

Background

Medication abortion is a safe and effective way to terminate a pregnancy. There are two FDA approved and commonly used medication regimens that are utilized for a medication abortion. The first regimen uses a combination of the medications mifepristone and misoprostol, and the second regimen uses misoprostol only.

Misoprostol was first developed in the United States in 1973 to treat peptic ulcers, which are sores that develop on the inside lining of the stomach or small intestines. In addition to helping repair the lining of the stomach and small intestines when ulcers have occurred, misoprostol has additional mechanisms of action including stimulation of prostaglandin receptors in the uterus which causes the cervix to soften and open and induces cramping of the uterus.ⁱ Its use to end a pregnancy was discovered by women in Brazil in the late 1980s who were seeking to end their pregnancy at a time when abortion was illegal in the country.ⁱⁱ Misoprostol is also used for a variety of medical indications including the treatment of pregnancy loss, induction of labor, cervical ripening – the softening and opening of the cervix, and treatment of postpartum hemorrhage.ⁱⁱⁱ

Mifepristone, which works by blocking progesterone receptors thereby causing a pregnancy to stop growing, was developed by researchers in France in the 1980s. It later became available in the United States when the U.S. Food and Drug Administration (FDA) approved its use for medication abortion in 2000. The FDA approval was the result of years of rigorous testing and comprehensive review of scientific evidence. The FDA has continued to evaluate the drug, and more than 100 studies affirm the safety and efficacy of mifepristone.^{iv} Today, the FDA has approved the use of mifepristone to 10 weeks gestation. The World Health Organization supports its use up to 12 weeks for medication abortion as well as its use later in pregnancy to aide in procedural abortion care.^v Since the FDA approval of mifepristone, it has been used in combination with misoprostol to end pregnancies and to manage pregnancy losses.

In 2023, medication abortion accounted for 63% of all abortions in the United States, an increase from 53% in 2020.^{vi} The majority of medication abortions performed in the United States are done using a regimen of mifepristone and misoprostol. However, many countries across the globe as well as providers and

individuals in the United States use misoprostol alone, without the addition of mifepristone to provide this care.

Mechanism of Action

Mifepristone is an antagonist of progesterone receptors. This means that it works by binding to progesterone receptors, thereby interrupting the hormone progesterone.^{vii} Progesterone is the primary hormone that works to maintain the pregnancy by preparing the endometrium, the inner lining of the uterus, for implantation and sensitizing the body to the effects of prostaglandins. When progesterone receptors are blocked, the pregnancy can no longer grow.

Misoprostol is a prostaglandin agonist that works by binding to prostaglandin receptors on the smooth muscle cells of the uterine lining, which causes cervical ripening and uterine cramping, thereby causing the uterus to expel the pregnancy and empty.

Mifepristone and Misoprostol Combined Protocol and Efficacy

The combination regimen of mifepristone and misoprostol is approved by the FDA for terminating a pregnancy until 10 weeks gestation using a dose of 200 mg of oral mifepristone followed by 800 mcg of misoprostol 24–48 hours later.^{viii} Misoprostol may be administered buccally (placed between the cheek and the gum), vaginally, or sublingually (placed beneath the tongue). This combination of mifepristone and misoprostol has an efficacy rate (successfully terminating the pregnancy) of >95%.^{ix} Beyond 10 weeks' gestation, mifepristone and misoprostol can be used to terminate pregnancy in repeated administrations.^x

Misoprostol Only Protocol and Efficacy¹

Misoprostol alone has been used for abortions by people globally for decades. Research shows that a regimen of 800 mcg of misoprostol every three hours sublingually or vaginally results in a completed abortion with effectiveness comparable to the combination regimen of mifepristone and misoprostol.^{xi} The

¹ We should consider whose values we are prioritizing in examining available protocols and assigning them worth. Researchers have found that a doctor's timeline for what defines a "completed abortion" might look shorter than a patient's timeline for a completed abortion, therefore skewing the data when we compare an empty uterus after one week versus four weeks post abortion. Moreover, the threshold for procedural intervention varies from person to person and provider to provider. Most beginning the medication abortion process will complete the process without additional intervention when given more time.

misoprostol only regimen successfully terminates pregnancy 80–100% of the time and has a complication rate of less than 1%.

