

March 1, 2021

The Honorable Joseph R. Biden, Jr
President
1600 Pennsylvania Avenue NW
Washington, DC 20500

The Honorable Kamala D. Harris
Vice President
1600 Pennsylvania Avenue NW
Washington, DC 20500

Dear President Biden and Vice President Harris:

Our organizations represent the nation's leading medical experts and health care professionals who are working on the frontlines of the COVID-19 pandemic to provide care in communities throughout the country. We appreciate your efforts to date to respond to the ongoing COVID-19 public health crisis, prioritize science and facts, and promote equity for all. We write to ask that you take swift action to end an unscientific and discriminatory policy pursued by the prior Administration that imposes heightened risk of viral exposure on our members and the patients they serve. Even as the prior Administration took extensive measures in response to the pandemic to enable patients to obtain health care without needless in-person contact, it continued to force patients prescribed mifepristone for pregnancy termination or treatment of early miscarriage to travel to a health center for the sole purpose of picking up their medication and signing a form. This policy, which is opposed by the nation's medical experts even under normal circumstances due to its arbitrary and unscientific nature, is—every day—putting patients and their families at serious risk for unwarranted exposure to a deadly virus. Moreover, enforcement of this policy disproportionately harms marginalized communities that have been hit hardest by the pandemic, especially communities of color.

With this letter, we urge you to take immediate action to end the prior Administration's discriminatory and unscientific policy that endangers patients and their health care professionals during the COVID-19 Public Health Emergency (PHE). We are available to consult with your Administration, as needed. It is imperative to us—as we know it is to you—that policy during the COVID-19 pandemic be driven by science, medical accuracy, and equity.

In March 2020, in response to the pandemic, the Food and Drug Administration (FDA) took steps to prevent the spread of COVID-19, including by suspending enforcement of Risk Evaluation and Mitigation Strategy (REMS) testing and imaging requirements and authorizing sponsors of clinical trials to forgo in-person visits during the PHE (even for drugs that are not yet approved for safe use).¹ Additionally, the Department of Health and Human Services (HHS) took significant action to promote the use of telemedicine to reduce the spread of COVID-19 while ensuring continued access to essential health care, and the Centers for Medicare and Medicaid Services adjusted reimbursement to accommodate this change in the delivery of care.² The Secretary of HHS also suspended mandatory in-person evaluation requirements for controlled substances.³

By suspending these in-person mandates, FDA and HHS enabled patients and clinicians to forgo unnecessary contact when, in the clinician's best judgment, a medication can be safely prescribed

and monitored through telehealth visits. Importantly, if a clinician determined, based on their best medical judgment, that a patient needed to be seen in person to obtain medications, the actions taken by FDA and HHS would not prevent that. Rather, FDA took action to allow clinicians to use their expert clinical judgment to determine whether travel was necessary for obtaining medications and provided flexibility in cases where it was determined that travel was not necessary. These actions reflect the clear scientific consensus that reducing in-person visits reduces the risk of COVID-19 transmission and infection as well as the risks associated with travel, childcare, and other logistical requirements of an in-person medical appointment. We know these challenges and barriers are even more pronounced for low-income, rural, and other underserved communities.

Notwithstanding the prior Administration's actions relaxing in-person mandates for many highly regulated medications, and despite urgent requests submitted to FDA last March and April by leading medical experts (including several of the undersigned),⁴ FDA refused to lift the in-person dispensation requirement for an essential women's health medication, mifepristone (brand name Mifeprex®). This decision needlessly forces women, their families, their communities, and their clinicians to risk exposure to a deadly virus.

