

National Right to Life Special Report

Why “Medication Abortions” without Medical Exam or Medical Supervision are a Really Bad Idea

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During the pandemic, the U.S. Food & Drug Administration (FDA) came under fire for the conditions it had long had in place on the prescription of mifepristone, the abortion pill. Advocates said that the drug could be safely dispensed by telemedicine, shipped by mail, and managed by the patients themselves and argued this was an option women needed while COVID was monopolizing the time and attention of health care providers. After the Biden administration agreed to suspend these regulations during the national health crisis, advocates pushed for the FDA to make suspension of these regulations permanent. These pleas to loosen limits and “expand access” ignore the long list and troubling record of significant medical concerns that motivated and continues to justify those limitations.

The REMS regulations imposed on mifepristone were a reasonable response by the FDA to concerns it had about the drug’s safety.

According to the U.S. Food & Drug Administration (FDA),

A Risk Evaluation and Mitigation Strategy (REMS) is a drug safety program that the U.S. Food and Drug Administration (FDA) can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks. REMS are designed to reinforce medication use behaviors and actions that support the safe use of that medication.¹

In light of the “serious safety concerns,” some detailed below, the FDA imposed the following conditions on prescribers ordering mifepristone, the drug used in most chemical abortions in the U.S., requiring that they have the ability to:

- assess the duration of pregnancy accurately
- diagnose ectopic pregnancies
- provide surgical intervention in cases of incomplete abortion or severe bleeding or have made plans to provide such care through others.
- assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary.

Healthcare providers prescribing the drugs must also review the FDA's Patient Agreement Form with the patient describing the procedure, major risks, and symptoms that should prompt the patient to seek emergency help. Both patient and prescriber are to sign the agreement; one copy going in the patient's medical record and the other being given to the patient along with a more detailed Medication Guide.

Any patient deaths are to be reported to the pill's authorized distributor. The pills are only to be distributed to clinics, medical offices or hospitals "by or under the supervision of a certified prescriber" (i.e., ones who have completed the certification process).

The distributor is to keep records and ensure that appropriate processes are being followed. Pills are not to be shipped to prescribers who become decertified. The distributor is to report any deaths of mifepristone patients to the FDA within 15 days of receiving such information.²

The FDA has had restrictions on the distribution of mifepristone from the time it first approved marketing in September of 2000. Over the years it has modified its label, issued warnings, and reinforced and extended these restrictions in light of issues and injuries that have come to light.³

Current REMS were issued in March of 2016 and, despite their suspension, remain on the books, reflecting the FDA's considered medical opinion and ongoing concerns about the drug based on over a decade and a half of experience with the drug.

Even when they work, these abortions are bloody, painful, time-consuming... and complicated.

The popular image of the drug induced chemical abortion as a relatively quick, easy, and painless procedure is at odds with the medical record and the experience of women who have actually taken the abortion pills.

The standard chemical or "medical" abortion, even when successful, involves several steps, not one, but two drugs, multiple pills, taken over a period of a couple of days, involving substantial pain and bleeding that may take weeks to be complete.

To be used as safely and effectively as possible, potential patients should be screened to make sure they are not over the gestational limit, do not have an ectopic pregnancy, and have no allergies or conditions that would make the pills ineffective or dangerous.⁴

Once a patient has been identified as an acceptable candidate for chemical abortion, a healthcare professional should instruct them as to the proper use and timing of the pills and counsel them on how to recognize signs of infection or abnormal bleeding that may require emergency treatment. The importance of a follow up assessment to determine success of the abortion is to be stressed as "prolonged heavy vaginal bleeding is not proof of a complete abortion."⁵

The process will not be over quickly. Unlike surgical abortion, which may be over and done in five to ten minutes,⁶ abortion pills take time to do their work. The mifepristone shuts down the support system sustaining and protecting the developing embryo,⁷ and then the second drug

stimulates powerful contractions to expel the emaciated corpse.⁸ Heavy cramping and bleeding are standard parts of the process and may continue on for days or even weeks, perhaps long after the baby has passed.⁹

While the abortion is happening, it may involve many anxious and uncomfortable moments where a woman is trying to determine whether the amount of pain she is experiencing and the amount of blood she is losing is normal or a sign of something gone wrong.¹⁰ She may find it psychologically challenging encountering and disposing of her aborted child.¹¹

A chemical abortion which is “painful, messy, and protracted,” as TIME magazine described it during U.S. trials of mifepristone in 1994, is hardly unusual.¹² If anything, it has proven to be the norm.

They don’t always work. And that can be a problem.

Even used within the framework set by the FDA, the medical abortion protocol has a significant failure rate. According to the FDA’s “Medication Guide” provided to patients,

About 2 to 7 out of 100 women taking Mifeprex will need a surgical procedure because the pregnancy did not completely pass from the uterus or to stop bleeding.¹³

For those who wish to continue their abortions, failure means, at a minimum, more medications, more waiting, and the possibility of a trip back to the clinic for the surgery they wished to avoid, along with all its risks.

Those are not insignificant numbers. We do not know exactly how many women attempted these abortions in 2017, but we do know that there were 339,640 chemical abortions recorded that year by the Guttmacher Institute.¹⁴ If these represented only the successful abortions, a two percent failure rate that year would have meant incomplete or failed chemical abortions for 6,931 women; seven percent would be 24,260.¹⁵ If growth in these types of abortions has continued since 2017, the numbers would be higher still.

Failure rates increase as gestation increases.¹⁶ With abortion providers publicly advertising willingness to perform these abortions at gestations beyond those specified on the FDA label, failed and incomplete abortion may be a problem for even more women.¹⁷

Again, failure of the drugs means, for many of these women, surgery to complete the abortion or to stop the bleeding.

