Policy & Practice

Teen Communication With Parents

Most adolescent girls who have been to publicly funded family planning clinics report having had conversations with their parents about sex. Nearly 42% of the girls said they had talked a "great deal" with their parents about how to say no to sex, according to a survey conducted by researchers at the Guttmacher Institute. But about half of the girls surveyed said they did not talk with their parents at all about how to use condoms. The researchers analyzed questionnaires given to more than 1,500 adolescent girls who obtained services at 79 publicly funded family planning clinics across the United States. The girls were asked about communication with parents about sexual health issues, parent-child connectedness, parental attitudes toward sex and contraception, and parental knowledge of the clinic visit.

Umbilical Cord Stem Cell Bill

President Bush last month signed into law a bill that would provide for the collection and maintenance of human cord blood stem cells for the treatment of patients and use in research. The Stem Cell Therapeutic and Research Act of 2005 (H.R. 2520) directs the secretary of Health and Human Services to enter into one-time contracts with cord blood banks to assist in the collection and maintenance of 150,000 new units of cord blood. This cord blood would be made available for transplantation through the C.W. Bill Young Cell Transplantation Program. This new program is the successor to the National Bone Marrow Donor Registry and would be charged with increasing the number of transplants for suitably matched recipients from biologically unrelated donors of bone marrow and cord blood. Rep. Mike Castle (R-Del.) and Rep. Diana DeGette (D-Colo.) praised the legislation but said it does not serve as a replacement for their proposal to expand government funding of embryonic stem cell research. Rep. Castle and Rep. DeGette are continuing to push for Senate passage of H.R. 810, the Stem Cell Research Enhancement Act of 2005, which passed in the House last May.

Breast Implant Investigation

Sen. Dianne Feinstein (D-Calif.) and Sen. Olympia Snowe (R-Maine) have asked the Food and Drug Administration to investigate claims of safety problems with the Mentor silicone breast implants. A former employee of the company has alleged publicly that there is a design flaw in the implants that has led to a higher rupture rate, which was not accurately reported to the FDA. In addition, the former employee has alleged that Mentor's implants used in surgery leak more than the ones that were used in demonstrations to physicians and patients. But officials at Mentor say the allegations are false and that the former employee has been indicted for stealing breast implants from the company and trying to sell them on eBay. Last summer, Mentor and another company received "approvable" letters from the FDA; however, silicone breast implants will not be available until the FDA sets conditional requirements for the manufacturers.

Teen Health Curriculum

The Physicians for Reproductive Choice and Health have launched a nationwide educational project aimed at teaching physicians more about teens and sexual health. The Adolescent Reproductive Health Education Project is a curriculum that offers modules on adolescent-friendly health services, adolescent reproductive health data, the physician as advocate for adolescent reproductive health, cultural competency, contraception, male adolescent reproductive health, pregnancy counseling, sexuality education, and minors' legal access to confidential health services. The program was developed from a pilot program in Georgia that provided information to physicians, educators, parents, and teens. The curriculum is available free from the Physicians for Reproductive Choice and Health by calling 646-366-1890.

Addressing Underage Drinking

The Century Council, a not-for-profit organization funded by leading distilled spirits manufacturers, has launched a public awareness campaign aimed at improving communication between mothers and daughters about underage drinking. "Girl Talk: Choices and Consequences of Underage Drinking" was designed to help mothers to start conversations about alcohol use. The program comes on the heels of a Century Council survey that showed mothers significantly underestimate their daughters' experience with alcohol. For example, the survey found that 30% of 16- to 18-year-old girls reported drinking with friends but only 9% of their mothers thought their daughters were drinking. The program was developed in partnership with the Society for Women's Health Research and the Montgomery County Maryland Alcohol Beverage Control Board. More information on the program is available at www.girlsanddrinking.org.

—Mary Ellen Schneider

FDA Reorganizing to Improve Drug Safety, Development

BY MARY ELLEN SCHNEIDER
Senior Writer

Officials at the Food and Drug Administration are planning to reorganize its Center for Drug Evaluation and Research in an effort to improve the agency's approach to drug safety and to help improve drug development.

The FDA plans to appoint a new associate director at the Center for Drug Evaluation and Research (CDER) to focus on broad drug safety, policy, and communication issues. Agency officials also plan to consolidate some drug safety–related activities and have that staff report to the new associate director. This would include MedWatch reporting staff and Drug Safety Oversight Board staff.

The reorganization plans also call for elevating the status of the current Office of Drug Safety, which is primarily responsible for epidemiology and surveillance activities, and its staff will report to the CDER director. The name of the office will also be changed.

