issue here (picking up the medication and signing a form) include no medical content whatsoever.

I. THE IN-PERSON REQUIREMENTS TO OBTAIN MIFEPRISTONE ARE NOT MEDICALLY NECESSARY

Even before the SARS-CoV-2 pandemic, there was an expert consensus that the in-person requirements for mifepristone are outdated and medically unnecessary, and that they harm patients by restricting access to care. The 2018 National Academies report confirmed that "[t]here is no evidence that the dispensing or taking of mifepristone tablets requires the physical presence of a clinician."[16] In 2018, the AMA adopted a resolution urging the FDA to lift the mifepristone REMS, based on testimony supporting a long history of safe mifepristone use, low

[16] NASEM Report at 79.

rates of serious adverse events, a mortality rate fourteen times less than pregnancy-related death, and a showing that eliminating the mifepristone REMS would increase access to treatment.[17] The American Academy of Family Physicians ("AAFP") adopted a similar resolution in 2018.[18]

In 2019, AAFP urged the FDA to remove the REMS, including the in-person requirements, for mifepristone in order "to conform to current evidence."[19] AAFP explained that millions of patients had used mifepristone between 2000 and 2019, "with a high degree of effectiveness (over 97%) and minor complication risks (less than 1%)."[20]

The American College of Obstetricians and Gynecologists ("ACOG"), the leading professional membership organization for obstetrician–gynecologists, has long recognized that medication abortion can be safely provided using telemedi-

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[17] Am. Med. Ass'n, AMA Policy H-100.948, *Ending the Risk Evaluation and Mitigation Strategy (REMS) Policy on Mifepristone (Mifeprex)*, https://policysearch.ama-assn.org/policyfinder/detail/Ending%20the%20Risk%20Evaluation%20and%20Mitigation%20Strategy%20%28REMS%29%20Policy%20on%20Mifepristone%20%28Mifeprex%29%20H-100.948?uri=%2FAMADoc%2FHOD.xml-H-100.948.xml. *See also* ACOG, *Improving Access to Mifepristone for Reproductive Health Indications* (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").

[18] 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.

[19] 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.

[20] *Id*.

cine.[21] And contrary to what Defendants' *Amici* States have asserted in this case, see "*Indiana et al. Br.*" 12, ACOG also recognizes that "[f]or patients with regular menstrual cycles, a certain last menstrual period within the prior 56 days, and no signs, symptoms, or risk factors for ectopic pregnancy, a clinical examination or ultrasound examination is not necessary before medication abortion."[22] Even before the pandemic, ACOG called for the REMS requirements to be removed, stating that they "are inconsistent with those for other medications with similar or greater risks . . . and serve as barriers to access without supporting demonstrated improvements to patient safety or outcomes."[23]

In fact, the FDA has only imposed an in-person dispensing requirement on a handful of drugs; and even among that extremely small class, mifepristone is singled out for unique treatment. In 2016, the FDA approved changes to the mifepristone labeling to make clear that the patient may take the medication at home or in another chosen location.[24] Mifepristone is the only medication subject to an in-person dispensing requirement that a patient may take without clinical supervi-

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[21] *Medication Abortion up to 70 Days of Gestation*, *supra* note 10.

[22] *Id.* Even for those patients who require in-person evaluation, injunctive relief would give providers the necessary flexibility to reduce the number of in-person visits. For example, an injunction would allow patients who need additional time to consider their options after being evaluated to receive the medications by mail rather than having to return to the health center, if they decide to go forward.

[23] ACOG, *Improving Access to Mifepristone for Reproductive Health Indications*, *supra* note 17.

[24] FDA, *Questions and Answers on Mifeprex* (Apr. 12, 2019), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifeprex; *Medication Abortion*, Guttmacher Institute (Nov. 2019), https://www.guttmacher.org/evidence-you-can-use/medication-abortion#.

sion.[25] All other drugs with in-person dispensing requirements must also be *administered* in-person, under clinical supervision. This policy conforms with what the science shows: the in-person dispensing requirement does not contribute in any way to the drug's strong safety profile. Further, when mifepristone is used for purposes other than abortion or miscarriage, at a higher dosage, the same chemical compound is not subject to any REMS and may be obtained from a mail-order pharmacy that delivers the drug to the patient's home.[26] This demonstrates that even the FDA has determined that mifepristone need not be dispensed in person.

