March 18, 2021

The Honorable Joseph R. Biden, Jr.
President of the United States
The White House
1600 Pennsylvania Ave.
Washington, DC 20500

Dear Mr. President:

The undersigned organizations write to urge your administration to immediately reverse a dangerous policy that is subjecting abortion and miscarriage patients to needless COVID-19 risk, and to prioritize the elimination of unnecessary barriers to medication abortion care. Specifically, we call for an immediate suspension of the in-person requirement for mifepristone, a safe and effective medication used for early abortion, during the COVID-19 public health emergency, as well as a comprehensive Food and Drug Administration (FDA) review of the full set of restrictions on mifepristone to bring patient access in line with the latest science and medical evidence.

Consistent with your important commitment to follow the science in responding to COVID-19, as well as your critical promise to tackle issues of systemic equity across the government, it is imperative that your administration prioritize safe access to medication abortion. Burdensome restrictions on medication abortion, which are not based in medical evidence, deepen the health inequities already experienced by those who are struggling to make ends meet, particularly people of color, who comprise a majority of medication abortion patients and are now being hit hardest by the COVID-19 pandemic.

Mifepristone is a prescription medication that patients have relied on for 20 years to safely and effectively end early pregnancies and, more recently, to treat early miscarriages.[1] Despite its excellent, extensive safety record,[2] FDA continues to subject mifepristone to a set of outdated and medically unnecessary restrictions, known as a Risk Evaluation and Mitigation Strategy (REMS). Leading medical authorities have long called to permanently lift the mifepristone REMS,[3] which unjustifiably obstructs patients' access to time-sensitive, essential health care, most severely in rural and low-income communities. These restrictions uniquely burden abortion patients: out of more than 20,000 drugs that FDA regulates, mifepristone, when used for abortion or miscarriage care, is the *only* one that FDA requires to be dispensed in a clinical setting, despite permitting patients to self-administer it at home.[4]

During the pandemic, that in-person requirement is also particularly dangerous. Patients must travel to a hospital, clinic, or medical office for the sole purpose of picking up the pill and signing a form, forcing them to risk needless COVID-19 exposure in order to access care.[5] Not only is this entirely medically unnecessary, its enforcement is also a glaring departure from the government's policy of minimizing in-person health care visits during the pandemic. As COVID-19 first surged across the nation last March, the Department of Health and Human Services (HHS) and FDA quickly suspended enforcement of other in-person requirements -- including for far *less* safe medications like opioids-- and encouraged the use of telehealth

wherever possible, consistent with the public health consensus that unnecessary in-person medical visits must be avoided to mitigate viral spread.[6] Leading medical authorities repeatedly called on FDA to do the same for mifepristone,[7] so that eligible patients could safely receive their prescriptions by mail, just as they would any other prescription. Instead, the Trump administration did everything in its power to continue subjecting abortion and miscarriage patients to this unique and dangerous requirement—fighting medical and reproductive justice organizations all the way up to the Supreme Court to reinstate the policy after it was blocked by a federal court.

In January, after six months of an injunction that allowed patients to safely obtain their mifepristone prescription by mail, the Court allowed the Trump administration to reinstate this dangerous travel mandate on its way out the door, in spite of soaring COVID-19 rates nationwide.[8] Since that disastrous decision, patients and their families are once again at risk every day. Despite a recent decline in new cases, there is still a very long road ahead in this unprecedented public health crisis: the U.S. recently marked half a million COVID-19 deaths, and new variants are spreading while vaccine plans are still being implemented. Your administration must reverse this dangerous approach and respond to the medical experts that the previous administration ignored. Continuing to impose the in-person requirement during this public health emergency is at odds with both science and common sense. No one should have to risk needless exposure to a life-threatening virus to access essential health care, including people who need abortion care.

It is important to note that the existing restrictions also harm patients who experience miscarriage—as an average of more than a million do each year—and seek medical care to complete it. While not yet an FDA-approved indication, there is robust clinical trial data to show that pre-treating patients with mifepristone before using the standard medical treatment of misoprostol results in a higher likelihood of successful management of first-trimester pregnancy loss than treatment with misoprostol alone. Given that the other alternatives are to wait out the miscarriage at home (which can take days if not weeks), or travel to a hospital emergency department or other health center for a procedure to evacuate the uterus, the REMS unduly limits miscarriage patients' access to a safe medical option and forces them to incur unnecessary viral exposure risks.

In addition, we call for a comprehensive FDA review of the full REMS on mifepristone. For far too long, these unwarranted restrictions have pushed care out of reach for people who already face significant barriers when it comes to accessing health care. Particularly as state abortion restrictions force people in many parts of the country to travel further and further to reach providers, the government must eliminate medically unnecessary obstacles that prevent people from accessing safe care. In light of this, an evidence-based review of the REMS is not only long overdue, but urgent.

