No. 20A34

IN THE

Supreme Court of the United States

UNITED STATES FOOD AND DRUG ADMINISTRATION, et al.,
Applicants,

v.

AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, et al.,
Respondents,

ON APPLICATION FOR A STAY OF THE INJUNCTION TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

MOTION FOR LEAVE TO FILE BRIEF OF AMICI CURIAE MEDICAL ASSOCIATIONS

Amici 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 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 Gynecology Oncology ("SGO"), Society of Gynecologic Surgeons ("SGS"), Society of OB/GYN Hospitalists ("SOGH"), and Society for Maternal-Fetal Medicine ("SMFM"), through their undersigned counsel, respectfully seek leave to file the accompanying brief as *amici curiae* in support of Respondents, and in opposition to the application for a stay, (i) without 10 days' advance notice to the parties of amici's intent to file as ordinarily required by Sup. Ct. R. 37.2(a), and (ii) in an unbound format on 8½-by-11-inch paper. All parties have consented to the filing of the brief without such notice.

Proposed *amici* are medical and public health associations that are familiar with the clinical use of mifepristone (brand name Mifeprex®) for reproductive health care.

The AMA is the largest professional association of physicians, residents, and medical students in the United States. Additionally, through state and specialty medical societies and other physician groups, seated in the AMA's House of Delegates, substantially all U.S. physicians, residents, and medical students are represented in the AMA's policy-making process. The objectives of the AMA are to promote the science and art of medicine and the betterment of public health. AMA members practice in all fields of medical specialization and in every state.

AAFP, headquartered in Leawood, Kansas, is the national medical specialty society representing family physicians. Founded in 1947 as a not-for-profit

corporation, its 136,700 members are physicians and medical students from all 50 states, the District of Columbia, Guam, Puerto Rico, the Virgin Islands, and the Uniformed Services of the United States. AAFP seeks to improve the health of patients, families, and communities by advocating for the health of the public and serving the needs of its members with professionalism and creativity.

AAP is a nonprofit professional organization founded in 1930 dedicated to the health, safety, and well-being of infants, children, adolescents, and young adults. Its membership is comprised of 67,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists. AAP has become a powerful voice for child and adolescent health through education, research, advocacy, and the provision of expert advice. AAP has worked with the federal and state governments, health care providers, and parents on behalf of America's families to ensure the availability of safe and effective reproductive health services.

ACNM is the professional association that represents the interests of 12,600 certified nurse-midwives ("CNMs") and certified midwives ("CMs") in the United States. ACNM promotes excellence in midwifery education, clinical practice, and research. With roots dating to 1929, ACNM's members are primary care providers for women throughout the lifespan, with a special emphasis on pregnancy, childbirth, and gynecologic and reproductive health.

Founded in 1934 and representing 2,700 providers, ACOOG is a nonprofit, nonpartisan organization committed to excellence in women's health through the holistic practice of obstetrics and gynecology. The purpose of the ACOOG is to educate and support osteopathic physicians to improve the quality of life for women by promoting programs that are innovative, visionary, inclusive, and socially relevant.

AGOS is the premier national organization comprised of leading experts in Obstetrics and Gynecology. For over a century, it has championed the highest quality of care for women and the science needed to improve women's health.

ASRM is a multidisciplinary not-for-profit organization dedicated to the advancement of the science and practice of reproductive medicine. Its members include approximately 8,000 professionals. ASRM accomplishes its mission through the pursuit of excellence in education and research and through advocacy on behalf of patients, physicians, and affiliated health care providers.

NAF is the professional association of abortion providers. Its mission is to unite, represent, serve, and support abortion providers in delivering patient-centered, evidence-based care. NAF's members include over 400 private and non-profit clinics, Planned Parenthood affiliates, women's health centers, physicians' offices, and hospitals. For over 40 years, NAF has ensured the safety and high quality of abortion practice by providing standards of care, protocols, and accredited continuing medical education. NAF members adhere to NAF's evi-

dence-based Clinical Policy Guidelines for Abortion Care (CPGs), which NAF formulates and continuously updates based on the expertise of its membership and Board. NAF's CPGs set the standards for evidence-based abortion care.

