Advocates Question Plan B Age Restriction After FDA Again Delays Decision

The Food and Drug Administration's (FDA's) recent decision to delay, once again, a final decision on whether to allow over-the-counter (OTC) sales of the emergency contraceptive Plan B prompted a fierce outcry among women's health advocates, scientists and key members of Congress. The announcement also, and for the foreseeable future, returned leadership on efforts to expand access to emergency contraception to the states.

Plan B has been available by prescription in the United States since 1999, and in 2003, the product's manufacturer applied for OTC status. Two FDA expert advisory panels, convened together in December of that year, voted overwhelmingly in favor of the switch. The 28-member joint body unanimously deemed the drug safe for OTC sales. Nonetheless, the FDA failed to approve the application in May 2004, citing concerns that OTC availability of Plan B might increase sexual activity, and therefore the risk of sexually transmitted infections, among young teens. The agency's "not approvable" letter explicitly encouraged the manufacturer, Barr Pharmaceuticals, to submit a revised application to permit OTC sales to most women but maintain prescription-only status for those under age 16.

Barr's amended application, however, languished for months with no response. The agency's failure to act prompted Sens. Hillary Clinton (D-NY) and Patty Murray (D-WA) to move earlier this year to block Lester Crawford's nomination to head the FDA from moving forward until they were assured by Health and Human Services Secretary Michael Leavitt that a yes-or-no decision would be rendered by September 1. Only days before the deadline, however, the FDA announced that it might lack legal authority to grant the dual-status scheme that it had recommended Barr pursue. The agency invited public input on the feasibility and legality of the idea, but gave no indication whether or when it might take further action.

This turnabout infuriated Clinton and Murray, who immediately called for a public hearing on the FDA's decision-making process. A bipartisan coalition of 13 senators sent a letter urging the Government Accountability Office (GAO) to quickly conclude its investigation into the basis for the FDA's rejection of the initial application to make Plan B available OTC to women of all ages. (The GAO report is expected to be made public by the end of October.) And members of the bipartisan Congressional Pro-Choice Caucus sent a letter to the FDA urging the agency to approve Barr Pharmaceuticals' application without further delay. The decision also prompted the resignation of Susan Wood, director of FDA's Office of Women's Health, who decried the extent to which the agency's decision-making around Plan B had become politicized. At least one prominent member of the FDA advisory panel on nonprescription drugs also resigned, citing the same concerns.

Leading women's health advocates, meanwhile, are now calling on the FDA to abandon its dual-status concept and to make Plan B available OTC without an age restriction. Although they agree with most experts that the agency, in fact, has the authority to approve the same drug as both a prescription-only and an OTC product, advocates also say such a plan is unnecessary and unwarranted in the case of Plan B.

Indeed, it would be unprecedented for the FDA to establish an age restriction for a contraceptive product. Long-standing policy of the division at the FDA that oversees reproductive health products makes no distinction between postpubescent adolescents and adult women with respect to the safety of contraceptive products. Plan B consists of the same active ingredient found in ordinary birth control pills, which have been safely used by adolescents for many years. Serious side effects of Plan B are rare, and no deaths have been attributed to use of the product. Moreover, studies have found that women given easier access to emergency contraceptives are no more likely to engage in unprotected sex or to use regular contraceptives less consistently than are women who were advised to obtain emergency contraceptives by prescription should they need it.

The absence of a federal policy on OTC status for Plan B leaves the battle around expanded access to emergency contraception squarely in the states. Currently, seven states (California, Massachusetts, New Jersey, New Mexico, New York, South Carolina and Washington) require hospital emergency rooms to dispense emergency contraception on request to women who have been sexually assaulted. Earlier this year, New Hampshire and Massachusetts joined six other states (Alaska, California, Hawaii, Maine, New Mexico and Washington) in granting pharmacists the authority—under collaborative practice agreements or other state-approved protocols—to provide women direct access to emergency contraception. At the same time, the issue of pharmacists refusing to fill prescriptions for emergency contraception is also heating up ("Rights vs. Responsibilities: Professional