The in-person requirements are also not necessary to ensure adequate counseling regarding medication usage, as the FDA suggests, because such counseling can be fully provided via telemedicine or at a prior in-person visit. Indeed, the REMS does not require in-person counseling, and clinicians use telemedicine widely to provide counseling for drugs with significantly higher risk profiles. In one stark example, HHS has waived the longstanding in-person evaluation and counseling requirement for opioids for the duration of the public health emergency caused by the COVID-19 pandemic.[27] In other words, the government now permits doctors to prescribe opioids to new patients and counsel them regarding their

[25] Decl. of Allison Bryant Mantha in Supp. of Pls.' Mot. for Prelim. Inj. ¶ 58, *ACOG v. FDA*, No. 20-cv-1320 (D. Md. May 27, 2020) (Dkt. 11-3).
[26] *See generally* FDA Ctr. For Drug Eval. & Research, *Risk Assessment and Risk Mitigation Review(s), Application no. 202107Orig1s000,* (Jan. 27, 2007), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/202107Orig1s000RiskR.pdf.
[27] U.S. DOJ, DEA, Diversion Control Division, *COVID-19 Information Page*, https://www.deadiversion.usdoj.gov/coronavirus.html.

use without a single in-person visit despite the significantly greater safety risk and counseling challenges that opioids present.[28] This HHS waiver reinforces what the evidence shows: that patients do not need in-person counseling, much less at the precise moment of dispensing, to understand the safe use of, or medical risks associated with, a particular medication.

Evidence-based medical practice does not support the mifepristone in-person requirements even in non-pandemic conditions. The mifepristone REMS and in-person requirements 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

Contrary to the Defendants' *Amici* States' representations, SARS-CoV-2 and the disease it causes, COVID-19, are uncontained in this country and continue to present a public health emergency. While vaccines have been introduced, the rollout has been slow: only 3.5% of the population has been fully vaccinated,[29] a far cry from the estimated 70 to 90% of the population necessary to achieve herd

[28] Rosenberg, *Using Telemedicine to Treat Opioid Addiction*, N.Y. Times (Aug. 4, 2020), https://www.nytimes.com/2020/08/04/opinion/opioid-telemedicine-covid.html.
[29] Keating, *At Least 35.4 Million People Have Received One or Both Doses of the Vaccine in the U.S.*, Wash. Post. https://www.washingtonpost.com/graphics/2020/health/covid-vaccine-states-distribution-doses/ (visited Feb. 12, 2021).

immunity.[30] Even once the vaccine becomes widely available, limiting person-to-person interaction will remain critical to stopping this pandemic.

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."[31] For example, the AMA published a twenty-six page guide listing the telehealth services covered by Medicare, which includes diabetes care, post-natal care, and ventilation management.[32] ACOG has put out extensive guidance to promote the use of telemedicine wherever appropriate, including assessment, counseling, consent, and follow-up for a medication abortion.[33] 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."[34] In light of the pandemic, in March 2020, the AMA, Physicians Foundation, Florida Medical Association, Massachu-

[30] McNeil Jr., *How Much Herd Immunity is Enough?*, N.Y. Times (Dec. 24, 2020) https://www.nytimes.com/2020/12/24/health/herd-immunity-covid-coronavirus.html.
[31] Am. Med. Ass'n, *AMA Telehealth Quick Guide* (Sept. 24, 2020), https://www.ama-assn.org/practice-management/digital/ama-telehealth-quick-guide.
[32] Am. Med. Ass'n, *Telehealth Services Covered by Medicare and Included in CPT Code Set* (May 1, 2020), https://www.ama-assn.org/system/files/2020-05/telehealth-services-covered-by-Medicare-and-included-in-CPT-code-set.pdf.
[33] ACOG, *Physicians FAQs: COVID-19 FAQs for Obstetrician-Gynecologists, Telehealth* (2020), https://www.acog.org/clinical-information/physician-faqs/covid-19-faqs-for-ob-gyns-telehealth; ACOG *Practice Advisory: Novel Coronavirus 2019 (COVID-19)*, https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2020/03/novel-coronavirus-2019#s4 (Dec. 14, 2020).
[34] Am. Acad. of Family Physicians, *Using Telehealth to Care for Patients During the COVID-19 Pandemic* (Dec. 10, 2020), https://www.aafp.org/patient-care/emergency/2019-coronavirus/telehealth.html.

