POLICY & PRACTICE

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Bill Calls for Coordinated Care

The American Association of Clinical Endocrinologists is urging Congress to create a National Diabetes Clinical Care Commission to coordinate federal efforts against the disease. Three Republican representatives from Texas introduced a bill to create the commission and encourage public-private efforts to make sure people with prediabetes and diabetes get needed care. "With annual rates of diabetes and prediabetes continuing to skyrocket, we need to have an honest discussion about what we're doing as a nation, and what is working and what is not working," Dr. Yehuda Handelsman, president of the association, said in a statement. Although 37 federal agencies have activities concerning the disease, the efforts aren't slowing the diabetes epidemic, according to Dr. Handelsman.

FDA Will Review Study

A Food and Drug Administration committee will review the results of Merck & Co.'s Study of Heart and Renal Protection, or SHARP, in a meeting Nov. 2. The 9,000-patient study is the first to show that a regimen of ezetimibe and simvastatin benefited patients with chronic kidney disease. Combining the two anticholesterol drugs reduced the relative risk of a major cardiovascular event by 16% vs. placebo in kidney patients with no history of heart disease. The Endocrinologic and Metabolic Drugs Advisory Committee will discuss Merck's application to relabel its ezetimibe-simvastatin combination (Vytorin) and ezetimibe (Zetia) in light of the SHARP results. This level of review of a "supplemental new drug application" is unusual, but areas of concern could include an absence of benefit in mortality or progression of renal disease, cancer risk, and questions about the study's end points.

Groups Fight Budget Cuts

As the Joint Select Committee on Deficit Reduction – the "Super Committee" – began its budget negotiations, the American Diabetes Association and other advocacy groups made their case against cuts to state Medicaid programs. Diabetes disproportionately affects low-income people, making Medicaid essential, according to the association. Currently, more than 950,000 people with diabetes are enrolled in Medicaid in Illinois, 550,000 in California, 350,000 in New York, and 260,000 in Texas, the diabetes association said in a report released by the Medicaid-advocacy group Families USA.

Companies Hit as Antigeneric

The Federal Trade Commission has issued a long-awaited report on the generic drug market and concluded that brand-name manufacturers have been actively discouraging copy-cat products. The brand-name makers often introduce their own generic versions to discourage generic-focused companies from entering the market when a patent runs out, the FTC said. The presence of an authorized generic tends to tamp down sales 40%-50% for a generic competitor, the agency said. FTC Chairman Jon Leibowitz said in a statement that "some brand companies may be using the threat of launching an authorized generic as a powerful inducement for generic companies to delay bringing their drugs to market." During that delay, consumers have to continue to pay the high price of the brand-name drug, he said.

Patients Think Newer Is Better

Patients are more likely to choose newer drugs over older when they're not provided information about the products' safety and effectiveness, according to a study published in Archives of Internal Medicine. The researchers gave participants a choice between two fictitious drugs for heartburn and two for high cholesterol. More people chose a drug described as older if they were also told the newer drug may not be as safe and effective. But for the heartburn drug, most people who were not given that warning chose the newer drug. In their Internet survey, the researchers also found that 39% of respondents believed that the Food and Drug Administration approves only "extremely effective" drugs and 25% believed the FDA approves only drugs without serious side effects.

–Naseem S. Miller