United States Senate
WASHINGTON, DC 20510

April 14, 2020

Stephen Hahn M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hahn:

In light of the growing coronavirus disease 2019 (COVID-19) pandemic in the United States, we write to ask the U.S. Food and Drug Administration (FDA) to take action to make sure Americans can access essential, time sensitive health care—including access to medication abortion care—during this public health emergency.

In order to limit the spread of the novel coronavirus, protect frontline health care workers, and preserve hospital capacity, hospitals and care providers across the country are postponing non-urgent or elective surgeries.[1] FDA also issued new guidance stating that it does not intend to take enforcement action for noncompliance with certain restrictions on drugs subject to a Risk Evaluation and Mitigation Strategy (REMS) in light of the COVID-19 public health emergency.[2] Despite growing calls to take up measures that maintain medical care while limiting face-to-face medical interaction when possible, steps to protect access to reproductive health care have not been taken in the same way. In fact, some states are actively restricting abortion care access, which both jeopardizes the health and well-being of patients seeking this time-sensitive health care and necessitates *greater* use of health care resources for prenatal, miscarriage, and childbirth care.[3]

People who need an abortion cannot delay care and should not needlessly risk coronavirus exposure. Given the years of scientific evidence indicating that medication abortion is a safe and effective treatment,[4] we ask that FDA take immediate steps to temporarily exercise

[1] Reuters, "U.S. hospitals, patients cancel elective surgery as coronavirus spreads," Deena Beasley, March 16, 2020, https://www.reuters.com/article/us-health-coronavirus-usa-surgery/u-s-hospitals-patients-cancel-elective-surgery-as-coronavirus-spreads-idUSKBN2133SK.
[2] FDA, "Guidance for Industry and Health Care Professionals: Policy for Certain REMS Requirements During the COVID-19 Public Health Emergency." March 2020, https://www.fda.gov/media/136317/download.
[3] New England Journal of Medicine, "Abortion during the COVID-19 Pandemic – Ensuring Access to an Essential Health Service," Michelle J. Bayesfsky et al., April 9, 2020, https://www.nejm.org/doi/full/10.1056/NEJMp2008006.
[4] Guttmacher Institute, "Medication Abortion," November 2019, https://www.guttmacher.org/evidence-you-can-use/medication-abortion.

enforcement discretion on in-person dispensing requirements,[5] so that people can more easily access abortion care without putting themselves or their health care providers at risk of infection from COVID-19.

Mifepristone is the first of two drugs used to complete a medication abortion or treat a miscarriage.[6] The drug has been heavily restricted and regulated by FDA since it was approved in the United States on September 28, 2000.[7] In 2011, the restrictions initially placed on the distribution of mifepristone so the agency could closely monitor the drug's use and collect safety data were converted to a REMS—a restricted distribution program imposed by FDA for "certain medications with serious safety concerns."[8] Under the REMS, mifepristone can only be prescribed and administered by "certified" health care providers who themselves are required to register with the manufacturer and are responsible for obtaining mifepristone supplies. In addition, mifepristone can only be dispensed to patients in clinics, medical offices, and hospitals by a certified health care provider. These requirements restrict access to medication abortion because mifepristone, unlike most medications, is not available at pharmacies and only a fraction of qualified clinicians are able to prescribe the drug.

On March 29, 2016, FDA approved a supplemental application for Mifeprex, revised the REMS for mifepristone, and updated the drug's labeling, noting that medication abortion's "efficacy and safety have become well-established by both research and experience, and serious complications have proven to be extremely rare."[9] Based on available data, FDA also updated the labeling to make clear that, while the medication must be dispensed in a clinic, medical office, or hospital, the patient may swallow it at home.[10] But FDA does not appear to have reconsidered the REMS in light of the current COVID-19 public health emergency.

Significant scientific evidence, research, and clinical experience has affirmed that medication abortion is safe and highly effective. Since 2000, over four million people in the United States have used mifepristone, and the adverse events reporting rate has been extremely low.[11] One study found that among over 13,000 women who completed the FDA-approved mifepristone-misoprostol regimen, 0.01% of participants experienced infections requiring

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[5] Risk Evaluation and Mitigation Strategy (REMS) single shared system for mifepristone https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2019_04_11_REMS_Full.pdf.

[6] Mifepristone is taken first to block pregnancy-enabling hormones. Within 48 hours, individuals take the second drug, Misoprostol, in order to induce uterine contractions; New England Journal of Medicine, "Mifepristone Pretreatment for the Medical Management of Early Pregnancy Loss," Courtney A. Schreiber et al., June 7, 2018, https://www.nejm.org/doi/full/10.1056/NEJMoa1715726.

[7] Associated Press, "FDA Approves Abortion Pill," September 28, 2000, https://washingtonpost.com/wp-srv/aponline/20000928/aponline115709_000.htm.

[8] U.S. Food and Drug Administration, "Risk Evaluation and Mitigation Strategies | REMS," August 8, 2019, https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems.

[9] FDA Center for Drug Evaluation and Research, "Application Number 020687Orig1020," March 29, 2016, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf.

[10] *Id*.

