PRACTICE TRENDS

CDC Eliminates HIV Exclusion
People seeking to immigrate to the United States will no longer be required to undergo HIV testing, under a final rule issued by the Centers for Disease Control and Prevention. “While HIV infection is a serious health condition, it is not a communicable disease that is a significant public health risk for introduction, transmission, and spread to the U.S. population through casual contact,” CDC officials wrote in the Federal Register in November. The rule goes into effect Jan. 4. Until now, CDC policy has been that individuals with HIV who are living outside the United States are not eligible to receive a visa for admission to the country. The CDC proposed the change earlier this year and received more than 20,000 public comments on it, the majority of which (about 19,500) supported removing HIV from the list of communicable diseases of public health significance, agency officials said.

Court Rejects Defamation Claim
A California appeals court has thrown out the defamation case against Dr. Bruce Flamm, a clinical professor of ob.gyn. at the University of California, Irvine. He was sued against Dr. Bruce Flamm, a clinical professor of ob.gyn. at the University of California, Irvine. He was sued by Dr. Kwang Cha, who was one of the authors of a 2001 study published in the Journal of Reproductive Medicine. The heavily criticized study purported to show that prayer significantly increased success rates on it, the majority of which (about 19,500) supported removing HIV from the list of communicable diseases of public health significance, agency officials said.

Embryo Donation Training
The nonprofit group called RESOLVE: The National Infertility Association is developing a series of training programs to help the medical teams at fertility clinics better understand the issues surrounding embryo donation. RESOLVE, which usually focuses on consumer education, will use a grant from the U.S. Health and Human Services Department to create training modules for health care providers, so they in turn can provide information to their patients. As part of the program, clinic staff will assess their knowledge and current practices related to informing patients about the option to donate embryos. The group RESOLVE also plans to develop online programs for continuing education credit and to offer social networking opportunities.

Pipeline Is Full of Treatments
Pharmaceutical and biotechnology companies have nearly 1,000 medications and vaccines in the pipeline to treat diseases that disproportionately affect women, according to a new analysis. Surveys of middle- and high-school students show that 39% of teens who had ever given birth to or fathered a child as a teenager were living with two biological or adoptive parents before the birth, the National Campaign to Prevent Teen and Unplanned Pregnancy reported. Another 19% of these teens said that they were living with one biological parent and one stepparent. About 72% of teens who had either fathered a child or given birth as a teenager were living in households that were above the federal poverty level. In fact, most of that group was living in households with incomes at or above 200% of poverty. “Despite what many may believe, teen childbearing is not limited to a particular income group or family structure, which means that prevention efforts must be broad in their design and reach,” Sarah Brown, CEO of the National Campaign to Prevent Teen and Unintended Pregnancy, said in a statement. The findings are based on an analysis of the National Longitudinal Study of Adolescent Health and a public opinion poll of more than 1,000 adults.

5.1 Clinical Trial Experience
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to rates in clinical trials of another drug and may not reflect the rates observed in practice. The data provided here are consistent with the experience of the use of Mirena in the adequate and well-controlled studies where cervical ring (n = 2,389) and heavy menstrual bleeding (n = 88). For the contraception indication Mirena was compared to a copper IUD (n = 1,865), to another formulation of levonorgestrel intrauterine system (n = 900) and to a combined oral contraceptive (n = 946) in women 18 to 35 years old. The data cover more than 92,000 woman-months of exposure. For the treatment of heavy menstrual bleeding indication (n = 80), the subjects included women aged 26 to 50 with confirmed heavy bleeding and exposed to a median of 168 treatment days (range 7 to 205 days). The frequencies of reported adverse drug reactions represent crude incidences.

The adverse reactions seen across the 2 indications overlap, and are reported using the frequencies from the contraception studies. The most common adverse reactions (≥5% users) are uterine/vaginal bleeding alterations (51.9%), amenorrhea (23.0%), intermenstrual bleeding and spotting (23.4%), abdominal/pelvic pain (12.8%), ovarian cysts (12%), headache/nystagmus (7.7%), acne (7.2%), depression/altered mood (6.4%), menorrhagia (6.3%), breast tenderness/pain (4.5%), vaginal discharge (4.0%), and IUD expulsion (4.0%). Other relevant adverse reactions occurring in ≥5% of subjects include nausea, dizziness, vulvovaginitis, dysmenorrhea, back pain, weight increase, decreased libido, menorrhagia, oligomenorrhea, acne, ataxia, breast engorgement, breast tenderness, hypoglycemia, hypertension, dyspareunia, anemia, alopecia, skin disorders including eczema, pruritus, rash and urticaria, abdominal distension, hirsutism and edema.

5.2 Postmarketing Experience
The following adverse reactions have been identified during post approval use of Mirena: device breakage and angioedema. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

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