POLICY & PRACTICE

Bill for Paralysis Research, Rehab

Members of Congress have reintroduced legislation that would direct the National Institutes of Health to expand and better coordinate paralysis research. The Christopher and Dana Reeve Paralysis Act (H.R. 307) would also create a Clinical Trials Network to design and test rehabilitation protocols. Finally, the lawmakers want a national action plan to improve quality of life for people with paralysis by emphasizing independent living and self-sufficiency. "It is critical to help people with disabilities achieve and maintain their independence and to ensure that we are using the best research and technology to improve their quality of life," Rep. Jim Langevin (D-R.I.), a cosponsor of the legislation, said in a statement. In the past Congress, the bill passed the House but not the Senate.

Veterans Sue Over Experiments

The Vietnam Veterans of America and six individual veterans are suing the Defense Department, the Central Intelligence Agency, and the U.S. Army for failing to care for them after they helped test toxic chemical and biologic substances starting in the 1950s. The lawsuit, which was filed last month in the U.S. District Court in the Northern District of California, alleges that until at least 1976 the government used troops to test nerve gas, psychoactive chemicals such as LSD, and toxic substances without proper informed consent. The plaintiffs are not seeking monetary damages but want medical treatment for such veterans in the future. The lawsuit also calls on the government to disclose all medical information about tests performed on the plaintiffs. The complaint is available in full online at www.edgewoodtestvets.org.

Lilly Settles Zyprexa Charges

As anticipated, Eli Lilly & Co. has agreed to settle various federal complaints about its off-label promotion of its antipsychotic Zyprexa (olanzapine). Lilly pleaded guilty to a misdemeanor violation of the Food, Drug, and Cosmetic Act for the illegal promotion of Zyprexa for dementia from 1999 to 2001. The company will pay $615 million in that plea. Lilly did not admit to civil allegations against it, but it will pay $800 million to settle those charges. Of that amount, $438 million will go to the federal government and $362 million will be set aside for ongoing state investigations. The manufacturer also entered into a corporate integrity agreement with the government that requires Lilly to submit to third-party review of all of its policies and procedures.

Most Favor Family Consent

University of Michigan health researchers say that a nationally representative survey of older adults shows that most of them believe that it's acceptable for a family surrogate to give consent for a cognitively impaired person to be a research subject. The surveyors questioned 1,515 people who were aged 51 years and older who had been randomly selected from the government-funded National Health and Retirement Survey. The group members responded to questions about a family member giving consent for a patient to join one of the following four research scenarios: a lumbar puncture study; a randomized, controlled trial of a new drug; a similar trial of a vaccine; or a gene-transfer study. In all, 82% of the subjects said that consent by a surrogate was allowable for a drug trial, 72% for a lumbar puncture, 70% for a vaccine trial, and 67% for gene transfer. The federal government defers to states on when surrogate consent may be authorized, but the states' rules are far from clear, the researchers reported in the survey. Their survey results have been published in the Jan. 13 issue of Neurology.

FDA Warns of Supplement Risk

The Food and Drug Administration is warning consumers to immediately stop taking the dietary supplement Venom Hyperdrive 3.0. The product contains significant, undeclared amounts of the appetite suppressant sibutramine, according to the FDA. Sibutramine is the active ingredient in an approved weight-loss drug, but it can increase blood pressure and pulse. The agency warned that the ingredient could be dangerous for individuals with a history of stroke or heart disease. The supplement came in 90-capsule, red plastic bottles labeled UPC# 094922534743. For more information about the recall, contact Applied Lifescience Research Industries Inc. at legal@alrindustries.com.

New EHR Certification Options

The Certification Commission for Healthcare Information Technology plans to endorse ambulatory electronic health record products that offer advanced capabilities in four new areas: clinical research, dermatology, advanced interoperability, and advanced quality. The commission currently offers voluntary certification in both the ambulatory and inpatient settings to vendors of electronic health records that support basic clinical tasks, are able to send and receive information, and provide security for medical information. The new options for product certification would be added in 2010. The certification commission is recognized by the federal government as the official reviewer of products in health information technology. "It's the right time to add more flexibility to our approach, so we can fine tune our programs to meet everyone's needs for health information technology certification," the commission chair Dr. Mark Leavitt commented in a statement. He added that in the next few years, the commission may extend optional add-on certification to electronic records used in eye care, oncology, obstetrics and gynecology, advanced security, and advanced clinical decision support.

—Mary Ellen Schneider

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