[11] Danco, "Mifeprex in the United States," https://www.earlyoptionpill.com/what-is-mifeprex/mifeprex-in-the-united-states/; Government Accountability Office, "Food and Drug Administration: Information on Mifeprex Labeling Changes and Ongoing Monitoring Efforts," March 2018, https://www.gao.gov/assets/700/691750.pdf.

hospitalization.[12] In general, major adverse events occur in less than 0.1% of cases[13]—which is less than the rates of adverse events reported with the use of many common medications without REMS, such as Tylenol or Viagra.[14] The National Academies of Science, Engineering, and Medicine (NASEM) affirmed the safety of medication abortion in a 2018 report, concluding, "[c]omplications after medication abortion, such as hemorrhage, hospitalization, persistent pain, infection, or prolonged heavy bleeding are rare—occurring in no more than a fraction of a percent of patients."[15] Studies also prove medication abortion's efficacy: a systematic review of 33,846 medication abortions conducted in 2015 found an overall effectiveness rate of 96.7% for gestations up to nine weeks.[16]

The medical community resoundingly agrees that any restrictions placed on the prescription and distribution of mifepristone are medically unnecessary.[17] Dr. Jane E. Henney, former FDA Commissioner at the time mifepristone was first approved, called on the agency to reevaluate the REMS last year.[18] And researchers at the University of California, San Francisco concluded that making mifepristone easily available in pharmacies would "likely improve access to abortion in the United States without increasing risks to women."[19]

Section 505-1 of the *Federal Food, Drug, and Cosmetic Act* requires FDA to only impose restrictions on drug distribution if the risks outweigh the benefits. Specifically, any ETASU required by FDA under 21 U.S.C. 355-1 must:

> (C) not be unduly burdensome on patient access to the drug, considering in particular patients with serious or life-threatening diseases or conditions; and patients who have difficulty accessing health care (such as patients in rural or medically underserved areas); and

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[12] Planned Parenthood, "Efficacy and Safety of Medical Abortion Using Mifepristone and Buccal Misoprostol Through 63 days," April 2015, https://www.ncbi.nlm.nih.gov/pubmed/25592080.
[13] FDA Center for Drug Evaluation and Research, "Application Number 020687Orig1020," March 29, 2016, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf.
[14] University of California San Francisco, "Analysis of Medication Abortion Risk and the FDA Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2018," Issue Brief, April 2019, https://www.ansirh.org/sites/default/files/publications/files/mifepristone_safety_4-23-2019.pdf.
[15] The National Academies of Science, Engineering and Medicine, *The Safety and Quality of Abortion Care in the United States*, Washington, DC: National Academies Press, 2018, http://nationalacademies.org/hmd/reports/2018/the-safety-and-quality-of-abortion-care-in-the-united-states.aspx.
[16] Chen, M. J., and M. D. Creinin. 2015. Mifepristone with buccal misoprostol for medical abortion: A systematic review. *Obstetrics & Gynecology* 126(1):12–21.
[17] American Medical Association (AMA), 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/media-browser/public/hod/a18-resolutions.pdf; American Academy of Family Physicians, "FPs Tackle Primary Care Spending, Other Weighty Topics," October 12, 2018, https://www.aafp.org/news/2018-congress-fmx/20181012cod-advocacy.html; American Congress of Obstetricians and Gynecologists (ACOG), ACOG Statement on Medication Abortion, March 30, 2016, https://www.acog.org/About-ACOG/News-Room/Statements/2016/ACOG-Statement-on-Medication-Abortion?IsMobileSet=false.
[18] New England Journal of Medicine, "Time to Reevaluate U.S. Mifepristone Restrictions," Jane E. Henney and Helene D. Gayle, August 15, 2019, https://www.nejm.org/doi/full/10.1056/NEJMp1908305.
[19] Journal of the American Pharmacists Association, "Medication Abortion: Potential for Improved Patient Access Through Pharmacies," July-August 2018, https://www.japha.org/article/S1544-3191(18)30182-1/abstract.

> (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.[20]

FDA has recognized the risks of in-person requirements at this moment. In March 2020, FDA issued guidance regarding the non-enforcement of REMS related to laboratory testing and imaging study requirements stating:

> FDA recognizes that during the COVID-19 PHE, completion of REMS-required laboratory testing or imaging studies may be difficult because patients may need to avoid public places and patients suspected of having COVID-19 may be self-isolating and/or subject to quarantine. Under these circumstances, undergoing laboratory testing or imaging studies in order to obtain a drug subject to a REMS can put patients and others at risk for transmission of the coronavirus.
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> For drugs subject to these REMS with laboratory testing or imaging requirements, health care providers prescribing and/or dispensing these drugs should consider whether there are compelling reasons not to complete these tests or studies during the PHE, and use their best medical judgment in weighing the benefits and risks of continuing treatment in the absence of laboratory testing and imaging studies. Health care providers should also communicate with their patients regarding these judgments, including the risks associated with it.[21]

In practice, by applying the REMS at this time, when state and local governments are taking aggressive measures to limit the spread of COVID-19, including by asking communities to avoid leaving their homes, FDA is forcing health care providers to choose between providing necessary health care to their patients and exposing themselves and their patients to additional risks. FDA has recognized the importance of giving health care providers discretion in this area during the current public health emergency, and should consider providing similar flexibility here, rather than letting any ideological objection to abortion care prevent health care providers from offering the safest care options to their patients. We request a staff-level briefing or written response regarding FDA's actions with regard to the REMS on mifepristone by no later than April 27, 2020.

Sincerely,

Elizabeth Warren
United States Senator

Patty Murray
United States Senator

[20] 21 U.S. Code § 355–1

[21] FDA, "Guidance for Industry and Health Care Professionals: Policy for Certain REMS Requirements During the COVID-19 Public Health Emergency." March 2020, https://www.fda.gov/media/136317/download.

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Tammy Baldwin
United States Senator