

Chemical Abortion: Risks Posed by Changes in Supervision

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A new trend in abortion advocacy is cause for concern.

When elective induced abortion was legalized in the U.S. in 1973, one oft-cited motivation was to improve abortion's safety, as it was frequently claimed that many women were injured and sometimes died from illegal abortions.¹

Recently, abortion advocates have changed their strategy. Whereas once they claimed they wanted abortion to be "safe, legal and rare," now they favor convenience and immediate access to abortion for all women experiencing unintended pregnancies, regardless of whether it might be more dangerous for a woman, or whether the law prohibits it. Thus, they have begun encouraging women to seek more dangerous "self-managed abortions," often through drugs unsupervised by a physician.

To fully understand the dangers of an unsupervised approach to medical, or chemical, abortion, one needs to understand how these abortions have traditionally been provided, and how under the guise of increasing "access" a much more dangerous approach is being substituted. For the purposes of clarity, these abortions will be referred to as "chemical abortion." "Medical" implies properties that promote health, and the intent of these chemicals is to cause the death of the unborn human.

The chemical abortion pill regimen approved by the Food and Drug Administration (FDA) consists of two components. The first, mifepristone (Mifeprex or RU486), blocks progesterone receptors to cut off hormonal support, disrupting the uterine lining, causing embryonic or fetal death. The second, misoprostol (Cytotec), is taken 24-48 hours later to induce contractions to expel the deceased baby and placental tissue.² Misoprostol is readily available because it is used for other indications, but mifepristone is only distributed in accordance with an FDA Risk Evaluation and Mitigation Strategy (REMS), due to a series of deaths from sepsis and other serious adverse events.³⁻⁵

Mifepristone was initially approved in 2000 for up to 49 days' gestational age. The physician prescriber became registered after specific training. The drug was to be dispensed in only certain medical settings, and patients were to be informed of the risk of serious side effects. Abortion providers were required to accurately determine gestational age, confirm an intrauterine location, and intervene surgically if needed (or have an arrangement with a provider who could perform that intervention).⁶

FDA approved a supplemental application in 2016. This loosened the restrictions and extended use until 70 days' gestational age, despite very few studies and much higher failure rates in later gestational ages.⁷ Dose, timing, and route of administration were modified. Abortion providers were no longer required to report a complication unless it resulted in a woman's death.⁸

Recent abortion trends document a steady increase in chemical abortion as percentage of all U.S. abortions, accounting for 54% of all abortions, according to 2020

Guttmacher Institute preliminary data.⁹⁻¹⁰ This increase is driven by factors that benefit the abortion provider, but not the woman.¹¹

Chemical abortion provision is lucrative. The average charge is \$535 for medications costing less than \$100.¹² Fewer physicians are willing to perform surgical abortions, many abortion facilities have closed, and laws protecting life have been implemented in many states.¹³

Yet, a surgical abortion is faster and far less likely to result in complications.^{14,15} The average woman undergoing a chemical abortion will bleed for nine to 16 days, and 8% will bleed longer than a month. Most will experience side effects of labor-like cramping, heavy bleeding, nausea, vomiting, fever, chills, headache, diarrhea, and dizziness.¹⁶ Many will experience the emotional devastation of observing their aborted child's body.

Hemorrhage and failure to empty the uterus of necrotic tissue are the most common complications, but mifepristone may also cause complications of infection and mental health issues through direct pharmacologic effects. Mifepristone blocks glucocorticoid receptors, contributing to an impaired inflammatory response, increasing the risk of *Clostridium sordellii* infection and sepsis, which has led to deaths.^{3,4} Additionally, it causes the release of inflammatory cytokines implicated in causing depression. In a rat model the mifepristone termination group had significantly decreased body weight, food intake, locomotor-related activity, and sucrose consumption, which are all animal proxies for depression and anxiety.¹⁷

Abortion Reporting Has Many Data Deficiencies

Abortion advocates' claim that chemical abortion is as safe as Tylenol or a shot of penicillin¹⁸ is based on analyzing chemical abortion complication reports known to be incomplete and comparing them to overdoses of Tylenol. The U.S. has never mandated reporting abortion incidence, complications, or deaths. The data that the U.S. Centers for Disease Control and Prevention (CDC) reports is voluntarily obtained and known to be of poor quality. For example, in the most recent year available for comparison, the CDC, which receives data from (some but not all) state health departments, reported 612,719 abortions,¹⁹ whereas the Guttmacher Institute, aligned with the abortion industry, reported 862,300.⁹ Although some states (28) have passed laws requiring abortion providers to report their complications, there is rarely an enforced penalty for noncompliance. Even fewer states (12) require other physicians, coroners, or emergency room personnel to report abortion-related complications or deaths for investigation.²⁰

