



WESTSIDE
REGIONAL CENTER

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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

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>Dear Commissioner McClellan:

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>As a practicing nurse with a specialty in Developmental Disabilities, I strongly support the overwhelming evidence-based and public health imperative for
>over-the-counter access to emergency contraceptive pills (ECPs).

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>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.

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>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.

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>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

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>to ECPs.

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>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®.

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>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.

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>Sincerely,



William A. Feeman, B.S., R.N., C.D.D.N.

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