High failure rates provide an additional source of anxiety for women having chemical abortions who may be uncertain if the baby has passed. Some women see the passage of the fetus and have a clear sense that the abortion is over (though bleeding may continue for several days). But others may cramp and bleed and pass clots without identifying the corpse. It is entirely possible to think one has aborted when one has not, or to think one has not and find out later one has. Absent some clear visual confirmation, an especially sensitive pregnancy test or a professional examination, some level of uncertainty is entirely warranted.¹⁸

There are several serious medical conditions for which health care professionals must screen potential chemical abortion patients.

The FDA has identified several conditions or contraindications which might render the use of mifepristone and misoprostol ineffective or dangerous. The label lists:

- Confirmed or suspected ectopic pregnancy or undiagnosed adnexal mass.
- Chronic adrenal failure
- Concurrent long-term corticosteroid therapy
- History of allergy to mifepristone, misoprostol, or other prostaglandins
- Hemorrhagic disorders or concurrent anticoagulant therapy
- Inherited porphyrias
- Use in patients with an intrauterine device (“IUD”) in place.¹⁹

Some of these conditions are more common than others and easily remedied (e.g., a woman can use mifepristone once her IUD is removed) but others carry potential for great harm if ignored.

Ectopic Pregnancy

Mifepristone and misoprostol do not work in circumstances of ectopic pregnancy, where the embryo attaches outside of the uterus. Ectopic pregnancy is a fairly common event, occurring in 1-2% of all pregnancies, so this is no small matter.²⁰ It is estimated that ectopic pregnancy complications account for up to 9% of all maternal deaths in the United States.²¹

Compounding the problem for those considering use of mifepristone, the common warning signs of ruptured ectopic pregnancy – abdominal pain, uterine bleeding – are expected parts of a standard chemical abortion.²² This can cause both patients and healthcare professionals to fail to recognize a rupturing ectopic pregnancy until it is too late, even if there has been an ultrasound.²³

Molar Pregnancy

Though not directly mentioned in the FDA’s contraindications, molar pregnancy presents a similar issue. A molar pregnancy, or hydatidiform mole, is characterized by the abnormal growth of placental tissue; sometimes there is the presence of a partially formed nonviable fetus, an entity that cannot survive.²⁴

Molar pregnancy can cause serious complications for the mother. Like ectopic pregnancy, women with molar pregnancies experience extended bleeding, nausea, vomiting, and severe pelvic pain, which are, of course, also the expected side effects of chemical abortions. Appropriate blood tests and ultrasound by a trained medical professional are needed to diagnose molar pregnancy when signs are present.²⁵

Chemical abortifacients like mifepristone and misoprostol are not usually considered to be the best treatment option for molar pregnancy.²⁶ Surgical removal of the molar tissue is the only effective treatment for molar pregnancy, though even after surgery a woman will need to be monitored for high hCG levels that could indicate the continued presence and growth of abnormal molar cells in her body. If still present, these cells can grow and change into cancerous

cells²⁷ and potentially rupture the uterus.²⁸ Molar pregnancy occurs in about one out of a thousand pregnancies.²⁹

Bleeding Disorders

The potential for hemorrhage is already significant with a method that considers extended and sometimes heavy bleeding a standard part of the process. Women bleed heavily, sometimes passing large clots, and continue to bleed for days or even weeks.³⁰

The possibility that the bleeding will get out of hand is something prescribers warn women to watch for and seek immediate help, and a reason why it is critical that women with bleeding disorders be screened before pills are prescribed.³¹

Rh Screening

The FDA's "Warnings and Precautions" section of the Mifeprex (mifepristone) label also includes this caution:

The use of MIFEPREX is assumed to require the same preventive measures as those taken prior to and during surgical abortion to prevent rhesus immunization.³²

It will not affect the current pregnancy, but a failure to identify and treat a woman with an Rh-negative blood type at this time can mean the death of children in subsequent pregnancies even if that child is wanted.³³

Other Conditions

Health care professionals prescribing mifepristone and misoprostol also need to screen potential patients for other conditions known to pose hazards, such as chronic adrenal failure, corticosteroid therapy, porphyrias, or allergies to any of the drugs.³⁴

FDA warnings are based on real deaths and injuries associated with use of mifepristone.

The FDA has issued special warnings on mifepristone on bleeding, infection, and risks associated with undetected ectopic pregnancy because it has received reports of numerous deaths and injuries associated with use of these pills.

The FDA's label for mifpristone includes a "Black Box Warning" which warns of "**SERIOUS AND SOMETIMES FATAL INFECTIONS OR BLEEDING**"(capitalization, bold type in original) associated with use of the drug. It specifies risks of:

- **Atypical Presentation of Infection. Patients with serious bacterial infections and sepsis can present without fever, bacteremia or significant findings on pelvic examination. A high index of suspicion is needed to rule out serious infection and sepsis.**
- **Bleeding. Prolonged heavy bleeding may be a sign of incomplete abortion or other complications and prompt medical or surgical intervention may be needed.**³⁵

This is no mere “scare tactic.” Since its approval, the FDA has recorded two dozen deaths and thousands of adverse events in the United States associated with the use of these drugs.³⁶

Infection

A third of those deaths involved rare clostridial infections, seven with *Clostridium sordellii*, a bacteria commonly found in soil, dust, and even the human gastro-intestinal tract. An anaerobic bacteria, certain strains of *C sordellii* have the capacity to turn deadly when in an oxygen poor environment where there may be dead or dying tissue and access to the bloodstream.³⁷

The medical literature has suggested that the vaginal self-administration of misoprostol may play a role in introducing the bacteria to the system³⁸ and researchers speculate that one or both of the drugs may facilitate infection by suppressing the immune system.³⁹

Clostridium sordellii infections are often deadly and thus typically difficult to overcome, but critical treatment may be delayed because of the similarity of the signs of these infections to the expected side effects of the chemical abortion process – vomiting, diarrhea, abdominal cramping – often occurring without the presence of fever that distinguishes other virulent infections.⁴⁰

Sadly, such was the case with Holly Patterson, a beautiful teenager who was one of abortion pill’s first casualties. After receiving mifepristone on Wednesday, September 10, 2003 at her local Planned Parenthood, she took home the misoprostol to administer to herself, vaginally, on Saturday. Cramping severely, she called the clinic and was told to take painkillers. Sunday, her father found her collapsed on the bathroom floor, unable to walk. She told him she was having a bad period.

