20-1784, 20-1824, 20-1970

IN THE

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,

—and—

STATE OF INDIANA, *et al.*,

Appellants.

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

BRIEF OF 157 MEMBERS OF THE UNITED STATES CONGRESS AS *AMICI CURIAE* IN SUPPORT OF PLAINTIFFS-APPELLEES

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rules of Appellate Procedure 26.1 and 29, and Local Rule 26.1, the undersigned counsel of record certifies that none of the *amici curiae* is a nongovernmental entity with a parent corporation or a publicly held corporation that owns 10 percent or more of its stock. This representation is made in order that the judges of this Court may evaluate possible disqualification or recusal.

Dated: February 12, 2021

/s/ Courtney M. Dankworth
COURTNEY M. DANKWORTH

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STATEMENT OF INTEREST OF *AMICI CURIAE*[1]

Amici curiae are a group of 24 United States Senators and 133 Members of the United States House of Representatives. Together, they represent 33 states and the District of Columbia.

As Members of Congress, *amici* are deeply committed to defending their constituents' access to reproductive health care. *Amici* include members of Congress who seek to protect their constituents' constitutional rights at issue in this case. Furthermore, *amici* are committed to protecting the health and safety of their constituents during the COVID-19 pandemic. Therefore, *amici* seek to ensure that medically unnecessary in-person requirements do not force their constituents to confront the risk of a deadly virus in order to access abortion and miscarriage care at this time.

INTRODUCTION

A patient's access to a safe and legal abortion is a constitutional right. *See Roe v. Wade*, 410 U.S.113 (1973). Personal decisions on whether to terminate a pregnancy are matters that involve "the most intimate and personal choices a person may make in a lifetime, choices central to personal dignity and autonomy,

[1] Pursuant to Fed. R. App. P. 29(a)(4)(E), counsel for *amici curiae* states that no counsel for a party authored the brief in whole or in part, and no person other than *amici curiae* or their counsel contributed money to fund the preparation or submission of this brief. *Amici* file this brief with the consent of all parties.

[and] are central to the liberty protected" by our Constitution. *Planned Parenthood of Se. Pennsylvania v. Casey*, 505 U.S. 833, 851 (1992). Despite the Supreme Court's recognition that the decision whether to bear a child is a Constitutional right that should be free from "unwarranted government intrusion," *id.*, patients continue to face onerous restrictions on their ability to access abortion care, even during a global health pandemic. This case involves one such restriction. Although Defendants-Appellants know the risks involved with traveling and in-person interactions during this time, they continue to impose mifepristone's Risk Evaluation and Mitigation Strategy ("REMS") requirements during the COVID-19 pandemic.

In 2000, the U.S. Food and Drug Administration ("FDA") approved Mifeprex®, the brand name for the drug mifepristone, as part of a two-drug regimen to end early pregnancies. The drug, taken in combination with another drug, misoprostol, can induce a medication abortion similar to an early miscarriage. More recently, the mifepristone-misoprostol regimen has also been commonly used to treat early pregnancy loss (i.e., miscarriage) in addition to early pregnancy termination. Though misoprostol can be used alone, mifepristone has

been shown to increase the efficacy of misoprostol for both miscarriage treatment and abortion.[2] In 2019, FDA approved a generic version of mifepristone.

When FDA approves a new drug, it may, under very limited circumstances, impose additional restrictions on the drug beyond its approved labeling called a Risk Evaluation and Mitigation Strategy or REMS, in order to ensure that the drug's benefits outweigh its risks. *See* 21 U.S.C. § 355-1(a)(1). "Elements to Assure Safe Use" ("ETASU") are the most burdensome category of REMS.

Mifepristone is subject to several ETASUs. One ETASU requires that mifepristone be dispensed to the patient in person at a hospital, clinic, or medical office. This requirement applies even though (1) FDA does not require any medical services to be provided to the patient when they pick up the medication, and (2) the patient may self-administer the drug in the location of their choice, such as their home. In fact, of the 20,000 FDA regulated drugs, mifepristone is the only drug that must be dispensed in a hospital, clinic, or medical office under the supervision of a certified prescriber, but may be self-administered by the patient. Another ETASU requires the patient to sign a special form in person at the dispensing hospital, clinic, or medical office in order to be handed the medication,

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[2] Elizabeth J. Raymond, et al., *Efficacy of Misoprostol Alone for First-Trimester Medical Abortion,* 133 Obstetrics & Gynecology 137, 137 (2012); Courtney A. Schreiber, et al., *Mifepristone Pretreatment for the Medical Management of Early Pregnancy Loss*, 378 New Eng. J. of Med. 2161, 2169 (2018).

even though FDA does not require any counseling to be provided to the patient at the time the patient signs the form, and all required medical counseling and eligibility assessments may be done via telemedicine.