Biased studies based on poor-quality data, published by researchers affiliated with the U.S. abortion industry, report low complication rates of abortion.^{21,22} These studies often analyze medical records of high-volume abortion providers and do not reflect the quality of all providers.²³ They often use

terms that contradict the public's understanding. For example, one study reported chemical abortion efficacy of 99.6% while acknowledging that 2.1% required surgery. Most would consider failed chemical abortion requiring surgery to be "ineffective." They usually ignore the large number of women lost to follow-up, in which the incidence of complications is unknown.²⁴⁻²⁹

Studies of emergency room use after abortion focus on the small number of ICD codes specific for induced abortion complications, ignoring the known lack of specificity of many electronic search engines, which may produce nonspecific codes or codes indicating a miscarriage as the precipitating event (particularly if the woman has not disclosed the prior abortion to emergency room staff).³⁰ In 2015, 60.9% of Medicaid-funded induced abortion-related emergency room visits in 17 states were miscoded as caused by spontaneous abortions.³¹ Since many abortion providers do not maintain hospital admitting privileges,³² complications are often managed by clinicians other than the abortion provider. The FDA's complication data records that less than 40% of surgeries required for failed chemical abortions were performed by abortion providers.³³⁻³⁴

The FDA estimates that 3.7 million chemical abortions occurred between 2000 and 2018.³⁵ If the rate of adverse events is conservatively estimated at 2%, then approximately 74,000 complications would have been anticipated. Yet, two analyses examining the FDA's mandated adverse event reports (AERs) from 2000 to 2019 obtained by Freedom of Information Act (FOIA) request documented only 3804 AERs, suggesting the FDA received reports on fewer than 5% of the estimated adverse events.^{33,34}

Planned Parenthood, which performs approximately 40% of U.S. abortions, published a study reporting 1,530 significant adverse events in only a two-year period (defined as emergency room evaluation, hospital admission, blood transfusion, intravenous antibiotics administration, ongoing pregnancy, undiagnosed ectopic pregnancy and death, but not including failed chemical abortions requiring surgery). This number, nearly half of all the FDA's documented complications from all abortion providers over an 18-year period, casts significant doubt on the reliability of the FDA's AER data. Whether Planned Parenthood failed to report all their complications to the FDA, or whether the FDA failed to provide all their reports to the FOIA request remains unknown.^{36,37}

Less-biased studies available internationally give a far different picture of the safety of chemical abortions. Epidemiological studies in Finland are of better quality than those in the U.S. because single-payer healthcare and meticulous medical recordkeeping ensure that all pregnancies and all medical events are accurately recorded. A records-linkage study of more than 42,000 abortions earlier than seven weeks gestational age documented four times as many complications after chemical (20%) than surgical abortions (5.6%). Hemorrhage (15.6 vs 2.1%) and retained pregnancy tissue (6.7 vs 1.6%) were the most common complications, and almost 6% of the women undergoing chemical abortions required surgical completion.³⁸

Current State of Chemical Abortion Provision

It has long been the goal of the abortion industry to remove all restrictions on chemical abortions so that they can be obtained outside of the medical system and be unregulated by the legal system. Recently, abortion advocates leveraged

the COVID-19 pandemic to promote further deregulation of chemical abortion.³⁹ The FDA complied with this pressure and temporarily (April 2021), and then permanently (December 2021), withdrew the requirement that mifepristone be administered in person. This allows mifepristone provision without an opportunity for the standard pre-abortion physical examination, ultrasound, and labs.

The FDA justified its action with studies comparing "telemedicine" abortions to "in-person" abortions, finding similar outcomes. Yet, many studies that claimed to document the safety of remote chemical abortion provision continued to implement standard pre-abortion screening including physical exam, ultrasound, and labs. They merely differed in whether the chemical abortion pills were provided to the woman by mail or through a local pharmacy or clinic instead of in person with the abortion provider. Sometimes they confusingly included hybrid groups that included both pre-screened and unscreened groups. Studies also often contained large groups of women for whom follow-up was unknown. Yet, these flawed studies are often cited as proof that lack of screening is safe.²⁴⁻²⁹

Inequality of abortion access is frequently argued as an important reason for providing chemical abortion pills by telemedicine and mail-order distribution to women who live remote from abortion clinics. Yet, the approximately one in 20 women who suffer a failed chemical abortion will require access to emergency care that is often far away, leaving them to suffer disproportionately. These women are often frightened and bleeding heavily. They may require hospital admission for immediate surgery, blood transfusion, or intravenous antibiotics. They may overwhelm the emergency rooms and blood banking systems that have already been overstressed due to the COVID-19 pandemic.

