RHTP Applauds FDA Label Update for Medication Abortion
Good Step Toward Evidence-Based Medicine, Some Barriers Remain

(Washington, D.C.) – This morning, the Food and Drug Administration (FDA) approved updated labeling for mifepristone (also known as the “abortion pill” or by its brand name Mifeprex®) that represents closer alignment with scientifically-proven, evidence-based medicine.

Since its initial approval for use in the U.S. in 2000, mifepristone has proven to be a safe, less clinical, and more private and non-invasive option for early abortion. Among women who decide to end their pregnancy, a growing proportion are choosing medication abortion: in 2011, nearly one in four women seeking a non-hospital abortion chose this method.

The FDA updates to the label more closely reflect the current science. Moreover, this change gives abortion providers in some states with strict mifepristone label adherence laws the ability to use the evidence-based regimen that most providers have been using for years.

However, the drug is still subject to a risk management plan known as REMS, which imposes a restricted distribution protocol on mifepristone and mandates an extra patient agreement, and the label still requires special registration of providers who wish to offer it in their practices – despite the complete lack of medical evidence showing the need for such requirements.

“This label change is good news for women, good news for science, and good news for the practice of medicine,” said Jessica Arons, President & CEO of the Reproductive Health Technologies Project (RHTP). “It means greater access to the abortion pill, particularly for rural women and other medically underserved populations.”

“That said, mifepristone remains burdened by unnecessary regulations that prevent it from being dispensed in pharmacies. Restrictions on medication abortion do nothing to make abortion safer — but they do make it more costly and less available,” said Arons.

“We will continue working to eliminate non-evidence-based barriers to the abortion pill and keep fighting to make this safe, effective option available to all women. Once a woman has decided to end a pregnancy, she should be able to choose the abortion method that best fits her preferences, circumstances, and needs.”

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