

March 6, 2023

The Honorable Robert M. Califf, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Commissioner Califf:

On behalf of the Society of Family Planning, the American College of Obstetricians and Gynecologists, and the Society for Maternal-Fetal Medicine, we submit this letter in regards to attacks on FDA's approval of mifepristone. 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. The American College of Obstetricians and Gynecologists is the nation's leading organization of physicians who provide health services unique to people seeking obstetric or gynecologic care. The Society for Maternal-Fetal Medicine is the professional society for the nation's maternal-fetal medicine subspecialists, who are obstetricians with additional training in caring for individuals experiencing high-risk pregnancies. Collectively, we represent the nation's providers of reproductive and obstetric healthcare, serving millions of patients every year.

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. As you know, mifepristone has been studied for three decades and the scientific evidence is unequivocal that the medication is safe and effective.

Notwithstanding the overwhelming evidence demonstrating the safety and efficacy of mifepristone, as well as FDA's approval of mifepristone for more than two decades, anti-science special interests are attacking FDA's approval of the medication. While these attacks are baseless, they have caused the provider community to become gravely concerned about the predictable future availability of mifepristone for patients. Our members are concerned about the availability of medication they use in a range of reproductive healthcare, patient access to this essential care, and concerns about its overall impact on scientific research and advancement.¹

¹ Zettler PJ, Adashi EY, Cohen IG. *Alliance for Hippocratic Medicine v. FDA - Dobbs's Collateral Consequences for Pharmaceutical Regulation* [published online ahead of print, 2023 Feb 22]. *N Engl J Med.* 2023;10.1056/NEJMp2301813. doi:10.1056/NEJMp2301813

There has been a lack of communication from FDA, to date, regarding how it would seek to manage any disruptions to the supply of mifepristone resulting from external attacks on FDA's approval of the medication. FDA is the body with the authority in the United States to oversee the withdrawal of an approved drug application. See 21 U.S.C. § 355 (e); *Weinberger v. Hynson, Wescott & Dunning, Inc.*, 412 U.S. 609, 633 (1973). Further, there are specific withdrawal procedures outlined in the Food Drug and Cosmetic Act ("FDCA") that must be followed prior to removing a product from the market, including processes recently discussed by a number of legal scholars.²⁻³ These processes are essential to the predictable distribution of medication – and are critical for our members who are on the ground to ensure that evidence-based care is not disrupted in the event of external interference with FDA's regulatory authority.

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 provide information as soon as possible regarding its plans, in the event of any type of interference with FDA's approval of mifepristone. We further ask that after the court issues any ruling that FDA promptly issue guidance and that FDA take all steps possible, including exercising enforcement discretion, if necessary, to preserve and enhance access to mifepristone.**

Sincerely,

Society of Family Planning
American College of Obstetricians and Gynecologists
Society for Maternal-Fetal Medicine

² Cohen DS, Donley G, Rebouche R. Actually, One Texas Judge Is Not the Final Decision-Maker on Medication Abortion. *Slate*. February 28, 2023. <https://slate.com/news-and-politics/2023/02/texas-judge-abortion-case-actually-limited-mifepristone.html>

³ *Alliance for Hippocratic Medicine v. FDA*. Brief of Amici Curiae Medical and Public Health Societies in Opposition to Plaintiffs' Motion for a Preliminary Injunction. February 10, 2023. <https://storage.courtlistener.com/recap/gov.uscourts.txnd.370067/gov.uscourts.txnd.370067.108.0.pdf>