Protocols from the [World Health Organization Abortion Care Guidelines \(2022\)](#) recommend the use of 400–800 mcg misoprostol, depending on the gestational age, administered vaginally, sublingually, or buccally in repeated doses until the abortion is completed. The WHO does not provide a maximum number of doses of misoprostol. As many doses as necessary can be used to complete the abortion.

Other organizations that endorse protocols for medication abortion using misoprostol alone include the [Society for Family Planning](#) and the National Abortion Federation using similar doses and frequency of admission.

Safety of Medication Abortion

There are very few contraindications to medication abortion pills. Those that exist include suspected or confirmed ectopic pregnancy, hemorrhagic disorder, allergy, chronic adrenal failure, inherited porphyria or an intrauterine device in place.^{xii} Complications following a medication abortion are very rare.^{xiii, xiv}

Moreover, telemedicine for medication abortion has been shown to be as safe as in-person clinic care. For example, a study demonstrated that the overall difference in the prevalence in adverse events between a telemedicine and in-person visit for medication abortion was only 0.13%.^{xv} The research supporting the safety and efficacy of telemedicine for abortion care prompted the FDA to temporarily suspend the in-person dispensing requirement for mifepristone during the COVID-19 pandemic as a public health measure. This led to the FDA permanently modifying its guidance to allow clinicians to prescribe medication abortion pills via telehealth and for medication abortion pills to be sent via mail.^{xvi} The number of US providers offering medication abortion via telehealth and mailing abortion pills increased in 2022 to 31%, from just 7% in 2020.^{xvii} Research published in 2024 reemphasized the safety and effectiveness of telemedicine for medication abortion, finding that the rate of serious adverse events was 0.2% – these numbers are similar to what is found for patients receiving medication abortion care in-person at clinics or doctor's offices.^{xviii}

Telehealth Medication Abortion

Telehealth allows clinicians to provide care to patients virtually without an in-person appointment. This allows patients to directly connect with a health care provider from any location without having to travel to a health care center. Telehealth can be synchronous, care is provided using video or phone calls, or asynchronous, care is provided via secure chat or messaging. Telehealth has become increasingly essential for abortion care since *Dobbs*.

Patients living in states with abortion bans rely on shield-law telehealth as a primary point of access to medication abortion care. A shield law allows providers living in a state where abortion is protected to use telehealth to prescribe and mail abortion medication to patients in a state where abortion is restricted or banned.^{xix} For patients living in states with total abortion bans, telehealth abortions provided under shield laws accounted for 97% – 100% of abortions within those states in 2025.^{xx} Since 2022 the proportion of abortions provided via telehealth has increased, with 28% of abortions in 2025 provided via telehealth.^{xxi}

Food and Drug Administration Risk Evaluation and Mitigation Strategy

Despite an enormous and rigorous body of evidence demonstrating the safety and efficacy of the medication, the FDA has restricted the distribution of mifepristone through the FDA's Risk Evaluation and Mitigation Strategy (REMS) program. REMS are safety programs put into place to prevent, monitor, and manage serious risk associated with a medication through informing, educating and reinforcing actions to reduce the frequency and severity of that risk. In 2007, the Food and Drug Administration Amendments Act of 2007 was passed and granted the FDA the authority to require a Risk Evaluation and Mitigation Strategy (REMS) for a drug if the FDA deems it necessary to ensure the drug's benefits outweigh its risks. Under this law, Congress deemed all drugs with existing restricted-distribution programs, including mifepristone, to require a REMS. The FDA approved the initial REMS for mifepristone in 2011, which at the time required in-person dispensing of mifepristone by or under the supervision of a certified physician, dispensing of misoprostol at the provider's office or clinic, and a mandated follow-up visit 14 days later.

Relying on extensive safety data and scientific evidence, the FDA has periodically updated the mifepristone REMS program. This includes extending the use of the combined medication abortion regimen of mifepristone and misoprostol from 7 weeks to 10 weeks gestation, removing the physician-only requirement to allow advanced practice clinicians to dispense the medications, removing the in-person dispensing requirement for mifepristone to allow the medication to be dispensed by mail, and expanding the distribution of mifepristone to include certified pharmacies in addition to certified clinicians.