Her boyfriend took her to the Emergency Room later that evening. She told the doctor she had taken the abortion pill. After a pelvic exam, she received more pain medication and was sent home.

Vomiting, nauseated, weak, she was rushed back the ER Wednesday morning. It was then doctors determined she had a massive reproductive tract infection. Though doctors struggled to treat her, the infection overwhelmed her system and she died around 2pm, September 17, just a week after taking the pills.⁴¹

An FDA investigation later identified the deadly bacteria as *Clostridium sordellii*, the same toxin that would take the lives of mifepristone patients Vivian Tran, Channelle Bryant, Orianne Shevin, and others.⁴²

Once these deaths and other injuries began to come to light, the FDA issued a public health advisory,⁴³ had the distributor send out warnings letters to doctors,⁴⁴ and made modifications to the drug’s label adding the warnings.⁴⁵

Those warnings also addressed issues of bleeding and ectopic pregnancy, which had also proven to be issues.

Ectopic Pregnancy

Brenda Vise, a 38 year old pharmaceutical representative from Tennessee died when her undetected ectopic pregnancy ruptured in September of 2001. She had traveled to Knoxville and took mifepristone to abort once a test confirmed her pregnancy. An ultrasound had found nothing in her uterus, but clinic personnel assured her the baby was simply too small to see.

When she began to experience severe pain and bleeding, Vise called the clinic. They assured her that her symptoms were “normal and routine” and suggested different medications for pain and nausea. When she worsened, her boyfriend called an ambulance to take her to the hospital where she was admitted in critical condition, suffering from a ruptured ectopic pregnancy. She died two days later.⁴⁶

Signs of ectopic pregnancy were missed by clinic personnel expecting the pain and bleeding that normally accompany chemical or “medication” abortion.

Vise’s case has not been the only ectopic pregnancy to garner the FDA’s attention. In its 2018 Post-Marketing Adverse Events analysis, the FDA reported 97 known cases of ectopic pregnancy among mifepristone patients, two of which were recorded as fatal.⁴⁷

The FDA warns that “some of the expected symptoms experienced with a medical abortion (abdominal pain, uterine bleeding) may be similar to those of a ruptured ectopic pregnancy” and reminds prescribers that use of mifepristone and misoprostol are not effective and thus contraindicated in patients with confirmed or suspected ectopic pregnancies.⁴⁸

Hemorrhage

The FDA’s 2018 Post-Marketing Summary for mifepristone listed hundreds of cases in the U.S. of blood loss so severe that transfusions were required and noted four cases in the U.S. and internationally where hemorrhage was a contributing factor in patient deaths.⁴⁹

Little is known about the hemorrhaging American patients, but cases like that of Swedish teen Rebecca Tell Berg illustrate the severity of the problem.

Rebecca didn’t want a chemical abortion but was talked into it by the doctor at the hospital in 2003. She took the mifepristone, returned two days later and was given the misoprostol. After about eight hours and some bleeding, Rebecca passed a big blob and went home.

Six days later, she remarked as to how tired she was. When her boyfriend suggested returning to the hospital, Rebecca told him she had been told to expect to bleed for several days. When he returned home at the end of the day, he found her lifeless body in the shower, where she had bled to death.⁵⁰

Another mifepristone patient, teenager Manon Jones bled to death in Wales in June of 2005. After the abortion, Jones complained of light-headedness and heavy bleeding. She visited the hospital for a scan and was told things were “normal.”

Still feeling unwell, she cut short a vacation with friends and returned to the hospital. Waiting four hours for a blood transfusion, she suffered a heart attack and seizures. Critical and in a coma, doctors removed life support once they determined she would not recover.

A coroner's inquest determined that "Miss Jones died of hypovolemia, an abnormal decrease in blood volume, and shock caused by 'retained products of conception,' namely the embryo."⁵¹

As FDA records show, hemorrhage can and does occur with chemical abortion,⁵² but caught soon enough, it can usually be resolved with drugs or surgery.⁵³ Failure to quickly recognize and address the problem right away, however, can prove deadly.

The active supervision of healthcare professionals is critical to the safety of medical abortion patients.

The chemical abortion process is inherently bloody, painful, and complicated. It doesn't work a significant percentage of the time. There are several common conditions for which health care professionals must screen potential chemical abortion patients, given that they could result in the drugs being ineffective or render their use more dangerous.

The FDA knows of multiple cases where women who appeared to be in prime physical condition took the drugs and died or experienced serious complications.

While some, including this organization, feel this is sufficient to merit the removal of this drug from market altogether,⁵⁴ at the very least, it clearly justifies as much control over the drug's distribution and utilization as possible in order to minimize patient deaths and injuries.

Studies that claim to prove that women can safely abort with telemedicine, that they can do without Rh testing, screen themselves for ectopic pregnancy and other contraindications, date their pregnancies, recognize signs of dangerous complications, etc., are plagued by high numbers of lost patients, leading to potentially inflated success rates and an overly enthusiastic interpretation of the results, minimizing or ignoring the seriousness of the risk of failure or complications for women for whom the pills do not work as expected.

Lost Women, Missing Data

For example, a recent five-state study of abortion by telemedicine by some of the nation's top abortion researchers claimed a success rate of 94%, leading authors to claim that their method was "safe, effective, efficient, and satisfactory." But only 177 of the original 248, or just 71% of those who were mailed the drugs were actually known to have successfully aborted with the pills. Some of these ended up having surgical abortions, a couple more continued their pregnancies, but the outcome for the other 23% of patients is unknown.⁵⁵

Even if the failure rate were only 6%, this would still represent a significant number of women having to seek medical help to surgically or chemically complete the abortion,⁵⁶ or find emergency assistance to deal with the bleeding, or to address other complications that arose. Even at that rate, this would represent more than 20,000 women if projected for all "medication abortion" patients in the country.⁵⁷

It is a mistake to assume failure and complication rates for missing telemedicine patients to be similar to those returning to the clinic or for whom the outcome is otherwise known.

