Policy & Practice

Another FDA Resignation

The Food and Drug Administration's delay in deciding whether to approve Plan B emergency contraception for sale over the counter has cost the agency another expert. Frank Davidoff, M.D., editor emeritus of the Annals of Internal Medicine, resigned his position as a consultant with FDA's Nonprescription Drugs Advisory Committee in September. This comes after Susan F. Wood, Ph.D., the director of the FDA Office of Women's Health, also resigned in protest over agency actions on Plan B. In a letter to FDA, Dr. Davidoff said he was resigning from the committee because of the agency's move to postpone its decision on Plan B. "I can no longer associate myself with an organization that is capable of making such an important decision so flagrantly on the basis of political influence, rather than the scientific and clinical evidence," he said in the letter. He added that he plans to encourage other members of FDA advisory committees to resign as well. FDA released a statement thanking Dr. Davidoff for his work on the committee. "His decision to resign as a consultant is an unfortunate loss of expertise as we work toward solving the complex policy and regulatory issues related to Plan B," the FDA said.

Case Could Head to High Court

The court battle over the "Partial Birth Abortion Act of 2003" may be headed to the Supreme Court. The U.S. solicitor general petitioned the court on Sept. 23 to review the U.S. Court of Appeals ruling that struck down Gonzales v. Carhart, one of three challenges to the law, as unconstitutional. If the court accepts the case, it would likely be decided by next summer, according to the National Right to Life Committee. But abortion rights advocates, who have been successful so far in challenging the law, are opposing this move. In the meantime, there are two other related cases still pending in lower courts.

National Stem Cell Bank

WiCell Research Institute, a nonprofit organization headquartered at the University of Wisconsin, Madison, will be home to a new national stem cell bank thanks to a $16.1 million grant from the National Institutes of Health. The stem cell bank will consolidate many of the human embryonic stem cell lines eligible for federal funding in one place, reduce the costs that researchers have to pay for the cells, and maintain quality control, according to NIH. "This will optimize and standardize the techniques used for comparing the properties of stem cells, a critical step for both the basic and translational research that is needed for the eventual development of potential therapies," NIH Director Elias A. Zerhouni, M.D., said in a statement. But critics of the federal policy on stem cell research funding said the move is overdue and doesn't go far enough. "A stem cell bank is only as good as the lines in it. Without federal funding we will simply not have the resources to develop the number and diversity of lines researchers need," said Rep. Diana DeGette (D-Colo.), who has cosponsored legislation to expand the number of stem cell lines that will be eligible for federal funding.

Court Upholds Refusal Clause

A provision of the law that withholds federal funds from government agencies that discriminate against providers and insurers for failing to provide abortion services has withstood its first legal challenge. The National Family Planning and Reproductive Health Association (NFPRHA) had filed a suit claiming the law was "unconstitutionally vague" because it didn't define the types of entities governed by it or the types of discrimination it prohibits. The group argued that following the provision would put it at odds with its obligations under Title X to provide abortion referrals upon request. The U.S. District Court judge ruled against NFPRHA and denied its request for a preliminary injunction.

Anticonvulsant Education

The Epilepsy Foundation is telling women of childbearing age who take anticonvulsant medications to talk with their doctors about their treatment options. The group issued a "call to action" in an effort to make women aware of the risks to the fetus from these drugs. Since the risks from these drugs occur early in pregnancy and about half of pregnancies in the United States are unplanned, it leaves women unprepared, according to the Epilepsy Foundation. The call to action "places a sense of urgency for all women of childbearing age to reevaluate their current drug treatment," Eric Hargis, president of the Epilepsy Foundation, said in a statement. This call to action is part of a larger effort to education women about reducing the risks associated with anticonvulsant drugs, according to the group. More than 56 million prescriptions were written last year for anticonvulsants, making it the fifth most prescribed class of medications, according to the Epilepsy Foundation.

—Mary Ellen Schneider