Mifepristone is one of two FDA-approved prescription medications used in combination to end an early pregnancy (medication abortion) or manage a miscarriage. Mifepristone's safety and efficacy are "well established by both research and experience,"⁵ and major adverse events are "exceedingly rare."⁶ Nevertheless, FDA requires mifepristone patients to travel to a health center to receive the pill in person, even if they plan to take the drug safely in the privacy of their own home—which FDA permits.⁷ FDA does not require any medical care or counseling during the patient's visit to pick up their medication, and all evaluation and counseling can occur via telemedicine for medically eligible patients. Yet, FDA forces mifepristone patients to travel just to pick up a pill and sign a form. Of the more than 20,000 drugs regulated by the FDA, mifepristone, when used to treat early pregnancy loss or pregnancy termination, is the only drug that patients are required to receive in person at a health care facility yet may self-administer at any location of their choosing.⁸

The medical community has long opposed the REMS requirements for mifepristone as unnecessary and unscientific even in non-pandemic times; however, reiterating our well-documented positions on the permanent lifting of these restrictions is not the purpose of this letter. Our reason for writing now is to urge you to swiftly reverse the prior Administration's singling out of mifepristone, when used to treat women's health conditions, from its policy of permitting clinicians to use their best clinical judgment to forgo unnecessary in-person visits for their patients during the COVID-19 pandemic. **Specifically, we ask that your Administration work with the FDA to immediately lift the in-person dispensing requirement for mifepristone during the pandemic, to align with the FDA's treatment of other medications.**

Continuing to require in-person dispensation of mifepristone during the pandemic, especially when this requirement has been lifted for medications with much higher risk profiles, is unscientific, discriminatory, and unnecessarily puts lives at risk of COVID-19 infection. The ability to terminate a pregnancy, or to manage an early pregnancy loss, is an essential and time-sensitive component of comprehensive health care. A delay of several weeks, or even in some cases days, increases health risks and may make care completely inaccessible. The prior Administration's refusal to relax in-person requirements for mifepristone—as it did for other medications to facilitate the use of telehealth in accordance with accepted clinical guidance—creates an undue burden on access to

this essential health care. **This unjust and discriminatory burden disproportionately impacts women of color and women in lower socioeconomic brackets, communities that have been hit hardest by COVID-19.**

The nation’s leading medical experts urged the prior Administration to take this action nearly a year ago—and it refused to do so. Out of concern for women’s lives and in response to real on-the-ground accounts of harms that the prior Administration’s policy had on communities throughout the country, leading medical organizations and a leading national organization committed to reproductive justice and equity were forced to bring a lawsuit in federal court to seek relief from the policy. **Unsurprisingly, the prior Administration’s arbitrary policy singling out patients seeking mifepristone for pregnancy termination was found to be unconstitutional and was temporarily enjoined on a nationwide basis in July.** In so ruling, the federal district court found that the in-person requirements force abortion patients to engage in travel “fraught with health risk [for the patients] themselves, medical professionals, others they encounter during such trips, and the members of their households to whom they return.”⁹ The Court also concluded, based on un rebutted expert testimony, that the mifepristone in-person dispensation requirements “do not advance ... patient safety and thus constitute unnecessary health regulations.”¹⁰ A panel of the U.S. Court of Appeals for the Fourth Circuit unanimously declined the Administration’s request to stay the injunction, leaving the federal court’s decision in place.¹¹ Undeterred, the Administration brought its request to the U.S. Supreme Court, which issued an order in October deferring ruling on the stay application.¹²

In late October, the Administration renewed its motion in the district court for a stay of the injunction, arguing that the risks and burdens associated with health care travel during the PHE had all been “eliminated or mitigated.”¹³ This position, on its face, was not based in science, contradicts the Administration’s actions suspending similar restrictions for other (less safe) medications, and was contrary to the learned, expert judgment of the nation’s medical community.