"Over the past year, the Center has been the focus of intense internal and external scrutiny regarding drug safety," Dr. Steven K. Galson, CDER director, said in a memo to the center staff. "The current organizational structure perpetuates the misperception that ensuring drug safety is solely the responsibility of the current Office of Drug Safety."

While the Office of Drug Safety is a small unit, about half of CDER's resources are dedicated to drug safety activities, said Deborah Henderson, R.N., director of the Office of Executive Programs at CDER.

But the proposal includes no plans to make the Office of Drug Safety independent from CDER, as some in Congress have proposed. When reviewing drugs, FDA staff members need to balance the effectiveness of the drug against the risks, Ms. Henderson said, so pulling the safety activities out of the center wouldn't be in the best interests of public health.

FDA officials plan to implement the changes over the next 6 months.

The changes will also help to improve regulatory and drug development science through the agency's Critical Path Initiative—a top FDA priority that calls for partnering with industry and academia to improve the drug development process.

Through the Critical Path Initiative, FDA hopes to help industry find better biomarkers and improve clinical trial designs, Ms. Henderson said, which would ultimately lead to better, more targeted drugs. While a number of CDER staff have been working on the Critical Path Initiative, there has not been a central office within CDER. Under the proposed reorganization, the FDA will create a new office that will report to the CDER director and provide a hub for Critical Path activities.

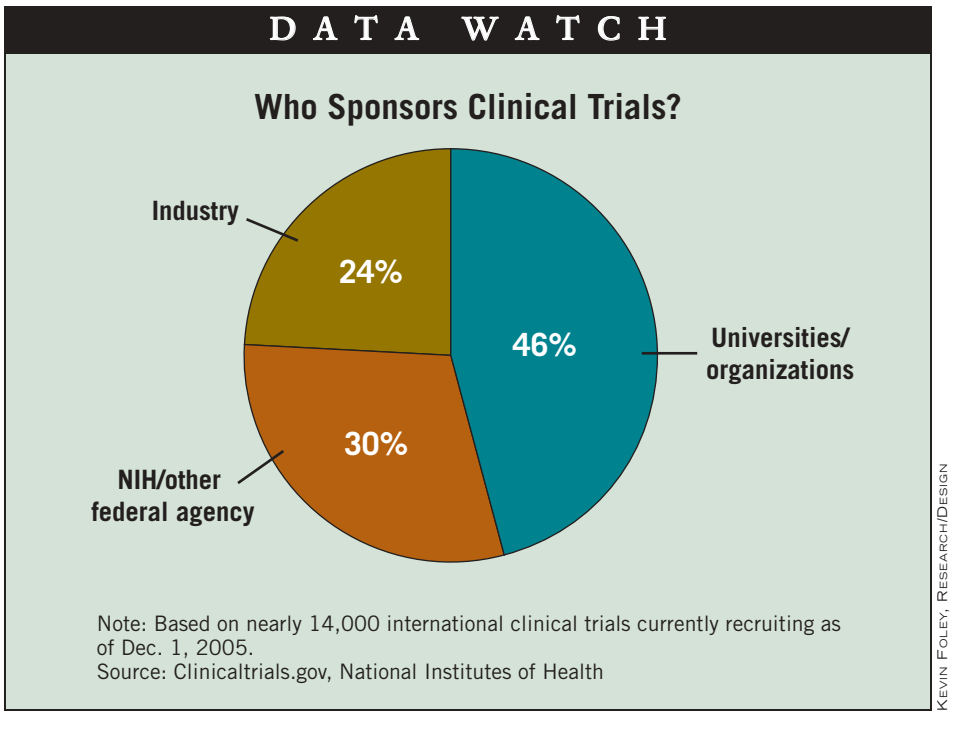
"A reorganization is not designed to achieve instant solutions to the challenges CDER faces, although I believe it will address many of the criticisms and suggestions which have been offered on how to approach our work, including drug safety," Dr. Galson said in his memo to CDER staff.

But real improvements in drug safety need to happen outside the FDA, said Curt D. Furberg, M.D., Ph.D., professor in the department of public health sciences at Wake Forest University in Winston-Salem, N.C.

Congress needs to act to give the FDA greater authority to change labels, withdraw drugs, and levy penalties against drug makers who don't live up to their postmarket promises, he said. "FDA can't do that on its own," Dr. Furberg said. "Congress is failing."

The streamlining being proposed by the FDA is a good idea, he said, but it won't address the larger problem. "The issue of safety is much bigger," he said. ■

DATA WATCH



Note: Based on nearly 14,000 international clinical trials currently recruiting as of Dec. 1, 2005.
Source: Clinicaltrials.gov, National Institutes of Health

Kevin Foley, Research/Design

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