

April 28, 2020

BY ELECTRONIC MAIL

Janet Woodcock, M.D., Director
Center for Drug Evaluation and Research
United States Food and Drug Administration
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Re: Request Regarding COVID-19, Docket: FDA-2020-D-1106

Dear Dr. Woodcock,

We, the undersigned, respectfully request the U.S. Food and Drug Administration (FDA) reconsider its limitation of the recently released Policy for Certain REMS Requirements During the COVID-19 Public Health Emergency (Docket FDA-2020-D-1106).

The policy waives certain Risk Evaluation and Mitigation Strategies (REMS) requirements – namely laboratory tests and imaging – but not others. The requirements that certain drugs must be dispensed in-person by certain medical professionals provides similar burdens and risks to patients and providers as the waived requirements. Therefore, we request that in-person dispensation requirements, specifically for mifepristone, be included in this policy as temporarily waived.

Primarily, we are concerned that any delay in accessing abortion care is unsafe for patients. The in-person requirements in the Elements to Assure Safe Use (ETASU) of the REMS for mifepristone, is hindering access to medication abortion care and jeopardizing the health and safety of both patients and healthcare providers. Numerous medical associations, including the American Medical Association, American Academy of Family Physicians, and American College of Obstetricians and Gynecologists support the removal of REMS on mifepristone.

The REMS on mifepristone is requiring patients, unnecessarily, to access medical services in-person, instead of using telemedicine and mail-order pharmacy options. This unnecessarily raises the risk for many individuals, including medical providers who are required to see patients in-person to dispense or prescribe medication, their staff, and their patients.

As you know, the virus has up to a 14-day incubation period wherein people could be infected or carriers of the virus without symptoms. Patients and family members could be infected with COVID-19 and unwittingly carry the virus into medical offices. Not only could healthcare providers become infected, but they could potentially spread the virus to other patients, their families and other parts of the community. Unnecessary in-person visits make medical offices potential transmission sites for the virus.

During this unprecedented public health crisis, it is imperative that patients, especially those who are vulnerable or who live in rural areas, can use telehealth and mail-order pharmacy services to access needed healthcare without unnecessary restrictions, particularly for medications that do not pose a risk of abuse or overdose.

The change in REMS is needed to help reduce the risk to patients and alleviate the extreme burden on the rest of the healthcare system presently. The same compelling public health argument that allows temporary waving laboratory tests and/or imaging requirements also applies to in-person dispensation requirements of REMS for mifepristone. Please include in-person dispensation requirements of the mifepristone REMS under enforcement discretion during this public health emergency.

We thank you for your swift attention to this issue.

Sincerely,

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Abortion Care Network
Advocates for Youth
American Civil Liberties Union
American College of Nurse-Midwives
American College of Obstetricians & Gynecologists (DC Section)
American Humanist Association
American Medical Women's Association
American Society for Reproductive Medicine
AMPLIFY GA
California Nurse-Midwives Association
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Center for Reproductive Rights
Chicago Abortion Fund
Colorado Academy of Family Physicians
Equity Forward
Expanding Medication Abortion Access (EMAA) Project
Feminist Women's Health Center
Global Justice Center
Grandmothers for Reproductive Rights GRR!
Guttmacher Institute
Hesperian Health Guides
Hey Jane
Ibis Reproductive Health
If/When/How: Lawyering for Reproductive Justice
In Our Own Voice: National Black Women's Reproductive Justice Agenda
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Medical Students for Choice – The University of Iowa Carver College of Medicine Chapter
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NARAL Pro-Choice America
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National Abortion Federation
National Asian Pacific American Women's Forum (NAPAWF)
National Council of Jewish Women
National Health Law Program
National Institute for Reproductive Health (NIRH)
National Latina Institute for Reproductive Justice
National Organization for Women
National Partnership for Women & Families
National Women's Law Center
New York State Academy of Family Physicians
Northland Family Planning Centers of Michigan
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Planned Parenthood Ohio
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