GRETCHEN WHITMER
GOVERNOR

STATE OF MICHIGAN
OFFICE OF THE GOVERNOR
LANSING

GARLIN GILCHRIST II
LT. GOVERNOR

July 21, 2022

Dr. Robert Califf
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Califf:

I write today to urge the U.S. Food and Drug Administration (FDA) to remove the mifepristone Risk Evaluation and Mitigation Strategy (REMS) restrictions in order to eliminate yet another burdensome requirement that threatens timely and essential reproductive health care. We are facing a health care crisis in Michigan following the decision in *Dobbs v. Jackson Women's Health Organization.* Health care workers are going above and beyond to provide reproductive health care to a tremendous number of women, well exceeding their typical caseloads. Women are traveling to Michigan from regions where abortion is now illegal, and where women, nurses, and doctors face the threat of jail time for seeking or providing reproductive health care. Searches for abortion clinics have increased over 1,300% since the *Dobbs* decision. As such, I need to ensure that women have full access to care. The FDA's REMS restrictions are preventing many from accessing abortion care. You have the power to eliminate a major roadblock for women—I am asking you to exercise that power to help women and families.

While more work needs to be done to increase mifepristone accessibility, I commend the administration for taking steps to do just that in the last year. After the FDA announced it would not enforce the in-person dispensing requirement for medication abortion including mifepristone through the duration of the COVID-19 public health emergency, the agency went a step further by issuing permanent modifications to the REMS, including permanent removal of the in-person dispensing requirement.

It is critical that you further exercise FDA's authority and remove the REMS restrictions altogether. Leading medical organizations have found that mifepristone is both safe and effective, and several leading health associations, including the American College of Obstetricians and Gynecologists, the American Medical Association, and the American Academy of Family Physicians, have advocated for the removal of the REMS. The medical community has generally opposed REMS requirements because they place an unnecessary

burden on patients who want to access safe, effective medicine. In fact, mifepristone is safer than Tylenol, Viagra, and many other widely used medications.[1]

For too long, politics has undermined science when it comes to allowing women to make their own reproductive health decisions. Following the Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization*, the FDA must follow the science and advice of medical professionals to remove unnecessary burdens to reproductive health care. The mifepristone REMS prevent women from accessing the full range of reproductive health options.

In the face of a relentless assault on reproductive health, your agency must act now to provide women with options to make the best decision for them. We need to use every tool in our toolbox and get creative.

Sincerely,

Gretchen Whitmer
Governor

[1] *Safety and effectiveness of first-trimester medication abortion in the United States*, Advancing New Standards in Reproductive Health (August 2016) (online at https://www.ansirh.org/sites/default/files/publications/files/medication-abortion-safety.pdf)