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**Medical and Social Risks Associated with
Unmitigated Distribution of Mifepristone: A Primer**

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Chemical abortions, or “medication” abortions, have become a [more prevalent](#) method of abortion in recent years in the United States. In 2000, the [Food and Drug Administration \(FDA\) approved](#) the use of mifepristone, in conjunction with the drug misoprostol, as an abortion-inducing, two-drug process. By 2018, the Charlotte Lozier Institute [estimates](#) that 41% of U.S. [abortions](#) were chemically induced. In recent years, abortion advocates have taken the stance that health [regulations](#) surrounding chemical abortions should be softened or removed. Some activists even suggest that the drugs should no longer require a prescription and should be offered over-the-counter and available for order online and delivery by mail. Removing or loosening safety standards, also known as the FDA’s Risk Evaluation and Mitigation Strategy (REMS), puts women at risk both medically and socially.

Definitions

What is a Chemical Abortion?

Many abortion providers euphemistically refer to chemical abortion as “medication abortion,” misrepresenting pregnancy as an illness to be treated with medication. A more accurate description of “medication abortion” is chemical abortion. A chemical abortion is just that: an abortion induced by chemicals. To “self-manage” a chemical abortion means to induce an abortion on oneself without formal medical supervision, most commonly using the drugs mifepristone and misoprostol.

What is Mifepristone?

The name brand drug, Mifeprex, is distributed by Danco Laboratories, LLC, and the generic mifepristone is distributed by GenBioPro, Inc.

What is a Risk Evaluation and Mitigation Strategy (REMS)?

[According to the FDA](#), a REMS is a “drug safety program that the [FDA] can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks.” The FDA further [explains](#) that “REMS are designed to reinforce medication use behaviors and actions that support the safe use of that medication.” [REMS](#) do not monitor all adverse events that may occur following the use of certain medications, but rather “focus on preventing, monitoring and/or managing a specific serious risk by informing, educating and/or reinforcing actions to reduce the frequency and/or severity of the event.” Thus the FDA [asserts](#) what a REMS is, its purpose, and what it is not.

REMS: A drug safety program put in place by the FDA for specific medications with “serious safety concerns.”

The Purpose of a REMS: To “prevent,” “monitor,” and “manage” a “specific serious risk” through education and “reinforcing actions to reduce the frequency and/or severity of the event.”

What a REMS is Not: A REMS does not monitor ALL possible adverse events relating to a specific medication.

Additionally, a REMS may include **Elements to Assure Safe Use (ETASU)**, a stronger set of requirements put in place to ensure that the drug is used safely. According to the FDA, ETASU are “required medical interventions or actions by healthcare professionals prior to prescribing or dispensing the drug.” In the case of mifepristone, ETASU includes the following:

- 1) Providers prescribing mifepristone must be specially certified.
- 2) Mifepristone may only be dispensed at approved facilities by certified prescribers.
- 3) Patients receiving mifepristone must present “evidence or other documentation of safe use conditions.”

What is a Mifepristone Sponsor?

A mifepristone sponsor is an organization that distributes mifepristone to certified providers. Currently, there are two mifepristone sponsors in the United States, Danco Laboratories and GenBioPro, Inc.

What is a Certified Provider?

A healthcare professional who fulfills the [necessary criteria](#) to dispense mifepristone to patients.

REMS and ETASU for Mifepristone

Mifepristone is approved by the FDA for distribution by only two pharmaceutical companies in the United States. A REMS applies to both the name brand and generic of this drug. A REMS has been put in place for the dispensing of mifepristone to ensure that specific risks associated with the drug are reduced. Additionally, ETASU have been put in place for mifepristone and include the following additional steps under the three REMS requirements:

- 1) Providers prescribing mifepristone must be specially certified. To be certified, [providers must](#):
 - Review prescribing information
 - Complete [Prescriber Agreement Form](#) which says the prescriber has the following qualifications:
 - Ability to assess the duration of the pregnancy accurately.
 - Ability to diagnose ectopic pregnancies.
 - “Ability to provide surgical intervention in cases of incomplete abortion or severe bleeding, or to have made plans to provide such care through others, and ability to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary.”

- Agrees to fulfill criteria relating to patient agreement form.
- Review the [Patient Agreement Form](#) with the patient present and explain the risks associated with chemical abortion and answer any questions the patient has.
 - The Patient Agreement Form must be signed by both the patient and provider and placed in the patient's medical record.
 - Serial numbers for each packet of mifepristone must be placed in the patient's record.
- Report all deaths associated with mifepristone to sponsors.

2) Mifepristone may only be dispensed at approved facilities by certified prescribers.

Mifepristone sponsors must:

- Ensure that mifepristone is only dispensed to patients at hospitals, clinics, and medical offices by certified providers.
- Ensure that the mifepristone distributed to a certified provider is not sold or dispensed anywhere except specified areas above.

3) Patients receiving mifepristone must [present](#) "evidence or other documentation of safe use conditions."

- Patient must read and sign the patient agreement form.
- Patient must receive counseling from the prescriber regarding the risks associated with mifepristone.

Additionally, sponsors such as Danco Laboratories and GenBioPro, Inc. have the following responsibilities:

- Ensuring that healthcare providers dispensing their products are properly certified.
- "Decertifying" those who are lacking criteria for proper certification.
- Ensuring that their products are being dispensed at medical offices, hospitals, or clinics overseen by certified providers.
- Ensuring that their products are not being "distributed" or "dispensed" at "retail pharmacies" or in other unqualified settings.

Medical Risks Associated with Mifepristone

Various risks, including serious infection and even death, have been connected with mifepristone use and [reported](#) to the FDA. These risks should be carefully analyzed and a REMS should remain in place to ensure that women are not harmed through the careless distribution of mifepristone.