This uniquely stringent regulatory regime imposes a number of medically unnecessary obstacles. Mifepristone's efficacy and safety is well established. Mifepristone has been used by patients to end early pregnancies for over 20 years. According to FDA's 2016 medical review of the drug, major adverse events associated with the drug are "exceedingly rare" and "generally far below 0.1% for any individual adverse event."[3] Moreover, medical counseling and assessments associated with mifepristone may be done remotely. *See* JA at 145–46. "[M]aintaining the FDA's in-person requirements for mifepristone during the pandemic not only treats abortion exceptionally, it imposes an unnecessary, irrational, and unjustifiable undue burden on [patients] seeking to exercise their right to choose." *Food & Drug Admin. v. Am. Coll. of Obstetricians & Gynecologists*, 141 S. Ct. 578, 585 (2021) (Sotomayor, J., dissenting).

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[3] *See infra* note 6. *See also* U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Res., Medical Review of Mifeprex 1, 47 (Mar. 29, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf; U.S. Food & Drug Admin., Full Prescribing Information for Mifeprex 1,7-8, Tables 1 & 2 (Mar. 2016), https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf.

Under normal circumstances, the REMS requirements imposed by FDA on mifepristone are onerous, especially for low-income, rural, or medically underserved patients. With the onset of the novel coronavirus, the in-person requirements also have become dangerous, requiring patients to needlessly travel, interact with others, and risk contracting COVID-19.

Recognizing the increased risks of COVID-19 infection associated with traveling and in-person interactions, the CDC has encouraged patients and medical professionals to utilize telemedicine and mail order prescription and delivery services as a means to decrease in-person contact for individuals who need medical care at this time. FDA and the Department of Health and Human Services ("HHS") have promoted the use of telemedicine in lieu of in-person visits for a variety of drugs, many of which carry greater health risks than mifepristone. Yet FDA continues to enforce the unnecessary and burdensome in-person REMS requirements for mifepristone. Thus, *amici* ask the Court to affirm the District Court's nationwide preliminary injunction on Plaintiffs-Appellees' due process claim and reverse the District Court's denial of Plaintiff-Appellees' equal protection claim to reinstate urgently needed relief for miscarriage and medication abortion patients and their medical providers during the pandemic.

ARGUMENT

I. FDA subjects mifepristone patients and providers to special in-person requirements, despite the drug's proven safety and widespread use.

More than four million people in the United States have used mifepristone to end a pregnancy.[4] Recent estimates indicate that medication abortions comprise 60% of all abortions in the first 10 weeks of pregnancy.[5] While millions of patients have taken mifepristone, serious adverse events have been exceedingly rare. Studies have shown that mifepristone-induced abortions have an estimated mortality rate of just 0.00063%, which is 14 times safer than carrying a pregnancy to term.[6]

On March 29, 2016, FDA recognized the drug's proven safety record, noting that medication abortion's "efficacy and safety have become well-established by both research and experience, and serious complications have proven to be

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[4] Danco, *Mifeprex in the United States*, https://www.earlyoptionpill.com/what-is-mifeprex/mifeprex-in-theunited-states.

[5] Rachel K. 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.

[6] Mifeprex REMS Study Group, *Sixteen Years of Overregulation: Time to Unburden Mifeprex*, 376 New Eng. J. of Med. 790, 791 (2017); Elizabeth G. Raymond & David A. Grimes, *The Comparative Safety of Legal Induced Abortion and Childbirth in the United States*, 119 Obstetrics & Gynecology 215, 216 (2012).

extremely rare."[7] Consistent with this determination, FDA updated the labeling for mifepristone to allow the drug to be self-administered by a patient at home, rather than in the presence of a health care provider.[8]

Despite mifepristone's well-established safety, FDA subjects it to stringent regulations, forcing patients who seek mifepristone for either pregnancy termination or pregnancy loss to overcome significant obstacles to obtain their prescribed medication. Mifepristone is subject to three ETASUs, two of which are relevant here: the in-person dispensing ETASU and the Patient Form ETASU.[9] *See* 21 U.S.C. § 355-1(f)(3).

