POLICY & PRACTICE

Von Eschenbach Confirmed for FDA

Almost 9 months after he was first nominated to be Food and Drug Administration commissioner, Dr. Andrew von Eschenbach finally was confirmed by the Senate by an 80-11 vote in the wee hours of the 109th Congress. Confirmation came after an 89-6 vote to limit debate on his nomination. The naysayers included Sen. Chuck Grassley (R-Iowa), one of Dr. von Eschenbach's most vocal critics. As chairman of the Finance Committee, he and his staff have been investigating what they call an inappropriate approval of Ketek (telithromycin). Sen. Grassley maintains that Dr. von Eschenbach has stonewalled committee investigators, and in an agitated floor statement during the nomination vote, he accused the nominee of hiding documents and intimidating FDA employees who dissented. Sen. Grassley warned his colleagues that Dr. von Eschenbach was a prime illustration of concerns about the lack of Senate oversight of the Bush administration. "I believe we need to send a message to the executive branch that it's not okay to impede congressional investigations. It's not okay to limit the Senate's access to documents, information, and employees of the executive branch," the senator said.

Researcher Pleads Guilty

A senior Alzheimer's disease researcher at the National Institutes of Health pleaded guilty this month to violating federal conflict of interest regulations. Dr. Pearson "Trey" Sunderland III, who served as chief of the geriatric psychiatry branch at the National Institute of Mental Health from 1997 to 2004, admitted to accepting approximately $300,000 in consulting fees and travel expenses from Pfizer Inc. without disclosure to and approval from NIH officials. In a federal "criminal information" filing made in December by the U.S. Attorney for the District of Maryland, Dr. Sunderland is alleged to have agreed to work as a consultant to Pfizer on two research projects that he was already involved with in his official capacity at NIH. Under an agreement with prosecuters, Dr. Sunderland faces 2 years of probation provided he forfeits the income and expenses from Pfizer, performs 400 hours of community service, and pays a yet-to-be determined fine. At press time, the NIH had no comment on the case. In a statement, Pfizer officials said the company's actions complied with applicable laws and ethical standards.

Coverage for Intracranial Stenting

Officials at the CMS announced plans to cover intracranial percutaneous transluminal angioplasty (PTA) and stenting for the treatment of cerebral artery stenosis of 50% or greater in patients with intracranial atherosclerotic disease. But Medicare coverage will include only PTA and stenting that is done under the auspices of a Category B Investigational Device Exemption clinical trial using FDA-approved protocols. Any other use is still uncovered. Prior to the new coverage decision, PTA of the carotid artery was covered by Medicare when it was performed on patients who were at high risk for carotid endarterectomy and who also had symptomatic carotid artery stenosis of 70% or greater, and performed in a Medicare-approved facility with FDA-approved carotid artery stenting systems and embolic protection devices. While the studies reviewed by CMS showed a benefit to the use of PTA and stenting, Medicare officials also noted that there was "insufficient evidence" to conclude that the devices should be used without some type of limitations. CMS is separately evaluating a request to expand coverage for humanitarian use devices such as the Wingspan Stent System, marketed by Boston Scientific Corporation.

Power Mobility Device Coverage

Medicare officials announced that CMS will increase the fees for complex rehabilitation power wheelchairs used by the severely disabled. Fees for standard geriatric mobility power wheelchairs will also increase. The price increases are intended to reflect the greater durability and performance of these chairs, compared with others, according to officials from CMS. The refinements are based on updated and validated information related to manufacturer applications and test results. For more information on the code, see: https://www.cms.hhs.gov/DMEPOSFeeSched/01a_Power_Mobility_Devices.asp.

Part D Model Guidelines

The United States Pharmacopeia (USP) has recently released a draft of the third version of the Medicare Part D Model Guidelines, which list therapeutic categories, pharmacologic classes, and key formulary drug types from which drug plans should offer medications. About 80% of Part D drug plans base their formularies on the guidelines. The USP expert panel will submit a finalized version of the guidelines to CMS officials by Feb. 5, 2007. The draft guidelines are available online at www.usp.org.

—Mary Ellen Schneider