Women supposedly choose telemedicine because a visit to the clinic is not desirable or convenient.⁵⁸ If and when they have problems, it is likely to be easier and more secure to visit a woman's regular local doctor or an emergency room where physicians are trained to deal with trauma than to call or visit a clinic which is far away and with whom the patient has little personal relationship.

If so, researchers would never hear of those incomplete abortions or complications unless the patient or doctor recontacted the prescriber.

The situation is made worse by the explicit advice of some advocates of self-managed abortions that emergency room physicians cannot tell if a woman is having a miscarriage or a chemical abortion and do not need to be told of the attempted abortion,⁵⁹ contradicting advice given by the FDA.⁶⁰

Under the circumstances, assurances of the safety of telemedical abortion patients, particularly with high numbers lost to follow up, are difficult to take at face value.

Lost Pills

Inherent in the internet and mail order scheme is an inability to guarantee that the person ordering and taking the pills is the right age, the right gestation, has no disqualifying conditions, and will use them as directed. Or to even ensure that the person is real.

FDA requirements that pills only be distributed to certified prescribers who are personally responsible for ensuring that the patient they have screened and counseled is actually the one that takes the pill and initiates the chemical abortion process helps to avoid those pills getting lost or getting into the wrong hands.

Anyone can order the pills and say that they are 18, that they are 9 weeks pregnant, that they are not allergic to the pills, etc., and simply have them sent to the address they give, so long as they have functioning credit card. Once receiving them, they can take them, save them, sell them, or dispose of them however they wish.

Even if the supplier of the pills gives the buyer the appropriate screening and warnings, there is no assurance this information will be passed on to the ultimate recipient of the pills. And, as demonstrated above, those pills can prove dangerous.

Allowing the purchase of abortion drugs over the internet further expands the potential for abuse. Men may order and give the drugs to unsuspecting partners to abort children the fathers do not want or do not want to support, attempting to have the women abort without the woman's knowledge or consent. This has already happened with abortion pills bought illegally;⁶¹ it will certainly be worse if the FDA decides to allow these sales.

Lack of professional screening

Advocates' assurances that women can estimate gestational age, forego Rh factor testing and screening for ectopic pregnancy are unjustified and irresponsible.

Despite a clear medical record showing decreased effectiveness and increased complications with increasing gestational age,⁶² researchers advocating the "no-test" method are satisfied that most women can estimate gestational age for themselves. Admitting that this "will inevitably result in treatment of some fraction of patients whose true GAs [gestational ages] exceed 77 days," they reassure (citing their own studies) that these medications will work at later gestations than those approved by the government and that serious "adverse events" will be "rare."⁶³

Again, even if most women estimate gestational age with some accuracy, that a certain percentage do not⁶⁴ means a higher level of risk of failure or complications for those patients, which translates into more women hemorrhaging trying to get to the emergency room.

While true that only a certain percentage of abortion patients have an Rh-negative blood type, a failure to identify and treat such women can mean the death of children in subsequent pregnancies.⁶⁵

Abortion pill researchers advocating the "no-test" self-managed chemical abortion method say "Rh testing is not a requirement for abortion in any setting" and argue that such testing is "unnecessary for patients who can report a Rh-positive blood type or who are certain that they want no future children after the planned abortion."⁶⁶

It is unclear how providers of the pills would make these high stakes plain to prospective patients or what steps they might take to limit distribution to patients willing to accept those dire consequences, but even if they did it would have the effect of forcing a woman to make an important and irrevocable decision at a time when she may be most desperate and uncertain about her future.

As many as 2% of identified pregnancies in the U.S. are ectopic, that is, where the unborn child implants outside the womb. If not identified and addressed, they can grow and rupture, placing the mother's life at risk.⁶⁷ Mifepristone and misoprostol do not work in the case of ectopic pregnancy, though the symptoms of a rupture – uterine pain, cramping, bleeding – are, at least initially, difficult to distinguish from the normal side effects of a chemical abortion.⁶⁸

Advocates of the "no-test" chemical abortion know of the abortion pill's lack of effectiveness in such situations and the risk it poses. But they blithely advise that even if ectopic pregnancies are missed by their self-screening methods, they "can be detected and managed afterwards."⁶⁹

These advocates are suggesting that these "no-test" chemical abortions can be performed at gestations up to 11 weeks, or more.⁷⁰ Given that the rupture of ectopic pregnancies can occur anywhere between the 6th and 16th week of pregnancy⁷¹ and produce symptoms disturbingly similar to chemical abortion side effects, assurances that they "can be detected and managed afterwards" sound irresponsibly optimistic.

The problem of complications

Women taking mifepristone do face ruptured ectopic pregnancies, hemorrhages, and dangerous infections, the medical record clearly shows. There is no medical reason to believe that these will suddenly become less frequent when women begin to manage these chemical abortions at home than they were when they received their pills at the clinic.

Complications will follow chemical abortion, as they always have. The question is, how well will these be handled?

Under the current REMS limited distribution system, a woman seeking to obtain these pills at her local clinic is to be specifically warned about the risk of complications that come with mifepristone. She is supposed to be advised on how to recognize these complications and told when and where to seek treatment. She may or may not be given such counsel with drugs purchases over the internet.⁷²

The certified healthcare provider mandated by the FDA plays a critical role in making sure the woman appreciates these risks, that she is able, for example, to distinguish the kind of bleeding that is normal from the sort that requires a quick return to the clinic or to the emergency department. This is not an inconsequential responsibility. If that provider has been certified, this means they are supposed to have been adequately trained, that they should be able to treat a hemorrhaging patient or assess them and send them to someone who is prepared to halt the bleeding.⁷³

An online doctor, if there is one and if he or she is inclined, can try to make this clear when prescribing the pills, but how attentive a woman will be to stranger she has just met and sees only briefly on her computer screen is a serious question. In any case, whether because of skill level or distance, that online clinician is unlikely to be available to treat the patient should problems arise.

