The Facts on Mifepristone



What is Mifepristone?

Mifepristone is the first of two medications used in a medication abortion (also known as the "abortion pill"). Mifepristone has been safe and legal in the United States since the U.S. Food and Drug Administration (FDA) approved the brand name Mifeprex nearly 20 years ago. In April 2019, the FDA approved the first generic form of mifepristone, following a review of the evidence that medication abortion is a safe, effective way to end an early pregnancy – with a safety record of over 99%.

What Happens in a Medication Abortion?

The "abortion pill" is the common name in the United States for using two different medications – mifepristone and misoprostol – to end an early pregnancy. In general, it is used up to 70 days, or 10 weeks, after the first day of your last menstrual period.

- 1. **Mifepristone** works by blocking the hormone progesterone. Without progesterone, the lining of the uterus breaks down and the pregnancy cannot continue.
- 2. Misoprostol, the second medication, is taken either right away or up to 48 hours later and causes the uterus to empty. It's like having a heavy, crampy period and is very similar to an early miscarriage.

Medication abortion is extremely effective in ending an early pregnancy, working approximately 95-99% of the time, and gives patients the option to end their pregnancy at home or in another setting in which they feel comfortable, while still providing them with the medical support and information they need.

A growing number of patients in the United States are choosing to end their pregnancy with medication abortion. In fact, in 2014, nearly one in three people seeking abortion outside of a hospital used medication abortion.

The World Health Organization has concluded that misoprostol, taken in certain doses, can be used safely and effectively to end an early pregnancy in situations where using the combination of both mifepristone and misoprostol is not available - although taking only misoprostol is less effective than the combined mifepristone/misoprostol regimen. In the United States, the FDA-approved regimen is for patients to take both mifepristone and misoprostol.

What Else is Mifepristone Used for?

Mifepristone is also used for evidence-based indications in (1) medical management of miscarriage, (2) cervical preparation for later 2nd trimester abortion, and (3) management of 2nd and 3rd trimester pregnancies when the fetus has died before birth.

Use in Miscarriage Care

Mifepristone, in combination with misoprostol, offers the most effective medication regimen for managing an early miscarriage. A 2018 study published in the New England Journal of Medicine found that adding mifepristone to the medication misoprostol was more effective for the management of early miscarriage than taking misoprostol alone and reduced the likelihood of patients needing an additional procedure.

Claims of "Abortion Reversal"

There is no medical evidence to support the assertion that a medication abortion can be "reversed" if someone is given a high dose of progesterone after taking mifepristone. This claim is primarily led by Dr. George Delgado, an acknowledged anti-abortion activist. In recent years, his unproven concept of "abortion reversal" has been introduced into legislatures across the country by those opposed to legal abortion. In 2015, Arizona was the first state to pass a law requiring providers to tell their patients that their medication abortions could be "reversed." A number of other states have since followed suit, despite the lack of evidence.

Planned Parenthood continually reviews available research and medical evidence to inform our Medical Standards & Guidelines and patient education materials. The treatment that Delgado has proposed, as well as the legislative efforts requiring health care providers to inform people seeking abortion of that treatment, are not evidence-based. Experts such as the American College of Obstetricians and Gynecologists reject these claims, as they have not been proven in reliable medical studies. In 2019, a study testing the claim of "abortion reversal" was halted early due to patient safety concerns.

Medically Unnecessary Restrictions on Mifepristone

Currently in the United States, patients cannot access mifepristone through a pharmacy. It remains out-ofreach for many people across the country, particularly those living in remote or rural areas, due to the FDA's Risk Evaluation and Mitigation Strategy (REMS) restrictions. The REMS restrictions on mifepristone are not supported by research and create medically unnecessary barriers for patients accessing both medication abortion and the best method of managing a miscarriage.

- REMS restrictions on mifepristone require that patients must be given the medication at a doctor's office, hospital, or health center from a health care provider who has pre-registered with the drug manufacturer and arranged to stock the medication at their facility (or is under the supervision of another health care provider who has).
- These unnecessary restrictions limit the number of health care providers who prescribe mifepristone and severely limit patients' access to this option, since patients aren't able to fill a prescription for the medication at a pharmacy, as they could with any other equally safe medication.

- The REMS restrictions on mifepristone are not supported by research and are yet another example of reproductive health care especially abortion being treated differently than other kinds of health care in ways that only make things harder for patients.
- Because they're not supported by medical science, leading medical associations including the American College of Obstetricians and Gynecologists and American Academy of Family Physicians – support removing REMS restrictions on mifepristone entirely.

A number of states have additional laws further regulating the administration of medication abortion. For example, there are currently 18 states that effectively ban providing medication abortion via telemedicine, even though there is no scientific basis for these bans.

Planned Parenthood believes that everyone should be able to have a safe and legal abortion, if and when they make that decision. Planned Parenthood health centers in 14 states currently use health-center-telemedicine to provide patients with access to medication abortion. Providing medication abortion via telemedicine is just as safe and effective as when the health care provider is in the same health center as the patient. This is just one part of the work we do to ensure that all people get the reproductive health care they need, no matter where they live.