The in-person dispensing ETASU ("ETASU C," pursuant to 21 U.S.C. § 355-1(f)(3)(C)) mandates that mifepristone only be dispensed in a hospital, clinic, or medical office, under the supervision of a certified prescriber. As a result, patients cannot obtain mifepristone from either a mail order or retail pharmacy, or

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[7] U.S. Food & Drug Admin., Ctr. for Drug Evaluation and Res., *Application Number 020687Orig1020* (Mar. 29, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf.

[8] *Id.*

[9] A third ETASU, the Prescriber Certification ETASU ("ETASU A," pursuant to 21 U.S.C. § 355-1(f)(3)(A)), requires health care providers who wish to prescribe mifepristone to attest to their clinical abilities and agree to comply with reporting requirements.

by mail or delivery from their clinician. Instead, they must travel in order to obtain their medication in person.

FDA imposes this restriction even though patients are allowed to take the medication at the location of their choice. In other words, even though FDA does not require mifepristone to be *administered* under the supervision of a certified prescriber, this ETASU mandates that it must be *dispensed* in person under the supervision of a certified prescriber. As stated above, FDA does not require any medical counseling or eligibility assessments to be completed at the time the patient picks up the medication. Out of the 20,000 drugs that FDA regulates, FDA subjects only 17 to in-person dispensing requirements. With the exception of mifepristone, all the drugs subject to this ETASU must also be administered by health care personnel. Mifepristone is the only one that may be self-administered without clinical supervision.[10] *See* JA at 153–54; 1352.

The Patient Form ETASU ("ETASU D," pursuant to 21 U.S.C. § 355-1(f)(3)(D)) requires the prescriber and patient to review and sign a form that

[10] Misoprostol, which is taken in conjunction with mifepristone for both abortions and miscarriage treatment, is not subject to REMS requirements and may be obtained either through a mail order or retail pharmacy, or directly by mail. In 2016, FDA clarified that misoprostol could be obtained and self-administered without an in-person requirement partly to "[m]inimize loss of income (for childcare or missed days of work)" and to "avoid another visit and the time, transportation, loss of work, inconvenience, etc. that such a visit would involve." JA at 1462.

contains information about mifepristone's regimen and risks in person at a hospital, clinic, or medical office. This counseling may be done virtually via telemedicine, and the patient can sign the form later when given the prescription. A copy of this form is then placed in the patient's chart, and another copy is given to the patient for their own records. The information included in this form is also in mifepristone's labeling, which comes with the prescription.

Taken together, these in-person requirements constitute a strict regulatory regime that places significant obstacles between patients and their prescribed medications. These barriers cannot be reconciled with the demonstrated safety of mifepristone. Even before the pandemic, mifepristone stood apart among FDA-regulated drugs, and is unique in the requirements FDA imposes on its dispensation. As noted above, even FDA itself has acknowledged mifepristone's proven safety record. Despite that acknowledgment, these in-person requirements persist, continuing to impede patients' access to this medication. During the coronavirus pandemic, these restrictions have become even more onerous, subjecting patients to the risk of contracting a deadly virus.

II. As COVID-19 continues to surge, travel entails inherent risk.

On January 31, 2020, Defendant HHS Secretary issued a nationwide public health emergency in light of the number of confirmed cases of the novel

coronavirus.[11] Since that date, the Secretary has renewed this determination nationwide four times on April 21, 2020, July 23, 2020, October 2, 2020, and January 7, 2021.[12]

While the world's understanding of the novel coronavirus continues to evolve, it is undeniable that travel and in-person interactions increase one's risk of exposure to COVID-19. Despite the CDC's warning that travel "can increase [one's] chance of spreading and getting COVID-19" and that "staying home is the best way to protect yourself and others,"[13] Defendants-Appellants argue that the District Court "was mistaken in concluding that the pandemic creates a *substantial* obstacle to obtaining medication abortions using [mifepristone]" because a "one time clinic visit, even if an obstacle, is not a substantial one." *See* Defs'-Appellants/Cross-Appellees' Opening Br. at 31, ECF. No. 47 (emphasis in

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[11] U.S. Dep't of Health and Human Servs., *Determination that a Public Health Emergency Exists* (Jan. 21, 2020), https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx.

