EDITORIAL

BY ROBERT L. BARBIERI, MD
■ Editor-in-Chief

OBG MANAGEMENT

Sometimes a vote of 23 to 4 is a tie

In May 2004, the Food and Drug Administration (FDA) rejected the application of Barr Laboratories for over-the-counter sales of the emergency contraceptive, Plan B (levonorgestrel 0.75 mg taken within 72 hours of intercourse, and an additional 0.75 mg taken 12 hours later). The acting director of the FDA's Center for Drug Evaluation and Research, Steven Galson, signed the rejection letter himself because members of his own FDA staff refused to. He noted that of the 585 women treated with Plan B, only 29 were less than 16 years of age. In his opinion, this sample size was too small to fully assess the safety of Plan B in this age group.

Although his statement is technically accurate, his decision was not consistent with 3 of the major guidelines that have historically influenced FDA action:

- respect the opinion of the expert panels that review the safety and effectiveness of our nation's drugs,
- use consistent rules to guide FDA decisions, and
- in the interest of public health, optimally balance the benefits and risks of a medication.

1. Respect the opinion of the expert panels.

In December 2003, two FDA expert advisory panels, working collaboratively, concluded that the benefits of allowing over-the-counter sales of Plan B outweighed the potential risks associated with such a change. The FDA panels reviewed extensive evidence on the safety and efficacy of Plan B, including results from about 40 clinical studies. Members voted 23 to 4 that Plan B should be sold over the counter, and 27 to 0 that Plan B could be safely sold over the counter. The experts on the FDA panel are knowledgeable, and their near-unanimous opinion should be a strong basis for FDA approval of over-the-counter sales of Plan B.

2. Use consistent rules to guide FDA decisions.

It is not clear whether the FDA has consistently required detailed data on the effects of over-the-counter drugs on individuals 13 to 16 years of age. If this has been the consistent policy of the FDA, then it would make sense to ask for such information for Plan B. In the United States, teens 15 to 19 years of age become pregnant at a higher rate (about 8% each year) than in other developed countries. In addition, pregnant teens are far more likely to choose pregnancy termination than pregnant adult women. Teens are a population most likely to benefit from over-the-counter Plan B. Approval of over-the-counter status for Plan B would likely decrease both teen pregnancy and teen abortion rates.

3. In the interest of public health, optimally balance the benefits and risks of a medication.

Most experts believe that emergency contraception with Plan B is both efficacious and safe. In one double-blind, controlled clinical trial,[1] 1,998 appropriately

selected women were randomized to either Plan B or the Yuzpe regimen (ethinyl estradiol 0.1 mg plus levonorgestrel 0.5 mg within 72 hours of intercourse and repeated 12 hours later). After a single act of intercourse, the expected pregnancy rate of 8% (with no contraception) was reduced to approximately 1.1% with Plan B and 3.2% with the Yuzpe regimen. Plan B reduced the expected number of pregnancies by about 85%. The most common adverse symptom was nausea, occurring in about 25% of the treated women.

The benefits of emergency contraception are clear. The risks of over-the-counter sales of Plan B appear to be minimal.[2] As eloquently stated by Dr. David Grimes, "Emergency hormonal contraception, like fire extinguishers, should be readily available in homes across the nation. Seventy-five percent of US homes have 1 or more fire extinguishers; few have emergency contraception on hand."[3]

An important public health issue

Fundamentally, the vote of the FDA expert panel indicated the important public health benefit of over-the-counter Plan B. By ignoring a vote of 23 to 4, the FDA has not effectively responded to this important public health need. Women would be best served by easier access to emergency contraception.

Until this goal is achieved, the American College of Obstetricians and Gynecologists strongly recommends that Ob/Gyns provide advance prescriptions for emergency contraception to all reproductive-age women at every office visit.

obg@dowdenhealth.com

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