

POLICY & PRACTICE

Wyeth Loses Prempro Suit

A Pennsylvania jury has found that the hormone therapy Prempro was a cause of a woman's breast cancer in the case of *Jennie Nelson v. Wyeth*. At press time, the liability phase of the trial was set to begin; the jury will determine whether Wyeth is liable and is required to pay \$1.5 million in compensatory damages. The jury will also decide whether punitive damages should be awarded to the plaintiff. Wyeth officials plan to argue that they "acted responsibly" by performing and supporting studies that evaluated the benefits and risks of hormone therapy, according to a company statement. Wyeth officials also disagreed with the jury's conclusion that Prempro caused the plaintiff's breast cancer, saying there was no scientific basis for that finding. The decision comes on the heels of a September Wyeth victory in a federal case alleging that the Premarin and Prempro products had caused the plaintiff's breast cancer. In the case of *Linda Reeves v. Wyeth*, the jury said that the plaintiff had not proved that the company had inadequately warned patients of the known risks of hormone therapy treatment.

Teen Abortion Restriction Stalled

Abortion rights advocates are claiming victory after attempts to bring up the Child Interstate Abortion Notification Act were stopped in the Senate. The lack of votes in the Senate means that the legislation, which passed the House in September, is unlikely to reach the president's desk this year. S. 403 would impose fines or prison time on anyone who assisted a minor in crossing state lines to access abortion services in an effort to skirt parental notification and consent laws in the minor's home state. Physicians would also be liable under the law if they performed an abortion on a minor from another state unless they notified the parent at least 24 hours before the procedure.

AIDS Treatment Wait Lists Persist

State AIDS Drug Assistance Programs continue to struggle to keep up with demand, according to the October report of the National Alliance of State and Territorial AIDS Directors. As of September 2006, 302 individuals were on waiting lists for HIV treatment in six states. AIDS Drug Assistance Programs (ADAPs) around the country serve individuals with HIV/AIDS who are low-income, uninsured, or underinsured. Three states also have implemented cost-containment measures such as offering a reduced formulary or imposing an annual per capita expenditure limit. Increased funding is needed to meet demand, according to Julie Scofield, executive director of the National Alliance of State and Territorial AIDS Directors, estimated at \$197 million more than the fiscal year 2006 funding levels. "Without a permanent commitment to stable, predictable funding at levels that keep pace with demand, waiting lists will soon become a permanent feature of ADAPs," she said in a statement.

Supplement Use Undisclosed

More than one-fifth of individuals taking prescription drugs also took a non-vitamin dietary supplement in the last year, according to a study published recently in the Archives of Internal Medicine. Further, 69% of those who used both prescription drugs and supplements failed to tell a physician about their supplement use, the researchers found. The researchers analyzed data from the 2002 National Health Interview Survey, which included 31,044 respondents. Of prescription medication users, the highest rates of supplement use were among menopausal women (33%), individuals with chronic gastrointestinal disorders (28%), and individuals with severe headache or migraine (28%). Patients with heart failure, coronary heart disease, or a history of myocardial infarction were among those reporting the lowest rate of supplement use.

Coalition Seeks More FDA Funds

A coalition of strange bedfellows has joined together to call on the White House and Congress to increase funding for the Food and Drug Administration, saying that the agency's mission and responsibilities have expanded hugely while its appropriations have failed to keep up with inflation or with the growing largess going to other agencies like the National Institutes of Health. That NIH investment will likely result in a large number of new products, all of which the FDA will have to regulate, according to the Coalition for a Stronger FDA. The agency also needs help coping with growing pharmaceutical, medical device, and food safety issues, the group said. The coalition includes the Consumer Federation of America, the Center for Science in the Public Interest, the Grocery Manufacturers Association, the Biotechnology Industry Organization, and the Advanced Medical Technology Association, among others. Cochairing the coalition are the last three secretaries of Health and Human Services: Tommy G. Thompson, Donna E. Shalala, and Louis Sullivan.

Underage Binge Drinking Mapped

The highest rates of underage binge drinking in the United States occurred in the northeast region of North Dakota in 2002-2004, with the lowest rates reported in the District of Columbia's Ward 7, according to a report from the Substance Abuse and Mental Health Services Agency. The report, based on the results of the National Survey on Drug Use and Health, presented rates of binge drinking (consuming five or more drinks on the same occasion) in 340 substate areas among individuals aged 12-20 years. The lowest rate of binge drinking was 10.4% of the 12- to 20-year-old population. The highest rate was 36.1%, according to the SAMHSA report. The full report is available at www.oas.samhsa.gov/substate2k6/substate.pdf.