[12] U.S. Dep't of Health and Human Servs., *Renewal of Determination that a Public Health Emergency Exists* (Jan. 7, 2021), https:// https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-07Jan2021.aspx.

[13] Ctrs. For Disease Control & Prevention, *Domestic Travel During the COVID-19 Pandemic* (last visited Jan. 29, 2021), https://www.cdc.gov/coronavirus/2019-ncov/travelers/travel-during-covid19.html.

original). Not so. Any travel outside of one's residence risks exposure to COVID-19.

According to the CDC, as of February 8, 2021, 27,127,858 individuals in the United States have been infected with COVID-19, and 470,110 individuals have died from the virus, and these numbers will continue to rise.[14] The District Court noted that the number of daily coronavirus cases in the United States had grown exponentially since it issued the preliminary injunction in July, rising from 44,000 per day in July to over 200,000 per day in December. *See Am. Coll. of Obstetricians & Gynecologists v. United States Food & Drug Admin.*, No. CV TDC-20-1320, 2020 WL 7240396, at *2 (D. Md. Dec. 9, 2020). Since then, COVID-19 infection rates and deaths have continued to surge. Dr. Robert R. Redfield, director of the CDC, warned that this winter will be "the most difficult time in the public health history of this nation."[15] Dr. Anthony Fauci, head of the National Institute of Allergy and Infectious Diseases, sounded a similar note: "All

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[14] Ctrs. For Disease Control & Prevention, *CDC COVID Data Tracker* (last visited Feb. 11, 2021), https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days.

[15] Sheila Kaplan, *Redfield Warns This Winter May Be 'The Most Difficult Time in the Public Health History' of the U.S.*, N.Y. TIMES (Dec. 2, 2020), https://www.nytimes.com/live/2020/12/02/world/covid-19-coronavirus/redfield-warns-this-winter-may-be-the-most-difficult-time-in-the-public-health-history-of-the-us.

the stars are aligned in the wrong place as you go into the fall and winter season, with people congregating at home indoors. You could not possibly be positioned more poorly."[16] Unfortunately, these warnings have proved prescient.

While navigating life during the pandemic has been difficult for all Americans this winter, people of color and low-income communities have been hit the hardest. The data show that Black, Indigenous, Latinx, and other people of color are disproportionately impacted by the virus due to health disparities resulting from deeply rooted historic and ongoing social and economic injustices.[17] Based on data collected by the CDC, American Indian/Alaska Native persons are 4.0 times as likely to be hospitalized, and 2.6 times as likely to die from the coronavirus as compared to White, Non-Hispanic persons; Black/African-American persons are 3.7 times as likely to be hospitalized, and 2.8 times as likely to die from the coronavirus as compared to White, Non-Hispanic persons; and Hispanic/Latinx persons are 4.1 times as likely to be hospitalized, and 2.8 times as

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[16] John Dawsey and Yasmeen Abutaleb, *"A Whole Lot of Hurt": Fauci Warns of COVID-19 Surge, Offers Blunt Assessment of Trump's Response*, WASH. POST (Oct. 31, 2020).

[17] The COVID Tracking Project, *The COVID Racial Data Tracker*, https://covidtracking.com/race (last visited Dec. 6, 2020); *see also* Elise Gould and Valerie Wilson, *Black Workers Face Two of the Most Lethal Preexisting Conditions for Coronavirus—Racism and Economic Inequality*, Economic Policy Institute (June 1, 2020), https://www.epi.org/publication/black-workers-covid/.

likely to die from the coronavirus as compared to White, Non-Hispanic persons.[18] Data also show that in some states, Native Hawaiian and Pacific Islanders have the highest death rate from COVID-19 as compared to all other racial and ethnic groups in those states.[19] These disparities are in part due to lack of access to health care, higher rates of employment in essential industries, higher rates of poverty, and crowded living conditions that disproportionately affect people of color in this country. Research has also shown that there is a higher infection rate and death toll in areas with lower-than-average incomes.[20]

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[18] Ctrs. for Disease Control & Prevention, *COVID-19 Hospitalization and Death by Race/Ethnicity* (last updated Nov. 30, 2020), https://www.cdc.gov/coronavirus/2019-ncov/covid-data/investigations-discovery/hospitalization-death-by-race-ethnicity.html.