NASPAG, founded in 1986, is dedicated to providing multidisciplinary leadership in education, research, and gynecologic care to improve the reproductive health of youth. Its focus is to serve and be recognized as the lead provider in Pediatric and Adolescent Gynecology ("PAG") education, research, and clinical care, conduct and encourage multidisciplinary and inter-professional programs of medical education and research in the field of PAG, and advocate for the reproductive well-being of children and adolescents and the provision of unrestricted, unbiased, and evidence based practice of PAG.

The NPWH mission is to ensure the provision of quality primary and specialty health care to women of all ages by women's health and women's health focused nurse practitioners. Its mission includes protecting and promoting a woman's right to make her own choices regarding her health within the context of her personal, religious, cultural, and family beliefs. NPWH will strive to continuously improve access and quality of health care for women. This will be accomplished through excellence and innovation in continuing education and professional development; leadership in policy, practice, and research; and through support and services for our members.

Planned Parenthood is the oldest and largest provider of reproductive health care in the United States. Its mission is to provide comprehensive reproductive health care services and education and to advocate for public policies that ensure access to health services. Planned Parenthood affiliates operate more than 600 health centers that provide care to approximately 2.4 million individuals each year, and have provided care to one in five women in the United States. In particular, Planned Parenthood is at the forefront of providing high-quality reproductive health care to individuals and communities facing serious barriers to obtaining such care—especially individuals with low income, individuals in rural and other medically underserved areas, immigrant populations, LGBTQ individuals, and communities of color. Planned Parenthood is also at the forefront of developing and promoting evidence-based standards for reproductive health care, including the use of telemedicine to expand access to care.

RHAP is a national nonprofit organization that mobilizes, trains, and supports clinicians to make reproductive health care accessible to everyone. RHAP focuses on three key areas: abortion, contraception, and management of early pregnancy loss. RHAP teaches and supports providing evidence-based clinical care in an unbiased, patient-centered manner.

SFP is the source for science on abortion and contraception. SFP represents approximately 800 scholars and academic clinicians united by a shared interest in advancing the science and clinical care of family planning. The pillars of

SFP's strategic plan are: 1) building and supporting a multidisciplinary community of scholars and partners who have a shared focused on the science and clinical care of family planning, 2) supporting the production of research primed for impact, 3) advancing the delivery of clinical care based on the best available evidence, and 4) driving the uptake of family planning evidence into policy and practice.

SGIM is a member-based internal medical association of over 3,300 of the world's leading academic general internists, who are dedicated to improving the access to care for all populations, eliminating health care disparities, and enhancing medical education. SGIM's mission is to cultivate innovative educators, researchers, and clinicians in academic general internal medicine, leading the way to better health for everyone. The members of the Society advance the practice of medicine through their commitment to providing comprehensive, coordinated, and cost-effective care to adults, educating the next generation of outstanding physicians, and conducting cutting-edge research to improve quality of care and clinical outcomes of all patients.

The SGS membership is comprised of the key leaders in gynecologic surgery. The SGS mission is to promote excellence in gynecologic surgery through acquisition of knowledge and improvement of skills, advancement of basic and clinical research, and professional and public education.

The SGO is the premier medical specialty society for health care professionals trained in the comprehensive management of gynecologic cancers. With 2,000 members representing the entire gynecologic oncology team in the United States and abroad, the SGO contributes to the advancement of women's cancer care by encouraging research, providing education, raising standards of practice, advocating for patients and members, and collaborating with other domestic and international organizations. In that mission, the SGO strives to ensure access to women's health care as part of an overall prevention strategy for gynecologic cancer.

SOGH is a rapidly growing group of physicians, midwives, nurses, and other individuals in the health care field who support the OB/GYN Hospitalist model. SOGH is dedicated to improving outcomes for hospitalist women and supporting those who share this mission. SOGH's vision is to shape the future of OB/GYN by establishing the hospitalist model as the care standard and the Society values excellence, collaboration, leadership, quality, and community.

SMFM, founded in 1977, is the medical professional society for obstetricians who have additional training in the area of high-risk, complicated pregnancies. Representing over 5,000 members, SMFM supports the clinical practice of maternal-fetal medicine by providing education, promoting research, and engaging in advocacy to reduce disparities and optimize the health of high-risk preg-

nant women and their babies. SMFM and its members are dedicated to ensuring that medically appropriate treatment options are available for high-risk women.

