## POLICY & PRACTICE

### Plan B Decision Delay Spawns Lawsuit

An advocacy group is suing the Food and Drug Administration for delaying its decision on over-the-counter status for the emergency contraceptive Plan B (levonorgestrel). "Half of the 3 million pregnancies in the U.S. are unintended each year. By denying women over-the-counter access to a safe and effective drug that would significantly reduce those numbers—including pregnancies that end in abortion—the FDA is acting unlawfully," said Nancy Northrup, president of the Center for Reproductive Rights, which filed its suit in a New York district court. The FDA had been scheduled to issue a decision in late January on a second application for OTC status for Plan B by its manufacturer, Barr Pharmaceuticals. Steven Galson, M.D., acting director of the FDA's Center for Drug Evaluation and Research, had rejected Barr's initial request for over-the-counter marketing status last spring, citing a lack of sufficient evidence regarding the effects of OTC availability of emergency contraception in younger women. The FDA should be completing its review in the near future, Barr indicated in a statement. "The company remains optimistic that the agency will approve Plan B for OTC sale."

### Emergency Contraception Omitted

A coalition of abortion rights advocates and health care professionals is urging the U.S. Department of Justice to add information about emergency contraception to its "National Protocol for Sexual Assault Medical Forensic Examination." The group is asking the Justice Department to revise its protocol to include the routine offering of emergency contraception to rape victims at risk of pregnancy. "The failure to include a specific discussion of emergency contraception in the first national protocol for sexual assault treatment is a glaring omission in an otherwise thorough document," the coalition said in a letter to the Justice Department. The protocol, which provides medical treatment guidelines for sexual assault patients, was released late last year. The coalition includes the American College of Obstetricians and Gynecologists.

### Misleading Ads

The Food and Drug Administration recently warned Barr Research that one of its advertisements for the oral contraceptive Seasonale (levonorgestrel/ethinyl estradiol) was misleading consumers. "By omitting and minimizing the risks associated with Seasonale, the TV ad misleadingly suggests that Seasonale is safer than has been demonstrated by substantial evidence or substantial clinical experience," the FDA said in a letter. The ad fails to mention that patients using Seasonale may experience breakthrough bleeding or spotting for up to a year, according to the letter. In addition, the ad minimizes risk information through fast-paced scene changes, background music, and compelling visuals, according to the FDA. Barr intends to work with FDA to make the necessary change to the ad, according to company spokesman Carol A. Cox. "Seasonale is safe and effective oral contraception when used as directed, and we intend to continue to educate all consumers and health care providers about the product, its indications, risks, and side effects," she said.

### HIV Prevention

Although current law allows for the delivery and financing of HIV-prevention programs through Medicaid and the Ryan White Comprehensive AIDS Resources Emergency Act grants, neither program delivers a significant level of services, according to an analysis by the Kaiser Family Foundation. Financial pressures contribute to the situation, according to the study, but organizational barriers also keep prevention from being integrated into clinical care. The study said prevention could be enhanced through the development of models of integration in primary care and increased training of health care providers on incorporating HIV prevention practices into routine practice activities.

### The Malpractice Debate

President Bush hit the road in January to drum up support for his medical liability reform legislation. The president traveled to Illinois to draw attention to the problem of frivolous lawsuits and called on Congress to enact a $250,000 cap on noneconomic damages in medical malpractice cases. He also called on Congress to pass joint and several liability reform and to work on reform for class action lawsuits. "It's important for the United States senators from this state and other states to recognize the significance of the problem and get a meaningful, real medical liability bill to my desk," President Bush said during his speech in Illinois. But Sen. Byron Dorgan (D-N.D.) said the proposal would shelter drug manufacturers from lawsuits. "In its zeal to support the big drug companies, the Bush administration is seriously overreaching with this proposal," he said in a statement.

**—Mary Ellen Schneider**