

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' OPPOSITION TO DEFENDANTS' MOTION FOR STAY
PENDING APPEAL**

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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: 8/4/2020

Counsel for: Amici Curiae (above)

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 Gynecologic Surgeons, and Society of Ob/Gyn Hospitalists, and Society for Maternal-Fetal Medicine.

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INTERESTS OF AMICI CURIAE

Amici the 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”), and Society of Ob/Gyn Hospitalists (“SGOH”), 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 healthcare 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 curiae* certify that all parties have consented to the filing of this brief. No party’s counsel, nor any person other than *amici curiae*, authored or funded this brief.

SUMMARY OF ARGUMENT

Amici ask this Court to deny Defendants' motion to stay the District Court's order of a preliminary injunction enjoining 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 individuals seeking pregnancy termination or miscarriage care. The Food and Drug Administration ("FDA") requirement that mifepristone be dispensed in person is not only medically unnecessary but is burdensome and harmful to patients. While the FDA has relaxed certain in-person requirements for access to other drugs in response to the COVID-19 pandemic, instead empowering clinicians to use their medical judgment, it has not done so for mifepristone.

Consistent with guidance from the Centers for Disease Control and Prevention ("CDC") and the Department of Health and Human Services ("HHS"), healthcare professionals are attempting to limit certain person-to-person interactions and leverage telemedicine when, in the clinician's judgment, it is medically appropriate. Implicit in this guidance is the recognition that clinicians are best suited to determine when telehealth visits may be appropriate and when a patient requires an 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, resulting in unnecessary risk for patients during the current pandemic.

As the country works to contain SARS-CoV-2, while new cases continue to rise nationwide,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 or in arranging childcare for the travel period. Due to lack of private transportation, insufficient funds, and childcare burdens, 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 deny Defendant's request for a stay of the district court's well-reasoned, medically-supported order.

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,

² See Coronavirus Tracking Center, Johns Hopkins, *America is Reopening. But Have we Flattened the Curve?*, <https://coronavirus.jhu.edu/data/new-cases-50-states> (last accessed Aug. 2, 2020).

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.³ The FDA has noted that major adverse events from the use of mifepristone are “exceedingly rare, generally far below 0.1% for any individual adverse event.”⁴

Since 2000, under its authority to issue Risk Evaluation and Mitigation Strategies (“REMS”), the FDA has required that Mifeprex® 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. These REMS apply both to Mifeprex® and its generic mifepristone (“mifepristone”).

³ 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>.

⁴ 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

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 mifepristone REMS. 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, and a showing that eliminating the mifepristone REMS would increase access to treatment.⁵ The American Academy of Family Physicians (“AAFP”) adopted a similar resolution in 2018, noting that “the mifepristone REMS classification is not founded in evidence.”⁶

⁵ *2008 Annual Meeting, Appendix 1 – Reference Committee 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.”)

⁶ 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>.

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 nearly 3 million patients had used mifepristone between 2000 and 2019, “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; mifepristone is unique among them. In 2016, the FDA approved a revised protocol for administering mifepristone in which the patient may take the medication at home or in another chosen location,⁹ making it the only medication subject to an in-person dispensing requirement that a patient may take without clinical supervision and in the patient’s chosen location.¹⁰ Even if there were once a credible justification for the in-person dispensing requirement, this change would have made that justification obsolete. This revised policy conforms

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 *Questions and Answers on Mifeprex*, FDA (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#>.

¹⁰ Decl. of Allison Bryant Mantha in Supp. of Pls.’ Mot. for Prelim. Inj. ¶ 58, No. 20-1320 (D. Md. May 27, 2020) (Dkt. 11-3).

with what the science shows: the in-person dispensing requirement does not contribute in any way to the drug's strong safety profile. The in-person dispensing requirement is also not necessary to ensure adequate counseling regarding medication usage, as such counseling can be fully provided via telemedicine or at a prior in-person visit. Further, 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 REMS and may be obtained from a mail-order pharmacy that delivers the drug to the patient's home.¹¹

Evidence-based medical practice 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

¹¹ 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.

services are critical to the safe management of the COVID-19 pandemic.”¹² 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.”¹³ 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.”¹⁴

In the months since the SARS-CoV-2 public health crisis began, healthcare professionals and practices have evolved to include use of telemedicine where effective to treat patients for various issues, including many that traditionally 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

¹² *AMA Quick Guide to Telemedicine in Practice*, American Medical Association (July 27, 2020), <https://www.ama-assn.org/practice-management/digital/ama-quick-guide-telemedicine-practice>.

¹³ *Using Telehealth to Care for Patients During the COVID-19 Pandemic*, American Academy of Family Physicians (June 2, 2020), <https://www.aafp.org/patient-care/emergency/2019-coronavirus/telehealth.html>.

¹⁴ *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>.

would have to travel in order to obtain in-person care, whether and what precautions may be taken to prevent the spread of the virus as the patient travels and obtains care, and the patient's own condition and concerns. For example, AMA published a twenty-six page guide listing the telehealth services covered by Medicare, which includes diabetes care, post-natal care, and ventilation management.¹⁵ Similarly, Planned Parenthood affiliates now offer telehealth services in all fifty states.¹⁶ 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.¹⁷

Healthcare providers are best positioned to determine in what instances telehealth visits would be appropriate and when in-person visits would best serve

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 Abrams, *Planned Parenthood is Expanding Telehealth to All 50 States Amid the Coronavirus Pandemic*, TIME (April 14, 2020), <https://time.com/5820326/planned-parenthood-telehealth-coronavirus/>.