The Court should grant *amici* leave to file the accompanying brief. *Amici*'s extensive experience in patient care provides them with a special understanding of the practice of medicine, and how that practice has adapted in response to the unique conditions created by the COVID-19 pandemic. *Amici* have firsthand experience in how clinicians have adopted or increased the use of telemedicine and delivery of prescriptions through the mail, even in situations that traditionally might have involved an office visit, and have been supportive of the expanded availability of telehealth. *Amici* are thus uniquely qualified to assist this Court in evaluating the in-person dispensing requirement in the Risk Evaluation and Mitigation Strategy ("REMS") program for mifepristone (brand name Mifeprex®) and its effect on patients, including vulnerable populations such as native people, people of color, and low-income people, who face heightened barriers in attempting to access health care at all times, but particularly during the current pandemic.

The proposed brief would support respondents' opposition to the motion to stay the District Court's order of a preliminary injunction. No party's counsel authored the brief in whole or in part. No party or its counsel has contributed money to fund the preparation and/or submission of the brief.

The proposed brief is attached as Exhibit 1.

Respectfully submitted,

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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"), 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 Gynecology Oncology ("SGO"), 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 200,000 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 when 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 provide the medications they deem necessary for their patients via telemedicine so that their patients can stay closer to home and avoid travel and interactions that would put them, as well as providers, 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 an estimated 3.7 million people in the U.S. have safely used mif-

[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 (visited Sept. 3, 2020).

epristone to terminate a 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. One of those requirements -- that it be dispensed in person -- is the subject of this lawsuit.

Based on clear-cut medical evidence, a federal district court preliminarily enjoined that requirement only during the COVID-19 pandemic to promote patient safety during this unprecedented time. As the court properly found, the in-person dispensing requirement results 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 dispensing requirement particularly harms low-income patients and patients of color. 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 dispensing requirement during the pandemic, or to have these risks prevent them from being able to access abortion at all. The preliminary injunction entered by the

[3] FDA, Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2018, https://www.fda.gov/media/112118/download (visited Sept. 7, 2020).

district court protects against these risks while still ensuring safe use of mifepristone during the period of time that this public health crisis remains.

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 reject the FDA's request to stay 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. Sixty percent of abortions performed up to 10 weeks of pregnancy are medication abortions.[4] Similarly, a significant number of medical facilities that provide abortions only offer medication abortions.[5] 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.[6] 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 in-

[4] Jones & Witwer, *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#.

[5] *Id.* (one-quarter of nonhospital abortion providers (269/1069) and one-third of clinic abortion providers (269/808) offer only medication abortion).

[6] *Medical Versus Surgical Abortion*, University of California San Francisco Health, https://www.ucsfhealth.org/education/medical-versus-surgical-abortion (visited Sept. 7, 2020).

struments inserted into their vagina.[7] For patients with certain medical conditions, medical abortion is their safest option because it allows them to avoid additional medical risk from a procedural abortion.[8] In the two decades since its FDA approval, mifepristone has been safely and widely used to treat patients who seek abortion (more than 3.7 million people); more recently, in accordance with high-quality evidence, it has also been used to improve the efficacy and safety of miscarriage care.[9]

While the FDA and *amici* States supporting the stay attempt to suggest that mifepristone is a dangerous medication, in fact, 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."[10] 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 to those of commonly prescribed and

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[7] *See Planned Parenthood of the Heartland v. Reynolds ex re. State*, 915 N.W.2d 206, 215 (Iowa 2018).

[8] ACOG, *Practice Bulletin 225: Medication Abortion Up to 70 Days Gestation* at 2 (Aug. 2020), https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2020/08/medication-abortion-up-to-70-days-gestation.

[9] 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.

[10] *See* FDA Ctr. For Drug Eval. & Research, *Medical Review, Application No. 020687Orig1s020* at 47, (Mar. 29, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf.

over-the-counter medications such as antibiotics and NSAIDs such as aspirin and ibuprofen.[11]

Despite mifepristone's extremely strong safety profile, the FDA since 2000 has imposed a Risk Evaluation and Mitigation Strategy ("REMS") requiring, among other things, 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).[12] 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. Nor does it require that the patient take the mifepristone at the health center.

