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Abortion Pill Labeling Catches Up With The Scientific Evidence And Access Is Expected To Improve

The Food and Drug Administration on Wednesday updated the label on the so-called abortion pill to reflect the way most doctors had been using it anyway.

But Dr. Alan Braid called it the best news he'd heard in quite awhile. "Next to the news of my youngest grandchild's birth," Braid told me. "He's 11, by the way."

That's because Braid co-owns an abortion clinic in Texas, one of a few states that have restricted the use of Mifeprex, the brand name for mifepristone or RU 486, by requiring that doctors stick to the FDA-approved protocol on the drug's labeling, which was developed back in the late 1980s in France.

Until Wednesday, the labeling hadn't changed since the FDA approved it more than 15 years ago, even though research published in scientific journals had shown that a simpler regimen was just as effective. In most states, the outdated label didn't matter much, because once the FDA approves a drug, doctors are free to prescribe it "off-label"–except in the states where lawmakers tried to tell physicians how to use Mifeprex.

"Practice had already changed for the better over time," said Susan Wood, executive director of the Jacobs Institute of Women's Health at George Washington University's Milken Institute School of Public Health.

Published research had shown that one 200-milligram tablet is just as effective as the three 200-milligram tablets in the original protocol. The smaller dose, now on the label, is cheaper and less likely to cause side effects (Texas lawmakers have allowed abortion providers in that state to use the smaller dose because it has been recommended by the American College of Obstetricians and Gynecologists). In addition, studies had shown that Mifeprex can be used up through 10 weeks' gestation, another change from the old label, which said it could be used only through the seventh week of pregnancy.

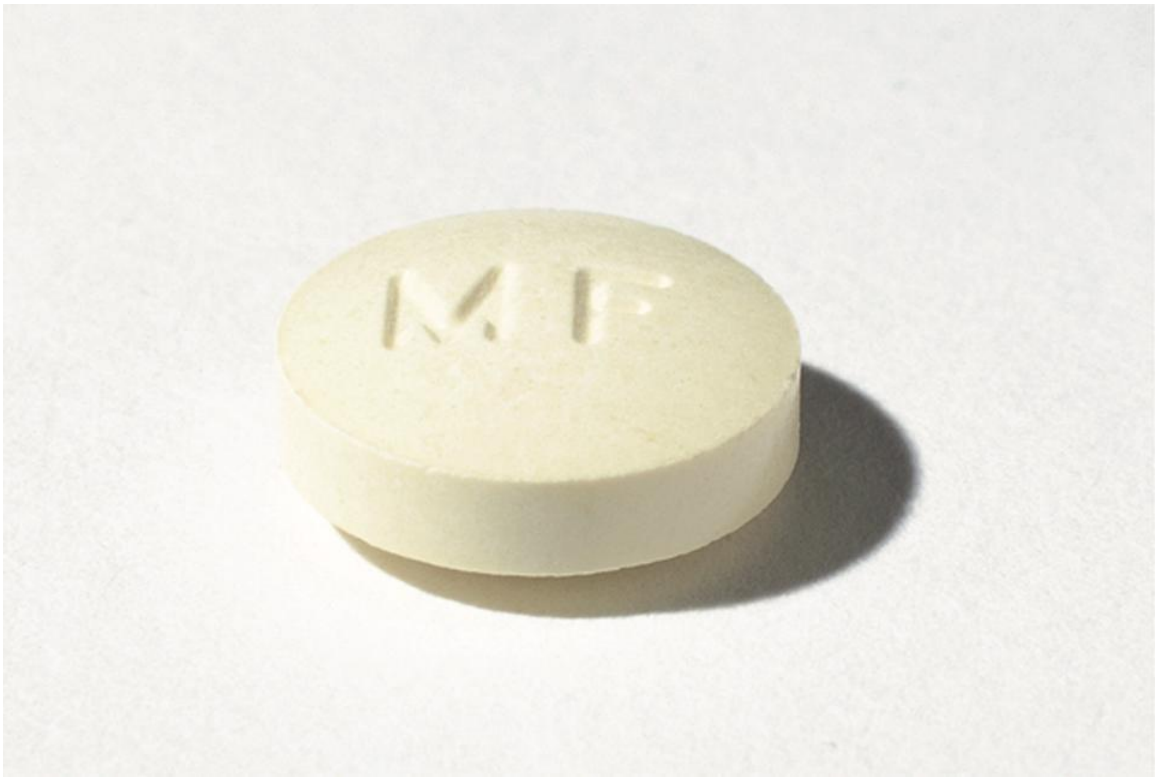
"This label change underscores just how medically unnecessary and politically motivated restrictions on medication abortion in