¹⁷ See *Telehealth Basics*, American Telemedicine Association, <https://www.americantelemed.org/resource/why-telemedicine/#:~:text=Improved%20Quality%20%E2%80%93%20Studies%20have%20consistently,in%20traditional%20in%2Dperson%20consultations> (last accessed Aug. 3, 2020).

the patient. In sum, healthcare professionals are following CDC guidance and safeguarding their patients' health by using telemedicine when, in their professional judgment, it is medically appropriate and in the patient's best interest 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 healthcare facility carries a risk of exposure to a deadly virus. The administration has supported the medical community's efforts to reduce the risk to patients and clinicians, including by advocating the use of telemedicine and mail order delivery of medications, where possible, and relaxing certain in-person and REMS requirements.¹⁸

Outbreaks of SARS-CoV-2 spread rapidly, creating hotspots where cases grow rapidly, putting the community at risk.¹⁹ Individuals from these locations

¹⁸ See, e.g., *Prepare Your Practice for COVID-19*, CDC (June 12, 2020), <https://www.cdc.gov/coronavirus/2019-ncov/hcp/preparedness-resources.html>; *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>.

¹⁹ Bravo and Haseman, *How Coronavirus Spread So Quickly and How You Can Slow It Down*, USA Today (July 21, 2020), <https://www.usatoday.com/pages/interactives/news/coronavirus-covid-spread-quickly-how-to-slow-it-down/>; Joseph, *The Coronavirus is Washing Over the U.S. These Factors Will Determine How Bad it Gets in Each Community*, Stat (Apr. 1, 2020), <https://www.statnews.com/2020/04/01/coronavirus-how-bad-it-gets-different-communities/>.

may travel across the country, sparking the growth of new hotspots.²⁰ Given the current state of the pandemic in the United States with new areas of uncontrolled spread continuing to emerge and the need to limit travel and in-person interactions, the district court's injunction permitting the delivery of mifepristone without an in-person visit wherever appropriate protects patients, providers, and public health in general. The SARS-CoV-2 risk is unlikely to subside until the national population has obtained widespread immunity to SARS-CoV-2, most likely with the assistance of a vaccine.

III. THE IN-PERSON DISPENSING REQUIREMENT HARMS CLINICIANS AND PATIENTS.

The in-person dispensing requirement prevents clinicians from exercising 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 patients the best possible care. AMA policy obligates physicians individually and collectively to ensure that the care patients receive is “safe, effective, patient centered, timely,

²⁰ See, e.g., Kelleher, *Travel Watch: Covid-19 is Spreading Along Interstate Highways, Per New Research*, Forbes (July 2, 2020), <https://www.forbes.com/sites/suzannerowankelleher/2020/07/02/travel-watch-covid-19-is-spreading-along-interstate-highways-per-new-research/#67aef5e66f05>.

efficient, and equitable.”²¹ Yet the REMS on mifepristone in the context of abortion and miscarriage care prevents clinicians from carrying out this obligation. Rather than evaluating the concerns of each patient individually, clinicians are forced to schedule in-person visits even when the clinician has determined that a visit would be detrimental to the 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, dozens of healthcare 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 [ETASU] of the REMS for mifepristone, is hindering access to medication abortion care” and by preventing clinicians from determining when in-person visits are necessary, risks “jeopardizing the health and safety of both patients and healthcare providers.”²² 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

²¹ *Code of Medical Ethics Opinion 1.1.6*, American Medical Association (Nov. 14, 2016), <https://www.ama-assn.org/delivering-care/ethics/quality>.

²² Letter from healthcare organizations and providers to Janet Woodcock, Director of the Center for Drug Evaluation and Research, FDA (Apr. 28, 2020).

not pose a risk of abuse or overdose,”²³ and that “these antiquated and superfluous requirements put patients and their physicians at risk, with no demonstrated benefit.”²⁴ Nevertheless, the FDA continues to maintain the restriction requiring an in-person visit during the public health crisis. The injunction entered by the district court is necessary to ensure patients seeking abortion care, like other patients, can access care in the safest manner – based on their clinicians’ best medical judgment. There is no medical reason to stay enforcement of the injunction, and indeed, ordering that the injunction be stayed would create serious medical risks for both patients and practitioners.

CONCLUSION

For the reasons stated above, *amici* urge this Court to deny the Defendants’ motion for a stay pending appeal.

²³ Letter from John Cullen, Board Chair, American Academy of Family Physicians to Stephen Hahn, Commissioner, FDA (Mar. 25, 2020).

²⁴ 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: August 4, 2020

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on August 4, 2020, 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.

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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 limitation of Fed. R. App. P. 32(a)(7)(B).

1. Exclusive of the exempted portions of the brief, as provided in Fed. R. App. P. 32(a)(7)(B), the brief contains 2,599 words.

2. The brief has been prepared in proportionally spaced typeface using Microsoft Word 2003 in 14 point Times New Roman font. As permitted by Fed. R. App. P. 32(a)(7)(C), the undersigned has relied upon the word count feature of this word processing system in preparing this certificate.

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