



Questions & Answers:

The FDA's Latest Decision to Allow Pharmacies to Stock and Sell the Abortion Pill Mifepristone

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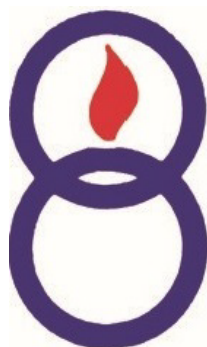
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On January 3, 2023, the U.S. Food and Drug Administration (FDA) officially published new rules authorizing appropriately certified pharmacies to stock and distribute abortion pills to women with prescriptions from a certified prescriber. Exactly what this means, and how it affects people in states where there are currently legal protections in place for unborn children and their mothers, are a few of the matters Dr. Randall K. O'Bannon, National Right to Life's Director of Education and Research addresses here. Dr. O'Bannon has closely monitored the issue of chemical abortion for nearly thirty years.

Is my neighborhood drug store going to become an abortion clinic?

Q. Does this mean that abortion pills are now available over the counter at my local pharmacy without a prescription?

A. No. While that is clearly the ultimate aim of abortion pill promoters, at this point the FDA only authorized pharmacies to dispense these under strict conditions. That pharmacy, whether a brick-and-mortar retail store or an online entity, must certify that they have a designated person to complete a *Pharmacy Agreement Form* and ensure pharmacy compliance. This person is to review the FDA's prescribing information for mifepristone and is required to verify that they have, on file, a *Prescriber Agreement Form* from any health care provider sending them a prescription.

Under the terms of their certification, the pharmacy is not to sell or distribute the abortion drugs to anyone who does not have a prescription from a verified certified prescriber; this rules out over-the-counter sales or even prescriptions from doctors or other medical agents unknown to the pharmacy. Drugs are to be delivered to the patient within four calendar days, with the pharmacy tracking and recording all shipments. The pharmacy is also responsible for reporting all deaths to the prescriber who is to report these to the distributor.

A pharmacy which does not agree to comply with these conditions is not authorized to stock and sell these abortion pills.

Q. Weren't pharmacies already stocking and filling prescriptions for mifepristone and misoprostol all along? How did the FDA's decision change things? When does this start?

A. Prior to this point, this combination of two pills was only available from the healthcare provider—the prescriber who filled out forms and agreements—and he or she got those pills directly from the FDA authorized distributor. Patients taking these pills could get them by visiting the prescriber or having him or her ship them to their homes from the prescriber's clinic or office.

Previously, abortion pills were not shipped or stocked in U.S. pharmacies.

However, at the request of the newly installed Biden administration, in May of 2021, the FDA conducted a review of REMS (Risk Evaluation and Mitigation Strategies) regulations regarding mifepristone. The REMS are rules that the FDA has put in place to ensure that certain drugs with

serious safety concerns (like mifepristone) can be used in a way designed to reduce those risks. Upon completion of that review in December of 2021, the FDA announced that it was revising the REMS to drop the requirement that the drugs be dispensed in person to the patient. The FDA also said that it would no longer limit distribution to prescribers and their offices: pharmacies would now also be allowed to stock and dispense the abortion drug.

The new rules were not formally spelled out until January 3rd of 2023, when the FDA published the modified REMS and new procedures explaining how this could be done. Any pharmacy completing the certification process could legally begin filling prescriptions for abortion pills at that point. However, even for those wishing to do so, it will likely take some time for stores to train employees, set up the system, and fill out the proper paperwork.

Before this, any online pharmacy or mifepristone promoter selling pills was either doing so illegally or possibly operating under the older regulations using a previously certified prescriber to order and distribute the pills.

Q. Will my local CVS, Walgreens, or Rite Aid be stocking and filling prescriptions for the abortion pill?

A. After the FDA announced its decision, corporate offices of CVS, Walgreens, and Rite Aid all announced their intentions to comply with the certification procedure and stock and distribute the drug. As of this writing, none have claimed to have set up the program in any of its drug stores yet. That is, none had indicated that they had trained the appropriate staff, filled out the required certification forms, set up the database of certified prescribers or set up the system for shipping and tracking deliveries of pills to patients.

It may take some time for these corporations to fully set up the system at stores, to identify and train the appropriate employees, and some stores and staffs may not wish to take part in it. For now, the drugstore chains have said they will confine their dispensing of the drugs to stores in states where these chemical abortions are allowed by state law.

