

As 'abortion pill' turns 15, debate rages on

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Fifteen years after its approval in the United States, the drug mifepristone is used in nearly a quarter of all abortions, a proportion that has grown steadily even as the national abortion rate has fallen to a historic low.

Federal data also show that <u>mifepristone</u> has accelerated the shift toward early pregnancy terminations - before 10 weeks - when it is safest and has the most public acceptance. Maker Danco Laboratories says more than 2 million women have used its "early option pill."

The impact, however, has not fit the predictions of either side in the nation's bitter <u>abortion</u> divide. Mifepristone has not made abortion more common or endangered women's health, as opponents said it would. It has done little to make abortion more accessible or part of private medical practices, as supporters hoped.

What mifepristone has done is open another front in the political battle over abortion rights. Supporters have worked to enable mifepristone to be prescribed by nonphysicians such as nurse practitioners, and remotely through "telemedicine" technology, while abortion opponents have worked to block such measures.

A few states, notably Texas, have put up high barriers to medication abortion - although legal challenges have removed or delayed most of the measures. For example, these states require doctors to stick to the outdated prescribing regimen proposed by Danco 15 years ago and approved by the U.S. Food and Drug Administration, which limits



mifepristone use to no later than seven weeks of pregnancy. The simpler, lower-dose regimen used through nine weeks is recommended by medical groups and the World Health Organization.

"It's clear that the anti-abortion movement has targeted this technology for restrictions," said Daniel Grossman, an obstetrician-gynecologist at the University of California, San Francisco, who studies abortion access.

Cheryl Sullenger, senior policy adviser with Operation Rescue, countered with the anti-abortion view: Medication abortion is risky, painful, and involves insufficient medical supervision.

"I think it's a moneymaking scheme for the abortionist, an opportunity to make a lot of money with a little effort," she said.

The divide over abortion is as deep as ever. Planned Parenthood, a main provider of medication abortions, is facing Republican congressional challenges to its federal funding. Anti-abortion activists have accused the group of improprieties in donating fetal tissue for medical research, which Planned Parenthood vigorously denies.

Medication abortion actually involves mifepristone, developed in the 1980s by the French company Roussel-Uclaf, plus a second drug, misoprostol.

The mifepristone pill, taken by the patient at the abortion clinic, triggers bleeding by blocking a hormone needed to sustain pregnancy. Up to 48 hours later at home, she takes misoprostol to cause uterine contractions and ensure expulsion of the grape-sized fetus. An ultrasound or blood test two weeks later confirms the abortion.

The process feels like a heavy menstrual period, said Dayle Steinberg, president and chief executive of Planned Parenthood of Southeastern



Pennsylvania.

"Most women experience strong cramps, and it takes longer than a <u>surgical abortion</u>," she said.

The method has been well-studied by researchers, the FDA, and the Centers for Disease Control and Prevention:

Surgery is needed to complete about 5 percent of medication abortions. About 0.2 percent of patients suffer serious complications such as hemorrhage. There have been 14 deaths among women taking the drugs, one since 2011, and none that the FDA could definitely link to the abortion drugs.

Very early termination - through six weeks - has risen from 19 percent of all abortions in 1998, to more than a third now. The increase was greatest in the two years after mifepristone's approval, suggesting it fueled the trend.

Medication abortion requires minimal medical equipment. A study found 193 of the nation's abortion facilities (17 percent) offered only this option in 2011. The cost of an abortion through 12 weeks, whether surgical or medication, averages \$500.

Exactly how many private physicians provide the abortion pill is unclear, but there are not many.

In 2011, 286 doctors' offices did some type of abortion, and the total number of procedures was about 14,000 - 1 percent of the nation's one million abortions, according to the Guttmacher Institute, a research center that supports abortion rights. Danco says 7 percent of its mifepristone sales last year were to private physicians.



"There are many reasons why private doctors may not offer it," said Beverly Winikoff, a public health physician who worked to get mifepristone licensed and approved. "There are many building leases that prohibit them from performing abortions. Or their partners don't want them to. Or they fear the political situation. Why should they take on that monster problem? In that sense, I have to say the anti-choice people have kind of won because people have to be so terrified all the time."

Because abortion access remains a problem - 35 percent of women of childbearing age live in counties with no providers - some activists want to expand telemedicine.

Here's how it works where it is now permitted: The patient goes to an <u>abortion clinic</u>, where a nurse does the usual work-up, which includes taking a medical history and doing an ultrasound to verify that she is less than 10 weeks pregnant.

Then the patient is connected via videoconference with a doctor in a distant location. After reviewing her records and answering questions, the doctor remotely opens a drawer in front of the patient containing two pills. The patient takes the mifepristone while the doctor and nurse observe, goes home with misoprostol, and returns in two weeks.

This option is now available in only two states - Iowa and Minnesota.

The FDA-approved but outdated <u>abortion-pill</u> regimen has also been the subject of legal fights in at least five states, even though physicians have discretion to prescribe approved drugs in "off-label" ways. Danco, a privately held, one-product company in New York, is "very aware" of this issue, said spokeswoman Abigail Long.

"But it costs money to change the label. We are a small company, so we



have to think carefully about it. It would cost a little over \$1 million," she said.

"At the appropriate time, we'll have a discussion with the FDA about it."

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