May 2, 2025

The Honorable Martin Makary, MD, MPH
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Commissioner Makary:

On behalf of the Society of Family Planning, we submit this letter urging the Food and Drug Administration (FDA) to rely on the overwhelming evidence demonstrating the safety and efficacy of mifepristone for all decision-making regarding this drug. The Society of Family Planning is the academic society for Complex Family Planning subspecialists and represents the nation's community of clinicians, scholars, and partners who specialize in the science and medicine of abortion and contraception.

Mifepristone is safe and effective. Mifepristone has been studied for three decades and the scientific evidence is unequivocal that the medication is safe and effective. It is indicated for induced abortion and miscarriage management, and major adverse events are exceedingly rare. Our members rely on medications approved and regulated by FDA, including Mifeprex® (mifepristone) 200mg tablet and its approved generic bioequivalent, to provide evidence-based care to our patients.

Claims questioning mifepristone's safety are scientifically unsupported and should be dismissed. Notwithstanding the overwhelming evidence, we understand you have received requests to apply scientifically invalid claims about its safety to a review of mifepristone's label. Of note, we have grave concerns about a recent such request that relies on a self-published, non-peer-reviewed paper released on April 28, 2025, which makes clearly unsupported claims about the rate of serious adverse events following medication abortions. Among its deficiencies, the paper:

- Incorrectly counts emergency room visits as serious adverse events, which contradicts FDA guidance.
- Wrongly classifies subsequent treatment to complete an abortion as a serious adverse event, when it is an expected occurrence in 3-5% of cases.

- Conflates abortion with miscarriage and other uses of mifepristone, which leads to an inflated rate of complications.
- Lacks a standardized definition of hemorrhage, likely capturing normal bleeding as a serious adverse event.
- Incorrectly includes ectopic pregnancy as a complication of medication abortion in the study.

This paper's authors subsequently extrapolate unfounded policy recommendations for the FDA's labelling of mifepristone, which are not supported by their own findings, nor can their analyses be verified, due to a lack of transparency about the data source. In short, this paper is not a methodologically rigorous, evidence-based resource, and does not warrant consideration, particularly in scientific spaces. **We urge the FDA to dismiss the paper–and all claims inconsistent with strong scientific standards–as irrelevant to its regulatory decision-making.**

Mifepristone is currently subject to burdensome regulatory requirements that impede access to safe, essential care. FDA continues to subject mifepristone to unique regulatory requirements that impose burdens on healthcare providers and hamper patients' access to this medication. Earlier this year, the Society of Family Planning joined other clinician organizations in submitting a citizen petition requesting that the FDA eliminate its existing medically unnecessary barriers to mifepristone. We urge the FDA to align the mifepristone label with the science and clinical best practices outlined in this citizen petition.

FDA, as the body that oversees the approval and withdrawal of drug applications, is foundational to drug safety and access in the United States. We ask that the agency rely on high standards of evidence for any decision-making regarding mifepristone, and are available to answer any questions you may have regarding these issues.

Sincerely,

Society of Family Planning