

FDA panel to consider new 'morning-after pill'

June 8 2010, By Rita Rubin

A Food and Drug Administration advisory committee will meet June 17 to consider whether the agency should approve a new emergency contraceptive that studies show is more effective than Plan B, the only "morning-after pill" on the U.S. market.

HRA Pharma of Paris launched ulipristal acetate in October 2009 and sells it in 21 European countries under the brand name ellaOne. As in Europe, ulipristal would be available only by prescription in the U.S. Plan B, the brand name for levonorgestrel, is available without a prescription to women 17 and older, but those under 17 require a prescription.

Plan B is approved for use up to 72 hours after unprotected sex; even within that window, though, it becomes less effective over time. But two company-funded trials involving more than 3,000 women, published in February, found that ulipristal was consistently effective up to 120 hours, or five days, after unprotected sex.

In one randomized study, researchers compared ulipristal to levonorgestrel in women who had sought emergency [contraception](#) at family-planning clinics in the U.S., Britain and Ireland within five days of having unprotected sex.

About 1,700 of the women received emergency contraception within 72 hours of having unprotected sex. Half got ulipristal and the other half received levonorgestrel. In the ulipristal group, 15 ended up getting

pregnant, compared with 22 who took levonorgestrel.

Among 203 women who received emergency contraception 72 hours to 120 hours after unprotected sex, there were three pregnancies, all in women who had been given levonorgestrel.

The other study published in February focused on 1,241 women who had come to Planned Parenthood clinics for [emergency contraception](#) 48 to 120 hours after unprotected sex. All of them received ulipristal. About 2 percent, or 26, still ended up getting pregnant, but those who took the pill five days after [unprotected sex](#) were no more likely to get pregnant than those who took it two days afterward.

"If it were my daughter, I'd want her to have ulipristal rather than Plan B in her medicine cabinet," said Paul Fine, co-author of the studies, professor of obstetrics, gynecology and urology at Houston's Baylor College of Medicine and medical director of Planned Parenthood of Houston, southeast Texas and Louisiana.

More safety data are needed before ulipristal could be sold without a prescription, Fine and his co-authors wrote Feb. 13 in The Lancet.

Ulipristal and levonorgestrel work by inhibiting ovulation, Fine said. He disputed comments filed with the FDA on June 1 by Americans United for Life, an anti-abortion group that likened ulipristal to RU-486, the so-called abortion pill, which is its chemical cousin.

But Fine counters that ulipristal did not cause abortions in [women](#) who got pregnant after taking it.

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Distributed by McClatchy-Tribune Information Services.

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