Potential Harms from Lack of Supervision

In-person supervision can reduce the risk of significant, even lethal complications.

Failure Due to Underestimation of Gestational Age

Providing chemical abortion pills by telemedicine without ultrasound, or on-line ordering/distribution by mail assumes that a woman will be able to accurately calculate her gestational age based on her last menstrual period (LMP), but these estimations are often inaccurate. Many women have irregular menses or may not recall their LMP. A woman may conceive while using contraception or have implantation bleeding that she assumes is her menses even though she is already pregnant. Thus, it is a frequent occurrence for a woman to underestimate her gestational age by a month or more.⁴⁰ Numerous studies have documented that ultrasound dating is more accurate than recollection of last menstrual period.^{41,42}

A meta-analysis of more than 33,000 chemical abortions revealed that failures requiring surgical completion increase steadily as gestational age increases. Less than 2% (1.9%) failed at less than 7 weeks, 3.3% failed between 7 and 8 weeks, 4.8% failed between 8 and 9 weeks, and 6.9% failed between 9 and 10 weeks.^{15,43} Another meta-analysis of more than 45,000 chemical abortions revealed an overall failure rate of 4.8%, with the risk of failure much higher at gestational ages greater than 8 weeks.⁴⁴

If a woman miscalculates her gestational age and has entered the second trimester when she ingests mifepristone and misoprostol, the likelihood that she will require surgery

increases dramatically. A Finnish records-linkage study of more than 18,000 women found 38.5% of second-trimester chemical abortions required surgical completion (versus 7.9% in the first trimester). Additionally, 4% of the later abortions were complicated by infections (versus 1.9% of the earlier ones).⁴⁵

Failure to Diagnose an Ectopic Pregnancy

Ultrasound is considered the gold standard for diagnosis of an ectopic pregnancy.⁴⁶ Omitting ultrasound will increase the likelihood of failing to make the diagnosis. Mifepristone exerts its effects on the uterine lining, so when an embryo is implanted in another location, the chemical abortion regimen has no effect. Continued growth may cause a Fallopian tube or other visceral organ to rupture. Catastrophic hemorrhage in these situations sometimes leads to maternal deaths.

Although there are many known risk factors for ectopic pregnancy, the American College of Obstetricians and Gynecologists' (ACOG) website states that half of women with ectopic pregnancies do not have any risk factors.⁴⁷⁻⁴⁸ It cannot be ruled out merely by history screening. ACOG's practice bulletin on ectopic pregnancy acknowledges, "Tubal ectopic pregnancy in an unstable patient is a medical emergency that requires prompt surgical intervention."⁴⁹ Although ectopic implantations occur in only 2% of recognized pregnancies, they account for up to 10% of maternal deaths.⁵⁰ During a surgical abortion the provider can verify the removal of pregnancy tissue, but with a woman suffering her chemical abortion alone, no such opportunity for confirmation exists.

A woman who experiences ectopic warning symptoms, such as pain or bleeding, while undergoing a chemical abortion may be less likely to report them to a physician, because she has been warned to expect these symptoms as a sign that the abortion pills are working. A woman is 30% more likely to die from an ectopic while undergoing an abortion than if she had an ectopic but had not sought an abortion.⁵¹ A case report describes one such woman who was found unconscious with 1.3 liters of blood in her abdomen.⁵² Despite these concerns, Planned Parenthood recently published a study recommending chemical abortion provision even if the pregnancy location could not be confirmed.⁵³

Anti-D immunoglobulin (RhoGAM)

ACOG's 2014 practice bulletin on alloimmunization states, "Rh D immune globulin should be given to Rh D-negative women who have a pregnancy termination, either medical or surgical."⁵⁴ ACOG's 2020 practice bulletin on chemical abortion also states, "Rh testing is recommended in patients with unknown Rh status before medication abortion, and Rh D immunoglobulin should be administered if indicated." Yet, paradoxically, the next sentence recommends, "in situations where Rh testing and Rh D immunoglobulin administration is not available or would significantly delay medication abortion, shared decision making is recommended so that patients can make an informed choice about their care."⁵⁵ Without any additional evidence, this pro-abortion organization relaxed its own standards to allow remote abortion without Rh testing or RhoGAM administration.