[19] UCLA Center for Health Policy Research, *NHPI COVID-19 Data Policy Lab Dashboard* (last updated Dec. 2, 2020), https://healthpolicy.ucla.edu/health-profiles/Pages/NHPI-COVID-19-Dashboard.aspx. Many states do not disaggregate data on the infection and death rates for Native Hawaiian and Pacific Islander ("NHPI") populations in their states, so it is unclear how NHPI communities have been impacted by the coronavirus nationally. For many of the states that have disaggregated data, the infection and death rates for NHPI either exceed or rival those of other racial and ethnic groups in the state.

[20] Samrachana Adhikari et al., *Assessment of Community-Level Disparities in Coronavirus Disease 2019 (COVID-19) Infections and Deaths in Large US Metropolitan Areas* 2, (JAMA Network Open, Open Research Letter, July 28, 2020), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2768723.

III. Both FDA and HHS have recognized the importance of using telemedicine in reducing the spread of COVID-19.

National health authorities have overwhelmingly supported the use of telemedicine during the COVID-19 pandemic. Because of the ongoing risks associated with the novel coronavirus, the CDC provided guidance with best practices to help medical professionals protect their patients and health care workers from COVID-19. The guidance acknowledges that "[l]everaging telemedicine whenever possible is the best way to protect patients and staff from COVID-19."[21]

Indeed, the District Court found that during the COVID-19 pandemic, HHS and FDA have "taken specific actions to effectively waive various in-person requirements relating to drug distribution for the duration of the pandemic." JA at 1463. These actions have included issuing non-enforcement guidance documents that give medical professionals the authority to determine whether in-person requirements remain necessary prior to prescribing certain drugs, as well as temporarily suspending certain mandatory in-person evaluation requirements.

For example, in March 2020, FDA relaxed the REMS requirements for in-person laboratory testing or imaging studies during the public health emergency.

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[21] Ctrs. For Disease Control & Prevention, *Prepare Your Practice for COVID-19*, (last updated June 12, 2020), https://www.cdc.gov/coronavirus/2019-ncov/hcp/preparedness-resources.html.

The guidance recognizes that "completing the REMS-required laboratory testing, or imaging studies may be difficult because patients may need to avoid public places" and other patients who are "suspected of having COVID-19 may be self-isolating and/or subject to quarantine."[22] Furthermore, FDA states that it will not take any enforcement action against health care providers for any "accommodations made regarding laboratory testing or imaging study requirements . . . during the [public health emergency], provided that such accommodations were made based on the judgment of a health care professional."[23]

Similarly, in national guidance issued in March 2020 and updated in September and December 2020 and most recently in January 2021, FDA relaxed in-person requirements for drugs that are the subject of clinical trials. The guidance encourages sponsors and clinical investigators to consider using phone contact or virtual visits and "alternative secure delivery methods" for these drugs for trial participants who may not be able to travel to an investigational site.[24]

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[22] U.S. Food & Drug Admin., *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.

[23] *Id.*

[24] U.S. Food & Drug Admin., *Conduct of Clinical Trials of Medical Products During the COVID-19 Public Health Emergency: Guidance for Industry,*

In-person requirements have even been relaxed for the prescription of controlled substances. On March 16, 2020, Defendant HHS Secretary, with the concurrence of the Acting Administrator of the Drug Enforcement Administration ("DEA"), designated that telemedicine evaluations may be used, in lieu of in-person evaluations, to prescribe Schedule II–V controlled substances to patients during the COVID-19 public health emergency.[25] This telemedicine allowance applies nationwide. Notably, the Controlled Substances Act defines Schedule II controlled substances as drugs or other substances that have a currently accepted medical use in treatment, but also have a "high potential for abuse," which "may lead to severe psychological or physical dependence." 21 U.S.C. § 812. Schedule II controlled substances include such drugs as Vicodin, OxyContin, and fentanyl. Despite the risks associated with these drugs, health practitioners have been afforded "flexibility in the prescribing and dispensing of controlled substances to ensure necessary patient therapies remain accessible" during the pandemic.[26]

Investigators, and Institutional Review Boards 5 (Mar. 2020), https://www.fda.gov/media/136238/download.

[25] U.S. Dep't of Justice, Drug Enforcement Admin., *COVID-19 Information Page: Telemedicine*, https://www.deadiversion.usdoj.gov/coronavirus.html#TELE (last visited Dec. 1, 2020).

