



# Physicians for Reproductive Health

## MEDICATION ABORTION | FACT SHEET | MAY 2024

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### BACKGROUND

Medication abortion is a safe and effective way to terminate an early 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.<sup>i</sup> 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.<sup>ii</sup> Misoprostol is also used for a variety of medical indications including the treatment of early pregnancy loss, induction of labor, cervical ripening – the softening and opening of the cervix, and treatment of postpartum hemorrhage.<sup>iii</sup>

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.<sup>iv</sup> 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 aid in procedural abortion care.<sup>v</sup> 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.<sup>vi</sup> 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.<sup>vii</sup> 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 antagonist that works by binding to the smooth muscle cells of the uterine lining which causes cervical ripening and cramping of the uterus, thereby causing the pregnancy to express and the uterus to empty.<sup>viii</sup>

## 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.<sup>ix</sup> 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%.<sup>x</sup> However, in one randomized controlled trial, 400 mcg of misoprostol was found to be equally as effective as 800 mcg.<sup>xi</sup> Beyond 10 weeks' gestation, mifepristone and misoprostol can be used to terminate pregnancy in repeated administrations.<sup>xii</sup>

## MISOPROSTOL ONLY PROTOCOL AND EFFICACY<sup>1</sup>

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.<sup>xiii</sup> The 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

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<sup>1</sup> 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.

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.<sup>xiv</sup> Complications following a medication abortion are very rare.<sup>xv xvi</sup>

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%.<sup>xvii</sup> 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.<sup>xviii</sup> The number of US providers offering medication abortion via telehealth and mailing abortion pills increased in 2022 to 31%, from just 7% in 2020.<sup>xix</sup> 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.<sup>xx</sup>

## **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 intended to focus on preventing, monitoring, and managing a 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.

Since 2011, The FDA has periodically updated the mifepristone REMS program by 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 which allows 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.<sup>xxi</sup> 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.

## **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 abortion care to physicians, required waiting periods and patient counseling, and funding bans.

At the time of publication of this brief, fifteen states have restricted medication abortion 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.<sup>xxii</sup> In fact, studies have shown that abortion complications were clinically equivalent between nurse practitioners, physician assistants, and physicians.<sup>xxiii</sup> Five states where abortion remains legal also restrict access to medication abortion via telemedicine by requiring the patient have an in-person visit with a physician and two states ban the mailing of medication abortion pills to a patient.<sup>xxiv</sup>

Patients across thirty-three states must receive state mandated counseling, with twenty-nine of those states dictating the information that providers must give, information that is often medically inaccurate and/or not relevant to the abortion care the individual is seeking, and sixteen requiring the counseling be provided in person before the waiting period begins.<sup>xxv</sup> 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 child care. Moreover, twenty-eight states require a mandatory waiting period that ranges from 24-72 hours, further creating barriers to care.<sup>xxvi</sup>

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'.<sup>xxvii</sup> 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.

## **LEGAL CHALLENGES TO MIFEPRISTONE**

### ***Washington v. Food and Drug Administration***

On February 24, 2023, Attorney Generals from seventeen states (Washington, Oregon, Arizona, Colorado, Connecticut, Delaware, Hawaii, Illinois, Maine, Maryland, Michigan, Minnesota, Nevada, New Mexico, Pennsylvania, Rhode Island, and Vermont) and the District of Columbia challenged the remaining REMS restrictions on mifepristone, described above, claiming they are unnecessary and limit

the availability of mifepristone.<sup>2</sup> On April 7, 2023, Judge Thomas Rice of the Eastern District of Washington issued a decision in the case in which he ordered the FDA to maintain the current availability of mifepristone. This decision applies only to the seventeen states and DC who are party to the case.

