MedicalXpress

US regulators ease label requirements on abortion pill

March 30 2016

US regulators Wednesday eased labeling requirements on a medication that induces abortion, a move that women's health advocates said should improve access to abortion, particularly in certain embattled states.

The US Food and Drug Administration's decision applies to Mifeprex, also known as mifepristone, which is taken along with another medication called misoprostol to end an early pregnancy.

The label will now say it is safe to take up to 70 days after the woman's last period, instead of 49 days as the original label said.

The dosage of the drug is also reduced from 600 milligrams to 200 mg on the new label.

The American College of Obstetricians and Gynecologists applauded the changes.

"ACOG is pleased that the updated FDA-approved regimen for mifepristone reflects the current available scientific evidence and best practices, and includes many of the recommendations that ACOG had presented to the agency," it said a statement.

"Extending approved use of mifepristone through 70 days of gestation is proven to be safe and effective, and will give women more time to make the decision that is right for them."

Mifeprex was approved by the FDA in 2000. It was previously known by the name RU-486.

Planned Parenthood said the new labeling brings the United States in line with the protocol recommended by the World Health Organization.

"The benefit of this announcement will be most immediately felt by women and providers in Ohio, Texas and North Dakota," where state laws have required strict adhesion to the label, Planned Parenthood said in a statement.

ACOG also pointed out that "medication abortion has been subject to legislative attacks in various states across the country, including mandated regimens that do not reflect the current scientific evidence.

"We hope that these states take the FDA label into account, making safe, effective medication abortion available in a way that is medically appropriate and putting health care decisions back in the hands of patients and their trusted health care providers."

The National Women's Health Network said the changes mean that women may have to make fewer visits to a clinic when seeking medication for an abortion because "follow-up does not have to be provided during an in-person clinic visit and the second part of the regimen, misoprostol, can be taken at home."