CHEMICAL ABORTION (ABORTION BY PILL) WHAT YOU NEED TO KNOW

What is chemical abortion?

Chemical abortion ("medication abortion" and "abortion pills") is a nonsurgical way to terminate a pregnancy in the early stages using prescription (currently) pills.

The most common regimen involves taking two pills: mifepristone (Mifeprex) and misoprostol (Cytotec). The first pill, mifepristone, kills the unborn child by blocking progesterone, a hormone that occurs naturally in women and that is needed to support pregnancy. The second pill, misoprostol, causes cramping and bleeding to expel the dead child and empty the uterus.

What is the difference between the abortion pill and the morning after pills?

Ella

Ulipristal (Ella) is an oral "emergency contraceptive" known as *the morning after pill* that is used to prevent pregnancy after unprotected sex or contraceptive failure. It contains ulipristal acetate, a progesterone agonist/antagonist that inhibits implantation of the unborn baby to the womb.

It is reported to help prevent implantation of the baby into the womb immediately after intercourse, making it an abortifacient.

How common is chemical abortion?

Very.

It is estimated that as of 2024, two-thirds of abortions in the United States are chemical, and that number is increasing.

The actual number of chemical abortions is difficult to assess because of mail-order prescriptions and lack of reporting.

Are there baby's age (gestational) limits for chemical abortions?

Yes.

According to the Food and Drug Administration ("FDA"), the approved package insert, and the Risk Evaluation and Mitigation Strategy ("REMS") prescriber agreement form, mifepristone is to be used only through 70 days (10 weeks) gestational age.

Gestational age describes how far along the pregnancy is, measured from the first day of the woman's last menstrual cycle to the current date.

Prescription of mifepristone beyond 10 weeks gestation is considered off-label; however, use up to 12 weeks' gestation is accepted by some abortionists.

The FDA originally allowed self-managed abortions only up to seven weeks and did not extend to 10 weeks until 2016. Since then, though, the international consensus has shifted. The World Health Organization now recommends 12 weeks, or the end of the first trimester, as the cutoff for self-managing a chemical abortion. The FDA is trying to extend the gestational age once again.

Are there mother's age limits for chemical abortion?

Sometimes

The legal age for making abortion decisions, including by pills, is typically 18, but this varies by State law.

Some states allow minors to decide independently. Some states require parental consent, notice, or a judicial order.

Who can get abortion pills?

A woman of legal statutory age may obtain abortion pills through a REMS certified prescriber.

How does a woman get the abortion pills?

On January 3, 2023, the FDA modified the REMS for mifepristone, allowing access to mifepristone by telehealth and by mail after the end of the COVID-19 public health emergency.

A REMS provider visit, in person or by telemedicine, for prescribing is mandatory in addition to the use of a REMS pharmacy for dispensing.

The abortion pills require a prescription and, therefore, a provider "appointment."

The lack of an in-person visit with a provider means the woman does not receive a physical examination. The lack of an examination raises several medical concerns, such as the inability to assess abdominal tenderness, signs of domestic violence or trafficking, actual versus estimated gestational age, fetal heart tone monitoring, and ultrasound imaging.

Are abortion pills controlled substances?

Not according to the federal government, but some states are starting to list them as "controlled dangerous substances," which in fact they are.

A controlled substance is a drug or chemical that is regulated by the government in terms of its use, possession, and manufacture. Controlled substances include prescription medications that are designated by law and illicitly used drugs. Controlled substances are classified into schedules, which are based on the substance's potential for abuse.

Although abortion drugs are REMS regulated, they are not "controlled substances," according to the federal government.

Are abortion pills sold at pharmacies?

Yes

To become certified to dispense mifepristone, pharmacies must complete a Pharmacy Agreement Form. Certified pharmacies must be able to ship mifepristone using a shipping service that provides tracking information. Certified pharmacies must ensure that mifepristone is dispensed to the patient promptly.

The FDA's January 2023 REMS permanently removed the in-person dispensing requirement. Additionally, pharmacies can now choose to become certified to dispense mifepristone to patients. All other previous mifepristone REMS requirements remain in effect, including the need for prescriber certification and completion of Prescriber and Patient Agreement Forms.

On February 1, 2023, Missouri Attorney General Andrew Bailey led a coalition of 20 state attorneys general who wrote to CVS and Walgreens, informing them that their announced plan to use the mail to distribute abortion pills is both unsafe and illegal.

Ella requires a prescription but does not have a REMS requirement.

How much do abortion pills cost?

About \$600.1

Does the woman need a follow-up appointment after taking abortion pills?

Yes.

According to the FDA package insert, follow-up with a provider is recommended.

A follow-up appointment should be scheduled seven to 14 days after taking abortion pills. This visit is crucial to confirm the complete termination of the pregnancy and to assess the level of bleeding. Up to 8% of women may experience bleeding for more than 30 days. Persistent heavy or moderate bleeding at the follow-up appointment could indicate an incomplete abortion.

However, in actual practice this is not likely unless there is a reported adverse event, such as excessive bleeding.

¹ Medical management of early pregnancy loss is cost-effective compared with office uterine aspiration. Nagendra D., et al., <u>Am J Obstet. Gynecol.</u> 2022 Nov;227(5):737.e1-737.e11. doi: 10.1016/j.ajog.2022.06.054. Epub 2022 Jun 30. PMID: 35780811; PMCID: PMC10302401., the PreFaiR noted surgical abortion is more expensive (\$828) than chemical abortion (\$661).

Can abortion pills be obtained through the mail?

Yes.

On January 3, 2023, the FDA modified the REMS for mifepristone, allowing access to mifepristone by telehealth and by mail even after the end of the COVID-19 public health emergency. The COVID-based temporary elimination of an in-person clinic visit before a physician prescribed chemical abortion was permanently embodied in the January 2023 FDA REMS update. This change followed Executive Order 14076 of July 8, 2022, Protecting Access to Reproductive Healthcare Services.

The Biden administration then provided United States Postal Service ("USPS") workers immunity by *OLC Slip Opinion*, December 2023.

Can abortion pills be mailed from a pro-abortion state to a non-abortion state?

Unclear.

Some states have passed laws against it, but the federal government appears to sanction it.

Pharmacies must still meet REMS certification based upon a state's abortion statutes; however, prohibiting the mailing of abortion drugs across state lines does not appear to be enforceable—absent application of the Comstock Act, which offers at best a weak 1800s argument.

Dismantling the USPS immunity requires more evidence of abortion pills' imminent danger to women. But this evidence will be hard to come by, as presently only "deaths" (not other serious complications) attributable to mifepristone are tracked. It is unclear what complications related to misoprostol, if any, are tracked.

What are the big medical and procedural problems?

The absence of an in-person examination may lead to inaccuracies in determining gestational age, as it relies on the date of the last menstrual period ("LMP"), as reported by the mother, rather than an ultrasound. LMP dating is often inaccurate, and there is little way to verify the information provided by the mother.

There is no required confirmed receipt or signature by the person actually getting the abortion pills.

Whether, when, and who actually takes the pills is uncertain.

Standard medical follow-ups are often never made or missed.

Reporting of chemical abortion use and results is uncertain.

Delivery time by USPS takes days and varies wildly with weather, postage, time of year, mail volume, address changes, and the like, potentially adding a week or more to the gestational age.
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