A 2003 review on alloimmunization demonstrated that nearly all medical societies recommended Rh D immunoglobulin in Rh-negative women undergoing abortion, because termination of pregnancy may lead to transplacental hemorrhage. Isoimmunization has been documented to occur with exposure to as little as 0.1 ml of fetal blood, and it

is estimated that fetal blood volume is 0.33 ml at eight weeks' gestation. Risk of isoimmunization in Rh-negative women after first-trimester surgical abortion appears to be 4.6% without Rh D immune globulin, but no studies are available examining the risk after chemical abortion.⁵⁶ Nonetheless, a pilot study of only 28 women is used as the basis for removing the RhoGAM recommendations by the National Abortion Federation (NAF).⁵⁷

The consequence of failing to prevent anti-D alloimmunization is great in a subsequent pregnancy. About 14% of untreated affected infants are stillborn, and half of liveborn untreated infants suffer neonatal death or brain injury. Treatment is difficult and invasive, often requiring repeated in-utero transfusions to counteract severe fetal anemia. Approximately 15% of the U.S. population is at risk, and current recommendations of providing anti-D immunoglobulin to at-risk women have reduced the risk of alloimmunization from 13–16% to 0.14–0.2%.⁵⁸ The recommendation of abortion advocates to forgo the standard intervention of Rh D immune globulin could result in catastrophic complications in future pregnancies.

Reproductive Coercion

FDA REMS used to require that a woman seeking a chemical abortion receive the mifepristone in the presence of the abortionist to ensure the woman has been counseled and desires the abortion. As with any medical intervention, a thorough discussion of the advantages, disadvantages, risks, and alternatives is essential. The moral significance of abortion makes this interaction even more important, and women sometimes regret this decision afterward.

The potential for misuse and coercion is high when there is no way to verify who is consuming the drug and whether she is doing so willingly. ACOG and NAF have documented that women seeking abortions are at risk for reproductive coercion defined as "partner using threats and coercion to enforce his will about the pregnancy outcome," but somehow they ignore the opportunity for sex traffickers, domestic abusers, and men who do not want to become fathers to surreptitiously give abortion pills to women when these drugs can be easily obtained by anyone.⁵⁹⁻⁶³ Many women experiencing sex trafficking have been forced into multiple abortions. Interaction with the medical system is an opportunity for these women to be identified and helped, but ready availability of chemical abortion pills to their abusers will remove this opportunity for intervention.⁶⁴

The government of England recently ended its approval of chemical abortion "pills by post" when it became aware of the frequent issue of domestic abuse. About 70% of public commenters were concerned that remote provision would have a negative impact on the safety of women seeking abortion, particularly the "risk of women being coerced into an abortion when they are not physically being seen in a service." This concern seemed to be validated when a BBC poll documented that 15% of respondents said they experienced pressure to terminate a pregnancy when they did not want to, and 3% reported being given something to cause an abortion without their consent.⁶⁵ Unfortunately, this commonsense measure was overruled by Parliament for political, not safety, reasons.

Quality of Mail-order Medications

A widely promoted website, PlanCPills.org, instructs buyers on how to circumvent their state's restrictions to purchase pills

from unregulated on-line pharmacies. Mail-order distribution fails to account for transit time and condition of the pills on arrival. An indecisive woman may not take the pills when they arrive (which could be days or weeks after ordering), but then change her mind and take them later, when the risk of failure is much higher.

A study on obtaining abortion pills from international distributors found that no prescription or clinical information was required, the pills averaged two weeks to arrive, analysis of the drugs demonstrated that some misoprostol pills contained only 15% of the advertised amount, often the packages arrived damaged, and no instructions were contained in any of the packages.⁶⁶

A small Indian study examining the feasibility of providing chemical abortion pills over the counter found that 27% of 40 women consumed the pills past the recommended gestational age cutoff, with 17% consuming them more than three weeks past the cutoff. This resulted in excessive hemorrhage in 77% of the women, surgical evacuation in 68%, severe anemia requiring transfusion in 12%, and hemodynamic shock in 5%.⁶⁷

Currently, an abortion provider must intentionally register to prescribe mifepristone; removing this restriction will create pressure on other providers and pharmacists to provide abortion pills. Only 7–14% of obstetrician/gynecologists say they will perform an abortion.^{68–69} Pressure on physicians to violate their conscience by providing a life-ending drug in violation of their Oath of Hippocrates is likely to exacerbate the critical shortage of physicians our country is experiencing.