states like Texas and Oklahoma truly are–and demonstrates the lengths politicians will go to single out reproductive healthcare to restrict women's rights," Nancy Northup, president and CEO of the Center for Reproductive Rights, said Wednesday in a prepared statement.

Northup said her organization has challenged medical abortion restrictions in four states in recent years: Texas, Oklahoma, Arizona and North Dakota. The courts have blocked implementation of the restrictions in the latter two states, she said. The Guttmacher Institute, a nonprofit research, policy and education organization that focuses on sexual and reproductive health, says Ohio also requires medical abortion providers to follow the FDA-approved protocol.

The Texas legislature passed House Bill 2, which included four new restrictions on abortion care, in July 2013. The provision requiring that doctors adhere to the FDA-approved Mifeprex protocol went into effect in late October 2013.

Before that, Braid says, about half of the abortions at his Alamo Women's Clinic in San Antonio were with Mifeprex, which he could use up through the ninth week of pregnancy. But the FDA-approved protocol said the drug could be used only through the seventh week, so, Braid said, the proportion of medical abortions at his clinic fell to one-third.



The Food and Drug Administration on Wednesday updated the labeling on Mifeprex, the so-called abortion pill, for the first time since approving the drug in 2000. This is a photo was shot when the pill first came on the market. (Photo by Newsmakers)

The decline statewide was more precipitous, said Dr. Dan Grossman, a professor of obstetrics and gynecology at the University of California, San Francisco, and an investigator with the Texas Policy Evaluation Project. By April 2014, medical abortions in Texas had dropped by 70%, from about 28% of all abortions to about 10%, according to a study Grossman coauthored. "The restriction has had a profound effect in the state," he said.

Plus, it's not unusual these days for Texas women to travel great distances to get to the nearest abortion clinic, because more than half in the state closed after the introduction of House Bill 2, according to other research by Grossman.

On Wednesday, Braid saw a patient who'd driven more than five hours from her home in Midland, Tex. Only five or six weeks pregnant, she sought a medical abortion.

With the old protocol, medical abortion would be a two-step process: On Day 1, she would take three tablets of Mifeprex, which blocks progesterone, the hormone that prepares the lining of the uterus for a fertilized egg and helps maintain a pregnancy. Then on Friday, Day 3, she would have to return to Braid's clinic to take two tablets of misoprostol, a prostaglandin drug that causes the uterus to contract and helps complete the process.

Braid asked her if she was staying at a hotel or with friends in San Antonio. When the woman replied, "No, I'm driving back to Midland," he grew concerned. He told her he couldn't give her the misoprostol and then send her back to Midland bleeding and cramping on the highway.

According to the new label, though, the woman could have taken the misoprostol–most effective when taken 24-48 hours after Mifeprex, a shorter interval than on the original label–at home. "She could have gotten the pills, all of them, today and not have to come back at all," said Braid, who did not learn of the labeling change until after the woman left his clinic. "I'm going to check with lawyers to find out if I can just call in her prescription."

Whether medical abortion providers in Texas and other states that have restricted Mifeprex use can go ahead and start following the protocol on the updated label isn't clear. "The Center for Reproductive Rights is currently working with our partners and healthcare providers in states across the country to determine the

impact on women seeking medication abortion in light of this announcement," Northup said, referring to the new labeling.

Perhaps just as significant as the Mifeprex labeling change is the fact that "FDA was able to make a decision without having a lot of political pressures brought to bear, because there wasn't a big public debate about it," Wood told me.

She should know. Wood, a biologist, directed the FDA's Office of Women's Health for nearly five years before resigning in 2005 out of frustration over then-FDA Commissioner Lester Crawford's delay in making emergency contraception, or "morning after pills," available without a prescription, which agency scientists had recommended.