If you haven't let the corporate offices of CVS, Walgreens, and Rite Aid know of your opposition to their plans, do so immediately. Ask that they consider whether selling abortion drugs is good business, much less an appropriate activity for a company supposedly devoted to healthcare.

But also contact your local CVS, Walgreens, or Rite Aid stores, particularly ones where you might previously have done business, and find out whether they intend to participate in the announced corporate program. Find out how they feel about turning your local store into an abortion clinic or an abortion pill outlet. You may find that they are as troubled by the prospect as you and could use your support in fighting against the corporate policy.

New regulations may make use of these abortion pills more dangerous.

Q. Why the focus on mifepristone? Doesn't the typical chemical abortion involve two drugs – mifepristone and misoprostol?

A. In official announcements, the FDA generally refers primarily to mifepristone, the popularly known “abortion pill” developed in France in the 1980s originally designated as “RU-486.” But the drug has almost from the beginning been used in conjunction with a second drug, a prostaglandin, typically misoprostol. Mifepristone blocks the action of the pregnancy hormone progesterone, vital to maintaining the safe and nutritive environment for the developing child planted in the uterine wall. With that progesterone signal blocked, the child is starved or suffocated and begins to shrivel. But because mifepristone is not always totally “effective” on its own, the abortionist gives the woman misoprostol, a prostaglandin which triggers powerful contractions to expel the dead or dying corpse from the mother’s uterus.

While the U.S. sponsor of the abortion pill specifically sought and obtained the FDA’s marketing approval for mifepristone, the approved protocol actually lists and requires the use of *both* of the drugs in tandem. Mifepristone is taken the first day, misoprostol is taken a day or so later after the mifepristone has had time to do its work.

Though misoprostol can and has been used by itself as a stand-alone abortifacient, particularly in countries where mifepristone has not been approved, it is believed to be less effective than the combo of mifepristone and misoprostol used together.

The manufacturer of misoprostol has never sought approval for this abortifacient use.

Misoprostol was developed and approved for an entirely legitimate medical use, long before its forced association with mifepristone, as an anti-ulcer drug for people who have to take a lot of NSAIDs (Non-Steroidal Anti-Inflammatory Drugs) or medications.

Because of its legitimate medical purpose and because the manufacturer does not support its use as an abortifacient, there is no good reason to try and control or limit misoprostol’s use or prescription by doctors or its distribution by drugstores except when it is specifically and intentionally used for abortion as it is in conjunction with mifepristone.

Q. After all these changes, what is the current protocol? How late can it be used? How many visits? What sort of screening is required? How many pills over how many days? Etc.

A. The FDA does not spell out the steps in the prescriber agreement, but requires that, in order to prescribe the drug, the prescriber certify their ability to assess the duration of the pregnancy and diagnose ectopic pregnancies. This appears to presume some sort of interview or screening of, or at least the filling out of some questionnaire by the patient that must be done prior to the health care provider’s writing of the prescription.

The form filled out by the patient directs the healthcare provider to “Counsel the patient on the risks of mifepristone” and has the doctor and patient sign and date the agreement which details that mifepristone will be taken on Day 1 and the misoprostol tablets will be taken 24 to 48 hours after the mifepristone.

That signed patient form documents that the prescriber has told the patient (at least in general terms), about the risks of “heavy bleeding” or “infection” and that the patient knows to contact the “clinic/office/provider” right away in the case of a fever of 100.4° F lasting more than four hours, heavy bleeding, severe abdominal pain, or other gastrointestinal issues. The form also notes that the healthcare provider is to have told the patient who to contact in the event of an emergency if the prescriber cannot be reached.

Patients are told to follow up with the provider 7 to 14 days later to determine whether the chemical abortion has been completed and that they are well.

Patients are cautioned that the pills do not work for 2-7% of the women who take them and are told to talk to their provider about a surgical procedure to “end my pregnancy” if it still continues.

There are therefore no “required visits” in this new protocol. It’s implied that there are at least two encounters between the patient and the prescriber: one to screen and counsel the patient and arrange delivery the pills, the second to confirm whether or not abortion is complete. The official mifepristone label indicates that dosages are one 200mg pill of mifepristone, taken orally, followed at least 24 hours later by four 200 mcg pills of misoprostol, taken buccally (in the pouch between cheek and gum).

It is unclear whether this is made clear to the patient. Dosages and administration for misoprostol are not specified in either the prescriber or patient agreements. The abortion industry has been known to tinker with these in the past, controversially suggesting vaginal self-administration of the misoprostol, for example.