[26] U.S. Dep't of Justice, Drug Enforcement Admin., DEA086, *Use of Telephone Evaluations to Initiate Buprenorphine Prescribing* (Mar. 31, 2020),

Recognizing the severity of the current crisis, Defendants-Appellants have responded quickly in the above cases, relaxing in-person requirements and promoting telemedicine for medical assessment and drug dispensing by mail order prescription and delivery services. In doing so, Defendants-Appellants have permitted health care providers to use their best clinical judgment to determine whether patients require in-person assessment or care, and to allow patients to avoid unnecessary travel and in-person contact whenever possible.

Defendants-Appellants' treatment of mifepristone, however, offers a stark contrast to these non-enforcement policies. Defendants-Appellants continue to insist on enforcing the in-person REMS requirements for mifepristone, requiring patients to travel during the pandemic to pick up the medication and potentially expose themselves to the virus. While other health care providers are encouraged to use their best clinical judgment and weigh the benefits and risks of in-person contact, Defendants-Appellants refuse to allow the same flexibility to mifepristone prescribers and patients.

Defendants-Appellants' divergent treatment of mifepristone becomes all the more apparent when considering its safety. Mifepristone's safety is well

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https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-022)(DEA068)%20DEA%20SAMHSA%20buprenorphine%20telemedicine%20%20(Final)%20+Esign.pdf.

established, and its incidence of serious adverse events has been exceedingly rare. While HHS and FDA have been willing to suspend in-person requirements for drugs with higher risk profiles, such as unproven drugs undergoing clinical trials and controlled substances, they continue to impose these restrictions on the dispensation of mifepristone.

A national medical consensus has emerged against in-person requirements for mifepristone during the public health emergency. In fact, many medical professionals deemed the in-person requirements to be medically unnecessary and burdensome even before the COVID-19 pandemic.[27] In light of the current pandemic, however, these requirements have become not only burdensome, but dangerous.[28] By singling out mifepristone and refusing to relax in-person

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[27] Brief of Amici Curiae Medical Associations In Support of Plaintiffs' Opposition to Defendants' Motion for Stay Pending Appeal, ACOG v. FDA, No. 20-1824 (4th Cir. Aug. 4, 2020) (representing the American Medical Association, American Academy of Family Physicians, American Academy of Pediatrics, Abortion Care Network, American College of Nurse-Midwives, 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, Society of OB/GYN Hospitalists, and Society for Maternal-Fetal Medicine).

[28] *Id.* at 12.

restrictions, Defendants-Appellants continue to require patients seeking the drug to encounter potentially life-threatening risks in order to access their medication.

IV. FDA's in-person dispensing requirement for patients seeking mifepristone during the COVID-19 pandemic contravenes the intent of the agency's governing statute.

A. *The Federal Food, Drug, and Cosmetic Act requires that any REMS that imposes ETASU not be unduly burdensome on patients.*

The Federal Food, Drug, and Cosmetic Act ("FD&C Act") does not solely require FDA to consider a risk-benefit balance before imposing an ETASU for a drug—it also directs the agency to "assur[e] [patient] access" to the drug and to "minimiz[e] burden." 21 U.S.C. § 355-1(f)(2). Specifically, the statute states that any ETASU must:

> (C) not *be unduly burdensome* on patient access to the drug, considering in particular – (i) patients with serious or life-threatening diseases or conditions; and (ii) patients who have difficulty accessing health care (such as patients in rural or medically underserved areas) . . . and
>
> (D) to the extent practicable, so as to minimize the burden on the health care delivery system – (i) conform with elements to assure safe use for other drugs with similar, serious risks; and (ii) be designed to be compatible with established distribution, procurement, and dispensing systems for drugs.

Id. § 355-1(f)(2)(C), (D) (emphasis added). These statutory requirements are particularly salient in the context of reproductive health care and abortion access.

Even under normal circumstances, the mifepristone ETASUs requiring in-person contact are burdensome on patients. Travel—as well as its associated

burdens and costs, including lost wages, child care, transportation, and accommodations—is a major barrier to patients accessing abortion care.[29] Three out of four abortion patients are poor or low-income.[30] One half of abortion patients live below the federal poverty level.[31] The majority of abortion patients have had at least one previous birth, making it more likely that travel for abortion care also strains childcare arrangements and requires incurring additional costs.[32]

Furthermore, these burdens are disproportionately imposed on patients who reside in rural or medically underserved areas.[33] Because of abortion provider

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[29] Jenna Jerman et al., *Barriers to Abortion Care and Their Consequences for Patients Traveling for Services: Qualitative Findings from Two States*, 49 Persps. on Sexual and Reproductive Health 95, 95 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5953191/.