I. THE IN-PERSON DISPENSING REQUIREMENT TO OBTAIN MIFEPRISTONE IS NOT MEDICALLY NECESSARY

Even before the SARS-CoV-2 pandemic, there was an expert consensus that the in-person dispensing requirement for mifepristone is outdated and medically unnecessary, and that it harms patients by restricting access to care. The National Academies report confirmed that "[t]here is no evidence that the dispensing or taking of mifepristone tablets requires the physical presence of a cli-

[11] Nat'l Acads. of Sci., Eng'g, & Med., *The Safety and Quality ofAbortion Care in the United States* 79 (2018) ("NASEM Report"]), http://nap.edu/24950.

[12] This REMS applies both to Mifeprex® and its generic mifepristone ("mifepristone").

nician."[13] 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 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.[14] The American Academy of Family Physicians ("AAFP") adopted a similar resolution in 2018.[15]

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."[16] 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%)."[17]

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[13] NASEM Report at 79.

[14] Am. Med. Ass'n, *2018 Annual Meeting, Appendix 1 – Reference Committee Reports*, https://www.ama-assn.org/system/files/2018-11/a18-reference-committee-reports.pdf. *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.")

[15] Porter, Am. Acad. of Family Physicians, *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.

[16] 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.

[17] *Id.*

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 telemedicine.[18] And contrary to what *Amici* Indiana et al. [Ind.] 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."[19] 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, including a 300-mg formulation of mifepristone used in treatment of Cushing's syndrome, and serve as barriers to access without supporting demonstrated improvements to patient safety or outcomes."[20]

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 a revised protocol

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[18] Creinin et al., *Medication Abortion up to 70 Days of Gestation*, Contraception Journal (Aug. 14, 2020), https://www.contraceptionjournal.org/article/S0010-7824(20)30301-2/fulltext.

[19] *Id.* Even for those patients who require in-person screening, the district court's injunction gives providers the necessary flexibility to reduce medically unnecessary visits. For example, the injunction would allow patients who need additional time to consider their options after being screened to have the medications provided by mail rather than having to return to the health center, if they decide to go forward.

[20] 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.

for administering mifepristone in which the patient may take the medication at home or in another chosen location,[21] 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.[22] 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 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.[23] This demonstrates that even the FDA has determined that mifepristone need not be dispensed in-person.

The in-person dispensing requirement is 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 vis-

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[21] 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#.

[22] 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).

[23] *See generally* FDA Ctr. For Drug Eval. & Research, *Risk Assessment and Risk Mitigation Review(s)* (Jan. 12, 2007), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/202107Orig1s000RiskR.pdf.

it. 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 in-person counseling requirement for opioids for the duration of the public health emergency caused by the COVID-19 pandemic.[24] In other words, the government now permits doctors to prescribe opioids to new patients and counsel them regarding their use without a single in-person visit despite the significantly greater safety risk and counseling challenges that opioids present.[25] 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 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

Contrary to *Amici* [Indiana..]'s representations, SARS-CoV-2 and the disease it causes, COVID-19, are still uncontained in this country and present a pub-

[24] Letter from Thomas W. Prevoznik to Qualifying DEA Practitioners (March 31, 2020), https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-022)(DEA068)%20DEA%20SAMHSA%20buprenorphine%20telemedicine%20%20(Final)%20+Esign.pdf.

[25] 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.

lic health emergency. Limiting person-to-person interaction is 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."[26] 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.[27] ACOG has put out extensive guidance to promote the use of telemedicine wherever appropriate.[28] 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."[29] In light of the pandemic, in March 2020, the AMA, Physicians Foundation, Florida Medical Association, Massachusetts Medical Society, and Texas Medical Association announced the

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[26] Am. Med. Ass'n, *AMA Quick Guide to Telemedicine in Practice* (July 27, 2020), https://www.ama-assn.org/practice-management/digital/ama-quick-guide-telemedicine-practice.

[27] 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.

[28] 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 (last updated Aug. 12, 2020).

