Policy & Practice

Unapproved STD Treatments

The Food and Drug Administration is cracking down on companies that market unapproved and misbranded drugs for the prevention and treatment of sexually transmitted diseases (STDs). Last month, FDA officials sent warning letters to six U.S. companies and one foreign individual for marketing these drugs over the Internet to U.S. consumers. The products identified by the FDA include Tetrasil, Genisil, Aviralex, OXi-MED, Imulux, Beta-mannan, Micronutrient, Qina, and SlicPlus. Some of the marketing includes false claims that the drugs have been approved by the FDA or that they are superior to conventional medicine, according to the FDA. For example, SlicPlus claims to offer the "greatest STD protection without condoms." Companies that fail to cease marketing of the products could face seizure of illegal products, injunction, and possible criminal prosecution, according to the FDA.

2006 ART Success Rates Posted

The Society for Assisted Reproductive Technology recently posted 2006 outcome data from its member clinics. The national dataset includes the results of 126,379 treatment cycles at 343 clinics. Of those cycles, more than 99% involved in vitro fertilization, with less than 1% involving gamete intrafallopian transfer or zygote intrafallopian transfer. Among women under age 35 years, 37,074 cycles were performed with 45% of cycles resulting in pregnancies and 39% resulting in live births. Among women age 35-37 years, there were 21,273 cycles performed with 37% of cycles resulting in pregnancies and 31% resulting in live births. Physicians and patients can view national summary reports or access data from individual clinics. The outcomes data are available online at www.sart.org.

U.N. Cites Disparities in U.S. Care

Racial dispartities continue to plague sexual and reproductive health care in the United States, according to a report from the United Nations Committee on the Elimination of Racial Discrimination. The U.N. committee cited the high maternal and infant mortality rates among racial and ethnic minorities, as well as the high incidence of unintended pregnancies among African American women as concerns. The committee's report also noted that the United States faces growing disparities in HIV infection rates for women in minority groups. The committee recommended that the United States reduce eligibility barriers for Medicaid coverage as a way to improve access to maternal health care, family planning, prenatal and postnatal care, and emergency obstetric services. The report also called on the U.S. government to provide adequate sexual education to prevent unintended pregnancies and sexually transmitted diseases.

Dr. Woodcock Named CDER Head

Dr. Janet Woodcock has been named director of the FDA's Center for Drug Evaluation and Research. Dr. Woodcock, a rheumatologist, served as director of CDER once before, in the 1990s, and has served as acting director since October 2007. The drug industry's chief lobbying group, PhRMA, welcomed the appointment. Dr. Woodcock "has demonstrated willingness to work with diverse partners, including researchers, Congress, the White House, patients, and pharmaceutical research companies," said a statement from the group. But Public Citizen's health research group director, Dr. Sidney Wolfe, said in an interview that he's "not terribly hopeful" that Dr. Woodcock will lead the center well, because she doesn't like conflict or controversy. "I don't think she's the kind of CDER director we need right now," Dr. Wolfe said. "She's aware of a number of drugs on the market that should be taken off the market, but I don't think she has the fortitude to do something about it."

Physicians Respond to Medicare Cuts

The current uncertainty about Medicare payments to physicians is causing practices to postpone hiring staff, postpone investments in new technology, or even stop accepting new Medicare patients, according to a survey from the Medical Group Management Association. For example, 46% of respondents said that in light of the 10.6% cut in Medicare payments expected in July, they will refuse to accept new Medicare patients or limit the number of new Medicare patients. Nearly 28% said they would limit the number of appointments for Medicare patients. The pending cut could also affect the implementation of health IT systems, including e-prescribing. More than 60% of respondents said that they were more likely to postpone purchasing decisions related to e-prescribing because of the Medicare payment situation. The results are based on responses from more than 1,000 group practices, according to MGMA.

—Mary Ellen Schneider