Policy & Practice

U.S. Investigating Botox Promotions

The U.S. Attorney's office for the northern district of Georgia has subpoenaed Allergan, seeking documents that might show off-label promotion of Botox (botulinum toxin type A) for treatment of headache. The company confirmed the inquiry in a statement, and said that while it currently has Botox in phase III studies for headache, "it is Allergan's policy to promote its products only in a manner consistent with the FDA-approved product labeling." Allergan also intends to comply "with all applicable laws, rule and regulations," according to the statement. Botox is Allergan's second-biggest-selling product, with $1.2 billion in sales in 2007.

New Neurotechnology Legislation

In an effort to expand neurotechnology research at the federal level, Rep. Patrick Kennedy (D-R.I.) plans to introduce legislation that would create a National Neurotechnology Initiative within the federal government. The legislation would coordinate neurotechnology research and development at the federal level and in partnership with small businesses, authorize $80 million in fiscal year 2009 for the ongoing Blueprint for Neuroscience Research at the National Institutes of Health, and authorize an additional $30 million in FY 2009 to increase neuroscience staff at the FDA."With so many Americans suffering from brain-related illnesses, it is crucial for us as a society to maximize our efforts and continue learning about the many facets of the brain, leading to a healthier life for all Americans," Rep. Kennedy said in a statement.

Parkinson's Disease Data Available

Researchers can now access data from genomewide association studies on Parkinson's disease through the National Institutes of Health. The data will be added to dbGaP (the database of Genotype and Phenotype). Having access to these raw data will allow researchers to combine them with their own data to improve analytical power. The database contains individual-level data on genotype, genetic makeup, phenotype, and observable traits and characteristics, according to NIH. The data comes from a study conducted by researchers at the Mayo Clinic in Rochester, Minn., and Perlegen Sciences Inc. in Mountain View, Calif. This is the second genomewide Parkinson's study available through the NIH database. Researchers can access the information online at www.ncbi.nlm.nih.gov.

Fallout From Pay Uncertainty

Current uncertainties about Medicare payments is causing physician groups to postpone hiring and technology investment, and even to stop accepting new Medicare patients, according to a survey from the Medical Group Management Association. For example, 46% of respondents said that in light of a potential 10.6% cut in Medicare payments expected in July, they will refuse to accept new Medicare patients or will limit the number of new Medicare patients. Nearly 28% said they would limit the number of appointments for Medicare patients. The pending cut could also affect the implementation of health IT systems, including e-prescribing.

Woodcock Named CDER Head

Dr. Janet Woodcock has been named director of the FDA's Center for Drug Evaluation and Research. Dr. Woodcock, a rheumatologist, served as director of CDER once before, in the 1990s, and has served as acting director since October 2007. The drug industry's chief lobbying group, PhRMA, welcomed the appointment. Dr. Woodcock "has demonstrated willingness to work with diverse partners, including researchers, Congress, the White House, patients, and pharmaceutical research companies," said a statement from the group. But Public Citizen's health research group director Dr. Sidney Wolfe said in an interview that he's "not terribly hopeful" that Dr. Woodcock will lead the center well, because she doesn't like conflict or controversy. "She's aware of a number of drugs on the market that should be taken off the market, but I don't think she has the fortitude to do something about it," Dr. Wolfe said.

—Mary Ellen Schneider

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