Even a hotline, if there is one, may only be able to direct her to the nearest hospital where she may await treatment from staff unfamiliar with and unappreciative of the gravity of her condition, especially if this information is withheld from them.⁷⁴

At least with the FDA's REMS system, there should be a certified healthcare professional to take responsibility for ensuring that women are fully briefed on risks of the drug and will make sure they can get the treatment they need if and when a complication occurs.

Failure to recognize failure

Though they disagree about percentages, all abortion pill researchers grant that abortion pills don't always work. And when they don't, a woman must decide whether to take more medications, have a surgical abortion, or let the pregnancy continue.

But how does one know whether or not one is done? For some women, it is obvious. They see their aborted child and their side effects taper off. But it is possible for a mifepristone patient to

endure painful cramps, bleed for days, pass huge clots, think one has aborted, but later find out different.⁷⁵

Eric Schaff, an early pioneer in the chemical abortion campaign, noted early on that

Even though a woman may have experienced cramping and bleeding, she cannot know for certain that her abortion is complete until a provider performs either a sonogram or a hormonal pregnancy test.⁷⁶

The FDA cautions that “Lack of bleeding following treatment usually indicates failure; however, prolonged or heavy bleeding is not proof of a complete abortion.”⁷⁷

Advocates of the “no-test” chemical abortion argue that women can confirm completion of the pregnancy with a high sensitivity urine pregnancy test (HSPT). But because these come with high “false positive” rates, women are supposed to wait four weeks after taking the misoprostol before taking their first one. Continued positive results at that time may still end up requiring a clinical visit to conclusively determine the abortion has failed and to plan a woman’s next steps.⁷⁸

By contrast, the follow up with a trained health care provider that the FDA recommends at 7-14 days can provide a reliable and earlier verification of completion by clinical examination, medical history, ultrasound scan, or human Chorionic Gonadotropin (hCG) testing.⁷⁹

Summing Up: REMS limits are essential to the safety of mifepristone patients.

Some women, perhaps even most, may be able to endure a DIY, self-managed, “no-test” or telemedical abortion without any immediate or obvious long lasting physical damage. But drugs or protocols like chemical or “medication” abortion that pose demonstrated risks to a significant number of potential users require special management and monitoring, if not outright removal from the market.

Because the pills pose special risks to certain populations, women need to be professionally screened for blood conditions, drug allergies, molar or ectopic pregnancy and other conditions.

Testing for Rh antibodies needs to be done so as not to force a woman to sacrifice her reproductive future.

Her pregnancy needs to be dated by a medical professional trained to do so or with access to ultrasound equipment in order to ensure that the drugs not be prescribed at gestations where both failure and more serious side effects are more likely.

Being counseled in person about the risks and the warning signs by the health care professional conducting the examination and prescribing the pills will surely make a stronger impression than the talking head of a stranger on a webcam, and that information could prove critical to her health and safety.

If she does have excessive bleeding or some other complication, she has someone to whom and somewhere she can go where there are medical professionals familiar with her case and the operation of the drugs and can hopefully provide her the immediate sort of help she needs.

With every protocol out there, these drugs fail a certain percentage of the time. Though in some cases it is easy to tell whether or not they have worked, women may sometimes bleed and cramp and pass clots and believe they have aborted only to find out later that they did not. The surest and quickest way to find out is to be checked out or tested by a specially trained medical professional.

Distribution of these drugs must continue to be managed to ensure drug purity and safe use.

Pills should not be sent by mail from uninspected, unaccountable foreign pharmaceutical makers offering poorly packaged drugs of questionable dose or purity and missing due warnings or even basic instructions.

Mifepristone and misoprostol should not be available from over-the-counter pharmacies selling the pills to women who have not met with and been screened and counseled by trained and certified prescribers.

The tracking of patient outcomes and safety is hard enough already with patients who come into the clinics and receive the drugs and take the mifepristone on site; knowing with any reasonable certainty who ultimately receives these pills and how they fare will be difficult if not impossible when patient and prescriber never physically meet.

The FDA's current REMS regulations, if followed, offer women some safeguards, helping mitigate these demonstrated risks.

The promoters of these drugs may be willing to live with a certain amount of risk, to accept a number of failures and complications, but the FDA must consider the health and safety of all the women who may use these drugs.

