



The Safety of Medication Abortion Care

What is medication abortion care?

Medication abortion care is a safe and effective FDA-approved medication regimen for ending an early pregnancy. It is a non-invasive abortion option that is approved for use up to 10 weeks in pregnancy.

- The medication abortion regimen involves two different pills. One pill, called mifepristone, is taken first and then pills, called misoprostol, are taken 24-48 hours later.
- A growing proportion of women are deciding to end their pregnancies with medication abortion care. In 2017, 4-in-10 of women seeking abortion chose this method.¹
- An overwhelming majority of women who choose medication abortion care are satisfied with the method. One study found that 97% of women would recommend the method to a friend.²

Is medication abortion care safe?

Since the FDA approved medication abortion care in 2000, it has been used by more than 4 million people in the U.S. It has a well-documented safety record, demonstrated in real-world use and more than 100 research publications.

- The National Academy of Science, Engineering, and Medicine (NASEM) conducted a systematic review of medication abortion care. Of nearly 34,000 medication abortions, NASEM found an overall effectiveness rate of 96.7% for gestations up to 63 days (9 weeks).³
- The FDA has stated that medication abortion care is well-established as safe and effective, and that serious complications are extremely rare.⁴

Why isn't medication abortion care more available?

Federal and state regulations have restricted patient access to medication abortion care.

- The restrictions FDA put in place almost 20 years ago require providers to act as both prescribers and pharmacists by stocking and dispensing the medication themselves. This limits the numbers of doctors willing to offer medication abortion care.
 - A recent survey of OB/GYNs found that 72% reported having a patient who wanted or needed an abortion in the last year, but only 24% provide abortion services. Of those not providing abortion services, 28% said they would start offering medication abortion care if distribution restrictions were changed.⁵
 - FDA restrictions also mean the medication cannot be dispensed by mail-order or at a pharmacy, except in FDA-approved clinical trials.
- In addition to federal regulations, 18 states require the prescribing healthcare provider to be physically present when medication abortion is dispensed, which effectively bans telemedicine.⁶
 - State restrictions on abortion, including waiting period laws and facility requirements, also apply to medication abortion care.

¹ Guttmacher Institute. [Evidence You Can Use: Medication Abortion](#). November 2019.

² D. Hollander. [Most Abortion Patients View Their Experience Favorably, But Medical Abortion Gets a Higher Rating than Surgical](#). *Perspectives on Sexual & Reproductive Health*. October 2000.

³ National Academies of Sciences, Engineering, and Medicine (NASEM). [The Safety and Quality of Abortion Care in the United States](#). Page 53. March 2018.

⁴ U.S. Food and Drug Administration. [Clinical Review of NDA 020687/S-020 Mifeprex \(2016\)](#). March 2016.

⁵ D. Grossman, et al. [Induced Abortion Provision Among a National Sample of Obstetrician-Gynecologists](#). *Journal of Obstetrics & Gynecology*. March 2019.

⁶ Guttmacher Institute. [State Laws and Policies: Medication Abortion](#). February 2020.

Medical societies and public health organizations recognize medication abortion care as safe. Many are calling on FDA to reevaluate the current restrictions.

Key Safety Statements:

- **Food and Drug Administration (FDA):** Medication abortion has been increasingly used as its efficacy and safety have become well-established by both research and experience, and serious complications have proven to be extremely rare.
- **World Health Organization (WHO):** Medical abortion plays a crucial role in the provision of access to safe, effective and acceptable abortion care.
- **Centers for Disease Control and Prevention (CDC):** Likewise, the development of early medical abortion regimens has allowed for abortions to be performed very early in gestation, with completion rates for regimens that combine mifepristone and misoprostol reaching 96%–98%.
- **National Academies of Science, Engineering and Medicine (NASEM):** The risks of medication abortion are similar in magnitude to the risks of taking commonly prescribed and over-the-counter medications such as antibiotics and NSAIDs.

Calls to Reevaluate FDA Restrictions:

- **Dr. Jane Henney (Former FDA Commissioner):** Women should have access to FDA-approved products whose safety and effectiveness are confirmed. Since the evidence available today indicates that the current restrictions are overly prescriptive, we urge the FDA to reevaluate whether they are still necessary.
- **American College of Obstetricians and Gynecologists (ACOG):** The current U.S. Food and Drug Administration (FDA) Risk Evaluation and Mitigation Strategy (REMS) and Elements to Assure Safe Use (ETASU) requirements for Mifeprex® (mifepristone, 200 mg) are outdated and substantially limit access to this safe, effective medication. Therefore, ACOG urges the removal of the REMS and ETASU for Mifeprex®.
- **American Academy of Family Physicians (AAFP):** The AAFP seeks changes in the drug's current REMS designation to conform to current evidence...Recent research also indicates the agency's safety protocols are particularly stringent for the drug. Most importantly, the current drug label creates an unnecessary health care barrier for women who need it the most.
- **American Medical Association (AMA):** Resolved that our American Medical Association support efforts urging the Food and Drug Administration to lift the Risk Evaluation and Mitigation Strategy on mifepristone.