Use of Misoprostol Alone

Due to increasing state level restrictions on mifepristone, abortion advocates have begun promoting the use of only the second component of the chemical abortion regimen, misoprostol, for “self-managed” abortion. They acknowledge that the reason they are doing so is that misoprostol is much easier to obtain than mifepristone. Misoprostol is FDA-approved for other indications, such as peptic ulcer disease, and can be obtained by prescription in the U.S., and over the counter in Mexico. Yet, misoprostol alone works poorly as an abortifacient and is successful only 70–90% of the time. In fact, a worldwide metanalysis of more than 12,000 women found 22% (nearly one in four) required surgical completion because misoprostol failed to completely empty the uterus of the dead tissue.^{70–72}

Abortion Pill Reversal (APR) Allows Another Option

Despite the harmful recommendations documented above, there is some life-saving news. It is often possible to reverse the effects of mifepristone to allow a pregnancy to continue. Some women are coerced into abortions, some are undecided but feel compelled to take mifepristone in the clinic, and some change their minds after consuming the drug. When women experience immediate regret, an internet search often leads them to discover the option of abortion pill reversal.

Natural progesterone will reverse the effects of mifepristone by outcompeting for the progesterone receptors, but fewer than one out of four fetuses will continue to live after mifepristone alone if misoprostol is not taken.⁷³ Reversal of mifepristone’s effects by progesterone supplementation has been documented. A retrospective study of more than 750 women demonstrated that two-thirds of the women had

continuing pregnancies after receiving the most effective progesterone protocols to reverse the effects of mifepristone. The study showed no increase in the rate of birth defects in the children born after reversal.⁷⁴

Progesterone supplementation during pregnancy is standard for indications such as conception through assisted fertility, low progesterone levels, bleeding, or prior pregnancy losses. It is also used at later gestational ages to prevent preterm births.^{75–78} Based on this research, a network of more than 1,000 physicians, through the Abortion Pill Rescue Network, offer supplemental progesterone to women who desire to reverse the abortion-causing action of mifepristone.⁷⁹

In 2019, a study intending to disprove the efficacy of APR was conducted by a paid consultant of mifepristone’s manufacturer and has been widely referenced to imply that APR is dangerous. It was stopped early for “safety concerns” because three of the 10 study participants required hospital evaluation for hemorrhage. Two of five women (40%) who took mifepristone alone required emergency surgery, and one of these also required transfusion. One of five women (20%) who took mifepristone plus progesterone experienced heavy bleeding, but this resolved without intervention. So, although the study was too small to make any definitive conclusions, the trend demonstrates the danger of mifepristone, and the potential life-saving effect of progesterone supplementation. Importantly, four of five women who took the APR regimen had ongoing viable pregnancies (80%) compared with only two of five (40%) in the placebo group.⁸⁰

Pro-choice medical organizations have made vehement statements opposing any further research on the effectiveness of this intervention. ACOG has denounced progesterone provision as “unproven and unethical.”⁸¹ The American Medical Association calls it “contrary to science.” Abortion advocates voice support for a woman’s choice to end a pregnancy. Are they willing to acknowledge that abortion coercion does occur and that some women do regret their abortion decisions? Do they support a woman’s choice to change her mind and try to save her unborn child?

The Abortion Industry Agenda

In the wake of increasing state level restrictions on abortion, abortion advocates have redefined their terms. In years past, “self-managed abortion” was frequently used to scare women and legislators with the implication of danger and harm if abortion were restricted, but now “self-managed abortion” is being promoted widely to women experiencing unintended pregnancies. The abortion industry has demonstrated that its priority is fetal death, not women’s safety.

In a 2018 position paper, the Guttmacher Institute outlined its plans for chemical abortion,⁸² and subsequent years have seen progress toward implementation of these goals. The Institute has succeeded in convincing the FDA to lift the REMS requirement of in-person dispensing, making unsupervised abortion available through telemedicine and on-line ordering. Complete removal of the REMS provider certification would force medical providers to violate their conscience when pro-abortion medical societies generate guidelines requiring abortion provision on request. Soon, direct pharmacy provision may be permitted, which will also impact pharmacists who have a moral opposition to abortion.⁸³ The end goal is over-the-counter provision dissociated from the medical system entirely (except, of course, for the emergency physicians who will be called upon to care for complications).

Abortion advocates note that stigma remains a deterrent, and thus have begun promoting chemical abortion's use for "menstrual regulation" to bring on a delayed menses without performing a pregnancy test first.⁸⁴

Conclusion

Physicians must question the assertions made by the abortion industry, much as we questioned the tobacco industry when it claimed its product could not cause harm. Abortion is often offered as the solution to every unplanned pregnancy, and many medical professionals have strayed far from the professed motive of caring for women and their unborn children. Whereas once the mantra of "safe, legal and rare" was voiced, we now see that "safe" and "legal" no longer appear to be a concern in the quest for widespread abortion access, and that the abortion industry seeks to make abortion anything but "rare."

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