Medication Abortion

Medication abortion, also known as the abortion pill, RU-486 or Mifepristone, is an abortion method that can safely be used up to the first 10 weeks of pregnancy. Since the FDA first approved the drug in 2000, its use in the United States has quickly grown and now almost one-third of all abortions at 8 weeks gestation or less are medication abortions. However, this method is subject to many of the same restrictions as surgical abortion at both the state and federal level, even though it does not involve a surgical procedure. While some states have also passed laws specifically regulating medication abortion, others have looked to expand access. This factsheet provides an overview of medication abortion, discusses federal and state regulations pertaining to both the provision and coverage of the drug, and reviews emerging strategies to affect women’s access to medication abortion.

What is Medication Abortion?

The most common regimen in the United States involves the use of two different medications: Mifepristone, sold under the brand name Mifeprex, and misoprostol. Mifepristone blocks progesterone, a hormone essential to the development of a pregnancy. Misoprostol, taken 24-48 hours later, works to empty the uterus by causing cramping and bleeding, similar to an early miscarriage. A follow-up visit is scheduled a week or two later to confirm the pregnancy was terminated via ultrasound or blood test. Early medication abortion is a safe and highly effective method of pregnancy termination. If the pills are administered at 8 weeks’ gestation or less, the pregnancy is terminated successfully 98 out of 100 times, with 0.05% risk of major complications, and an associated mortality rate of less than one percent (0.00063%).1,2

Use

Although the overall rate of abortion has continued to decline, the use of medication abortion has greatly increased over the years, and now makes up roughly one-third (32.8%) of all abortions at 8 weeks gestation or less (Figure 1).3 According to Danco Laboratories, the sole drug manufacturer for mifepristone, 2.75 million women in the United States have used Mifeprex since its FDA approval in 2000.4 Data from the CDC shows that the availability of

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<td>Mifepristone dosage and administration</td>
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Note: *LMP – Last Menstrual Period
Medication abortion may have played a role in shifting abortion to earlier in the pregnancy when there is lower risk of complications. From 2004 to 2013, reported abortions at 8 weeks gestation or less increased by 4.4%, while abortions performed from 9 to 13 weeks decreased by roughly 10%. In 2014, early medical abortion performed up to 9 weeks gestation accounted for 31% of all nonhospital abortions, and an estimated 45% of all abortions before 9 weeks’ gestation.

**FDA Protocol**

The FDA first approved Mifeprex in 2000 for combined use with misoprostol for early nonsurgical abortion through the first seven weeks of pregnancy. At that time, the FDA-approved regimen required three office visits by the patient: one to dispense misoprostol, one to dispense Mifeprex, and a follow-up visit to confirm the termination had occurred. This now outdated practice used a higher dose of Mifeprex, which was associated with more side effects. However, after extensive research and with the support of professional organizations, the agency approved a new evidence-based regimen and drug label in 2016. The updated label requires women to take a lower dosage of mifepristone, allows for use up to 10 weeks of pregnancy, and permits home administration of the pills (Table 1). While this regimen had already been in common practice for years, three states (Texas, Ohio, and North Dakota) had required providers to administer Mifeprex in accordance with the older FDA protocol. With the revised Mifeprex label, providers in these states no longer have to adhere to the outdated regimen. The new drug label also has the potential to make medical abortion less expensive due to the reduced dose of mifepristone (from three pills to one) and fewer office visits, and may expand access to first trimester medication abortion by lengthening the gestational period at which it can be prescribed, potentially increasing the proportion of all abortions eligible for mifepristone use from 37% to 75%.

**Mifeprex Risk Evaluation and Mitigation Strategy (REMS)**

Mifeprex is not dispensed by retail pharmacies; rather women can only obtain the drug directly from a certified medical provider who has received special training from the manufacturer about the proper use of the drug. This is because the FDA has applied a Risk Evaluation and Mitigation Strategy (REMS) for
Mifeprex since 2011 (See Box). The FDA-approved REMS program for Mifeprex also includes Element to Assure Safe Use (ETASU), a stronger version of REMS, and contains three provisions:

1) Mifeprex may only be dispensed in a clinic, medical office, or hospital by or under the supervision of a certified provider;
2) A provider must become a certified prescriber by completing and sending a Prescriber Agreement Form to the distributor, which confirms they are able to assess the duration of a pregnancy, diagnose ectopic pregnancies, and provide surgical abortion in the case of an incomplete abortion;
3) The certified prescriber must obtain a signed Patient Agreement Form from the woman before dispensing the drug.

What are REMS and ETASU?

