Policy & Practice

Statin Use Soars

Americans spent $20 billion on statin medications in 2005. This was a massive rise from just 5 years earlier, when that tally was about $8 billion, according to the Agency for Healthcare Research and Quality. The 156% increase in spending went toward well-known drugs such as Lipitor, Lescol, Pravachol, and Zocor, the agency reported. In 2000, a total of 16 million people said they had purchased at least one statin. By 2005, almost twice as many people (30 million) had purchased a statin. Outpatient prescriptions of statins zoomed from 90 million to 174 million Each of the individuals who took a statin saw expenditures increase in this period from $484 per year to $661 annually. The AHRQ did not determine in its analysis how much of that expenditure was covered by insurers and how much of it was out-of-pocket cost to the individual patients. The AHRQ data are drawn from the Medical Expenditure Panel Survey, which details the health services that are used by civilian, noninstitutionalized Americans.

Speedier Device Reviews

The Food and Drug Administration reports that it is reviewing medical devices more quickly than it has in the past, but it is not by much. And they reported that the number of submissions directed to the agency has declined both for breakthrough devices—called premarket approval (PMA) applications—and for those devices that are substantially equivalent to those already on the market—known as 510(k) applications. The agency's Office of Device Evaluation received a total of 31 PMAs in fiscal 2007, compared with 66 submissions in fiscal 1997. In fiscal 2007 there were a total of 3,192 510(k) submissions, compared with 5,049 in fiscal 1997. Of the 2007 submissions, 2,640 were approved. The number of supplemental PMA applications, however, has been increasing. A supplemental PMA usually seeks an additional indication or use for the same device. The average time it took to review original and supplemental PMA applications by the FDA has declined somewhat since the agency began charging the device companies a fee for review in 2002—dropping from 292 days in that fiscal year to 283 days in fiscal 2006. The FDA has not reported fiscal 2007 data yet because many of those products were still under review at the time the report was being compiled.

Dems Seek to Restore Device Suits

Democrats in the House of Representatives were not happy when the U.S. Supreme Court ruled in February that device makers are immune from state lawsuits brought by patients who allege that they were harmed by a product that was approved by the FDA under the premarket approval process. House Democrats have introduced a bill, the Medical Device Safety Act of 2008 (H.R. 6381), in order to reverse that decision. The charge is being led by Reps. Frank Pallone (D-N.J.) and Henry Waxman (D-Calif.), and the bill now has 64 cosponsors. A companion bill is expected to come from Sens. Edward Kennedy (D-Mass.) and Patrick Leahy (D-Vt.), but had not been introduced at press time. The Supreme Court ruling in *Reigel v. Medtronic Inc.* "ignores both congressional intent and 30 years of experience in which FDA regulation and tort liability played complementary roles in protecting consumers from device risks," according to a joint statement from Reps. Pallone and Waxman. The device industry trade group AdvaMed criticized the "patchwork approach" that has been in existence thanks to the allowance for state suits and said that H.R. 6381 "will not improve patient safety but will result in needless delays in patient access to essential medical technologies, more lawsuits, and ultimately higher health care costs."

Feds Scrutinize Generic Maker

India's Ranbaxy Inc.,which is one of the top 10 generic drug makers in the world, is now being investigated by various arms of the U.S. federal government for allegedly introducing "adulterated or misbranded products" into the United States market. In addition, the company's auditor, Parexel Consulting, has come under federal scrutiny for violations. According to a subpoena for documents that was filed in the U.S. District Court for the District of Maryland by the Department of Justice and the U.S. Attorney's Office in Maryland, Ranbaxy Inc. allegedly submitted false information to the U.S. Food and Drug Administration regarding sterility and bioequivalence, covered up good manufacturing practice violations, and defrauded Medicare. Reps. John Dingell (D-Mich.) and Bart Stupak (D-Mich.) said that they would formally investigate the Ranbaxy situation. "If these allegations are true, Ranbaxy has imperiled the safety of Americans in a manner similar to the generic drug scandal we uncovered 20 years ago," said Rep. Dingell. "I would like to know whether FDA officials knew about these allegations and what, if any, action was taken."

Medicare Issues PQRI Payments

Physicians who successfully reported their quality measures to Medicare in 2007 as part of the Physician Quality Reporting Initiative should have received their bonus payments last month. Officials at the Centers for Medicare and Medicaid Services recently announced that they had already paid out more than $36 million in bonuses to physicians and other health professionals as part of the PQRI. Of the approximately 109,000 health care professionals who reported data on Medicare services provided during July-December 2007, more than 56,700 met the reporting requirements and would be receiving bonus checks, according to the CMS. The average bonus paid to an individual provider was more than $600, and the average bonus for a physician group practice was more than $4,700. The largest payment to a physician group practice was more than $205,700, the CMS.reported. "These payments to physicians for participating in the PQRI are a first step toward improving how Medicare pays for health care services," Kerry Weems, acting administrator, said in a statement. Under the PQRI, physicians could earn bonus payments of up to 1.5% of their total allowed Medicare charges by successfully reporting quality data for Medicare services provided from July to December 2007. In addition to the bonus payments, physicians and other health professionals can also start accessing confidential feedback reports on their performance. To access the feedback reports, providers must register with the Individuals Authorized Access to CMS Computer Services–Provider Community (IACS-PC). More information on the program is available at www.cms.hhs.gov/pqri.

—Alicia Ault

CLASSIFIEDS

www.ecardiologynews.com

PROFESSIONAL OPPORTUNITIES

2008 Classifieds

Cardiology News Rates
4 Column Classified Ads
From 1" to 12"
Sizes from 1/48th of a page to a full page

For Deadlines and More Information Contact:
Brian Vishnupad
360 Park Avenue South
New York, NY 10010
Tel: 212-633-3129
or fax your ad to: 212-633-3850
Email ad to: b.vishnupad@elsevier.com

Moving?
Look to Classified Notices for practices available in your area.

Disclaimer

Cardiology News assumes the statements made in classified advertisements are accurate, but cannot investigate the statements and assumes no responsibility or liability concerning their content. The Publisher reserves the right to decline, withdraw, or edit advertisements. Every effort will be made to avoid mistakes, but responsibility cannot be accepted for clerical or printer errors.