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February 9, 2021

Dr. Janet Woodcock
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Woodcock:

We are writing to request that the Food and Drug Administration (FDA) lift the medically unnecessary in-person dispensing requirement for mifepristone, a prescription medication that has been used to safely end early pregnancies for more than two decades in our country.[1] Imposing this requirement in the midst of a deadly pandemic—one that has disproportionately impacted communities of color across the United States—needlessly places patients and providers in harm's way, and further entrenches longstanding health inequities.

The FDA created the Risk Evaluation and Mitigation Strategies (REMS) program to ensure the safe use of medications that pose "serious safety concerns" for patients.[2] For mifepristone—the first of two drugs used to complete a medication abortion—FDA requires that the pill be dispensed to patients in person by certified health care providers, and only in certain health care settings. Of the more than 20,000 drugs regulated by FDA, mifepristone is the only drug that FDA requires patients to obtain in person at a hospital, clinic, or medical office, but does not restrict the ability of patients to self-administer—unsupervised—at home or at a location of their choosing.[3]

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[1] Kaiser Family Foundation, *The Availability and Use of Medication Abortion* (June 8, 2020) (online at www.kff.org/womens-health-policy/fact-sheet/the-availability-and-use-of-medication-abortion/); Rachel K. Jones and Stanley K. Henshaw, *Mifepristone for Early Medical Abortion: Experiences in France, Great Britain, and Sweden, Perspectives on Sexual and Reproductive Health*, Guttmacher Institute (May/June 2002) (online at www.guttmacher.org/journals/psrh/2002/05/mifepristone-early-medical-abortion-experiences-france-great-britain-and#:~:text=Mifepristone%20is%20approved%20for%20use,Great%20Britain%E2%80%A0%20and%20Sweden).

[2] Food and Drug Administration, *Risk Evaluation and Mitigation Strategies* (online at www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems) (accessed Feb. 9, 2021).

[3] Plaintiffs' First Complaint for Declaratory and Injunctive Relief (May 27, 2020), *Food and Drug Administration, et al. v. American College of Obstetricians and Gynecologists, et al.*, D. Md. (No. 8:20 CV 01320 TDC) (online at www.acog.org/-/media/project/acog/acogorg/files/advocacy/acog-v-fda-complaint-mifepristone-covid19.pdf?la=en&hash=2C5C6C65F3E6C8A693ACD649C7C12129).

Since its approval by the FDA in 2000, more than four million people in the United States have used mifepristone.[4] According to data made available by FDA, less than 0.1% of patients who took mifepristone experienced major adverse events.[5] By comparison, hundreds of people in the United States who carry their pregnancies to term die annually in childbirth.[6] According to the American College of Obstetricians and Gynecologists (ACOG), FDA's REMS restrictions for mifepristone "have no medical basis, provide no patient benefit, and unnecessarily restrict access to care."[7]

Early in the pandemic, FDA suspended certain in-person REMS requirements, acknowledging the health risk of these requirements and the difficulty they posed for patients who are self-isolating or quarantining. Despite lifting other REMS restrictions, including in-person prescribing requirements for regulated medications, FDA declined to suspend the in-person dispensing requirement for mifepristone.[8]

On May 27, 2020, ACOG led a group of plaintiffs in asking a federal court to order FDA to suspend the in-person dispensing requirement for mifepristone during the coronavirus pandemic.[9] On July 13, 2020, the U.S. District Court for the District of Maryland ordered FDA to suspend the in-person dispensing requirement, concluding that "such infringement on the right to an abortion would constitute irreparable harm" and noting that in-person requirements had been waived for many other drugs in the interest of protecting public health.[10]

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[4] Danco Laboratories, LLC, *Mifeprex in the United States* (online at www.earlyoptionpill.com/what-is-mifeprex/mifeprex-in-the-united-states/) (accessed Feb. 9, 2021).

[5] Food and Drug Administration¸ *Center for Drug Evaluation and Research Application Number: 020687Orig1s020 Medical Review(s)* (Mar. 29, 2016) (online at www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf). *See also* National Academies of Science, Engineering, and Medicine, *The Safety and Quality of Abortion Care in the United States* (2018) (online at www.nap.edu/catalog/24950/the-safety-and-quality-of-abortion-care-in-the-united-states) (finding that complications of medication abortion occur in "no more than a fraction of a percent of patients").

