POLICY & PRACTICE

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ICD Maker Pleads Guilty

Boston Scientific has pleaded guilty to failing to report problems with a subsidiary's implantable cardioverter defibrillators (ICDs) to the Food and Drug Administration. Previously, the company paid $296 million in criminal penalties for making false statements to the FDA and failing to notify the agency about material changes to an ICD. Now, however, a federal judge in Minnesota has rejected the plea deal, saying that the government should have insisted on probation in addition to the fine to hold the company more accountable for its actions. It is not clear where the case will go from here. The devices in question were from subsidiary Guidant, which recalled them in 2005. But this March, Boston Scientific recalled eight of its own ICDs. The company said that it had neglected to notify the FDA about manufacturing changes, seemingly a repeat of the Guidant situation. In mid-April, the company said the FDA had approved a resumption of sales for two ICDs: the Cognis and the Telegen. Boston Scientific is still working with the FDA on five other models and hopes to resume sales soon, the company said.

Company Warned on Rings

Showing that it will continue to pursue paperwork and reporting violations, the FDA warned Irvine, Calif.–based Edwards Lifesciences that it failed to properly and promptly notify the agency about problems with several models of its annuloplasty rings. In the letter, the FDA said that six complaints "were not reported within 30 calendar days and are adverse events that resulted in a death or serious injury." The letter said that the warning related to inspections conducted in September 2009.

Cardiologists Are Reform Skeptics

A small survey showed that a majority of cardiologists are skeptical that health care reform will help them or their patients. The survey of 225 cardiologists was conducted in late March by MedAxiom, an information and networking resource for cardiologists based in Neptune, Fla. Eighty-one percent of those surveyed said they thought the law would hurt their practices, and 83% said their revenue would decrease; 71% said that the law would hurt their ability to serve patients.

Few Complaints to Device Office

The FDA's Center for Devices and Radiological Health (CDRH) has issued its ninth annual ombudsman's report on complaints, disputes, and inquiries from the industry, health care providers, and consumers. Of the 250 contacts to CDRH in 2009, 53% were complaints, 21% were to dispute an agency action, and 26% were inquiries. Source of contacts were 70% from industry, 17% from consumers, and 9% from health providers. Most of the complaints and disputes were about the agency's policies or procedures, followed by the agency's data or testing requirements. Safety or adverse events were the subject of only 4% of the contacts.

CV Admissions High for Women

The Agency for Health Research and Quality (AHRQ) reported that there were 2 million cardiovascular disease–related hospital stays for women in 2007, making it the second biggest reason for admission after pregnancy and childbirth. The reasons for admission included treatment of coronary artery disease, congestive heart failure, heart attacks, atrial fibrillation and other arrhythmias, and chest pain with no determined cause. Other top reasons for admission included pneumonia, osteoarthritis, depression and bipolar disorder, urinary tract infections, blood infections, and skin infections. The data is from the AHRQ's Healthcare Cost and Utilization Project report for 2007.

Generics 75% of Dispensed Drugs

More introductions of lower-cost generics dampened sales of brand name prescription drugs last year, but overall sales were still up 5%, according to IMS Health. U.S. sales grew to $300 billion, with 3.9 billion prescriptions dispensed in 2009. Generics made up 75% of dispensed prescriptions, an increase of almost 6% since 2008. Prescriptions dispensed as branded products decreased by almost 8%. There were 32 novel drugs introduced in 2009, but those "drove a limited increase in drug spending," IMS Senior Vice President Murray Aitken said in a statement. The top-selling class was antipsychotics, whose $14 billion in sales equaled the 2008 total. Proton pump inhibitors were second, hitting $13.6 billion in sales last year. Lipid regulators accounted for $13 billion in sales, a figure held down by generics, and antidepressants were fourth-largest in sales at $9.9 billion.

Pfizer Details Pay to Physicians

As part of a settlement with the federal government, Pfizer has posted its first report detailing how much it pays health care professionals for consulting and other duties, including clinical trial participation. No other company has detailed trial payments. The data, posted at www.pfizer.com/responsibility, show $35 million paid to 4,500 health care professionals from July 2009 to December 2009. According to the company, $15 million was for trial collaborations. About 1,500 people were paid an average of $5,000 for consulting, and 2,800 professionals were paid an average of $3,400 for speaking engagements. Pfizer's disclosures cover meals, travel expenses, and the cost of educational items such as pill dispensers and anatomical models if they are worth $25 or more. Next year, the company will report even the lower-cost transactions.

—Alicia Ault

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