While prescribers would have access to this material as part of the FDA approved label, what sort of additional instructions are included in the packages given to patients who have these pills delivered by mail is unclear.

Q. Isn’t this more dangerous?

A. By the FDA’s own criteria, it would certainly seem so.

The FDA imposed its REMS (Risk Evaluation and Mitigation Strategy) regulations specifically because it felt certain conditions needed to be met to increase the likelihood of these drug’s safe use. Two of the things on which they have consistently concentrated throughout every new iteration of their regulations and prescriber agreements have been the necessity of the prescriber’s ability to determine the gestational date of the pregnancy and his or her ability to diagnose ectopic pregnancy.

The pills “effectiveness” drops the farther along the pregnancy is. And with that drop in effectiveness, the risks of failure and complications like hemorrhage or infection increase. The problem with an undetected ectopic pregnancy is that the signs of a potentially deadly rupture look an awful lot like the normal expected side effects of a chemical abortion. In both cases, women have painful cramps and bleeding. If doctor and patient both just assume these are part of the abortion and simply wait for the process to play itself out, she could easily bleed to death or at least suffer serious damage to her reproductive system if an ectopic rupture is the actual cause of these symptoms.

When the FDA required at least one visit to the abortionist’s office, there was a presumption that some part of the screening or interview would be done in person. This might entail a physical exam or, ideally, an ultrasound to more precisely gauge the gestational age or to determine whether or not the child had implanted in the uterus.

Now that patient and prescriber are no longer required to actually meet in person, it is unclear how thorough this screening will be. Certainly, an online questionnaire asking that a patient recall the date of her last menstrual period will be nowhere near as reliable or precise as an ultrasound conducted and read by a professional at a medical office.

Likewise for a verbal query as to whether or not a patient had experienced early signs of an ectopic pregnancy. Even granting that this could catch some instances, the fact that these are common (occurring in 1-2% of pregnancies) and often do not manifest until later in the first trimester mean that a fair number are likely to be missed in the absence of a professional ultrasound examination.

If the FDA is right about the issues raised in its REMS, the number and severity of complications associated with mifepristone and misoprostol are likely to soar under this new looser protocol.

The abortion industry is pushing back against remaining legal limits on mifepristone.

Q. Why are abortion advocates complaining? Didn’t the FDA give them everything they wanted?

A. The abortion pill’s promoters envision a time when women can simply buy these online or pick these up at their local pharmacy any time they want without any testing, screening or formal prescription, the way one picks up cold or flu medications at the grocery store. Although having greatly relaxed requirements, this is not what the U.S. Food and Drug Administration (FDA) has authorized with these latest changes.

The FDA has gradually whittled down regulations on drugs over the years. It has changed doses, extended recommended gestational cutoffs (originally seven weeks after a woman’s last menstrual period, or LMP, now ten weeks), dropped the number of required visits from three down to zero, and expanded the pool of prescribers to include any certified health care provider. But the FDA has long maintained that because of certain inherent safety issues with the drugs,

the distributor and authorized prescribers need to follow certain guidelines regarding the abortion pill's distribution, prescription, and delivery.

Those include the prescriber's certification that he or she is qualified to accurately assess the duration of the pregnancy (as the "effectiveness" of these pills diminishes, while risks of complications increase, the farther along the woman is); an ability to diagnose ectopic or tubal pregnancies (which these pills do NOT treat); and an ability to provide "surgical intervention" in cases where the pills do not complete the abortion or cause severe bleeding.

If they cannot provide that needed "surgical intervention," they must have in place plans for their patient to receive that care from others. They must also assure that their patient has access to medical facilities equipped to provide blood transfusions or resuscitation if these are needed.

They must sign a *Prescriber Agreement Form* agreeing to the above and the prescriber and the patient must sign a separate *Patient Agreement Form* which reviews and explains the risks of the "mifepristone treatment regimen."

The abortion industry considers these conditions and the involved paperwork cumbersome and unnecessary. But the FDA continues to maintain that these are necessary to "mitigate the risk of serious complications associated with mifepristone."

Q. Is the FDA now authorizing women to buy abortion pills directly from online foreign groups and pharmacies?

A. In the last few years, thanks to the abortion industry's endless self-promotion, there's been a lot in the news about "self-managed" chemical abortions. Alongside those stories, plenty of websites have sprung up selling foreign-made "abortion pills" that can sometimes be had at fraction of the cost being charged by America's leading abortion chains.

