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Statement for the Record

U.S. Senate Committee on Health, Education, Labor and Pensions

Hearing on "Protecting Women: Exposing the Dangers of Chemical Abortion Drugs"

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Chair Cassidy and Ranking Member Sanders, on behalf of Families USA, we thank you for the opportunity to submit this statement for the record on today's hearing, *"Protecting Women: Exposing the Dangers of Chemical Abortion Drugs."* The focus of our statement is on the importance of maintaining access to safe and effective medication abortion, including medications like mifepristone.

Abortion is essential health care that helps women safely and effectively manage their health and pregnancy outcomes. Whether managing a miscarriage in the comfort of her own home, receiving lifesaving emergency room care, or due to a range of other reasons, one in four women in the United States are expected to need an abortion by age 45.[i] Mifepristone plays a key role for women who need safe and effective abortion care. The medication is approved by the U.S. Food and Drug Administration (FDA) and has been used by patients in the United States for more than two decades for abortion care, including the management of a miscarriage.

Ongoing legal and political attacks that baselessly question the safety of mifepristone not only jeopardize access to essential health care but also threaten the integrity of the FDA's gold-standard drug approval process. Allowing for judicial, legislative, or political interference in FDA decision-making risks far-reaching consequences for all Americans who need access to any FDA-approved medications. We urge the Committee to exercise great caution when considering actions that would second-guess or override the FDA's scientific drug approval process, and to consider the extensive body of evidence demonstrating that mifepristone is safe and effective, and that access to this medication is critical to protecting Americans' health and reproductive freedom.

<u>Mifepristone is safe and effective</u>

After an extensive and rigorous 54-month review process, the FDA approved mifepristone for use in abortion care more than 25 years ago.[ii] Prior to and after its approval, mifepristone has been the subject of nearly four decades of peer-reviewed research demonstrating that it is safe and effective.[iii] Beyond FDA approval and decades of clinical evidence, mifepristone's safety has been affirmed by the nation's leading medical authorities, including the American College of Obstetrics and Gynecology (ACOG) and the American Medical Association (AMA). The medication has also been approved for use in more than 100 countries globally.[iv]

When used in combination with misoprostol, the medications account for the majority of abortions in the United States, including most of the abortion procedures performed prior to 10 weeks of pregnancy.[v] Clinical research further demonstrates that mifepristone is safe for provision via telehealth, can be prescribed by qualified clinicians beyond physicians, and does not require burdensome or medically unnecessary regulatory restrictions.[vi] Calling into question the safety of mifepristone is antithetical to decades of scientific research and only serves to undermine public trust in evidence-based policymaking and in the government agencies and regulatory bodies that have been charged with protecting public health.

Because mifepristone is the safest and most effective non-surgical method for terminating a pregnancy, it has important clinical applications in the management of a miscarriage.[vii] Approximately 1.1 million women in the United States experience a miscarriage each year, a condition that can carry serious and, in some cases life-threatening risks. For many patients experiencing miscarriage, mifepristone is prescribed to help the body safely and effectively empty the uterus, reducing the risk of complications such as infection and hemorrhage.[viii] In these circumstances, access to mifepristone can be lifesaving.

Attacks on mifepristone are an attack on evidence-backed science and medicine

Efforts to restrict access to mifepristone under the guise of safety pose a direct threat to the gold standard, science-based approval and oversight process, which exists to ensure that consumers have access to safe and effective medications. Before a drug is approved for the U.S. market, experts at the FDA— including physicians, chemists, and pharmacologists— rigorously evaluate the full body of evidence to determine whether a drug's benefits outweigh any health risks for its intended population.[ix]

This expert-driven drug approval process was designed to protect the health and well-being of patients and promote public confidence in the nation's supply of medications. Increasingly, however, the FDA's decisions related to mifepristone are being challenged without sufficient medical or scientific evidence, raising concerns about the politicization of decisions that have traditionally been based on evidence and clinical judgement.

Court challenges to the FDA's approval of mifepristone, along with state and federal efforts to restrict, limit, or ban access to the medication, risk undermining the role of the FDA and the integrity of the scientific review process. When policymakers or judges, rather than scientists and clinicians, determine which FDA-approved drugs should be made available to consumers, the precedent it sets extends far beyond mifepristone. Such interference leaves ALL medications vulnerable to judicial, legislative, and political attacks, threatening stability, trust, and consumer access across the health care system.

Conclusion

We appreciate the efforts of the committee members and their staff to highlight the critical role of mifepristone in providing safe, timely and essential health care. Now more than ever, amid continued state- and federal-level attacks on access to reproductive health care, and on the patients and clinicians seeking and providing that care, Congress must take steps to maintain public trust in the FDA's gold-standard drug approval process.

Mifepristone's safety and efficacy are undisputed within the medical and scientific communities and should not be further politicized. Nearly 60 million women of reproductive age in the United States are depending on the FDA and Congress to maintain access to safe and effective abortion care. Families USA stands ready to support you is this essential and urgently needed work.

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