setts Medical Society, and Texas Medical Association announced the launch of a Telehealth Initiative to "help[] physicians implement telehealth services."[35]

For this reason, HHS "encourage[s] health care providers to adopt and use telehealth as a way to safely provide care."[36] The Centers for Medicare and Medicaid Services ("CMS") (which is also part of HHS) has temporarily expanded Medicaid coverage of telehealth services, and recommends optimizing telehealth services "to minimize the need for in-person services," specifically urging "individuals at higher risk for severe COVID-19 illness" to "continue to shelter in place unless their conditions warrant in-person health care."[37] And, according to the CDC, pregnant people might be at an increased risk for severe illness from COVID-19 and thus should take extra precautions to avoid exposure to the virus.[38]

Following this extensive guidance and their own best medical judgment, health care professionals and practices swiftly evolved to include use of telemedicine where effective to treat patients for various issues, including many that tradi-

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[35] Am. Med. Ass'n, *AMA Supports Telehealth Initiative to Improve Health Care Access* (Mar. 19, 2020), https://www.ama-assn.org/press-center/press-releases/ama-supports-telehealth-initiative-improve-health-care-access.

[36] U.S. Dep't of Health & Human Servs, *Telehealth: Delivering Care Safely During COVID_19*, https://www.hhs.gov/coronavirus/telehealth/index.html.

[37] *Id.*; Ctrs. For Medicare & Medicaid Servs., *CMS Recommendations: Re-Opening Facilities to Provide Non-emergent Non-COVID-19 Healthcare* (June 8, 2020), https://www.cms.gov/files/document/covid-recommendations-reopening-facilities-provide-non-emergent-care.pdf.

[38] Ctrs. For Medicare & Medicaid Servs., *CMS Recommendations: Re-Opening Facilities to Provide Non-emergency Non-COVID-19 Healthcare*, *supra* note 37; CDC, *Pregnancy, Breastfeeding, and Caring for Newborns* (Dec. 28, 2020), https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/pregnancy-breastfeeding.html; *see also* CDC, *Using Telehealth to Expand Access to Essential Health Services During the COVID-19 Pandemic* (June 10, 2020), https://www.cdc.gov/coronavirus/2019-ncov/hcp/telehealth.html.

tionally involved an in-person evaluation. For example, Planned Parenthood affiliates now offer telehealth services nationwide, and as of November 2020 the AMA found that more than 90% of physicians had connected remotely with at least some patients that year.[39] Provision of care through telemedicine provides practitioners with the same opportunity to comprehensively counsel and obtain informed consent from patients that practitioners have when providing in-person medical care, while reducing the risk of SARS-CoV-2 transmission and the risk that patients will forego important care during the pandemic.[40]

Defendants' *amici* suggest that telehealth appointments are less effective at screening patients for potential intimate-partner violence. However, health care professionals also report that they are as effectively able to screen for intimate-partner violence and domestic violence using telehealth as in a traditional in-person visit. The core elements of such a screening are building trust and rapport with patients—something which can be done as successfully using a telehealth appointment as an in-person visit. Clinicians are further able to safeguard patients' privacy during these screenings by utilizing technology like the "chat" function that accompanies telehealth platforms. In addition, clinicians may use written communi-

[39] Abrams, *Planned Parenthood is Expanding Telehealth to All 50 States Amid the Coronavirus Pandemic*, Time (Apr. 14, 2020), https://time.com/5820326/planned-parenthood-telehealth-coronavirus/; Andis Robeznieks, *Dr. Madera: Pandemic Demands Nimble Response and AMA is Delivering* (Nov. 13, 2020), https://www.ama-assn.org/house-delegates/special-meeting/dr-madara-pandemic-demands-nimble-response-and-ama-delivering.

