POLICY & PRACTICE

Bergenstal Elected to ADA Post

Dr. Richard M. Bergenstal is the new vice president for medicine and science at the American Diabetes Association. Dr. Bergenstal, a researcher who focuses on the link between glucose control and diabetes complications, previously served on the ADA's board of directors as well as several association committees. He also previously chaired the association's Council on Clinical Endocrinology, Health Care Delivery, and Public Health. Dr. Bergenstal is executive director of the International Diabetes Center at Park Nicollet in Minneapolis and clinical professor of medicine at the University of Minnesota.

Questions About BTC Drugs

The House Energy and Commerce Committee is investigating the wisdom of behind-the-counter drug dispensing. The committee has asked the Government Accountability Office to update a study it conducted in 1995, "Nonprescription Drugs: Value of a Pharmacist-Controlled Class Has Yet to Be Demonstrated." At a November public meeting on the subject, the agency said it had no intention of establishing a new BTC class in the immediate future.

Scant Number of New Approvals

The FDA approved only 17 new molecular entities (NMEs) in 2007, the lowest number since 2002. This comes on the heels of 2 previous years with only 18 NME approvals each. NMEs are unique products. Those approved in 2007 included two HIV therapies, four oncology products, two antihypertensives, one antibiotic, and one each to treat Parkinson's disease, pulmonary hypertension, impetigo, acromegaly, attention-deficit hyperactivity disorder, and phenylketonuria. Also approved were an imaging agent and injection to prevent blood volume loss during surgery, a handful of biologics, an influenza vaccine, and an avian flu vaccine.

Docs Mistrust Error Reporting Systems

U.S. physicians are willing to report medical errors but don't trust the current error reporting systems, according to a study in the January/February issue of Health Affairs. Between July 2003 and March 2004, researchers surveyed more than 1,000 physicians in rural and urban areas of Missouri and Washington state. They found that because of their mistrust of current systems, most physicians rely on informal discussion with colleagues as a way to report and share information about errors. Most physicians also reported that they had been involved in an error—56% with a serious error, 74% with a minor error, and 66% with a "near miss." When asked what would increase their willingness to formally report errors, 88% said they wanted information to be kept confidential and nondiscoverable, 85% wanted evidence that error information would be used for system improvements, and 53% said they wanted review activities confined to their department. "These findings shed light on an important question—how to create error-reporting programs that will encourage clinician participation," said Dr. Carolyn M. Clancy, director of the Agency for Healthcare Research and Quality, which funded the study. "Physicians say they want to learn from errors that take place in their institution. We need to build on that willingness with error-reporting programs that encourage their participation."

Judge Overturns Rx Info Law

A federal judge has overturned a Maine law that would have restricted medical data companies' access to physician prescribing information. In a decision that relied heavily on a previous ruling in New Hampshire, U.S. District Judge John Woodcock said that the law would prohibit "the transfer of truthful commercial information" and would violate the free speech guarantee of the First Amendment. The Maine law was challenged on constitutional grounds by IMS Health, Wolters Kluwer Health, and Verispan, all medical data companies that collect, analyze, and sell such data to pharmaceutical manufacturers. The companies also argued that the law bucks a national trend toward greater transparency in health care information.

FDA Cancels DTC User Fee Program

The Food and Drug Administration recently announced that it is pulling the plug on a voluntary user fee program for direct-to-consumer television advertisements. The agency had planned to charge pharmaceutical companies about $40,000 per ad to review their DTC television spots. But in January, the FDA issued a notice saying that it would not go forward with the user fee program because no money was appropriated for the program in the fiscal year 2008 consolidated appropriations bill. Under the law that authorized the program, the agency can collect fees only up to the amount provided in advance by congressional appropriations. As a result, the FDA plans to review any ads already submitted at no charge, as resources will allow.

—Joyce Frieden