[30] Jenna Jerman et al., *Characteristics of U.S. Abortion Patients in 2014 and Changes Since 2008*, Guttmacher Inst. 7 (May 2016), https://www.guttmacher.org/sites/default/files/report_pdf/characteristics-us-abortion-patients-2014.pdf.

[31] *Id.*

[32] *Id.*

[33] Heather D. Boonstra & Elizabeth Nash, *A Surge of State Abortion Restriction Puts Providers—and the Patients They Serve—in the Crosshairs*, 17 Guttmacher Pol'y Rev. 1, 11–13 (2014), https://www.guttmacher.org/sites/default/files/article_files/9-14_abortion_restrictions_w_jump.pdf.

shortages, rural residents must travel longer distances to access abortion care.[34] Rural residents are also more likely to be poor, lack health insurance, and lack access to public transportation.[35] FDA's in-person mifepristone requirements compound these disparities and unduly burden patient access to the drug, despite the FD&C Act's express requirement otherwise.

B. *The COVID-19 pandemic exacerbates the burdens of in-person REMS requirements for mifepristone.*

During the pandemic, the mifepristone in-person requirements have placed an even greater burden on patients, as they force patients to needlessly expose themselves to the risk of contracting COVID-19. Every additional in-person interaction increases viral exposure risk. A bus ride to a health center can lead to COVID-19 infection.[36] Even assuming perfect compliance, preventative measures

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[34] Jonathan Bearak et al., *Disparities and Change over Time in Distance Women Would Need to Travel to Have an Abortion in the USA: A Spatial Analysis*, 2 Lancet Public Health 1, 6–8 (2017), https://www.thelancet.com/journals/lanpub/article/PIIS2468-2667(17)30158-5/fulltext.

[35] The American College of Obstetricians and Gynecologists, *Health Disparities in Rural Women* 2 (Comm. on Health Care for Underserved Women, Committee Opinion No. 856, 2014), https://www.acog.org/-/media/project/acog/acogorg/clinical/files/committee-opinion/articles/2014/02/health-disparities-in-rural-women.pdf.

[36] *See* Ye Shen et al., *Community Outbreak Infection of SARS-CoV-2 Transmission Among Bus Riders in Eastern China*, JAMA Internal Med. E1, E3 (2020), https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2770172.

such as social distancing, hand washing, and masking reduce infection risk but do not eliminate it.[37]

The health risks and burdens of increased travel and in-person interactions to obtain mifepristone during the pandemic are inequitably distributed. Black, Indigenous, Latinx, and other patients of color suffer greater COVID-19 infection, hospitalization, and death rates, and represent 61% of abortion patients.[38] There are higher infection and death rates in areas with lower median incomes, where the vast majority of abortion patients are likely to reside. Patients with lower-than-average incomes are more likely to experience greater public exposure risk traveling to obtain mifepristone, as they are less likely to have access to private modes of transportation. These heightened health risks—compounded by historic and ongoing health, social, and economic inequities—impose an inordinate burden on low-income patients and patients of color seeking mifepristone during the pandemic. Indeed, rather than mitigating risk, the in-person REMS requirements

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[37] Ctrs. For Disease Control & Prevention, *Social Distancing* (Nov. 17, 2020), https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/social-distancing.html; Ctrs. For Disease Control & Prevention, *Hand Hygiene Recommendations* (May 17, 2020), https://www.cdc.gov/coronavirus/2019-ncov/hcp/hand-hygiene.html; Ctrs. For Disease Control & Prevention, *Scientific Brief: Community Use of Cloth Masks to Control the Spread of SARS-CoV-2* (Nov. 2, 2020), https://www.cdc.gov/coronavirus/2019-ncov/more/masking-science-sars-cov2.html.