[40] *See* Am. Telemedicine Ass'n, *Telehealth Basics*, https://www.americantelemed.org/resource/why-telemedicine/#:~:text=Improved%20Quality%20%E2%80%93%20Studies%20have%20consistently,in%20traditional%20in%2Dperson%20consultations (visited Sept. 7, 2020).

cation, such as self-administered or computerized screenings, to effectively screen patients for intimate-partner violence.[41]

This flexibility in providing care is important because the combined effects of the pandemic, including office and school closures and the need to travel, are forcing patients to delay seeking health care. As of June 30, 2020, an estimated 41% of U.S. adults reported having delayed or avoided medical care during the pandemic because of concerns about COVID-19, with Black and Hispanic adults reporting higher rates of avoidance of urgent or emergency care than white adults.[42] In a June 2020 survey, one in three women reported that they had to delay or cancel a visit for sexual or reproductive health care or had trouble accessing birth control.[43] These barriers were more common among Black and Hispanic patients than White patients.[44] Lower-income women were also more likely than higher-income women to report having experienced delays or being unable to get contraceptive or sexual and reproductive health care because of the pandemic.[45] This trend has continued, and is causing adverse health effects for those unable to

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[41] ACOG, *Intimate Partner Violence*, Committee on Health Care for Underserved Women (Feb. 2012), https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2012/02/intimate-partner-violence.

[42] CDC, *Morbidity and Mortality Weekly Report, Delay or Avoidance of Medical Care Because of COVID-19-Related Concerns-United States, June 2020 (MMWR)* (Sept. 11, 2020), https://www.cdc.gov/mmwr/volumes/69/wr/mm6936a4.htm.

[43] Lindbert et al., *Early Impacts of the COVID-19 Pandemic: Findings from the 2020 Guttmacher Survey of Reproductive Health Experiences* (June 2020), https://www.guttmacher.org/report/early-impacts-covid-19-pandemic-findings-2020-guttmacher-survey-reproductive-health#.

[44] *Id*.

[45] *Id*.

access care. An October 2020 study reported that 56% of surveyed primary care clinicians across 47 states saw an "increase in negative health burdens due to delayed or inaccessible care."[46]

The Defendants' *Amici* States claim that the SARS-CoV-2 concerns are "remote" and that in-person services no longer pose a risk. (*Indiana et al*. Br. 14.) This could not be further from the truth. The risks of the pandemic have, if anything, increased since the district court issued its ruling. The United States is quickly approaching 480,000 deaths and 28 million cases, with a recent average of over 104,000 new cases per day.[47] Outbreaks of SARS-CoV-2 continue to spread, creating hotspots where cases grow rapidly, putting the community at risk.[48] Moreover, scientists have identified thousands of virus variants, including several that are more easily transmissible.[49] The CDC projects that one such variant, which has already been detected in 12 states and is estimated to be as much as 50% more transmissible than the more common strain, will be the primary source of all

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[46] Primary Care Collaborative, *Primary Care & COVID-19: Week 22 Survey* (Nov. 17, 2020), https://www.pcpcc.org/2020/11/14/primary-care-covid-19-week-22-survey.

[47] *Coronavirus in the U.S.: Latest Map and Case Count*, N.Y. Times (Feb. 11, 2021), https://www.nytimes.com/interactive/2020/us/coronavirus-us-cases.html?name=styln-corona-virus&region=TOP_BANNER&block=storyline_menu_recirc&action=click&pgtype=LegacyCollection&impression_id=92c95a72-670c-11eb-a0d2-a15f93b21c0c&variant=1_Show.

[48] Bravo & Haseman, *How Coronavirus Spreads So Quickly and How You Can Slow It Down*, USA Today (Feb. 11, 2021), https://www.usatoday.com/pages/interactives/news/coronavirus-covid-spread-quickly-how-to-slow-it-down/; Chiwaya & Murphy, *Tracking New Coronavirus Cases in Hot Spots Across the United States*, NBC News (Feb. 4, 2021), https://www.nbcnews.com/health/health-news/coronavirus-count-state-day-2020-united-states-n1173421.