What are the Risks Associated with Mifepristone?

Many adverse events have been [reported](#) to the FDA regarding the use of mifepristone. Proper medical examination is important prior to the distribution of mifepristone because multiple conditions and medications mixed with mifepristone may cause serious complications. [According to the FDA](#), women should not take mifepristone under the following circumstances:

“A woman should not take Mifeprex [mifepristone] if it has been more than 70 days since the first day of her last menstrual period, or if she:

- has an ectopic pregnancy (a pregnancy outside of the uterus)
- has problems with the adrenal glands (the glands near the kidneys)
- is currently being treated with long-term corticosteroid therapy (medications)
- has had an allergic reaction to mifepristone, misoprostol or similar drugs
- has bleeding problems or is taking anticoagulant (blood thinning) drug products
- has inherited porphyria
- has an intrauterine device (IUD) in place (it must be removed before taking Mifeprex [mifepristone]).”

Additionally, according to FDA’s mifepristone [medication guide](#), women who do not fall under the above are still at risk of experiencing common and serious side effects after taking mifepristone.

Common [side effects of mifepristone](#) include:

- Vaginal bleeding
- Cramping

Additionally, the [medication guide](#) warns that patients should contact their medical providers or emergency services IMMEDIATELY if the following **serious complications** occur:

Heavy bleeding: “Contact your healthcare provider right away if you bleed enough to soak through two thick full-size sanitary pads per hour for two consecutive hours or if you are concerned about heavy bleeding. In about 1 out of 100 women, bleeding can be so heavy that it requires a surgical procedure (surgical aspiration or D&C).”

Abdominal Pain or “Feeling Sick:” “If you have abdominal pain or discomfort, or you are “feeling sick,” including weakness, nausea, vomiting, or diarrhea, with or without fever, more than 24 hours after taking misoprostol, you should contact your healthcare provider without delay. These symptoms may be a sign of a serious infection or another problem (including an ectopic pregnancy, a pregnancy outside the womb).”

Fever: “In the days after treatment, if you have a fever of 100.4°F or higher that lasts for more than 4 hours, you should contact your healthcare provider right away. Fever may be a symptom of a serious infection or another problem.”

The mifepristone [medication guide](#) further notes that “You may see blood clots and tissue” during the chemical abortion process.

Serious adverse events [reported](#) to the FDA connected to mifepristone:

- Ruptured ectopic pregnancy resulting in death

- Sepsis, including some cases resulting in death
- Significant blood loss requiring blood transfusion

Women taking mifepristone, and healthcare providers monitoring them, should watch their symptoms closely and understand that even in the [absence of a fever](#), a serious infection could be present with the above possible side effects of mifepristone.

Social Risks of Further Relaxing Mifepristone REMS

In recent years the illegal online sale of mifepristone and misoprostol for abortion has become more common, with the drugs distributed through websites such as Aid Access, those in the network of Rablon, and others. In 2019 the FDA sent out warning letters to both [Aid Access](#) and [Rablon](#) warning them against selling misbranded and unapproved drugs as they can harm consumers. Websites like Aid Access and Rablon are examples of what could happen with the distribution of mifepristone if the REMS were to be further relaxed or removed. Currently, the REMS prevents the unmonitored distribution of mifepristone, but both Aid Access and Rablon were found to be violating this requirement by selling packs of mifepristone and misoprostol online. Unmonitored distribution of abortion-inducing drugs puts vulnerable populations, such as pregnant women who are not seeking abortion, at risk.

In 2007, [Manishkumar Patel](#) of Wisconsin admitted to giving one mifepristone pill to his girlfriend without her knowledge, causing the death of their unborn baby. He later [testified](#), “I took a life of an unborn child... I realized that even if the child had some sort of medical problems, he would still have had a life.” Reports indicated Patel already had a child with medical problems and feared having another. Patel told police that he obtained the drugs in India. Unfortunately, this case is not unique. Multiple cases like this one exist.

In 2014, [Scott Bollig](#) of Kansas was arrested after his girlfriend suspected foul play in the death of her unborn child. An autopsy revealed the presence of mifepristone in the fetus. Bollig told police that he purchased the pills on the internet and put them in his girlfriend’s food with the intent to cause fetal demise.

In 2017, a Virginia physician named [Sikander Imran](#) was charged with slipping mifepristone into his girlfriend’s tea which ultimately caused fetal demise. Imran [pled guilty](#) to fetal homicide and was [sentenced](#) to three years in prison. He also lost his medical license upon arrest. Where Imran obtained the drugs is unknown.

In 2018, a Wisconsin man named [Jeffrey Smith](#) attempted to kill his unborn child by secretly spiking his girlfriend’s water bottle with mifepristone. His girlfriend became suspicious and gave the water bottle to authorities, who determined that mifepristone was present in the water. Smith purchased the mifepristone from an illegally operating

mifepristone dealer in New York named [Ursula Wing](#). Wing was later indicted and convicted on a charge of “[conspiracy to defraud the U.S. through misbranded drugs.](#)”

Those who acknowledge the humanity of the human person from conception know that every time an abortion occurs a human life is lost. While the FDA does not comment on this reality publicly, it does acknowledge the humanity of women seeking abortion. This respect for the humanity of women undergirds the guidelines put in place to keep women safe, both medically and socially. A REMS protects women by ensuring that they are informed of the risks associated with mifepristone, understand them, and have a healthcare provider in place should they experience severe bleeding, incomplete abortion, or severe infection. Finally, a REMS, properly enforced, helps protect women from domestic violence and from unwanted abortions forced on them by abusive partners. The mifepristone REMS should be upheld, strengthened, and acknowledged as necessary for protecting women and girls.

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