[29] Am. Acad. of Family Physicians, *Using Telehealth to Care for Patients During the COVID-19 Pandemic* (June 2, 2020), https://www.aafp.org/patient-care/emergency/2019-coronavirus/telehealth.html.

launch of a Telehealth Initiative to "help[] physicians implement telehealth services."[30]

Following this extensive guidance and their own best medical judgment, health care professionals and practices have swiftly evolved to include use of telemedicine where effective to treat patients for various issues, including many that traditionally involved an in-person evaluation. For example, Planned Parenthood affiliates now offer telehealth services in all fifty states.[31] 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.[32]

Health care professionals are following CDC and the Centers for Medicare and Medicaid Services ("CMS") (which is also part of HHS) and safeguarding their patients' health by using telemedicine when it is medically appropriate and in the patient's best interest to do so. Indeed, CMS continues to recommend op-

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[30] 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.

[31] 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/.

[32] *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).

timizing telehealth services "to minimize the need for in-person services" and specifically urges "individuals at higher risk for severe COVID-19 illness" to "continue to shelter in place unless their conditions warrant in-person health care.[33] 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.[34]

This flexibility in providing care is important because the combined effects of the pandemic, including office closures and the need to travel, are forcing patients to delay seeking health care. A May 2020 Kaiser Health poll found that 48% of Americans said that they or a family member has skipped or delayed medical care because of the pandemic; this caused the patient's condition to worsen for 11% of respondents.[35] In a June survey, one in three women reported that they had to delay or cancel a visit for sexual or reproductive care or had

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

[34] *Id.*; CDC, *If You Are Pregnant, Breastfeeding or Caring for Young Children* (June 25, 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

[35] *Nearly Half of Americans Delayed Medical Care Due to Pandemic*, Kaiser Health News (May 27, 2020), https://khn.org/news/nearly-half-of-americans-delayed-medical-care-due-to-pandemic/.

trouble accessing birth control.[36] These barriers were more common among Black and Hispanic patients than White patients.[37]

The *Amici* States urging a stay claim that the SARS-CoV-2 concerns are "remote" and that in-person services no longer pose a risk. [Indiana et al. Amicus Br. 14.] This could not be further from the truth. The United States is quickly approaching 200,000 deaths and 6 million cases, with the most recent million emerging in just 22 days.[38] Outbreaks of SARS-CoV-2 continue to spread, creating hotspots where cases grow rapidly, putting the community at risk.[39] Individuals from these locations may travel across the country, sparking the growth of new hotspots.[40] 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

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[36] 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#.

[37] *Id.*

[38] *U.S. Coronavirus Cases Top 6 Million*, N.Y. Times (Aug. 30, 2020, updated Sept. 8, 2020), https://www.nytimes.com/2020/08/30/world/coronavirus-covid.html?searchResultPosition=1.

[39] Bravo & 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/.

[40] *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.

delivery of mifepristone without an in-person visit wherever appropriate protects 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 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 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.[41] There is no medical basis for mifepristone to be treated differently.

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

The in-person dispensing requirement results 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

[41] *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.

equitable."[42] Yet the REMS on mifepristone in the context of abortion and miscarriage care 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 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, the FDA's suggestion that patients could instead have in-clinic procedural abortions makes no common or medical sense. The purpose of 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 would 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

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

require in-person dispensing, let alone require all patients to have an in-clinic procedure that would 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.[43] 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 unnecessary risk to patients without countervailing health benefits.[44] Alternatively, the pandemic may render patients simply unable to travel these distances and deprive patients of abortion care altogether.

For these reasons, dozens of health care organizations and hundreds of medical professionals (including some *amici*) have urged the FDA to remove the in-person dispensing requirement for mifepristone during the SARS-CoV-2 epidemic, warning that "[t]he in-person requirements in the [ETASU] of the REMS

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

[44] 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.

for mifepristone, is hindering access to medication abortion care" and risks "jeopardizing the health and safety of both patients and health care providers."[45] 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,"[46] and that "these antiquated and superfluous requirements put patients and their physicians at risk, with no demonstrated benefit."[47] 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. Staying the injunction would create serious medical risks for both patients and practitioners.

CONCLUSION

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

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

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

[47] 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).

Respectfully submitted.

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CERTIFICATE OF SERVICE

I, Kimberly A. Parker, a member of the bar of this Court, hereby certify that on September 8, 2020, all parties required to be served were served copies of the foregoing document via overnight courier at the addresses listed below:

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