[49] Iati & Fritz, *What You Need To Know About The Coronavirus Variants*, Wash. Post (Feb. 9, 2021), https://www.washingtonpost.com/health/interactive/2021/01/25/covid-variants/.

SARS-CoV-2 infections by March 2021.[50] The CDC cautioned that this strain "warrants universal and *increased* compliance with mitigation strategies."[51]

The risk is particularly acute for patients of color. Patients of color are more likely than white patients to contract SARS-CoV-2, and upon contracting the disease they face a greater likelihood of hospitalization and death.[52] Defendants' *Amici* States' categorization of the pandemic defies reality and CDC data. Given the current state of the pandemic in the United States with new areas of uncontrolled spread continuing to emerge, a slow vaccine rollout, and the need to limit travel and in-person interactions, injunctive relief permitting wherever appropriate the delivery of mifepristone without an in-person visit is critical to protect patients, health care professionals, and the public health in general.

Simply put, a mandate for in-person dispensing of mifepristone, regardless of the patient's circumstances, is inconsistent with best practices for medical treatment under pre-pandemic 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 and FDA have supported the medical community's efforts to reduce the risk to patients requiring other treatments and their clinicians, including by advocating the use of telemedicine and mail order delivery of medications,

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[50] Galloway, et al., *Emergence of SARS-CoV02 B.1.1.7 Lineage – United States, December 29, 2020-January 12, 2021*, CDC (Jan. 15, 2021), https://www.cdc.gov/mmwr/volumes/70/wr/mm7003e2.htm?s_cid=mm7003e2_w.
[51] *Id*. (emphasis added).
[52] CDC, *COVID-19 Hospitalization and Death by Race/Ethnicity*, *supra* note 4.

where possible, and relaxing certain in-person and REMS requirements.[53] There is no medical basis for mifepristone to be treated differently.

III. THE IN-PERSON REQUIREMENTS HARM PATIENTS AND CLINICIANS

The in-person requirements result in medically unnecessary increased viral exposure for patients and practitioners, as well as for their families and communities. Medical ethics require medical professionals to provide patients the best possible care. AMA policy directs physicians to ensure that the care patients receive is "safe, effective, patient centered, timely, efficient, and equitable."[54] Yet the REMS on mifepristone prevents clinicians from carrying out this obligation, forcing clinicians to schedule in-person visits even when the clinician has determined that such a visit would be detrimental to a patient's health. Because of SARS-CoV-2, medically unnecessary in-person visits are particularly likely to negatively impact patients' health and well-being.

For these reasons, Defendants' suggestion that patients could instead have in-clinic procedural abortions makes no common or medical sense. The purpose of

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[53] *See, e.g.*, CDC, *Prepare Your Practice for COVID-19* (June 12, 2020), https://www.cdc.gov/coronavirus/2019-ncov/hcp/preparedness-resources.html; FDA, *Policy for Certain REMS Requirements During the COVID-19 Public* Health *Emergency, Guidance for Industry and Health Care Professionals* 7 (Mar. 2020), https://www.fda.gov/media/136317/download; U.S. Dep't of Health & Human Servs. et al., *Conduct of Clinical Trials of Medical Products During the COVID-19 Public Health Emergency: Guidance for Industry, Investigators, and Institutional Review Boards* 3 (Mar. 2020; Jan. 27, 2021), https://www.fda.gov/media/136238/download (encouraging sponsors to "determine if in-person visits are necessary to fully assure the safety of trial participants" who have taken drugs not yet approved for safe use).

[54] Am. Med. Ass'n, *Code of Medical Ethics Opinion 1.1.6* (Nov. 14, 2016), https://www.ama-assn.org/delivering-care/ethics/quality.

the preliminary injunction is to *avoid* traveling to and contact with a health care provider which would necessarily be required to obtain any in-office procedure. Moreover, an in-office procedural abortion could expose a patient to even more risk of viral exposure than a medication abortion, due to the additional time at the practitioner's office and closer physical proximity. The FDA suggests there is no burden from forcing patients to have an in-clinic procedural abortion because medication abortion was not FDA-approved twenty years ago, but the government's job is not to turn back the clock on medical practice, let alone in a global pandemic. Medication abortion is a safe and effective treatment that millions of patients have chosen for very personal reasons, and there is no reason to require in-person dispensing, let alone require all patients to have an in-clinic procedure that could increase their risk of viral exposure.