Although the FDA has periodically updated the mifepristone REMS to more closely align with the medical and scientific evidence amassed since its initial approval, the REMS program continues to serve as a medically unnecessary barrier to accessing the medication.^{xxii} Currently, the REMS program for mifepristone require

health care providers and pharmacies to complete a Prescriber Agreement Form and Pharmacy Agreement Form, respectively, before being able to prescribe and dispense the medication. Patients must also review and sign a Patient Agreement Form and receive an FDA approved Medication Guide. By comparison, mifepristone has been shown to be safer than many other common medicines including Tylenol, Viagra, and penicillin – none of which are subject to REMS. Considering the extensive research and data supporting mifepristone's safety and ability of patients to use the medication as indicated, it is clear that these requirements are an unnecessary burden and not in line with medical evidence. Removing the remaining REMS is a necessary step towards reducing barriers to medication abortion care. Major medical associations including the American College of Obstetricians and Gynecologist, the American Medical Association, the American Academy of Pediatrics and the Society for Maternal Fetal Medicine have called for the permanent removal of restrictions on mifepristone.^{xxiii}

In 2026, the FDA commenced an internal review of mifepristone to examine the medication's safety record. This review came as the result of mounting pressure on the Agency from anti-abortion politicians and organizations as another attempt to limit access to medication abortion.^{xxiv} At time of this publication, results of this review are not available.

State Laws as a Barrier to Medication Abortion

Following the *Dobbs v. Jackson Women's Health Organization* decision, states have enacted various restrictions and barriers to abortion. This includes, but is not limited to, restrictions on telemedicine for medication abortion, restricting the provision of abortion care to physicians, required waiting periods and patient counseling, and funding bans.

At the time of publication, twenty-eight states restrict medication abortion. Twenty-six limit access by requiring the clinician prescribing the medication to be a physician, contrary to the World Health Organization, National Academies of Sciences, Engineering and Medicine, and National Abortion Federation who support the evidence that shows physician assistants and advanced practice nurses can safely provide medication abortions.^{xxv} In fact, studies have shown that abortion complications were clinically equivalent between nurse practitioners, physician assistants, and physicians.^{xxvi} Six states ban the use of telemedicine for medication abortion, eighteen states require an in-person visit for medication abortion, and three states ban the mailing of medication abortion pills to a patient.^{xxvii}

Patients across twenty-four states must receive state mandated counseling. Twenty-two require a waiting period between 18-72 hours creating further barriers to care, thirteen require the counseling be provided in person, and nine require providers share misinformation about medication abortion.^{xxviii} This is especially burdensome on those who are traveling long distances to seek care, individuals who may not have paid time off from work or childcare. Moreover, twenty-two states require a mandatory waiting period that ranges from 24-72 hours, further creating barriers to care.^{xxix}

Paying for abortion care has been shown to be an additional burden that individuals face. The Hyde Amendment, passed by Congress in 1977, and related provisions bans the use of any federal funds to pay for abortions except in extremely narrow circumstances such as when the pregnancy is the result of rape, incest, or it is 'necessary to save the life of a woman'.^{xxx} This restriction impacts people enrolled in Medicaid, Medicare and Children's Health Insurance Program enrollees; Federal employees and their dependents; Peace Corps volunteers; Native Americans; women in federal prisons and detention centers, including those detained for immigration purposes; women who receive health care from community health centers; survivors of human trafficking; and low-income women in the District of Columbia.

Attacks on medication abortion continue as states pursue new medically unnecessary restrictions on care. This includes attempts to classify mifepristone and misoprostol as controlled substances, restrict the sale, purchase and transportation of mifepristone, and claims of water contamination.^{xxxi} These restrictions exacerbate existing barriers to abortion care. In Louisiana, the first state to classifying mifepristone and misoprostol as a controlled substance in 2024, a report from the New Orleans Health Department found that patients experienced delays or denial of care across an array of sexual and reproductive health care.^{xxxii} Despite this finding, a variety of efforts to restrict access to mifepristone and misoprostol continue across states. Legislation targeting the sale, distribution and transportation of mifepristone are aimed at further limiting access to telehealth medication abortion. Claims of mifepristone contaminating waterways, which are rooted in mis- and disinformation, are used to push for legislation requiring wastewater to be tested for traces of the medication. These new and escalating attacks on medication abortion create additional barriers to care and introduce new pathways for criminalizing abortion care.

