

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

February 14, 2004

Dear Commissioner McClellan:

As a practicing Preventive Medicine specialist 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.

Indeed, in the wake of the convincing 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:

- *First, treatment must be self-diagnosable.* No one is more likely to diagnose contraceptive failure (or failure to use contraception) than the woman herself.

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- *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

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 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.

Sincerely,



Susie Baldwin, MD, MPH

Assistant Clinical Professor