Indeed, the REMS may prevent patients from obtaining abortion care at all. Because access to abortion is inconsistent across the United States and severely limited in many areas, many patients travel considerable distances to access care. Distance prevents access to care even under normal circumstances.[55] As medical facilities have closed and shifted resources during the pandemic, patients are forced to travel even greater distances to obtain care. This travel presents unneces-

[55] Fuentes & Jerman, *Distance Traveled to Obtain Clinical Abortion Care in the United States and Reasons for Clinic Choice*, 28 Journal of Women's Health 1623 (Dec. 10, 2019), https://www.liebertpub.com/doi/10.1089/jwh.2018.7496.

sary risk to patients without countervailing health benefits.[56] Alternatively, the pandemic may render patients simply unable to travel these distances and deprive patients of abortion care altogether.

For these reasons, in March and April 2020, dozens of health care organizations and hundreds of medical professionals (including some *amici*) urged the FDA to remove the in-person dispensing requirement for mifepristone during the SARS-CoV-2 pandemic, warning that "[t]he in-person requirements in the [ETASU] of the REMS for mifepristone, is hindering access to medication abortion care" and risks "jeopardizing the health and safety of both patients and health care providers."[57] 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 access needed care without unnecessary restrictions, particularly for medications that do not pose a risk of abuse or overdose,"[58] and that "these antiquated and superfluous requirements put patients and

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[56] This concern is particularly acute for patients who need to access the clinic using public transportation. *See* Rabin, *How a Bus Ride Turned Into a Coronavirus Superspreader Event*, N.Y. Times (Sept. 1, 2020), https://www.nytimes.com/2020/09/01/health/coronavirus-bus-china.html?referringSource=articleShare (describing a study in which 23 passengers on a bus were infected by a single asymptomatic passenger carrying SARS-CoV-2, and noting that "[i]t did not matter how far a passenger sat from the infected individual on the bus"). *See also* Shen et al., *Community Outbreak Investigation of Sars-CoV-2 Transmission Among Bus Riders in Eastern China*, JAMA INTERNAL MEDICINE (Sept. 1, 2020), https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2770172.

[57] Letter from health care organizations and providers to Janet Woodcock, Director of the Center for Drug Evaluation and Research, FDA (Apr. 28, 2020).

[58] Letter from John Cullen, Board Chair, American Academy of Family Physicians to Stephen Hahn, Commissioner, FDA (Mar. 25, 2020).

their physicians at risk, with no demonstrated benefit."[59] The District Court found that, despite requests from health care organizations, the FDA never reviewed the impact of requiring an in-person visit during the pandemic and continues to maintain the restriction.[60]

CONCLUSION

For the reasons stated above, *amici* urge this Court to affirm the grant of a preliminary injunction on Plaintiff's due process claim and reverse the denial of relief on the equal protection claim to reinstate relief for patients seeking medication abortion and miscarriage care during the pandemic.

Respectfully submitted.

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[59] 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).
[60] Mem. Op. at 53, *ACOG v. FDA*, 20-cv-1320 (D. Md. July 13, 2020) (Dkt. 90).

CERTIFICATE OF SERVICE

I hereby certify that on February 12, 2021, I filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Fourth Circuit by using the appellate CM/ECF system. All participants in the case are registered CM/ECF users and will be served by the appellate CM/ECF system.

/s/ Kimberly A. Parker
KIMBERLY A. PARKER

CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(a)(7)(C), the undersigned hereby certifies that this brief complies with the type-volume limitations of Fed. R. App. P. 32(a)(7)(B).

1. Exclusive of the exempted portions of the motion, as provided in Fed. R. App. P. 32(a)(7)(B), the motion contains 5,001 words.

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