### ***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.

On April 7, 2023, Judge Kacsmaryk issued a decision in *AHM v. FDA*, attempting to stay the FDA's 2000 approval of mifepristone. The Department of Justice quickly appealed this decision to the Fifth Circuit Court of Appeals, which refused to block the order from the lower court. The Department of Justice again quickly appealed this decision to the Supreme Court, which issued a stay of Judge Kacsmaryk's order, meaning there will be no changes to mifepristone access while the case makes its way through the courts.

On May 17, 2023, the Fifth Circuit Court of Appeals heard oral arguments on Judge Kacsmaryk's preliminary injunction and in the Fifth Circuit's decision, the court largely upheld Judge Kacsmaryk's preliminary injunction and would have reinstated the FDA's pre-2016 REMS on mifepristone, thereby threatening access to this essential medication. However, this decision did not go into effect due to the Supreme Court's decision in April staying Judge Kacsmaryk's order.

On September 8, The Department of Justice and Danco, the pharmaceutical company manufacturing Mifeprex – the brand name drug for mifepristone, asked the Supreme Court to review the Fifth Circuit decision. The Supreme Court agreed to hear the case and oral arguments occurred March 26, 2024 with a decision expected in June of 2024.

## **ADDITIONAL RESOURCES**

### **Factsheets**

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

### **Toolkits**

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<sup>2</sup> 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.

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

## ENDNOTES

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- <sup>iii</sup> Ibid.
- <sup>iv</sup> EMAA Project. "The Safety of Medication Abortion Care." (2022). <https://emaaproject.org/wp-content/uploads/2020/03/Fact-Sheet-The-Safety-of-Medication-Abortion-3.24.20.pdf>
- <sup>v</sup> World Health Organization. "Abortion care guideline." (2022). <https://www.who.int/publications/i/item/9789240039483>
- <sup>vi</sup> Jones RK, Friedrich-Karnik. "Medication Abortion Accounted for 63% of All US Abortion in 2023 – An Increase from 53% in 2020," *Guttmacher Institute*, (2024). <https://www.guttmacher.org/2024/03/medication-abortion-accounted-63-all-us-abortions-2023-increase-53-2020>
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- <sup>xv</sup> Chen MJ, Creinin MD. "Mifepristone With Buccal Misoprostol for Medical Abortion: A Systematic Review," *Obstet Gynecol*. 2015;126(1):12-21. doi:10.1097/AOG.0000000000000897
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<sup>xxi</sup> “Information about Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation,” *Food and Drug Administration*, March 23, 2023, <https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/information-about-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation>

<sup>xxii</sup> Jones RK, Friedrich-Karnik. “Medication Abortion Accounted for 63% of All US Abortion in 2023 – An Increase from 53% in 2020,” *Guttmacher Institute*, (2024). <https://www.guttmacher.org/2024/03/medication-abortion-accounted-63-all-us-abortions-2023-increase-53-2020>

<sup>xxiii</sup> Aiken ARA, Romanova EP, Morber JR, Gomperts R. “Safety and effectiveness of self-managed medication abortion provided using online telemedicine in the United States: A population based study,” *Lancet Reg Health Am*. 2022;10:100200. doi:10.1016/j.lana.2022.100200

<sup>xxiv</sup> Jones RK, Friedrich-Karnik. “Medication Abortion Accounted for 63% of All US Abortion in 2023 – An Increase from 53% in 2020,” *Guttmacher Institute*, (2024). <https://www.guttmacher.org/2024/03/medication-abortion-accounted-63-all-us-abortions-2023-increase-53-2020>

<sup>xxv</sup> Guttmacher Institute. “Counseling and Waiting Periods for Abortion, August 30, 2023, <https://www.guttmacher.org/state-policy/explore/counseling-and-waiting-periods-abortion>

<sup>xxvi</sup> *Ibid.*

<sup>xxvii</sup> Kaiser Family Foundation. “State Funding of Abortions Under Medicaid,” May 13, 2022, <https://www.kff.org/medicaid/state-indicator/abortion-under-medicaid/>