

Comprehensive Approach...
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lar basis and treatment services if necessary. This is especially important because the most common STIs

either are treatable and curable, or their sequelae—notably cervical cancer—are largely preventable; other STIs, if not curable, are at least manageable. Access to regular STI screening and treatment services,

plus balanced prevention efforts, would begin to constitute the kind of truly comprehensive national strategy for addressing STIs that the problem requires. ☉

For the Record

FDA Delays Its Decision on the Sale of Emergency Contraception

One week before it was slated to make its decision whether to grant over-the-counter status to the emergency contraceptive known as Plan B, the Food and Drug Administration (FDA) on February 13 announced that it would delay that decision for up to 90 days. The delay came as a surprise to those who had expected the FDA would follow the recommendations of its expert advisory panel, which met in December 2003 and voted overwhelmingly in favor of making the method available without a prescription. The 28-member panel was unanimous in finding that the drug is safe for use without a prescription.

The FDA action came amid pressure from social conservatives, who have urged the administration to reject the recommendation of its advisory panel and keep the postcoital contraceptive pill prescription-only. While not contesting the drug's safety or its effectiveness when taken within 72 hours of unprotected intercourse, they now argue that wider access will put young people at greater risk of sexually transmitted infections. On January 9, 2004, 49 members of Congress, led by Rep. Dave Weldon (R-FL), sent a letter to President Bush focusing on adolescent use: "We are very concerned that no data is available to suggest what impact this decision will have on the sexual behavior of adolescents and the subsequent

impact on adolescent sexual health. We are concerned that adolescent exposure to sexually transmitted infection will increase because of the availability of [Plan B] over-the-counter. This availability may ultimately result in significant increases in cancer, infertility, and HIV/AIDS."

The Weldon letter charges that the FDA panel did not consider the impact over-the-counter availability may have on the sexual health of adolescents and young people. In fact, the FDA had before it the results of a number of studies that examined whether wider access will lead to increases in risky sexual behavior and risk of disease. The original application for the over-the-counter switch, submitted in April 2003, included the results of eight behavioral studies, whose sample sizes ranged from 160 to 1,000 women aged 15–45. These studies found that women who receive supplies in advance are more likely to use emergency contraceptives; however, they are no more likely to engage in unprotected sex, nor are they more likely to use regular contraceptives, including condoms, less consistently than women who were advised to obtain emergency contraception by prescription should they need it.

Based on these studies and Plan B in actual use, the expert advisory panel was unanimous in concluding that

there is no evidence to suggest that over-the-counter availability of Plan B would lead to substitution of emergency contraception for regular use of other contraceptive methods. Moreover, the panel agreed by an overwhelming majority (22–5) that the plans for the introduction of Plan B over-the-counter were adequate with respect to consumer access and safe use. When asked specifically to comment on over-the-counter sales to adolescents, only three members of the panel objected to teens' access; these three felt that the evidence did not adequately assess the impact of wider access on adolescent sexual behavior, especially among the youngest teens.

While not explicitly acknowledging the Weldon letter, the FDA has said the 90-day extension will permit the agency to review the data on adolescent use. Bruce Downey, chairman and CEO of Barr Pharmaceuticals, the manufacturer and distributor of Plan B, has said that the company is committed to providing any additional data that the FDA may need. At the end of the extension period, the FDA could approve the Plan B application outright or with restrictions, such as an age-restriction on sales; the agency could deny the application; or it could extend the deadline again. Although some observers contend that the administration needs to make a decision in the next 90 days to maintain its scientific credibility, others expect the administration to delay its decision until after the November elections. —H. Boonstra ☉