Many, if not most of these, are from foreign manufacturers whose drug formulation, purity, and effectiveness is of dubious quality. The only distributors whose chemical formulations, manufacturing processes, and drug purity have been tested by the FDA are Danco Laboratories, out of New York, which sells mifepristone under the trade name Mifeprex, and GenBioPro, a distributor of generic mifepristone out of Nevada.

Danco's pills were originally produced by pharmaceutical firm in China, though more recent news stories say they are currently manufactured in Europe (ABC News, 6/24/22). Assurances have been given that both facilities passed full U.S. federal inspections of their drugs and manufacturing processes.

We do not know at this point who manufactures GenBioPro's pills, but to obtain FDA marketing approval for their drug, their manufacturer, foreign or domestic, would have had to pass FDA chemical analysis of their drugs and formal inspections of their manufacturing processes.

Groups obtaining and promoting pills from elsewhere are selling drugs of unproven purity, safety, or efficacy, even if they use the same names and claim to be identical formulations.

In the wake of the FDA's loosening of mifepristone regulations, particularly the dropping of required office visits, many independent companies sprung up offering some telemedical version of mifepristone. Those attempting to operate within the law likely relied on one or more certified prescribers who somehow oversaw the online screening process and assured compliance with all state and federal regulations. One assumes they will now adjust their business and delivery models to comply with the FDA's new regulations.

Others, like international abortion activist Rebecca Gomperts and her U.S. group, Aid Access, apparently ignored relevant state laws and made no commitment to follow the FDA's rules. They apparently decided for themselves how much or how little screening to do, how much follow up, how to deal with complications, and relied on uninspected foreign suppliers to provide and ship their pills in a safe and timely fashion.

Gomperts and Aid Access have published assurances of their patients' safety and success, but the reliability of their data, given the quality of their follow-up, is questionable.

Q. Will the FDA's new authorization override my state law protecting unborn children or otherwise limiting chemical or telemedical abortion? What about the Biden administration legal opinion saying that a long-time federal law prohibiting the mailing of abortion drugs can simply be set aside?

A. The Biden administration has taken a number of actions to assure its pro-abortion constituency that it means to guarantee women's access to the abortion pill.

On the day that the U.S. Supreme Court announced its *Dobbs* decision overturning *Roe*, Biden's Attorney General Merrick Garland went out of his way to note that "States may not ban Mifepristone based on disagreement with the FDA's expert judgment about its safety and efficacy."

In addition to actions by the FDA allowing both health care providers and pharmacies to dispense and deliver mifepristone by mail, the Biden administration's Office of Legal Counsel issued a memo. This memo declared that, in spite of an 1873 federal law specifically and directly prohibiting the mailing of abortifacients, the Justice Department was of the opinion that the Comstock act—despite being reaffirmed multiple times and still in force— "does not prohibit the mailing, or the delivery or receipt by mail, of mifepristone or misoprostol..." because the shipper's and recipient's intentions cannot be presumed.

Meanwhile, lawsuits have been brought in federal court against limits imposed on the sale and prescription of mifepristone in West Virginia and North Carolina. GenBioPro is arguing, as Attorney General Garland asserted in June of 2022, that state law prohibiting the use of mifepristone as part of a larger ban on abortion conflicts with a federal determination of the abortion pill's safety by the FDA. Similarly, a doctor in North Carolina says that a state law

requiring the abortion pill to be dispensed in person goes beyond regulations the agency says are sufficient for safe use. In each case, plaintiffs argue that the issue for the courts is whether the state or the federal government is entitled to declare what constitutes safe use of the drugs.

All these matters will eventually be resolved in court, but many legal experts say the Biden administration's case is weak. The Comstock Law is pretty direct in its prohibition on the mailing of abortifacients. Mifepristone mailers rely on the Justice Department's novel reading of the law at their own legal peril. Anyone mailing these pills and counting on the Biden administration's declaration as their defense will have nowhere to turn if and when a court rejects that argument or when a new administration takes office.

Much the same can be said regarding the upcoming tussle between federal and state governments over safety measures limiting the availability of mifepristone. States can and have had different laws and opinions regarding the safety of different drugs, products, and practices than the federal government and these have generally been allowed to stand in the name of state sovereignty and the Constitution's 10th amendment.

Furthermore, even though the state may raise several demonstrated safety issues associated with use of the mifepristone-misoprostol combination, the 2022 *Dobbs* decision allows the state to ban or regulate abortion as it sees fit, in the interest of protecting nascent human life (or any other reason), regardless of whether chemical abortion is or is not proven to be safe.