Standards and Provider Refusals," *TGR,* August 2005, page 7). Currently, four states—Arkansas, Georgia, Mississippi and South Dakota—explicitly allow pharmacists to refuse to dispense contraceptives, including Plan B. Countering this trend, Illinois and California have established policies designed to protect consumer access ("Beyond the Issue of Pharmacist Refusals: Pharmacies That Won't Sell Emergency Contraception," *TGR,* August 2005, page 10).—*H. Boonstra*

Administration Tightens Rules for Abstinence Education Grants

In August, public health officials in Maine announced that the state would reject federal funding for abstinence-only education for fiscal years 2005 and 2006, joining California and Pennsylvania as the only states to turn down the funding. Officials said they could no longer accept the state's annual $161,000 allotment given the federal government's recent move to tighten the rules that govern the program.

The program, which provides $50 million in annual grants to the states (and is matched by another $38 million in state funds), supports abstinence education programs that are required to conform to an infamous "eight-point definition" enshrined in section 510 of the federal Social Security Act. Some of the more controversial components of this definition include teaching "that a mutually faithful monogamous relationship in context of marriage is the expected standard of human sexual activity" and "that sexual activity outside of the context of marriage is likely to have harmful psychological and physical effects" ("Legislators Craft Alternative Vision of Sex Education to Counter Abstinence-Only Drive," *TGR,* May 2002, page 1).

When the "section 510" program was first created in 1996 as part of the welfare reform law, however, the Clinton administration's program guidance noted that states need not "place equal emphasis on each element of the [eight-point] definition," but that "a project may not be inconsistent with any aspect of the abstinence education definition." This small measure of flexibility prompted enduring criticisms from some social conservatives, who charged that governors were cherry-picking which aspects of the eight-point definition they wanted to emphasize and therefore diluting the abstinence-only thrust of the program ("Abstinence Promotion and Teen Family Planning: The Misguided Drive for Equal Funding," *TGR,* February 2002, page 1).

In response to these charges, the Bush administration in the summer of 2004 formally moved the program from a division of the Department of Health and Human Services (DHHS) that houses the federal public health bureaucracy (the Health Resources and Services Administration) to the Administration for Children and Families (ACF), which runs the administration's marriage promotion and fatherhood programs, among other things. Many observers believed that this shift would lead to significant programmatic changes for the 510 program.

These concerns were not unfounded. ACF's new guidance for the section 510 program, issued in March 2005, is in fact more stringent: "To the extent possible," the guidance reads, "we strongly encourage each State to develop programs that place *equal emphasis* on each element of the abstinence education definition" [emphasis added]. This interpretation is now much more consistent with that of a separate federal program, also recently moved to ACF, that bypasses the states entirely and provides funding directly to community-based organizations for abstinence-only education (CBAE). Since the inception of the program in 2001, CBAE grantees—many of which are faith-based organizations and crisis pregnancy centers—have operated programs responsive to *all* elements of the eight-point definition.

Recent ACF guidance, moreover, also explicitly addresses, for the first time, the critical question of the role of contraceptive information in the CBAE program. Because one of the eight-point definition's planks requires funded programs to have as their "exclusive purpose, teaching the social, physiological, and health gains to be realized by abstaining from sexual activity," there has been a long-standing, but until now unwritten, programmatic prohibition on discussing the potential benefits of contraception in federally funded abstinence-only education programs. The agency's request for proposals for the $104 million allocated to the CBAE program for FY 2005, however, notes that "Sex education programs that promote the use of contraceptives are not eligible for funding under this announcement." Moreover, objectives in prior funding announcements designed to discourage "premature sexual activity" and "abstinence decisions" have been changed to "premarital sexual activity" and "abstinence-until-marriage decisions," respectively. Unlike the changes to the section 510 guidance, which are likely to affect the substantive content of funded programs, these changes may simply clarify that which was always implicit. In any event, they bring into sharp relief this administration's philosophy on the respective roles of abstinence, contraception and marriage in protecting young people—and in fact people of any age—from the potential harms associated with sexual activity.—*C. Dailard*