POLICY & PRACTICE

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FDA Accepts Historical Controls

The Food and Drug Administration has begun accepting historical controls for studies testing new antiepilepsy drugs in treatment-resistant patients. The agency decision followed a New York University study in the journal Epilepsia that found that patients who were controls in past epilepsy-drug studies can also be valid controls for future studies. Previously, the agency required an internal control group in studies. In those studies, patients received a test drug or a suboptimal, maintenance dose of an established drug. In the process, the patient would undergo a withdrawal phase followed by a monotherapy phase. But since new antiepilepsy drugs rarely demonstrate superiority to existing therapies, placebos or pseudoplacebos were the only acceptable internal controls but were unsuitable because of the control patients' risk of seizures. Studies with historical controls will attract more patients and physicians than have studies with internal controls, the authors said.

MRI Better Than CT Scan in Stroke

The American Academy of Neurology has issued a new guideline calling diffusion MRI superior to noncontrast CT scanning for the diagnosis of ischemic stroke within 12 hours of symptom onset. "Specific types of MRI scans can help reveal how severe some types of stroke are" and find lesions early, said Dr. Peter Schellinger of the Johannes Wesling Clinical Center in Minden, Germany, in a statement on the academy's Web site. According to the guideline, published in the journal Neurology, a major study showed that MRI accurately detected stroke 83% of the time, whereas the figure for CT scanning was 26%. The guideline didn't address MRI for the evaluation of cerebral hemorrhage. Noncontrast CT is the current diagnostic standard for acute stroke, according the statement, and is still appropriate, depending on availability, cost, and other factors. To read the guideline in detail, visit www.neurology.org/cgi/reprint/75/2/ 177.

Bill: Part D Should Cover Off-Label Uses

Rep. Mary Jo Kilroy (D-Ohio) has introduced a bill to require Medicare Part D coverage for many off-label uses of prescription drugs in chronic diseases such as multiple sclerosis. "Doctors and patients should be able to decide the best safe and effective medications for their treatments," said Rep. Kilroy in a statement on the National Multiple Sclerosis Society's Web site. The bill proposes off-label coverage when the use is supported by peer-reviewed medical literature and is recognized by the Department of Health and Human Services. Medicare Part B generally recognizes off-label prescriptions, but Part D doesn't cover such use for drugs prescribed to patients with most chronic diseases. Because Part D does cover off-label uses of cancer drugs, the bill is entitled the "Part D Off-Label Prescription Parity Act."

Preventive Training Supported

The Department of Health and Human Services has awarded 15 grants totaling $9 million to train about 55 residents in preventive medicine. Some of the funds come from the American Recovery and Reinvestment Act of 2009. The support will go to accredited schools of public health and medicine, as well as hospital-based residency programs, according to the agency. Griffin Health Services Corp., the parent company of Griffin Hospital in Derby, Conn., was awarded the top grant of $1.4 million. The Johns Hopkins Bloomberg School of Public Health received $1.1 million, and the University of California, Davis, received about $1 million, DHHS said.

FDA to Share Drug-Risk Findings

The FDA will post on its Web site summaries of postmarketing safety analyses on recently approved drugs and biologics, including brief discussions of steps that are being taken to address identified safety issues. The new summaries will cover side effects—including previously unidentified risks and known adverse events that occur more frequently than expected—that might not become apparent until after a medicine becomes available to a large, diverse population. The initial reports will contain information on drugs and biologics approved since September 2007, including several drugs for infections, hypertension, and depression, according to the agency.

—Naseem S. Miller