

## Dangers of Abortion-Inducing Drugs and Need for Regulation

Because RU-486 is virtually unregulated in the majority of states, abortion providers have been misusing it for years.

For example, the Food and Drug Administration (FDA) tested and approved the RU-486 regimen to be used only in the first 49 days following a woman's last menstrual period (LMP), at a clinic or medical facility and under the supervision of a physician, and in the following manner:

Day One: Mifeprex Administration: Three 200 mg tablets of Mifeprex are taken in a single oral dose

Day Three: Misoprostol Administration: Two 200 mcg tablets of misoprostol are taken orally

Day 14: Post-Treatment Examination: The patient must return to confirm that a complete termination has occurred. If not, surgical termination is recommended to manage medical abortion treatment failures.<sup>1</sup>

However, abortion providers readily admit<sup>2</sup> that it provides RU-486 to women up to 63 days LMP and provides women with just a single oral dose of mifepristone, followed by a single dose of misoprostol, which it directs women to administer vaginally instead of orally. Some abortion providers even allow and direct women to take the drugs at home and in the absence physician oversight. Finally, no follow-up care is ensured.

Abortion providers in Iowa have begun using "telemed" services to provide RU-486 (i.e. a "telemed" abortion). Rather than meet with the woman personally, abortion provider Susan Haskell and Planned Parenthood of the Heartland have been consulting with patients over Skype or other teleconferencing systems. Under this scheme, Haskell briefly addresses abortion patients from a teleconferencing hook-up from her office in Des Moines. After explaining the medical abortion process, a button is pushed and an electronic drawer opens that contains the drugs. There is no examination, no physician-patient relationship, and no patient follow-up; but it does allow Haskell the opportunity to provide abortions to more women without ever having to meet with the women in person.

Women are not informed that "[n]early all of the women who receive Mifeprex and misoprostol will report adverse reactions, and many can be expected to report more than one such reaction."<sup>3</sup> These adverse reactions include bleeding more heavily than during a heavy menstrual period; abdominal pain and uterine cramping; nausea; vomiting; diarrhea; pelvic pain; fainting; headaches; dizziness; and asthenia (weakness or lack of energy).<sup>4</sup>

In fact, by May of 2006, the FDA acknowledged a total of 1070 adverse event reports related to the use of RU-486.<sup>5</sup> These adverse events included 6 deaths, 9 life-threatening incidents, 232 hospitalizations, 116 blood transfusions, and 88 cases of infection.<sup>6</sup> Since that time, there have been hundreds of additional

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<sup>1</sup> See Mifeprex Label, available at [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2000/206871bl.htm](http://www.accessdata.fda.gov/drugsatfda_docs/label/2000/206871bl.htm) (last visited August 23, 2010); Food and Drug Administration, *Mifeprex (mifepristone) Information* (Feb. 24, 2010), available at <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111323.htm> (last visited August 23, 2010).

<sup>2</sup> Planned Parenthood has documented this misuse in court records in both the Sixth Circuit Court of Appeals and a state court in Arizona.

<sup>3</sup> See Mifeprex Label, *supra* (emphasis added).

<sup>4</sup> *Id.*

<sup>5</sup> Staff Report, *The FDA and RU-486: Lowering the Standard for Women's Health*, prepared for the Chairman of the House Subcommittee on Criminal Justice, Drug Policy and Human Resources, at page 25 (Oct. 2006), available at <http://www.usccb.org/prolife/issues/ru486/SouderStaffReportonRU-486.pdf> (last visited August 23, 2010).

<sup>6</sup> *Id.*

adverse events reported, as well as additional deaths in the United States.<sup>7</sup> A European drug manufacturer has publicly stated that 29 women have died worldwide after using RU-486.<sup>8</sup>

Even when administered according to the approved FDA protocol, RU-486 can have devastating consequences for women. No ultrasound is required under this protocol, despite the fact that an ultrasound is necessary to determine the gestational age of the pregnancy and whether the pregnancy is ectopic. In fact, RU-486 is particularly dangerous because its side effects are confusingly similar to the symptoms of an ectopic pregnancy. Failing to properly diagnose an ectopic pregnancy can lead to a rupture of the fallopian tube, causing bleeding, severe pain, and even death.

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<sup>7</sup> *Id.* at 32.

<sup>8</sup> See, e.g., APM Health Europe, *Italy questions safety of Exelgyn's abortion pill, approval still not granted* (June 23, 2009), available at <http://www.apmhe.com/story.php?mots=MIFEPRISTONE&searchScope=1&searchType=0&numero=L15579> (last visited August 23, 2010).