The district court unsurprisingly rejected the Administration’s contentions, finding that the grave health risks to which the FDA’s requirements subject mifepristone patients “have only gotten worse.”¹⁴ Additionally, the court noted that the Administration had “offered no evidence that their temporary inability to enforce the In-Person Requirements ha[d] injured them or, for that matter, harmed a patient.”¹⁵ Nevertheless, **in December, the Administration again brought its arguments for a stay to the Supreme Court—this time before a newly constituted court. And, just days before you took office, a divided Court, over a vocal and furious dissent, granted the Administration’s request to reinstate the in-person requirements.**¹⁶

The Court’s ruling reversed a status quo of improved safety that had been in place for six months during a lethal pandemic. The status quo was protecting patients and health care professionals from needless viral exposure by allowing medically eligible patients to obtain mifepristone by mail or delivery, consistent with CDC guidelines.¹⁷ The Supreme Court’s decision stands in direct opposition to scientific evidence and undermines the guidance of the nation’s leading medical experts. This ruling conditions patient access to this essential medication on needlessly risking COVID-19 infection and endangers frontline medical professionals during the pandemic. As Justice Sotomayor’s dissent concluded, “FDA’s policy imposes an unnecessary, unjustifiable, irrational, and undue burden on women seeking an abortion during the current pandemic.”¹⁸ The Court’s stay decision represents an extreme act of judicial overreach with life-threatening health consequences for our patients. This harm continues to be felt most acutely by Black, Latinx,

Indigenous, and other communities of color who already face disproportionate economic and health outcomes, as well as illness and death, due to COVID-19. **Your immediate action is needed to remedy the dangerous and unjust circumstances imposed by this decision.** The ability to reverse the prior Administration’s enforcement policy (and the harmful effects of the Supreme Court’s stay) is undeniably within the purview of the Executive Branch and we ask that your Administration act without delay.

We urge your Administration to once again demonstrate your dedication to medicine, equity, scientific evidence, and public health by immediately working with FDA to issue non-enforcement guidance for the mifepristone REMS in-person dispensing requirement (and related in-person signature requirement) for the duration of the COVID-19 PHE. Ensuring the safety of patients and clinicians is a priority we all share. Common sense and evidence-based policymaking that aids in ending the COVID-19 pandemic is our common goal. We seek your assistance in enabling clinicians to provide patients with the best quality care possible, particularly during this national health crisis.

Thank you for your immediate attention to this urgent matter. We are ready and eager to work with you on this and other important women’s health issues. We appreciate your leadership and look forward to continuing to partner with you and serve as a resource to your Administration. To answer any questions or discuss further please contact Rachel Tetlow, Federal Affairs Director at the American College of Obstetricians and Gynecologists, at rtetlow@acog.org.

Sincerely,

American Academy of Family Physicians
American Academy of Pediatrics
American College of Nurse-Midwives
American College of Obstetricians and Gynecologists
American College of Osteopathic Obstetricians and Gynecologists
American Gynecological and Obstetrical Society
American Medical Association
American Society for Reproductive Medicine
Council of University Chairs of Obstetrics and Gynecology
National Abortion Federation
National Association of Nurse Practitioners in Women’s Health
North American Society for Pediatric and Adolescent Gynecology
Planned Parenthood Federation of America
Reproductive Health Access Project
Society for Academic Specialists in General Obstetrics and Gynecology
Society of Family Planning
Society of General Internal Medicine
Society of Gynecologic Oncology
Society of Gynecologic Surgeons
Society for Maternal-Fetal Medicine
Society of OB/GYN Hospitalists

¹ U.S. Food & Drug Admin., Policy for Certain REMS Requirements During the COVID-19 Public Health Emergency 7 (2020), <https://www.fda.gov/media/136317/download>; U.S. Food & Drug Admin., FDA Guidance on Conduct of Clinical Trials of Medical Products During the COVID-19 Public Health Emergency 3 (2020, updated 2021), <https://www.fda.gov/media/136238/download>

² See, e.g., *OCR Announces Notification of Enforcement Discretion for Telehealth Remote Communications During the COVID-19 Nationwide Public Health Emergency*, Health & Human Servs. (Mar. 17, 2020), <https://www.hhs.gov/about/news/2020/03/17/ocr-announces-notification-of-enforcement-discretion-for-telehealth-remote-communications-during-the-covid-19.html>; *President Trump Expands Telehealth Benefits for Medicare Beneficiaries During COVID-19 Outbreak*, Ctrs. for Medicare & Medicaid Servs. (Mar. 17, 2020), <https://www.cms.gov/newsroom/press-releases/president-trump-expands-telehealth-benefits-medicare-beneficiaries-during-covid-19-outbreak>; *Trump Administration Released COVID-19 Telehealth Toolkit to Accelerate State Use of Telehealth in Medicaid and CHIP*, Ctrs. for Medicare & Medicaid Servs. (Apr. 23, 2020), <https://www.cms.gov/newsroom/press-releases/trump-administration-releases-covid-19-telehealth-toolkit-accelerate-state-use-telehealth-medicaid>.

