

# FAMILY HEALTH INTERNATIONAL

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Family Health Institute

Department of Health and Human Services  
Food and Drug Administration  
Center for Drug Evaluation and Research  
"Over-the-Counter Drug Products" Part 15 Hearing  
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Statement of  
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Good morning. My name is Elizabeth Raymond. I am a gynecologist. I work at Family Health International, where I do research on contraception, and I also see patients at the Planned Parenthood clinic in Raleigh, North Carolina. FHI has had a contract with Women's Capital Corporation to assist with preparation of their new drug application for *Plan B*<sup>TM</sup> emergency contraceptive pills.

I am here today to tell you why emergency contraceptive pills should be made available over the counter.

Emergency contraceptive pills are basically high dose birth control pills that a woman can take after unprotected sex to prevent pregnancy. If taken within 3 days after intercourse, these pills reduce the chance of pregnancy by 75% or more, depending on the particular hormonal regimen. Recent data have shown that the efficacy of ECPs is significantly greater the sooner the pills are taken after sex. In a study from the World Health Organization, the pregnancy rate was approximately eight times higher if the woman waited three days after sex to take the pills than if she took them within the first 12 hours.

This is quite a remarkable finding. Women really must use this treatment right away in order to get maximal benefit from it. Hours count. This "need for speed" is the most compelling reason why ECPs should be sold over the counter. A prescription requirement, which usually involves an actual visit to a doctor or other practitioner, will inevitably delay the onset of treatment. If women can buy the pills directly from pharmacies, they can get them immediately whenever they need them. Making ECPs over the counter may be the only practical way to ensure that women have immediate access to this treatment.

The other reason that ECPs should be sold over the counter is that there is no medical reason for the prescription requirement.

A woman certainly doesn't need a doctor to diagnose the fact that she has had unprotected intercourse or to help her take the pills.

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The treatment is also very safe. The most recently approved regimen, which is marketed now under the brand name *Plan B™*, has only 3 contraindications listed on the FDA-approved label: allergy to the product, undiagnosed abnormal vaginal bleeding, and ongoing pregnancy.

The first of these, allergy, is extremely rare. And if allergy were a rationale for keeping a drug prescription, then no drug could be over the counter.

The second, abnormal vaginal bleeding, frankly doesn't make sense from a medical point of view. I can think of no particular reason why a woman with abnormal vaginal bleeding should not use this treatment. Other expert organizations such as the World Health Organization and Planned Parenthood Federation of America do not consider vaginal bleeding as a contraindication. In any case, a woman knows whether or not she has abnormal bleeding.

Finally, advice not to use during pregnancy can be found on the label of many drugs currently sold over the counter in this country. In the case of ECPs, pregnancy is a contraindication not because the treatment is dangerous for pregnant women or for their pregnancies - the FDA itself has declared that the treatment does not harm pregnancies - rather, it's listed because the treatment is ineffective in women who are already pregnant. If ECPs were made over the counter, undoubtedly some pregnant women would end up taking it, but no adverse consequences are expected to result from this.

Of course, ECPs, like all drugs, have some side effects, such as nausea and breast tenderness. But about ten thousand women have used ECPs in monitored studies, and many more in clinical settings. No serious or life threatening consequences have ever been attributed to ECPs. Judging from almost 40 years of experience with regular birth control pills, the chance of serious adverse effects from taking the hormones in ECPs for only one day is probably so small as to be unmeasurable. Furthermore, whether ECPs are distributed by prescription or over the counter will not affect either the incidence nor the severity of any side effects that do occur. With some drugs, a doctor may be able to screen out women who will have side effects, or treat them differently, but this is not possible with ECPs. Certainly ECPs are much safer than many other drugs that are currently available over the counter.

Unwanted pregnancy is a huge public health problem in this country, and it's a huge problem also for a woman who has one. ECPs have the potential to cut in half the number of unintended pregnancies - and also the number of resulting abortions - if women could obtain and take them promptly. Requiring ECPs to be distributed only by prescription restricts access and is medically unnecessary. In the interest of the public, the FDA should act swiftly to correct this situation.