

SAUNDERSTOWN INSTITUTE

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Mark B. McClellan, MD, PhD
U.S. FDA, Commissioner of Food and Drugs
Re: FDA delay of approval for OTC plan B

The Saunderstown Institute is a non-profit, independent group of tax-paying citizens working in the fields of architecture, economics, engineering, health-fitness, and pharmacy, concerned with political issues in the United States.

The Institute strongly urges the FDA to comply with the FDA's Reproductive Health Drugs and Non-prescription Drugs Advisory Committees' recommendation to approve Plan B, the emergency contraceptive drug, for over-the-counter (OTC) status. It is essential that the FDA not bow to intense political pressure, and instead use sound scientific judgment when considering the health needs of women in this country.

Plan B is a safe and effective method of emergency contraception that is not an abortifacient. Despite availability via a prescription, there are still obstacles for women to obtain the drug, as evidenced by the recent decision of an Eckerd pharmacist in Tyler, Texas to deny filling a Plan B prescription presented by a rape victim in January, 2004. (See attached news article from Reuters). Plan B offers the convenience of taking two tablets 12 hours apart, and is packaged in a foil blister pack. Prior to the approval of Plan B, women requiring emergency contraception were frequently dispensed a plastic ziplock bag with several tablets (either 8 tablets of Lo-Ovral, Nordette, or Tri-Phasil; or 10 tablets of Levlite). Handing a woman an unprofessional plastic bag filled with tablets, versus a professional package likely can contribute to the stigma many women feel when presenting their prescriptions to be filled for emergency contraception. The high-dose traditional oral contraceptives are used off-label for emergency contraception; Plan B offers another advantage in that it is specifically indicated for emergency contraception.

References:

1. Task Force on Postovulatory Methods of Fertility Regulation: World Health Organization. Randomised controlled trial of levonorgestrel versus the Yuzpe regimen of combined oral contraceptives for emergency contraception. Lancet 1998;352:428-33.

2. MMWR, February 12, 1999/Vol.48/No.5 (accessed from www.cdc.gov)

Additionally, since Plan B contains progestin alone (levonorgestrel 0.75 mg), without an estrogen component, the incidence of nausea is reduced compared to using the combination product Preven (4 tablets containing 0.25 mg levonorgestrel with 50 mcg of ethinyl estradiol.) The high incidence of nausea with Preven frequently results in patients vomiting the tablets, thus reducing its efficacy of this form of emergency contraception.

The CDC has estimated that 49% of pregnancies in the US are unplanned and unwanted. The continued interference of the political right with women's health issues in the US will unfortunately have unintended consequences for years to come. Once again, we urge the FDA to make the decision to switch Plan B from prescription to OTC status, based on scientific principles, and not political pressures.

Respectfully,
Members,
The Saunderstown Institute

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Reuters

**Texas Pharmacist Refuses Pill for Rape Victim**

Tuesday 3 February 2004 DALLAS (Reuters) - A Texas pharmacist was disciplined for refusing to fill the prescription of a rape victim seeking a morning-after pregnancy-prevention pill, the pharmacy chain that employed the man said on Tuesday.

Eckerd Corp. said the pharmacist considered it a violation of morals to give a rape victim, with a valid prescription, a pill that would prevent her from getting pregnant due to the sexual assault.

The incident took place on Jan. 23 at an Eckerd drug store in the Dallas suburb of Denton.

Eckerd spokeswoman Joan Gallagher said she could not give details of the disciplinary actions, but that the pharmacist had violated company policy.

"A pharmacist is obliged to fill a prescription if it is a valid, legal prescription," she said. "We do not make exceptions for any moral, religious or ethical concerns with regard to filling the prescription."

Florida-based Eckerd is owned by Texas-based retailer J.C. Penney Co..

Protesters, carrying signs reading "Got Raped? Let someone else help you" and "Rape violates my morals," have been picketing the store this week.

Kathryn Allen, a spokeswoman for Planned Parenthood of North Texas, said the situation could have been avoided if hospitals in the state mandated emergency contraception in sexual assault cases. Other states stipulate that hospitals must make emergency contraception available to victims of sexual assault, but Texas does not.

"What this pharmacist did was truly outrageous. It forces the woman to relive the assault," said Allen, adding that the prescription in question is essentially a high dose of birth control pills that prevents pregnancy.

The rape victim was able to have her prescription filled at another pharmacy in the area, they said.