ENDNOTES

- ¹ U.S. Food and Drug Administration, “Risk Evaluation and Mitigation Strategies | REMS,” content current 8/8/19, available at <https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems>, accessed 7/22/20)
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- ⁹ U.S. National Library of Medicine, Medline Plus, “Mifepristone (Mifeprex),” 5/15/16 revision. Available at medlineplus.gov/druginfo/meds/a600042.html, accessed 7/24/20.
- ¹⁰ Some examples of patient discomfort and concern be found at the “Ask a Patient” website where patients share their experiences with Mifeprex. See <https://www.askapatient.com/viewrating.asp?drug=20687&name=MIFEPREX&page=3>, accessed 7/23/20. A factsheet from Marie Stopes International entitled “Frequently Asked Questions (FAQs) for Medical Abortion” (website copyright 2019) addresses a woman’s concern about whether the amount of her bleeding is normal. Found at https://www.misoclear.com/media/1137/all_faqs.pdf , accessed 7/24/20.
- ¹¹ S. Marie Harvey, Linda J. Beckman, Mary Ann Castle and Francine Coeytaux, “Knowledge and Perceptions of Medical Abortion Among Potential Users,” *Family Planning Perspectives*, Vol 27, Number 5 (September/October 1995), pp. 203-207, at 206. Wendy Simonds, Charlotte Ellertson, Kimberly Springer, Beverly Winikoff, “Abortion, Revised: Participants in the U.S. Clinical Trials Evaluate Mifepristone,” *Social Science & Medicine*, Vol 46. No. 10, pp. 1313-1323, at 1321.
- ¹² Andrea Sachs, “Abortion Pills on Trial,” *TIME*, December 5, 1994, pp. 45-46, at 46.
- ¹³ FDA, “Medication Guide. Mifeprex (MIF-eh-prex) (mifepristone) tablets, for oral use,” Reference ID: 3909592, 3/2016, p.17.
- ¹⁴ Rachel K. Jones, Elizabeth Witwer, and Jenna Jerman, “Abortion Incidence and Service Availability in the United States, 2017” *Guttmacher Institute*, Table 6, p. 20. Available for download at <https://www.guttmacher.org/report/abortion-incidence-service-availability-us-2017#>, accessed 7/27/20.
- ¹⁵ The 339,640 would represent not the total chemical abortions, but the 98% or the 93% that were successful.
- ¹⁶ See Table 4, p.13, at FDA, “Mifeprex® (mifepristone) tablets Label,” 3/2016 Revision, Reference ID: 3909592, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf, accessed 7/27/20.
- ¹⁷ See Planned Parenthood, “The Abortion Pill” at <https://www.plannedparenthood.org/learn/abortion/the-abortion-pill> , accessed 7/27/20. Though the FDA protocol calls for mifepristone and misoprostol to be used up to ten weeks, Planned Parenthood tells women it can be used up to 11 weeks, offering the following reassurance: “For people who are 10-11 weeks pregnant, it works about 87 out of 100 times. If you're given an extra dose of medicine, it works about 98 out of 100 times.” The current 3/2016 FDA protocol does not endorse or provide data on this “extra does of medicine.” Women Help Women, an organization promoting at home use of abortion pills, tells women these can be used up through 12 weeks and offers women the opportunity to buy these pills. Women Help Women, “get abortion pills,” at https://consult.womenhelp.org/get-abortion-pills?z_language=en , accessed 7/28/20.

¹⁸ Carlyle Murphy, "RU 486: Abortion Pill Is Not as Simple as it Seems," Washington Post, February 4, 1997. Rose Stokes, "What Happens When an Abortion Doesn't Fully Work," Vice, August 15, 2019, available at https://www.vice.com/en_uk/article/7x5pqz/what-is-incomplete-failed-abortion, accessed 7/28/20. Stephen L. Fielding, Emme Edmunds, Eric Schaff, "Having an Abortion Using Mifepristone and Home Misoprostol: A Qualitative Analysis of Womens' Experiences," Perspectives on Sexual and Reproductive Health, Vol 34, No.1 (January/February 2002), pp 34-40. At page 37, authors declare:

Even though a woman may have experienced cramping and bleeding, she cannot know for certain that her abortion is complete until a provider performs either a sonogram or a hormonal pregnancy test.

¹⁹ FDA, "Mifeprex® (mifepristone) tablets Label," 3/2016 Revision, Reference ID: 3909592, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf, accessed 7/28/20. See "Contraindications, pp. 3-4.

²⁰ Danielle M. Panelli, Catherine H. Phillips, Paula C. Brady, "Incidence, diagnosis and management of tubal and non-tubal ectopic pregnancies: a review," Fertility Research and Practice, Vol 1, No. 15 (October 15, 2015), pp. 1-20, at 1. According to the authors, the incidence for those who have used assisted reproductive technology is even higher, at 2-5%.

²¹ CDC, "Current Trends Ectopic Pregnancy— United States, 1990-1992" MMWR Weekly, Vol. 44, No. 3 (January 27, 1995, pp. 46-48.

²² FDA, "Mifeprex® (mifepristone) tablets Label," 3/2016 Revision, Reference ID: 3909592, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf, accessed 7/28/20. See "Contraindications, pp. 3-4 and "Warnings and Precautions 5.4 Ectopic Pregnancy" at p. 6.

²³ The case of Brenda Vise, who died when her undetected ectopic pregnancy ruptured in 2002 is illustrative. In her case, this occurred despite an ultrasound screening which should have detected the presence of the fetus outside the womb. See "\$15 Million Lawsuit Filed In Case of Local Woman Who Died After Abortion," The Chattanooga.com, August 14, 2002. Story and text of lawsuit at <https://www.chattanooga.com/2002/8/14/25209/15-Million-Lawsuit-Filed-In-Case-Of.aspx>, accessed 7/28/20.

²⁴ Mayo Clinic Staff, "Molar Pregnancy: Overview, Symptoms & Causes" December 14, 2017, at <https://www.mayoclinic.org/diseases-conditions/molar-pregnancy/symptoms-causes/syc-20375175>, accessed 8/6/20.

²⁵ Mayo Clinic Staff, "Molar Pregnancy: Diagnosis & Treatment," December 14, 2017, at <https://www.mayoclinic.org/diseases-conditions/molar-pregnancy/diagnosis-treatment/drc-20375180>, accessed 8/6/20.

²⁶ According to the Royal College of Obstetricians and Gynaecologists:

Data from the management of molar pregnancies with mifepristone and misoprostol are limited. Evacuation of complete molar pregnancies with these agents should be avoided at present since it increases the sensitivity of the uterus to prostaglandins

Royal College of Obstetricians & Gynaecologists, "The Management of Gestational Trophoblastic Disease" Green-top Guideline No. 38, February 2010, p. 4. Available at https://www.rcog.org.uk/globalassets/documents/guidelines/gtg_38.pdf, accessed 7/29/20.

²⁷ North Bristol NHS Trust, "Molar Pregnancy (Gestational Trophoblastic Disease)" January 2017, p. 2. Available at https://www.nbt.nhs.uk/sites/default/files/attachments/Molar%20pregnancy_NBT003056.pdf, accessed 7/29/20.

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²⁹ Mayo Clinic, "Molar Pregnancy: Overview" at <https://www.mayoclinic.org/diseases-conditions/molar-pregnancy/symptoms-causes/syc-20375175>, December 14, 2017, accessed 7/29/20.

