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

Dear Commissioner Hahn:

On behalf of the Massachusetts Medical Society (MMS), representing over 25,000 physicians, residents, and medical students in the Commonwealth, I write to respectfully urge the U.S. Food and Drug Administration (FDA) to reevaluate the necessity of, and if maintained the composition of, the current Risk Evaluation Mitigation Strategies (REMS) classification for mifepristone to reduce barriers and improve access to reproductive health care.

Mifepristone is commonly used in combination with misoprostol to end pregnancy within the first 70 days of gestation. Mifepristone has been proven safe and highly effective (97%) with minor risk of complications (0.05%). Mifepristone is critical in managing early pregnancy loss. A 2018 study in the *New England Journal of Medicine* showed the combination of mifepristone and misoprostol is more effective than misoprostol alone to help women expel a miscarriage.[i] The CDC estimates that over 1 million American women have a first trimester pregnancy loss each year and the American College of Obstetricians and Gynecologists now officially recommends the two-drug regimen.[ii]

In 2016, the FDA modified the mifepristone label to align with more evidence-based dosing and gestational limits but retained the REMS classification. A REMS classification is intended to place restrictions only on the most dangerous drugs with known or suspected complications or contraindications. Despite being safe, effective, and essential to reproductive medical care, access to mifepristone is restricted in a way that makes it difficult for physicians to prescribe and creates unnecessary health care barriers for patients, disproportionately impacting patients of color. These constraints – specifically the requirement that mifepristone be dispensed in person – are particularly acute during the COVID-19 pandemic and may unnecessarily put patients at risk by requiring them to visit a clinic in person.

Thank you for consideration of this request. Please do not hesitate to reach out with questions or for more information.

Respectfully,

David A. Rosman, MD, MBA