[38] *See supra* Section II; Jerman et al, *supra* note 29 at 5.

for mifepristone increase health risks for patients—contravening the broader statutory objective of the REMS program.[39]

The COVID-19 pandemic has also created a national economic and social crisis, exacerbating the burdens of FDA's in-person mifepristone requirements. Under normal circumstances, mifepristone patients experience significant care access burdens due to structural, economic, social, and regional inequalities. The economic impact of the pandemic has only amplified these inequalities and burdens. In November, one in three adults in the United States reported difficulty paying ordinary household expenses.[40] Adults in households with children, which comprise a significant percentage of abortion patients, were more likely to report permanent loss of employment and food insecurity.[41] Labor-force participation

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[39] *See* U.S. Food & Drug Admin., *REMS: FDA's Application of Statutory Factors in Determining when a REMS Is Necessary Guidance for Industry* 4 (April 2019), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/rems-fdas-application-statutory-factors-determining-when-rems-necessary-guidance-industry (clarifying that the statute's "goal of risk mitigation is to preserve a drug's benefits while reducing its risks to the extent possible.")

[40] U.S. Census Bureau, *Week 19 Household Pulse Survey: November 11-November 23* (Dec. 2, 2020), https://www.census.gov/data/tables/2020/demo/hhp/hhp19.html#tables.

[41] Lindsay M. Monte, *New Census Household Pulse Survey Shows More Households with Children Lost Income, Experienced Food Shortages During Pandemic*, U.S. Census Bureau (May 27, 2020), https://www.census.gov/library/stories/2020/05/adults-in-households-with-

rates for women and women of color, in particular, are sharply declining, driven by loss of employment and pandemic childcare obligations.[42] The significant majority of abortion patients are poor and/or low income, women of color, or have had at least one previous birth—they are the very individuals who are suffering disproportionate economic harm during the pandemic. For most mifepristone patients, these cumulative financial and logistical burdens would make travel for treatment during the pandemic intractable.

These heightened social, logistical, and economic burdens can further magnify health burdens for already vulnerable abortion patients during the pandemic. Because the in-person requirements may effectively prevent patients from obtaining mifepristone for early medication abortions, some patients may be forced to undertake later, in-office, procedural abortions. These procedures generally involve greater in-person contact, further exposing medication abortion patients to unnecessary viral risk.

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children-more-likely-to-report-loss-in-employment-income-during-covid-19.html; Jerman et al., *supra* note 29 at 7.

[42] Julie Kashen et al., *How COVID-19 Sent Women's Workforce Progress Backward* (Center for American Progress Report, Oct. 30, 2020), https://www.americanprogress.org/issues/women/reports/2020/10/30/492582/covid-19-sent-womens-workforce-progress-backward/.

Despite Section 505-1's directive against ETASUs imposing undue burdens on patient access to mifepristone, FDA has continued to enforce the in-person REMS requirements for mifepristone during the pandemic. Notably, the District Court found that FDA has "provided no sign" that it ever conducted a formal review of whether upholding the mifepristone REMS requirements would be unduly burdensome because of the now-widespread use of telemedicine and in the context of the pandemic. *See* JA at 1473. In light of the present circumstances and Section 505-1's unambiguous directive, sustaining FDA's in-person REMS requirements for mifepristone during the pandemic contravenes the FD&C Act.

Upholding mifepristone's in-person REMS requirements during the COVID-19 pandemic is at odds with public health guidance, statutory intent, and common sense—it is medically unnecessary, burdens patient access to mifepristone, and imposes irreparable harm on miscarriage and medication abortion patients and their medical providers.

CONCLUSION

For the reasons set forth above, *amici* respectfully ask the Court to affirm the District Court's decision granting a nationwide preliminary injunction on Plaintiffs-Appellees' due process claim, and reverse the District Court's ruling on Plaintiffs-Appellees' equal protection claim to reinstate urgently needed relief for miscarriage and medication abortion patients and their medical providers during the pandemic.

Dated: February 12, 2021
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Respectfully submitted,

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I certify the following in accordance with Fed. R. App. 32(g)(1):

1. This brief complies with the type-volume limits because, excluding the parts of the document exempted by Fed. R. App. P. 32(f) (*i.e.*, cover page, disclosure statement, table of contents, table of authorities, certificate of counsel, signature blocks, proof of service, addendum), this brief contains 5,226 words.
2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Federal R. App. 32(a)(6), because it was prepared in a proportionally spaced typeface using Microsoft Word 2010 in 14-point font size and Times New Roman type style.

Dated: February 12, 2021

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CERTIFICATE OF SERVICE

Counsel for *amici curiae* certifies that on February 12, 2021, I electronically filed the foregoing with the Clerk of Court of the United States Court of Appeals for the Fourth Circuit by using the EM/ECF system.

I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

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