

# FDA Ordered to Lower Plan B Age Restriction

BY DENISE NAPOLI

A U.S. federal judge ordered the Food and Drug Administration on March 23 to make the emergency contraceptive Plan B (levonorgestrel) available to 17-year-olds without a prescription within 30 days. Currently, Plan B is available without prescription to women aged 18 years and older.

U.S. District Judge Edward R. Korman also ordered the FDA to reconsider approving over-the-counter sale of the drug without age or point-of-sale restrictions.

"While the FDA is free, on remand, to exercise its expertise and discretion," Judge Korman wrote, "no useful purpose would be served by continuing to deprive 17-year-olds access to Plan B without a prescription. Indeed, the record shows that FDA officials and staff both agreed that 17-year-olds can use Plan B safely without a prescription."

Dr. Beth Jordan, medical director for the Association of Reproductive Health Professionals, called the ruling "a clear message to the FDA that decisions about medical devices and drugs must be based on science—not ideology."

She added that "It is safe and easy for reproductive-age women to self-diagnose [their] own need for Plan B and then to use it—a fact the FDA's own panel of independent medical experts advised them on prior to the FDA's politically motivated decision" to restrict the drug.

The ruling is a reaction to a citizen petition filed by the nonprofit Center for Reproductive Rights, *Tummino v. Torti* (formerly known as *Tummino v. von Eschenbach*) which requested that the FDA make Plan B available without a prescription to women of all ages.

In his ruling, Judge Korman pointed out that "Plan B and other emergency

contraceptives with the same active ingredient are available without a prescription or age restriction in much of the world, including virtually all major industrialized nations."

Clearly, the ruling has sparked controversy. Chris Gacek, a senior fellow at the Family Research Council, a Christian nonprofit and lobbying group, said,

"There is a real danger that Plan B may be given to women, especially sexually abused women and minors, under coercion or without their consent." Forcing underage children to get a prescription for the drug from a health care provider can help identify sexual abuse victims and screen for sexually transmitted diseases in these patients, he said. ■

## Survey Implies Some Difficulties in Obtaining Plan B

SAN FRANCISCO — Emergency contraception is available in 69% of Los Angeles pharmacies, and patients usually receive accurate information when inquiring about it, according to a study using sham patients.

However, in one-third of encounters in the study, the patients received the information only after multiple calls and multiple recitations of their situation, Dr. Anita L. Nelson said at a conference on contraceptive technology sponsored by Contemporary Forums.

Some pharmacies provided inaccurate information. For example, of 1,206 pharmacies contacted, 74 (6%) referred the woman to her clinician for a prescription.

At the time of the study, Plan B was available without a prescription to women aged 18 years and older.

Dr. Nelson and Dr. Cindy M. Jaime of the Los Angeles Biomedical Re-

search Institute at Harbor-UCLA Medical Center, Torrance, Calif., conducted the study between October 2007 and October 2008. They attempted to contact all 1,440 unduplicated telephone numbers for pharmacies listed in the Yellow Pages for Los Angeles County (Contraception 2009;79:206-10).

Female interviewers were trained to speak hesitantly to the person who answered and to say that she and her boyfriend had had sex the day before and that he had just told her that he had not used a condom. She then said that she had heard that maybe there was something she could take to keep from getting pregnant, and asked the person on the telephone if he or she knew about this.

Of the 1,206 pharmacies the investigators were able to contact, 835 (69%) responded that they carried emergency contraception and had it available on

site without a prescription. An additional 232 (19%) responded that they did not have it in stock or did not carry it themselves but referred the caller to other pharmacies. Others provided inaccurate information regarding the timeframe in which Plan B must be taken. Seventeen pharmacists hung up the phone after hearing the caller's question, and several hung up repeatedly upon being called back. Others asked overly personal questions.

Dr. Nelson said that the study received no outside funding and she said that she has served on advisory boards and speakers bureaus, and has received research funding from, Duramed/Barr Pharmaceuticals Inc., which manufactures Plan B. Contemporary Forums and this news organization are owned by Elsevier.

—Robert Finn

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