Such a review is consistent with the law and adheres to the process authorized by Congress as part of the Federal Food, Drug and Cosmetic Act (FFDCA). Specifically, the statute allows for the Secretary, in consultation with the FDA, to modify a REMS to ensure the benefits of the drug outweigh the risks and to minimize the burden on the health care delivery system of complying with the restrictions.[9] Moreover, Congress required that any REMS "element to assure safe use" not be "unduly burdensome on patient access," with particular consideration of the impact on

those in rural or medically underserved areas, or who otherwise have difficulty accessing care.[10] A reevaluation of the mifepristone REMS is all the more pressing given its outsized impact on those populations. It must be a priority to ensure that patients' access to abortion and miscarriage care, like all other health care, is based on the latest science and medical evidence.

We urge your administration to act quickly to ensure that people can safely access the time-sensitive, essential care they need not only during the pandemic, but also after it ends. The past four years brought relentless attacks on access to safe, affordable reproductive health care from an administration that based its policy on false and inflammatory rhetoric rather than medical evidence. We welcome the opportunity to now work with your administration to reverse that course and ensure that science, not politics, guides access to reproductive health care, including abortion.

Sincerely,

American Civil Liberties Union
EMAA Project
Advocates for Youth
All* Above All
American Medical Student Association
American Society for Reproductive Medicine (ASRM)
Catholics for Choice
Center for Reproductive Rights
CHANGE (Center for Health and Gender Equity)
Community Catalyst
Hey Jane
Ibis Reproductive Health
If/When/How: Lawyering for Reproductive Justice
In Our Own Voice: National Black Women's Reproductive Justice Agenda
International Women's Health Coalition
Ipas
Jacobs Institute of Women's Health
Jewish Women International
Just The Pill
Lawyering Project
Medical Students for Choice
MomsRising
NARAL Pro-Choice America
NASTAD
National Abortion Federation
National Asian Pacific American Women's Forum (NAPAWF)
National Center for Lesbian Rights
National Council of Jewish Women
National Family Planning & Reproductive Health Association
National Health Law Program
National Institute for Reproductive Health
National Latina Institute for Reproductive Justice

National Network of Abortion Funds
National Organization for Women
National Partnership for Women & Families
National Women's Health Network
National Women's Law Center
Not Without Black Women
Our Justice
PAI
Physicians for Reproductive Health
Planned Parenthood Federation of America
Population Connection Action Fund
Population Institute
Power to Decide
Raising Women's Voices
SIECUS: Sex Ed for Social Change
Society for Maternal-Fetal Medicine
UCSF Bixby Center for Global Reproductive Health
Union for Reform Judaism
UnRestrict Minnesota
URGE: Unite for Reproductive & Gender Equity
VA NOW, Inc
We Testify
Women of Reform Judaism

Cc: Acting HHS Secretary Norris Cochran
Acting FDA Commissioner Janet Woodcock

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[1] Mifepristone is FDA-approved for use in combination with another drug, misoprostol, to end early pregnancies. While misoprostol alone has long been used to medically manage early pregnancy loss (i.e., miscarriage), it is now widely recognized that the superior miscarriage treatment regimen includes mifepristone. *See, e.g.*, Am. College of Obstetricians & Gynecologists, Practice Bulletin 200: Early Pregnancy Loss, https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2018/11/early-pregnancy-loss.

[2] In the FDA's words, mifepristone "has been increasingly used as its efficacy and safety have become well-established by both research and experience, and serious complications have proven rare." 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.

[3] *See, e.g.* American Medical Association, *Ending the Risk Evaluation and Mitigation Strategy (REMS) policy on mifepristone (Mifeprex)*, Policy H-100.948 (2018), https://www.ama-assn.org/sites/default/files/mediabrowser/public/hod/a18-resolutions.pdf; American Academy of Family Physicians, *FPs Tackle Primary Care Spending, Other Weighty Topics* (Oct. 12, 2018), https://www.aafp.org/news/2018-congress-fmx/20181012codadvocacy.html; American Congress of Obstetricians and Gynecologists, *ACOG Statement on Medication Abortion* (Mar. 30, 2016), https://www.acog.org/About-ACOG/News-Room/Statements/2016/ACOG-Statementon-Medication-Abortion?IsMobileSet=false.

[4] When mifepristone is used for purposes other than treating abortion or miscarriage, FDA allows the identical compound to be mailed in higher doses and vast quantities for chronic use.

[5] The REMS requires patients seeking abortion and miscarraige care to pick up the pill in person, even when they have already been evaluated by a clinician, will not receive in-person medical services at the time, and will swallow the pill later at home.

[6] *See, e.g.*, 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; *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; *COVID-19 Information Page, Telemedicine*, U.S. Drug Enf't Admin., https://www.deadiversion.usdoj.gov/coronavirus.html#TELE (last visited May 25, 2020).

[7] *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).

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

[9] 21 U.S.C. § 355-1(g)(4)(b).

[10] 21 U.S.C. § 355-1 (f)(2)(C)(ii).