

WOMEN'S INSTITUTE

for Fertility, Endocrinology and Menopause



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Mark B. McClellan, MD, PhD
Commissioner of Food and Drugs
U.S. Food and Drug Administration
5600 Fishers Land
Rockville, MD 20857

Dear Commissioner McClellan:

As a practicing Reproductive Endocrinologist and member of Physicians for Reproductive Choice and Health® (PRCH), I strongly support the overwhelming evidence-based and public health imperative for over-the-counter access to emergency contraceptive pills (ECPs).

Contraception, regrettably, is neither universal nor fail-proof. Unintended pregnancies occur in both the small percentage of women who don't use contraception, and in women for whom contraception fails. Of all the women who experienced an unintended pregnancy, more than half - 53 percent - were using contraception at the time of conception.

Extensive research also demonstrates that ECPs are extremely safe, including when self-administered. The hormones in ECPs have been used for more than thirty years as daily birth control by tens of millions of women, and serious complications have been extremely low.

Medical decisions should be rooted firmly in scientific evidence. Research on emergency contraception - including numerous randomized trials, data on actual use, and label-comprehension studies - has revealed that prescription-only status of ECPs is both gratuitous and harmful. Prolific research on ECPs documents their safety, efficacy, and ease-of-use, along with the economic benefits of OTC status for individuals, institutions, and public systems. The Institute of Medicine stated that establishing "evidence-based" medicine should be at the forefront of modern medicine's agenda, and has advocated in favor of aggressive efforts to reduce unintended pregnancy rates in America. The FDA can bring the medical community one step closer to reaching both goals by acknowledging the overwhelming evidence and granting OTC status to ECPs.

Professional and public support of the OTC switch is obvious, as more than 70 organizations are signators to the 2001 Citizen's Petition for Status Change for Emergency Contraception. Among the numerous medical and public health organizations supporting the switch are: the AMA, ACOG, the Association of Reproductive Health Professionals, the American Academy of Pediatrics, the American Medical Women's Association, the American Nurses Association, the National Association of Nurse Practitioners in Women's Health, the American Public Health Association, Planned Parenthood Federation of America, the Black Women's Health

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Imperative, Advocates for Youth, the American Pharmaceutical Association and Physicians for Reproductive Choice and Health®.

Condoms and spermicides are widely available over-the-counter. As a product that could drastically reduce the rate of unintended pregnancy, ECPs should share their over-the-counter status. Simply stated, emergency contraception is effective and safe and deserves to be available over-the-counter. I highly support over the counter status, and hope the FDA will follow science and make this a reality.

Despite being the wealthiest nation in the world, the United States has the highest rate of unintended pregnancy among industrialized nations. As of 1994, nearly half - 49 percent - of all pregnancies in America were unintended, and more than half - 54 percent - of those ended in abortion. Among women aged 15-44, 28 percent have had an unplanned birth, and 30 percent have had an abortion. These numbers are problematic, as unintended pregnancy is associated with both high maternal morbidity and economic costs. Fortunately, unintended pregnancies are largely preventable, and increasing use of effective contraception has led to an overall decline of unintended pregnancies since 1987. Health experts estimate that widespread use of emergency contraceptive could prevent as many as 1.7 million unintended pregnancies each year.

At least six major scientific studies have focused specifically on adolescents and ECPs. The conclusions uniformly report that adolescents will use the product correctly and infrequently. Findings from a University of Pittsburgh study indicated that adolescent girls given an advanced supply of ECPs were more likely to use it when needed, and reported fewer unintended pregnancies and sexually transmitted diseases. Other studies confirmed that teens' use of regular contraceptives like condoms do not decline with ECP use, and a study of young women in Britain found that using ECPs following a pregnancy scare may actually make women more likely to use an effective, ongoing contraceptive method.

Facilitating adolescents' access to ECPs is particularly important, as teenagers often have significant trouble gaining access to reproductive health information and care. Research shows that in settings as diverse as Scotland and Hong Kong, adolescents know more about emergency contraception and use it more frequently than in the United States. Currently, condoms and spermicides are widely available to minors over-the-counter. As a product that could drastically reduce the rate of unintended pregnancy among adolescents, ECPs should share their OTC status.

