

POLICY & PRACTICE

Assessing Pediatric Seizure Drugs

Officials at the National Institutes of Health are launching a large national trial to assess the safety and efficacy of two common seizure medications in the treatment of children with status epilepticus in the emergency department. Currently, diazepam (Valium) and lorazepam (Ativan) are prescribed based on the physician's judgment, but few data indicate which medication has the best safety and efficacy profile in children. "The Pediatric Seizure Study seeks to provide the most definitive information possible," Dr. Duane Alexander, director of the NIH's National Institute of Child Health and Human Development, said in a statement. Researchers at 11 hospitals will randomly assign children in status epilepticus to either lorazepam or diazepam. Because the medication must be administered within minutes of the patient's arrival at the ED, it will not be possible to obtain parental consent until the patients are stable, according to the NIH. The researchers will collect blood samples, and parents will be interviewed by phone after 48 hours and 30 days. Currently, diazepam is approved for use in adults and children. Lorazepam is approved to treat seizures in adults, but is prescribed off label for children. The study is being funded by the National Institute of Child Health and Human Development.

Stem Cell Victory in California

The California Supreme Court last month cleared the way for the state to

use bond funding to pay for a large-scale stem cell research initiative. The state's highest court refused to hear an appeal challenging the constitutionality of Proposition 71, the 2004 ballot initiative that called for spending \$3 billion for stem cell research. The California Institute for Regenerative Medicine, the state agency that is managing the initiative, has already issued \$158 million in grants financed through state loans and private funds. With the state Supreme Court action, the agency can now pay back those loans and move forward with the next round of funding.

ALS Registry Legislation Introduced

Senate Majority Leader Harry Reid (D-Nev.) introduced legislation that would create a single, national patient registry to collect data on amyotrophic lateral sclerosis (ALS). Under the legislation, the "Amyotrophic Lateral Sclerosis (ALS) Registry Act" (S. 1382), the registry would be housed at the Centers for Disease Control and Prevention. "Creating a national registry is crucial to understand patterns and examine causes of this debilitating disease," Sen. Reid said in a statement. If passed, it would authorize \$25 million in funding for fiscal year 2008 and additional funds to sustain the registry from 2009 through 2012. Sen. Reid originally introduced this legislation in the last session of Congress but it failed to gain traction. Meanwhile, Congress has provided funds to the CDC for pilot programs to support the development of an ALS registry. Rep.

Eliot Engel (D-N.Y.) introduced companion legislation (H.R. 2295) in the House.

OxyContin Maker Pays Fine

Purdue Pharma L.P. and three current and former executives pleaded guilty last month in federal court to criminal charges that they misbranded the company's product, OxyContin (oxycodone). The company agreed to pay about \$600 million in fines and other payments, while three top executives, including the company's president and its top attorney, agreed to pay a total of \$34.5 million in fines. Misbranding involves promoting a drug in unauthorized ways, potentially for unintended and unapproved uses. U.S. Attorney John Brownlee said that Purdue and its executives had deliberately downplayed OxyContin's potential for addiction when promoting it, and persuaded physicians to prescribe it.

Costs Grow for Medicare Drugs

Prices for 10 of the most prescribed brand-name medications have risen nearly 7% since December under Medicare Part D, though wholesale prices for the same drugs rose just 3%, investigators from the House Oversight and Government Reform Committee reported. The increases may indicate that despite initial success in containing prices, Part D may be losing leverage over drug makers, said to the investigators, who added Part D premiums rose 13% over the past year. Meanwhile, the rebates insurers get from drug manufacturers are less than expect-

ed. The committee looked at prices for the top 10 drugs of 2004, most of which have no generic alternatives. The cost of a month's supply of Lipitor (atorvastatin), for example, rose nearly 10% to over \$84 in mid-April, up from about \$77 in mid-December. Wholesale prices climbed 5% in that time. Pharmaceutical industry representatives disputed the panel's conclusions. "There is one big glaring omission in the Government Reform Committee's report: The Medicare prescription drug program continues to provide large cost savings to tens of millions of seniors and disabled Americans," PhRMA Senior Vice President Ken Johnson said in a statement. "The committee's report focuses on just a handful of medicines and tries to draw sweeping conclusions."

Hospital CEOs See MD Shortage

More than two-thirds of hospital CEOs responding to a survey identified physician shortages as a serious problem that must be addressed. Over three-quarters said the nurse shortage is a serious problem, according to the Council on Physician and Nurse Supply, which commissioned the survey from health care staffing company AMN Healthcare Inc. Almost all of the 400 CEOs said recruiting physicians was difficult or challenging, and almost all favored an expansion of physician training. In all, 86% are currently recruiting physicians; 80% of those are looking for primary care physicians, and 74% seek specialists.

—Mary Ellen Schneider

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