³ *COVID-19 Information Page, Telemedicine*, U.S. Drug Enf't Admin., <https://www.deadiversion.usdoj.gov/coronavirus.html#TELE>.

⁴ See, e.g., Letter from John S. Cullen, Board Chair, Am. Acad. of Family Physicians, to Stephen M. Hahn, Comm'r, U.S. Food and Drug Admin. (Mar. 25, 2020); Letter from Maureen G. Phipps, Chief Exec. Officer, Am. Coll. of Obstetricians and Gynecologists; Judette Louis, President, Soc'y for Maternal-Fetal Med.; and Matt J. Granato, Chief Exec. Officer, Soc'y for Maternal-Fetal Med., to Stephen M. Hahn, Comm'r, U.S. Food and Drug Admin. (Apr. 20, 2020); Letter from Public Health Experts and Advocates to Janet Woodcock, M.D., U.S. Food & Drug Admin. (Apr. 28, 2020).

⁵ U.S. Food and Drug Admin., Ctr. for Drug Evaluation & Res., *Medical Review of Mifeprex 12* (Mar. 29, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf [hereinafter "FDA 2016 Medical Review"]; see also U.S. Food & Drug Admin., Full Prescribing Information for Mifeprex 7–8, Tables 1 & 2 (approved Mar. 2016), https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf.

⁶ FDA 2016 Medical Review, *supra* n. 5, at 47.

⁷ The mifepristone REMS also includes a requirement that the patient sign a form in the presence of their prescribing clinician.

⁸ The mifepristone drug compound is also used under the brand name Korlym® to treat Cushing's syndrome, but the in-person dispensation requirement does not apply to that use. When not used for abortion or miscarriage, FDA permits the identical compound to be obtained by mail, even in much higher doses.

⁹ *Am. Coll. of Obstetricians & Gynecologists v. FDA*, 472 F. Supp. 3d 183, 214 (D. Md. 2020), *order clarified*, No. TDC-20-1320, 2020 WL 8167535 (D. Md. Aug. 19, 2020).

¹⁰ *Id.* at 217 (internal quotation marks and citations omitted).

¹¹ *FDA v. Am. Coll. of Obstetricians & Gynecologists*, No. 20-1824, Dkt. 30 (4th Cir. Aug. 13, 2020).

¹² *FDA v. Am. Coll. of Obstetricians & Gynecologists*, No. 20A34, slip. op., 2020 WL 5951467 (U.S. Oct. 8, 2020).

¹³ *Am. Coll. of Obstetricians & Gynecologists v. FDA*, No. TDC-20-1320, Dkt. 141-1, at 21; *accord id.* at 5.

¹⁴ *Am. Coll. of Obstetricians & Gynecologists v. FDA*, No. CV TDC-20-1320, 2020 WL 7240396, at *7, *12 (D. Md. Dec. 9, 2020).

¹⁵ *Id.* at *12.

¹⁶ *FDA v. Am. Coll. of Obstetricians & Gynecologists*, 141 S. Ct. 578 (2021).

¹⁷ U.S. Ctrs. for Disease Control & Prevention, Doctors Visits and Getting Medications (Sept. 11, 2020), <https://www.cdc.gov/coronavirus/2019-ncov/daily-life-coping/doctor-visits-medicine.html>.

¹⁸ *FDA v. Am. Coll. of Obstetricians & Gynecologists*, 141 S. Ct. 578, 585 (2021) (Sotomayor, J., dissenting).