High Profile Legal Challenges to Mifepristone

There are numerous ongoing legal challenges attempting to restrict or ban access to mifepristone. The information below highlights litigation that has already

or is expected to go before the United States Supreme Court. For up-to-date information please visit:

<https://litigationtracker.law.georgetown.edu/issues/medication-abortion/>

Alliance for Hippocratic Medicine v. Food and Drug Administration (AHM V. FDA)

In November 2022 following the Supreme Court of the United States decision in *Dobbs v. Jackson Women's Health Organization*, anti-abortion groups under the name Alliance for Hippocratic Medicine (AHM) sued the U.S. Food and Drug Administration over its 2000 approval of mifepristone. The lawsuit, *AHM v. FDA*, was filed in the U.S. District Court for the Northern District of Texas and assigned to Judge Matthew Kacsmaryk.

As the case made its way through the lower courts, Judge Kacsmaryk issued a preliminary injunction to stay the FDA's 2000 approval of mifepristone. This decision unilaterally reversed the FDA's 2000 approval of mifepristone. Through a series of appeals, the Supreme Court issued an emergency decision to stay this order thereby reversing Judge Kacsmaryk's decision and reinstating approval of mifepristone. This decision allowed access to mifepristone to remain available while the case made its way through the lower courts. Back in the lower courts, the Fifth Circuit Court of Appeals partially upheld Judge Kacsmaryk's preliminary injunction and would have reinstated the FDA's pre-2016 REMS to restrict access to mifepristone. However, that did not take effect since the Supreme Court had already stayed Judge Kacsmaryk's order. These decisions sowed fear and confusion for patients and providers who were left wondering if, when, and how access to this essential medication would change.

This case made its way to the Supreme Court in March 2024. In June 2024 the Supreme Court unanimously ruled that the plaintiffs in the case did not have standing to challenge FDA regulations and remanded the case to the lower court. AHM voluntarily dropped the case, however three states intervened to keep litigation alive.

Louisiana v. Food and Drug Administration (FDA)

In October 2025, Louisiana filed a lawsuit against the FDA challenging the 2023 REMS for mifepristone which allowed the medication to be mailed or dispensed at retail pharmacies. On May 1, 2026, the Fifth Circuit Court of Appeals temporarily paused the 2023 FDA rules that allow mifepristone to be dispensed without an in-person visit to a medical provider. This means access to mifepristone via telehealth and the mail would have been significantly upended for people throughout the country. This decision would have taken effect immediately, affecting abortion access nationwide not just in states where abortion is banned.

However, after legal back and forth with intervention from mifepristone manufacturers, the U.S. Supreme Court blocked the Fifth Circuit's order that would have restricted the nationwide distribution of mifepristone via mail or pharmacy. The Court's action leaves current FDA rules in place, allowing the drug to be prescribed via telehealth and dispensed by mail or at retail pharmacies while the litigation continues. The Fifth Circuit heard arguments on this case in September 2026, it will likely go to the U.S. Supreme Court for a final decision.

Additional Resources

Amicus Brief

PRH Brief to SCOTUS in *AHM v. FDA*:

<https://prh.org/resource/amicus-brief-fda-v-alliance-for-hippocratic-medicine/>

PRH Brief to SCOTUS in *LA v. FDA*:

<https://prh.org/resource/prh-amicus-brief-telehealth-mifepristone-supreme-court/>

PRH Brief to Fifth Circuit Court of Appeals in *LA v. FDA*:

<https://prh.org/resource/amicus-brief-urging-fifth-circuit-to-protect-access-to-mifepristone/>

Factsheets

PRH Medication Abortion Factsheet:

<https://www.prh.org/medication-abortion-fact-sheet>

PRH Emergency Contraception vs. Medication Abortion Factsheet:

<https://prh.org/wp-content/uploads/2022/05/Emergency-Contraception-vs.-Medication-Abortion-2.pdf>

PRH Miso-only Messaging Guidance:

<https://prh.org/wp-content/uploads/2023/04/Miso-Only-Messaging-PRH.pdf>

PRH Self-Managed Abortion Factsheet:

https://prh.org/wp-content/uploads/2023/09/SMAFactSheet_09182023.pdf

Toolkits

PRH *Alliance for Hippocratic Medicine v. Food and Drug Administration* Toolkit for Policymakers and Partners: <https://bit.ly/PRHToolkit>

Endnotes

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