—Mary Ellen Schneider

Funding, Disparity Challenges Seen Ahead for HPV Vaccine

BY HEIDI SPLETE
Senior Writer

WASHINGTON — The challenge of paying for vaccinations will become even greater once the human papilloma virus vaccine becomes available in 2007.

At a meeting of the National Vaccine Advisory Committee, representatives from several organizations reported that there isn't enough money to go around and that states will have to make tough choices about funding for the HPV vaccine, which is scheduled to become a standard immunization for 11- to 12-year-old girls.

The evidence used by the Advisory Committee on Immunization Practices to make vaccine recommendations includes economic factors as part of the public health perspective, said Dr. Lance Rodewald, director of the immunization services division at the Centers for Disease Control and Prevention. But the price of a vaccine cannot be a consideration for resolutions made by the Vaccines for Children (VFC) program. The key consideration in a VFC resolution simply is whether the vaccine is recommended for VFC-eligible children, he said.

Consequently, an ACIP recommendation raises the possibility for disparity, with VFC-eligible children receiving a vaccine because it is paid for, and children with private insurance not receiving the same vaccine because it is not paid for. Neither state-appropriated funds nor funds from Section 317 (a discretionary program within the Public Health Service Act that cov-

ers individuals whose insurance doesn't cover vaccines or who are not eligible for VFC funds) has kept up with VFC's need-based funding, Dr. Rodewald said.

What happens when the need outstrips the resources? "The programs are put in a tough spot," he said. "The states will need to prioritize vaccinations, and we are looking to other groups to help resolve the financing dilemma."

Dr. Poki Stewart Namkung, president of the National Association of County & City Health Officials, shared responses to a survey that solicited their members' concerns about implementing HPV vaccines. Key issues raised by the local health departments included how to vaccinate girls and young women who fall outside the bounds of public assistance given the limitations of the VFC program and Section 317.

States will receive VFC funding, but do not know what other funds to expect, said Claire Hannan, executive director of the Association of Immunization Managers (AIM). AIM members are involved in every aspect of vaccination, including distribution, purchasing, and provider and consumer education.

Uninsured individuals aged 9-18 years will be covered by VFC, and limited coverage for uninsured females aged 9-26 years may be available through Merck & Co.'s vaccine assistance program. Insured individuals are covered in theory, but AIM members are concerned that as new, expensive vaccines are added to the vaccine schedule, more insurance plans will not cover all the vaccines, Ms. Hannan said. ■

IOM Panel Urges Medicare to Morph Into Pay-for-Performance System

The U.S. Department of Health and Human Services should gradually replace Medicare's current payment system with a pay-for-performance system that would reward physicians and other providers for efficiency along with patient-centered, quality care, according to a report from the Institute of Medicine.

Pay-for-performance plans do not yet have an established track record of improving care, so IOM's report, "Rewarding Provider Performance: Aligning Incentives in Medicare," urges a phased-in program that will evaluate pay-for-performance initiatives as they are implemented.

Pay-for-performance will help transform the Medicare payment system into one that rewards both higher value and better outcomes, Robert Reischauer, Ph.D., president of the Washington-based Urban Institute, said at a press briefing sponsored by IOM. Dr. Reischauer served on the committee that wrote the report.

"The committee does not feel that pay-for-performance is the magic bullet," he said. "Pay-for-performance should be considered one of several key elements needed to restructure the current payment system."

Any changes in Medicare's payment sys-

tem would need to be approved by Congress. The panel's report urged lawmakers to adopt an initial system that would reduce base Medicare payments across the board and use the money to fund rewards for strong performance. At the same time, Medicare officials would evaluate the program to make certain it is having the desired effects.

The proportion of Medicare payment withheld would be small at first, and providers would be compensated both for excellent work and for improving their performance in areas that encompass care quality, efficiency, and "patient centeredness."

"We are recommending a performance-based system in which both excellence is rewarded and significant improvement is rewarded," Dr. Reischauer said. "Everyone can play and everyone can get back the money that was withheld initially from them."

Many large health care providers and organizations already have the capacity to begin participating in a Medicare pay-for-performance system and should be required to do so as soon as it is launched, the IOM report said.

—Jane Anderson