³⁰ British Pregnancy Advisory Service, "Caring for yourself after your abortion. What to expect after treatment: Bleeding," 2015, available at <https://www.bpas.org/abortion-care/abortion-aftercare/>, accessed 7/30/20. Also U.S. National Library of Medicine, Medline Plus, "Mifepristone (Mifeprex)," 5/15/16 revision. Available at medlineplus.gov/druginfo/meds/a600042.html, accessed 7/30/20.

³¹ Comprehensive Women's Health Center, "Aftercare Instructions: Medication Abortion," copyright 2012-2019, at <https://cwhccolorado.com/services/medication-abortion/aftercare-medication-abortion/index.html#:~:text=When%20to%20call%20the%20clinic,of%20the%20day%20or%20night>, accessed 7/30/20. FDA, "Medication Guide" page 16 of "Mifeprex® (mifepristone) tablets Label," 3/2016 Revision, Reference ID: 3909592, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf, accessed 7/30/20.

³² FDA, "Mifeprex® (mifepristone) tablets Label," 3/2016 Revision, Reference ID: 3909592, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf, accessed 7/28/20. See "Warnings and Precautions. 5.5 Rhesus Immunization," p. 6.

³³ Armando Fuentes, "Rh Incompatibility During Pregnancy," KidsHealth from Nemours, October 2018. Available at <https://kidshealth.org/en/parents/rh.html>, accessed 7/31/20. Also Kristi Stone Hamrick, "Abortion pills without Rh-testing could prevent many women from every having children," Washington Examiner, May 29, 2020, at <https://www.washingtonexaminer.com/opinion/abortion-pills-without-rh-testing-could-prevent-many-women-from-ever-having-children>, accessed 7/31/20.

³⁴ FDA, "Guidance for Industry: Warnings and Precautions, Contraindications, and Boxed Warning Sections of Labeling for Human Prescription Drug and Biological Products – Content and Format" October 2011, at <https://www.fda.gov/files/drugs/published/Warnings-and-Precautions--Contraindications--and-Boxed-Warning-Sections-of-Labeling-for-Human-Prescription-Drug-and-Biological-Products-%E2%80%94-Content-and-Format.pdf>, accessed 7/30/20.

³⁵ FDA, "Mifeprex® (mifepristone) tablets Label," 3/2016 Revision, Reference ID: 3909592, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf, accessed 8/3/20.

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⁴⁰ Marc Fischer, et al, "Fatal Toxic Shock Syndrome Associated with *Clostridium sordellii* after Medical Abortion, New England Journal of Medicine, Vol. 353, No. 22 (December 1, 2005), pp 2352-60, at p. 2359.

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⁴⁶ "\$15 Million Lawsuit Filed In Case of Local Woman Who Died After Abortion," *The Chattanooga.com*, August 14, 2002. Story and text of lawsuit at <https://www.chattanooga.com/2002/8/14/25209/15-Million-Lawsuit-Filed-In-Case-Of.aspx>, accessed 7/28/20.

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⁵⁵ Elizabeth Raymond, Erica Chong, Beverly Winikoff, et al, “TelAbortion: evaluation of a direct to patient telemedicine abortion service in the United States,” *Contraception*, Vol, 100, No. 3 (September 2019), pp. 173-177, at Fig.1, p175.

A more recent example can be found in a research letter by Ushma D. Upadhyay, Leah R. Koenig, Karen R. Meckstroth titled “Safety and Efficacy of Telehealth Medication Abortions in the US During the COVID-19 Pandemic” from August 24, 2021 edition of *JAMA Network Open*. Updhyay and her colleagues from the University of California San Francisco (UCSF) reported there that 95% of the patients with "outcome data" had complete abortions "without intervention."

This was, however, just of the 110 patients whose outcome was known. Researchers did not know what the outcome was for 18 other patients, and had actually lost track of another 13 patients who received "abortion care" from the telemedical abortion service. Considered as part of the entire group of women who received abortion pills by mail, researchers could only document 71% "successfully" aborting, and only some of these were confirmed by testing. Still others required additional "medical intervention" to complete their abortions.

⁵⁶ Or, it should be noted, to consider intervention with progesterone to potentially “reverse” the abortion.

⁵⁷ According to the Guttmacher Institute, 339,640, or 39% of all abortions performed in the U.S. in 2017 were “medication abortions.” Six percent of that figure is 20,378. Rachel K. Jones, Elizabeth Witwer, and Jenna Jerman, “Abortion Incidence and Service Availability in the United States, 2017,” Guttmacher Institute, September 2019, at https://www.guttmacher.org/sites/default/files/report_pdf/abortion-incidence-service-availability-us-2017.pdf, pp. 1-24, at 8 accessed 8/6/20.

⁵⁸ Katherine Ehrenreich, Shelly Kaller, Sarah Raifman, Daniel Grossman, “Women’s Experiences Using Telemedicine to Attend Information Visits in Utah: A Qualitative Study,” *Women’s Health Issues*, Vol. 29, No. 5 (September-October 2019), pp. 407-413, at 409-410.

⁵⁹ Multiple cites. Women on Web “How do you know if you have complications and what should you do?” webpage www.womenonweb.org/article-214-3n.html, captured 10/29/07. Women Help Women, “what are the symptoms of complications?” <https://consult.womenhelp.org/en/using-abortion-pills-for-safe-abortion-usa>, screenshot, 8/1/19. Aid Access, “How do you know if you have complications and what should you do?” <https://aidaccess.org/en/page/459/how-do-you-know-if-you-have-complications-and-what-should-you-do>, copyright 2020, accessed 8/6/20.

⁶⁰ FDA, “Medication Guide: Mifeprex (MIF-eh-prex) (mifepristone) tablets, for oral use,” Reference ID: 3909592, at p. 16 of 3/2016 Label.

⁶¹ Kevin Murphy, “Abortion-drug dealer pleads guilty, linked to Grand Rapids man accused of poisoning pregnant woman’s drink,” *Wisconsin Rapids Tribune*, March 5, 2020, <https://www.wisconsinrapidstribune.com/story/news/2020/03/05/abortion-pill-dealer-ursula-wing-guilty-case-tied-grand-rapids-man/4966488002/>, Shereen Siewert, “New York woman convicted of illegally selling abortion drugs in Wisconsin,” *Wausau Pilot & Review*, July 12, 2020, <https://wausaupilotandreview.com/2020/07/12/new-york-woman-convicted-of-illegally-selling-abortion-drugs-in-wisconsin/>, accessed 8/7/20.

