

emergency

contraception

ACCESSCAMPAIGN

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Food and Drug Administration  
Division of Dockets Management  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Re: Docket No. 2005N-0345

October 13, 2005

Dear Acting Commissioner von Eschenbach,

The Emergency Contraception Access Campaign (ECAC) is writing to express anger and disappointment at the FDA's refusal to expand access to emergency contraception (also known as the morning-after-pill) by making it available over-the-counter. The ECAC is a coalition of public health advocates, medical and health professionals, and community organizations across New Jersey.

The FDA's recent delay demonstrates its lack of respect for science and a willingness to jeopardize women's health by repeatedly denying American women access to a method of contraception that will help *prevent* unintended pregnancies. Clear medical evidence and the advice of countless experts has left no dispute that emergency contraception (EC) is an effective method of pregnancy prevention, safe enough for use by all women without a prescription.

The U.S. continues to have the highest rate of unintended pregnancy in the industrialized world – almost half of all pregnancies are unintended and half of those end in abortion. EC is an effective way to prevent unintended pregnancy after unprotected sex or a contraceptive failure. Widespread use could prevent as many as half of the three million unintended pregnancies each year, including as many as 700,000 that now end in abortion. However, speed is most important in maximizing the effectiveness of EC which is why over-the-counter access is so critical. If taken within 72 hours of intercourse, EC can reduce the risk of pregnancy by as much as 89 percent and efficacy is greatest if the drug is taken within 24 hours. The American College of Obstetricians and Gynecologists (ACOG) noted that the need to obtain a prescription from a doctor is one of the biggest barriers to EC use.

The FDA's ignoring of such scientific evidence signals that politics, not science, guides its actions. Despite admitting that there was conclusive scientific data to support over-the-counter availability of EC, the FDA again refused to release the contraceptive onto the market. Instead, they have buried any hope that women will have access to this medication deep in a maze of superfluous regulatory rule changing procedures that could

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have women waiting years for this important method of pregnancy prevention.

The result of the FDA's inaction will have a harmful effect on women's health nationwide; regardless of age, women will suffer the negative consequences of being denied this important method of contraception. The FDA continues to use the unfounded argument that EC would promote promiscuity among teenage girls. The ECAC shares the goals of promoting the health of young women, as evidenced by the fact that many of our coalition members, such as doctors and advocates, have dedicated their life's work to protecting the health and well-being of all adolescents, both men and women.

However, withholding access to contraception, confidential health care and trained medical professionals, does not equate to protecting the health of young women. In order to truly and effectively improve the health and well-being of adolescents, the FDA should make available the information, resources and tools necessary to protect teens from unintended pregnancy at an early age. Rather than truly defend young women from the potentially devastating repercussions of an unplanned pregnancy, the FDA's inaction has only increased the chances that a young women will face an unplanned pregnancy at a vulnerable age, when such an event is known to often times delay or completely derail her plans for an education or career.

We had hoped that when considering the application to make EC available over-the-counter, the FDA would give careful consideration to the scientific and medical experts of its *own* advisory panel, which overwhelmingly recommended by a 23-4 vote to make EC available without a prescription to women of *all* ages. However, the FDA has instead prioritized politics over science and, once again, refused to approve the application.

The FDA has abandoned its duty to serve the public health interests of the American people. The ECAC urges the FDA to suspend the unnecessary "rule-making" process and return to its stated mission of acting on scientific evidence to advance public health and approve the application to make emergency contraception available over-the-counter.

Sincerely,

The Emergency Contraception Access Campaign

(Enclosure)

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ACCESS CAMPAIGN

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## Emergency Contraception Access Campaign

*As of August 2005*

Cherry Hill Women's Center  
Family Planning Advocates of New Jersey  
HiTOPS, Inc  
La Casa de Don Pedro, Inc.  
NARAL Pro-Choice New Jersey  
National Coalition of Jewish Women  
National Latina Health Network  
New Jersey Coalition for Reproductive Choice  
Planned Parenthood Advocates of New Jersey  
Planned Parenthood of New Jersey  
Sierra Club  
Visiting Nurses Association of Central Jersey  
Women's Fund of New Jersey  
YWCA – Trenton