In the wake of overwhelming scientific data supporting OTC-ECPs' efficacy and safety, prescription-only status is medically unjustified and indefensible. When we consider each of the four FDA criteria for OTC status, ECPs meet them all:

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- First, treatment must be self-diagnosable. No one is more likely to diagnose contraceptive failure (or failure to use contraception) than the woman herself.
- Second, treatment must be effective when self-administered. Correct administration of ECPs relies only on how much time has elapsed since intercourse. All patients receive the same dose of ECPs, and any drug interactions would be harmless and unlikely to seriously affect efficacy.
- Third, treatment must be safe when self-administered. ECPs are nontoxic to women, as well as to a developing fetus in case of established pregnancy. The product has a low risk of abuse and few, minor side-effects.
- Fourth, labeling must be clear for self-administration. As demonstrated by research, ECP instructions are simple, clear, comprehensive, and easy-to-follow.

In addition to evaluating the safety and efficacy of ECPs, scientific research has also addressed actual-use questions specific to OTC availability. Common concerns include whether women will be less likely to use regular contraception, more likely to become repeat ECP-users, and/or more likely to engage in risky sexual behavior. At least six major studies on four continents have addressed these points. Results from these studies indicate that easier availability of ECPs neither undermines use of consistent contraception (like condoms and birth-control), nor increases the incidence of unsafe sexual behavior. Studies of advanced provision do, however, show that women with easier access are much more likely to use ECPs when necessary. Only a small proportion of studied ECP-users needed the product more than once or twice a year, which suggests that repeat use will not be a problem because consumers understand ECPs are not first-line contraceptives.

The majority of American women use contraception. Of the 60 million women aged 15-44, 64 percent practice contraception. Nearly all - ninety-three percent - of women aged 18-44 who are sexually-active, non-sterile, and not attempting to conceive use a form of contraception. Most of these women - 61 percent - use reversible contraceptives like condoms or the pill, and the remaining women rely on male or female sterilization. Overall, women use their contraception responsibly and effectively, as actual-use studies show success rates from 88 to 99.6 percent for reversible methods, and more than 99 percent for non-reversible methods of contraception.

Prescription-only status of ECPs is deeply frustrating for both patients and healthcare providers. As a physician, supplying an unnecessary, immediate prescription for this product adds to an already-busy practice. I often feel as though I'm racing against time while my patients overcome great hurdles to access a treatment for which my approval and guidance are gratuitous. A

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majority of my colleagues and our professional organizations share these sentiments. The American College of Obstetricians and Gynecologists has officially stated that ECPs "can meet the FDA criteria for OTC availability," and that "substantial

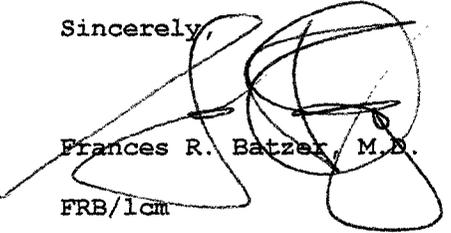
barriers exist to women obtaining this fallback contraceptive method that must be used within 72 hours after unprotected intercourse." Similarly, the American Medical Association declares that it will work to improve access to ECPs while promising to "support and monitor the application process of manufacturers filing for OTC approval of ECPs with the Food and Drug Administration."

Although the current package labels for ECPs list a number of contraindications, none of these are medically or scientifically-supported for hormonal emergency contraceptives. Rather, the lists are adapted from daily birth control labeling and, according to both the American College of Obstetricians and Gynecologists' Practice Patterns and the Consortium for Emergency Contraception, are unlikely to apply to ECPs because of variant use and duration. From this list, pregnancy is a contraindication to ECPs because the product is ineffective during pregnancy, not because of any safety concerns.

With such documented safety, ECPs do not require professional supervision or monitoring. The treatment duration with ECPs is only 12 hours, the hormones are not addictive, and side-effects are mild and limited. All women take the same dose of each regimen, and no harmful drug interactions are known to exist with ECPs. Although certain medications (like rifampin, some anticonvulsant drugs and St. John's Wort) may reduce ECP efficacy, there is no evidence how - or if - ECP dosage should be altered to accommodate these drugs. Researchers assert that, contrary to popular belief, there is also no credible evidence that commonly-used antibiotics, including penicillins and tetracyclines, reduce the efficacy of oral contraceptive pills. Small-scale studies have revealed no relevant effects of common antibiotics on serum levels of contraceptive steroids.

While considering improved ECP access, we must keep in mind that only a slim minority of women realize that this product exists: a 2003 survey revealed that only 6 percent of women in the United States who would need emergency contraception have ever used it (up from 1 percent in 1997). Women who are aware of ECPs must locate a provider, obtain a prescription, fill it at a local pharmacy, and take the pills within 72 hours. This deleterious delay of treatment exists despite the fact that ECPs are time-sensitive, safe, and easy to self-administer.

Sincerely,



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FRB/lcm