[6] Anita Slomski, *Why Do Hundreds of US Women Die Annually in Childbirth?*, JAMA (Mar. 13, 2019) (online at https://jamanetwork.com/journals/jama/fullarticle/2728576).

[7] American College of Obstetricians and Gynecologists, *ACOG Suit Petitions Court to Remove FDA's Burdensome Barriers to Reproductive Care During COVID-19* (May 27, 2020) (online at www.acog.org/news/news-releases/2020/05/acog-suit-petitions-the-fda-to-remove-burdensome-barriers-to-reproductive-care-during-covid-19) (accessed Feb. 9, 2021).

[8] Food and Drug Administration¸ *Policy for Certain REMS Requirements During the COVID-19 Public Health Emergency: Guidance for Industry and Health Care Professionals* (Mar. 2020) (online at www.fda.gov/media/136317/download).

[9] Plaintiffs included the American College of Obstetricians and Gynecologists, the Council of University Chairs of Obstetrics and Gynecology, the New York State Academy of Family Physicians, SisterSong Women of Color Reproductive Justice Collective, and Dr. Honor Macnaughton. Plaintiffs' First Complaint for Declaratory and Injunctive Relief (May 27, 2020), *Food and Drug Administration, et al. v. American College of Obstetricians and Gynecologists, et al.*, D. Md. (No. 8:20 CV 01320 TDC) (online at www.acog.org/-/media/project/acog/acogorg/files/advocacy/acog-v-fda-complaint-mifepristone-covid19.pdf?la=en&hash=2C5C6C65F3E6C8A693ACD649C7C12129).

[10] *Food and Drug Administration, et al. v. American College of Obstetricians and Gynecologists, et al.*, Civil Action No. TDC-20-1320 (D. Md. 2020) (online at.www.courthousenews.com/wp-content/uploads/2020/07/093111166803.pdf)

Following this ruling, the Trump Administration asked the Supreme Court to intervene and issue a stay on the District Court's injunction of the in-person dispensing requirement while it appealed the ruling.[11] The Supreme Court initially declined to intervene in the case, but a majority of justices agreed to reconsider the Administration's request after Justice Amy Coney Barrett joined the bench.[12]

On January 12, 2021, the Supreme Court granted the Trump Administration's request for a stay on the District Court's injunction, reinstating the in-person dispensing requirement for mifepristone. In a dissenting opinion, Justice Sonia Sotomayor, joined by Justice Elena Kagan, noted that "maintaining 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 women seeking to exercise their right to choose."[13]

In light of the clear danger that the reinstated requirement poses to people seeking comprehensive reproductive health care at the height of the coronavirus pandemic, we urge you to immediately eliminate the medically unnecessary in-person dispensing requirement for mifepristone.

The Committee on Oversight and Reform is the principal oversight committee of the House of Representatives and has broad authority to investigate "any matter" at "any time" under House Rule X. If you have any questions regarding this request, please contact Committee staff at (202) 225-5051.

Sincerely,

Carolyn B. Maloney
Chairwoman
Committee on Oversight and Reform

Ayanna Pressley
Member

Eleanor Holmes Norton
Member

Alexandria Ocasio-Cortez
Member

[11] *Trump Administration Asks Supreme Court to Reinstate Abortion Pill Restrictions Judge Has Suspended Due to Coronavirus*, CNBC (Aug. 26, 2020) (online at www.cnbc.com/2020/08/26/coronavirus-trump-administration-asks-supreme-court-to-rule-on-abortion-pill-restriction.html).

[12] *Supreme Court Reinstates Restrictions on Abortion Pill*, Politico (Jan. 12, 2021) (online at www.politico.com/news/2021/01/12/supreme-court-restrictions-abortion-pill-458436).

[13] *Food and Drug Administration, et al. v. American College of Obstetricians and Gynecologists, et al. on Application for Stay, 592 U..S. ___* (2021) (online at www.supremecourt.gov/opinions/20pdf/20a34_3f14.pdf).

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cc: The Honorable James R. Comer, Ranking Member