Since 2007, the FDA has had the authority to require Risk Evaluation and Mitigation Strategy (REMS) programs from drug manufacturers for specific drugs to ensure that its benefits outweigh its risks. The FDA must consider a variety of factors when determining the necessity of a REMS including: the seriousness of the disease or condition to be treated, the size of the population expected to use the drug, expected duration of treatment, and the seriousness of adverse events such as liver damage. There are currently 70 FDA approved REMS programs. REMS programs are typically required for drugs known to be associated with potential serious complications or contraindications, such as antipsychotics, opioids, testosterone, and drugs to treat type 2 diabetes, cancer, hypertension, and multiple sclerosis. These programs may include a medication guide, a patient package insert, and/or a communication plan to educate providers on the safe use of the drug.

If the FDA decides these measures are not sufficient to safely allow the drug on the market, the agency may require a more stringent version of REMS, including one or more Element to Assure Safe Use (ETASU). More than half of the currently approved REMS programs have one or more ETASU. FDA guidelines stipulate that an ETASU "must be commensurate with the specific serious risk listed in the drug’s labeling, and must not be unduly burdensome on access to the drug, especially for patients with serious or life-threatening diseases and who have difficulty accessing healthcare.”

On October 3, 2017, the American Civil Liberties Union (ACLU) filed a lawsuit on behalf of a group of providers against the FDA challenging the REMS requirements for mifepristone. Organizations, such as the American College of Gynecologists and Obstetricians (ACOG), support the elimination of REMS regulations for Mifeprex, which they maintain are medically unnecessary and impede access to medical abortion. They cite the low rate of complications associated with medical abortions and assert that other drugs with similar or more serious risks do not have REMS restrictions. They also claim that the REMS certification program delays care for women seeking the pill from uncertified providers, and restricts the use of telemedicine in abortion care (discussed below). The REMS program also requires the manufacturer to establish a costly distribution infrastructure instead of allowing sale of the drug through retail or mail order pharmacies, potentially preventing a less expensive generic from being developed. Finally, some advocates suggest that the certification process may limit the pool of providers, as a
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provider may be reluctant to register with the distributor due to the potential harassment faced by clinicians who provide abortions.¹³

Availability and Access

Federal and state-level regulations have effectively limited the impact of the drug, particularly in underserved areas without a nearby clinic. Studies show providers of medication abortion are mostly concentrated where surgical abortion is already available.¹⁴ Many state laws restricting the provision of abortion apply both to surgical and medication abortion, such as informed consent.

Twenty-seven states have waiting periods that require the woman to receive counseling a certain period of time before the abortion is performed.¹⁵ In the case of medication abortion, women in these states must wait between 18 and 72 hours after the initial consultation before receiving the pill. Many states have also passed laws specifically pertaining to medication abortion, such as specific counseling and provider requirements. Currently, the majority of states (36) permit only licensed physicians to dispense Mifeprex (Figure 2).¹⁶ Only one state, California, has a law authorizing advanced practice clinicians (APCs) such as nurse practitioners, physician assistants, or certified nurse-midwives to provide first trimester nonsurgical abortions.¹⁷ Several other states give APCs similar authorization through Attorney General opinions, state court rulings, and other administrative agency actions. Research has demonstrated that APCs can provide medication abortions as safely as physicians can.¹⁸ Arizona, Arkansas, Idaho, Utah and South Dakota enacted laws that require providers to counsel patients that medication abortion may be reversed if given a high dose of progesterone after taking mifepristone despite a lack of scientific evidence to support this claim.¹⁹ North Carolina and Georgia are currently considering similar bills in their 2017-2018 legislative sessions.

On May 29, 2018, the Supreme Court decline to accept a challenge requesting a stay to a 2015 Arkansas law requiring providers of medication abortion to have a signed contract with a physician with admitting privileges at a hospital within the state, allowing the law to go into effect immediately. This ruling deviates from a 2016 Supreme Court decision, Whole Women’s Health v. Hellerstedt, in which a similar law was struck down in Texas. Following the decision, the two Arkansas Planned Parenthood locations announced they had to cancel all abortion services, leaving the state with only one abortion provider, and...
none that offer medication abortion—the first state to restrict all access to the pill.20 After the Supreme Court declined to issue a stay, Planned Parenthood filed a motion with the US District Court for the Eastern District of Arkansas for a temporary restraining order to block the law while the court considers evidence about the number of women impacted by the law. A major study on abortion safety and quality issued by the National Academies of Sciences, Engineering and Medicine found no evidence that having hospital admitting privileges improves abortion safety and that laws, such as the Arkansas requirement, can negatively impact the quality of abortion care for women.21

