



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.

- 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.
- It is a non-invasive abortion option that is approved for use up to 10 weeks in pregnancy.

A growing proportion of people are choosing medication abortion care.

- In 2018, medication abortion accounted for 54% of abortions before 9 weeks.¹ The vast majority of these abortions happened outside of the clinic - most usually in the comfort of the patient's home or place of their choosing.
- 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
- An overwhelming majority of women who choose abortion report it was the right decision in the days after an abortion,^{3,4} and five years later 99% of women said it was the right decision for them.⁵

Is medication abortion care safe?

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

- The [FDA has stated](#) that medication abortion care is well-established as safe and effective, and that serious complications are extremely rare.⁶
- Leading medical and scientific organizations, including the American Medical Association,⁷ the American College of Obstetricians and Gynecologists,⁸ and the American Academy of Family Physicians,⁹ recognize medication abortion care as safe and effective.
- In January 2023, after a thorough review of the science and evidence, the FDA permanently lifted the requirement that a patient pick up their pills in person at a clinic and approved a program in which pharmacies can fill prescriptions. This means patients can get their prescriptions filled at a clinic, local pharmacy, or delivered to their own home.¹⁰
- New data from Canada demonstrates mifepristone can safely be prescribed and dispensed like any other drug. A 2021 study found no increase in abortion-related health complications among 315,000 patients in the 4 year period following the removal of restrictions on mifepristone.¹¹

¹ Kortsmits, K., Jatlaoui, T.C., Mandel, M.G., Reeves, J., Oduyebo, T., Petersen, E., & Whiteman, M.K. [Abortion Surveillance — United States, 2018](#). *CDC MMWR Surveillance Summaries*. November 2020.

² Hollander, D. [Most abortion patients view their experience favorably, but medical abortion gets a higher rating than surgical](#). *Perspectives on Sexual and Reproductive Health*. September 2000.

³ Ralph, L., Foster, D. G., Kimport, K., Turok, D., & Roberts, S. C. [Measuring decisional certainty among women seeking abortion](#). *Contraception*. October 2016.

⁴ Rocca, C., Kimport, K., Gould, H., Foster, D.G. [Women's emotions one week after receiving or being denied an abortion in the United States](#). *Perspectives on Sexual and Reproductive Health*. September 2013.

⁵ Rocca, C.H., Samari, G., Foster, D.G., Gould, H., Kimport, K. [Emotions and decision rightness over five years following an abortion: An examination of decision difficulty and abortion stigma](#). *Social Science & Medicine*. March 2020.

⁶ U.S. Food and Drug Administration. [Clinical Review of NDA 020687/S-020 Mifeprex](#). March 2016.

⁷ American Medical Association. [AMA applauds lifting restrictions on reproductive care medication](#). April 2021.

⁸ American College of Obstetricians and Gynecologists. [Medication Abortion Up to 70 Days of Gestation: Practice Bulletin Number 225](#). October 2020.

⁹ American Academy of Family Physicians. [Letter to Acting FDA Commissioner Sharpless](#). June 2019.

¹⁰ U.S. Food and Drug Administration. [Questions and Answers on Mifeprex](#). January 2023.

¹¹ Schummers, L., Darling, E. K., Dunn, S., McGrail, K., Gayowsky, A., Law, M. R., Laba, T.-L., Kaczorowski, J., & Norman, W. V. [Abortion Safety and Use with Normally Prescribed Mifepristone in Canada](#). *The New England Journal of Medicine*. January 2022.

- A 2021 study from the U.K. found that after in-person dispensing requirements were lifted, wait times for care were reduced from 10 or 11 days to 6 or 7 days with no difference in safety outcomes.¹²

If this medication is FDA approved, why do some people encounter barriers to access?

Although proven to be safe and effective, medically unnecessary state regulations restrict patient access to medication abortion care.

- Currently, 19 states prohibit telehealth options for medication abortion care or require the prescribing health care provider to be physically present when the medication is dispensed, which effectively bans telehealth models of care.¹³
 - State laws that mandate in-person visits for medication abortion care contradict FDA guidance and are not supported by medical and scientific evidence.
 - Other baseless state restrictions on abortion - including waiting period laws, staffing and facility requirements, and billing and reimbursement restrictions apply to medication abortion care.
- Unjustifiable bans on insurance coverage for abortion, including under Medicaid, limit access and disproportionately impact those who already face significant barriers to receiving quality care, such as people working to make ends meet, immigrants, young people, and women of color.

Even more disturbing, new litigation could result in overturning FDA approval, resulting in a *de facto* national ban on mifepristone for medication abortion care.

- On November 18, 2022, anti-abortion organizations filed a federal [lawsuit](#) in Texas against the U.S. Food & Drug Administration (FDA) and the U.S. Department of Health and Human Services (HHS) challenging the FDA's approval of mifepristone. Plaintiffs are asking the court to immediately enjoin the FDA's approval of the drug while the case proceeds.
- Lawsuits against the FDA's drug approvals are not unknown. However, such cases typically involve legal claims over a recent drug approval (or non-approval) and the FDA's interpretation of market exclusivity provisions, such as whether a drug company receives a monopoly and for how long. This lawsuit is highly unusual in that it challenges the approval of a drug which has been safely used by more than 4 million people over 20+ years and constitutes over half of abortions performed today.
- If the plaintiff's motion is granted, *it could block use of mifepristone for medication abortion nationwide as early as mid-February.*
- Such a decision would undermine the FDA's authority for purely political reasons and would have far-reaching implications for drug development in the US, not to mention Americans' access to needed medications like vaccines or birth control.

¹² Aiken, A., Lohr, P., Lord, J., Ghosh, N., & Starling, J. [Effectiveness, safety and acceptability of no-test medical abortion provided via telemedicine: a national cohort study](#). *British Journal of Obstetrics & Gynecology*. February 2021.

¹³ Guttmacher Institute. [State laws and policies: medication abortion](#). January 2022.