⁶² FDA, “Mifeprex® (mifepristone) tablets Label,” 3/2016 Revision, Reference ID: 3909592, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf, Table 4, p. 13. Accessed 8/6/20.

⁶³ Elizabeth Raymond, Daniel Grossman, Alice Mark, Ushma D. Upadhyay, Gillian Dean, Mitchell D. Creinin, Leah Coploy, Jamila Perritt, Jessica M. Atrio, Deshawn Taylor, Marji Gold, “Commentary: No-test medication abortion: A sample protocol for increasing access during a pandemic and beyond,” *Contraception*, Vol 101, No. 6 (June 2020) pp. 361-366, at 363.

⁶⁴ A 2007 study appearing in the *British Journal of Obstetrics & Gynaecology* found that women’s estimates of pregnancy duration were 19 days fewer [two and half weeks shorter] than ultrasound estimates. K. Blanchard, Beverly Winikoff, et al, “A comparison of women’s provider’s, and ultrasound assessments of pregnancy duration among termination of pregnancy clients in South Africa,” *BJOG*, Vol. 114, No. 5 (May 2007), pp. 569-75. Even supposing these misestimations are not intentional to meet the gestational deadline, it is possible, for example, that women may miscalculate by mistaking early spotting for a menstrual period.

⁶⁵ Armando Fuentes, “Rh Incompatibility During Pregnancy,” *KidsHealth* from Nemours, October 2018. Available at <https://kidshealth.org/en/parents/rh.html>, accessed 7/31/20. Also Kristi Stone Hamrick, “Abortion pills without Rh-testing could prevent many women from ever having children,” *Washington Examiner*, May 29, 2020, at <https://www.washingtonexaminer.com/opinion/abortion-pills-without-rh-testing-could-prevent-many-women-from-ever-having-children>, accessed 7/31/20.

⁶⁶ Elizabeth Raymond, Daniel Grossman, Alice Mark, Ushma D. Upadhyay, Gillian Dean, Mitchell D. Creinin, Leah Coploy, Jamila Perritt, Jessica M. Atrio, Deshawn Taylor, Marji Gold, “Commentary: No-test medication abortion: A sample protocol for increasing access during a pandemic and beyond,” *Contraception*, Vol 101, No. 6 (June 2020) pp. 361-366, at 363.

⁶⁷ Antonette T. Dulay, “Pregnancy,” *Merck Manual Professional Version*, June 2019, at <https://www.merckmanuals.com/professional/gynecology-and-obstetrics/abnormalities-of-pregnancy/ectopic-pregnancy>, accessed 8/6/20.

⁶⁸ FDA, “Mifeprex® (mifepristone) tablets Label,” 3/2016 Revision, Reference ID: 3909592, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf, accessed 7/28/20. See “Contraindications, pp. 3-4 and “Warnings and Precautions 5.4 Ectopic Pregnancy” at p. 6.

⁶⁹ Elizabeth Raymond, Daniel Grossman, Alice Mark, Ushma D. Upadhyay, Gillian Dean, Mitchell D. Creinin, Leah Coploy, Jamila Perritt, Jessica M. Atrio, Deshawn Taylor, Marji Gold, “Commentary: No-test medication abortion: A sample protocol for increasing access during a pandemic and beyond,” *Contraception*, Vol 101, No. 6 (June 2020) pp. 361-366, at 363.

⁷⁰ Elizabeth Raymond, Daniel Grossman, Alice Mark, Ushma D. Upadhyay, Gillian Dean, Mitchell D. Creinin, Leah Coploy, Jamila Perritt, Jessica M. Atrio, Deshawn Taylor, Marji Gold, “Commentary: No-test medication abortion: A sample protocol for increasing access during a pandemic and beyond,” *Contraception*, Vol 101, No. 6 (June 2020) pp. 361-366, at 362, 363.

⁷¹ Antonette T. Dulay, “Pregnancy,” *Merck Manual Professional Version*, June 2019, at <https://www.merckmanuals.com/professional/gynecology-and-obstetrics/abnormalities-of-pregnancy/ectopic-pregnancy>, accessed 8/6/20.

⁷² Chloe Murtaugh, Elisa Wells, Elizabeth G. Raymond, Francine Coeytaux, Beverly Winikoff, “Exploring the feasibility of obtaining mifepristone and misoprostol from the internet,” *Contraception*, Vol. 97, No. 4 (April, 2018), pp 287-291, at 289.

⁷³ FDA, “Risk Evaluation and Mitigation Strategy (REMS)” for NDA 020687 MIFEPREX® (mifepristone) Tablets, 200 mg” 3/2016. Reference ID: 3909592. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020RemsR.pdf, accessed 7/22/20, and FDA, “Mifeprex (mifepristone) tablets Label,” Reference ID: 3909592, 3/2016, at

https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf, accessed 7/6/20.

⁷⁴ Given that ability to treat complications is not a requirement for prescriber certification (they only need to be able to refer patients to someone who can), if they do seek help at the emergency room, at least those emergency personnel should have the skills to address those problems.

⁷⁵ Carlyle Murphy, "RU 486: Abortion Pill Is Not as Simple as it Seems," *Washington Post*, February 4, 1997. Rose Stokes, "What Happens When an Abortion Doesn't Fully Work," *Vice*, August 15, 2019, available at https://www.vice.com/en_uk/article/7x5pqz/what-is-incomplete-failed-abortion, accessed 7/28/20.

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⁷⁷ FDA, "Mifeprex (mifepristone) tablets Label. 2.3 Post-treatment Assessment: Day 7 to 14," Reference ID: 3909592, 3/2016, p. 4, at https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf, accessed 7/6/20.

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