**TELEMEDICINE AND HOME ACCESS**

Telemedicine, or telehealth, is used to expand access to health services in areas with no provider or where the number of providers is limited. It is regularly used for a broad range of specialties and services including assessments of medical history, remote patient monitoring for chronic and high-risk conditions, imaging services, medication management, and psychiatric evaluations.22 Although the FDA REMS requirement that Mifeprex must be dispensed directly by a certified provider is intended to assure the safe use of the drug, advocates argue that it is medically unnecessary and limits the potential for the widespread availability of medication abortion through telemedicine. In 2014, 39% of reproductive age women lived in a county with no abortion provider23 (and seven states currently have only one abortion provider), making travel to a clinic to obtain the drugs problematic, especially for women who live in rural communities and may have to drive long distances to the nearest clinic. In addition, the updated FDA label now allows women to take the pills after leaving the clinic, leading some to question the relevance of an in-office dispensing requirement.24 Many states have also taken action to limit the use of telemedicine for abortion. Twenty-one states have enacted laws that require the clinician providing a medication abortion to be physically present during the procedure, effectively prohibiting the use of telemedicine to prescribe medication for abortion remotely (Figure 3). While insurance coverage for telemedicine varies greatly by state and service type, states do not often explicitly ban drugs or services from telemedicine.

At the same time, some states have taken steps towards increasing abortion access through telemedicine. In 2008, the Planned Parenthood clinic system in Iowa began the first tele-medical abortion
program in the United States. This program permits women seeking medical abortions to teleconference with an off-site physician who, after reviewing prior lab work, can remotely unlock a drawer to dispense and administer the medication. In 2015, the Iowa Supreme Court unanimously struck down a 2013 ruling by the Iowa Board of Medicine that required a physician to be physically present when dispensing the medication, allowing the pilot program to continue. Evaluations of the telemedicine program confirm it is an equally safe and effective practice as an in-person physician visit, and women who chose it were satisfied with the service. These studies also showed that women in rural areas were more likely to get an abortion earlier in their pregnancy, which is both safer and less expensive than later abortion. Following Iowa’s example, similar telemedicine programs were established in Alaska, Minnesota, and Maine.

These programs have the potential to expand abortion services to underserved areas by allowing clinics without a physician on-site to provide medication abortion, however, women must still travel to clinic to obtain and take the pill. Home administration could further expand access and increase privacy for women seeking abortions and reducing ancillary expenses such as travel and childcare. In 2016, Gynuity Health Projects launched their FDA-approved TelAbortion study to evaluate home use of mail-order medication abortion drugs. Unlike Iowa’s tele-medical abortion program, eligible participants may videoconference with a physician using a home computer and pills are sent by overnight mail directly to the patient’s home. The woman may complete all required lab work at a medical facility near her home. The study is currently operating in four pilot states: Washington, Oregon, Hawaii, and New York.

Some online international organizations, such as Women on the Web and Safe2Choose, offer mail-order pills and information to women seeking medication abortions. However, due to legal barriers, they do not ship to women in the United States. Instead, a few projects, such as the Plan C Campaign, are now working to spread information to women in the US who may acquire misoprostol or mifepristone on their own, including how to appropriately take the drugs, and how they might access funds to pay for them. Women Help Women, which already operates to provide pills to women in other countries, recently launched their US-based project, Self-managed Abortion; Safe and Supported (SASS), to provide information about self-managed medication abortion to women in the United States. Danco laboratories, the pill’s sole manufacturer, currently has no plans to seek FDA permission to distribute through the mail or in pharmacies in the United States.

COSTS AND INSURANCE COVERAGE

On average, a first trimester abortion costs $497, with no significant difference between the average costs of an aspiration abortion and a medical abortion. Most women pay at least some out of pocket costs for their abortion. In 2011, most women seeking first trimester abortion had insurance coverage; however, the majority (69%) did not or could not use it to pay the procedure. Of those who did not use their insurance to pay for their abortion, 49% say it was because their insurance did not cover it, and 29% say they did not use it because they were not sure if it was covered. Insurance coverage for abortion is heavily regulated at both the federal and state level. Since 1977, the federal Hyde Amendment has banned the use of any federal funds for abortion, unless the pregnancy is a result of rape, incest, or if it is determined to endanger the woman’s life. After the FDA approved Mifeprin in 2000, this law also applied to medication abortions. Many states have also limited abortion coverage in private plans and in the ACA Marketplace plans.
Conclusion

Even as overall rates of abortion decline, the use of medication abortion has grown significantly since its approval by the FDA in 2000. The updated FDA label extended the gestational age at which Mifeprex is recommended, increasing the number of pregnancies eligible for its use. While the drug’s availability may have shifted the average time of abortion earlier in the pregnancy, its impact has been limited by federal and state regulations, especially for women living in rural and underserved areas without a nearby clinic. Meanwhile, some states are exploring ways of increasing access by allowing non-physician clinical providers to prescribe Mifeprex as well as experimenting with the use of telemedicine for wider distribution.

Endnotes

8 Following the 2016 label change, the provider no longer is required to give each woman a copy of the Mifeprex Medication Guide.
14 Jones RK and Jerman J. Abortion Incidence and Service Availability in the United States, 2011.
17 California Legislative Information. Assembly Bill No. 154, Chapter 662.
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32. TelAbortion: The Telemedicine Abortion Study.


35. Ibid.