More Postmarketing Data to Be Shared on FDA Web Site

BY ALICIA AULT
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WASHINGTON — Food and Drug Administration officials said they have started several new initiatives in response to the Institute of Medicine's call to overhaul drug safety efforts. The projects, including one to more closely monitor the postmarketing safety of four new molecular entities and a plan to put more postmarketing data on the agency's Web site, were revealed at a meeting sponsored by the IOM.

In a September 2006 report lambasting FDA's safety oversight, the IOM called on the agency to issue an interim report on selected drugs' postmarketing safety at least 18 months, and no longer than 5 years, after launch.

"Five years is too late to find out what a drug is doing," said Dr. Robert Temple, associate director for medical policy at the FDA.

The FDA's Center for Drug Evaluation and Research has begun a pilot project with four new molecular entities to pull together all available data at 1, 2, and 3 years after launch. Officials will look at the Adverse Events Reporting System database, ongoing postmarketing studies, and other data to see how much can be learned about each drug at each time point, said Dr. Temple. He would not disclose which drugs are part of the pilot.

The FDA also plans to publish on its Web site up-to-date information on a drug's postmarketing experience.

In addition, the IOM report urged Congress to give the FDA greater enforcement powers to compel pharmaceutical manufacturers to fulfill commitments to gather postmarketing data.

Peter Barton Hutt, a former FDA general counsel and now senior counsel with Covington and Burling in Washington, said FDA had all the enforcement power it needed already; however, it does need more funding outside of the user fees it collects.

Critics have said the FDA is unduly beholden to industry because of user fees. Former FDA Deputy Commissioner Mary Pendergast noted that fees were likely to make up 80% of the agency's drug review and safety budget if Congress did not provide additional money for fiscal 2007.

She also noted that as of fiscal 2006, companies had 1,632 pending postmarketing commitments. The number of studies being requested is on the rise, said Ms. Pendergast, noting that the average was 1.5 per approved drug before 2003 and 5 per approved drug in 2003-2004.

In the fiscal 2006 report to Congress, 63% of those studies had not been started, she said. ■

ACC Planning to Develop a Registry of Outpatient Data

BY ALICIA AULT
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The American College of Cardiology's burgeoning stable of registries will likely include one to collect outpatient data by late this year or early next year, according to the organization.

Ten years ago, the ACC launched the National Cardiovascular Data Registry (NCDR). It has subsequently launched the CathPCI Registry, the ICD Registry, and, just last year, the CARE (Carotid Artery Revascularization and Endarterectomy) Registry, all of which are centered on hospital-based procedures.

Clearly, outpatient data represent both a gap and an opportunity, Dr. Ralph Brindis, chief medical officer for the NCDR, said in an interview. "As we've developed an increasing portfolio, there's been a lot of interest among cardiologists and payers, and interest from the American Board of Internal Medicine, in how we can actually assess quality in the outpatient arena," he continued.

Pharmaceutical manufacturers are also interested in outpatient registries to help assess long-term safety and efficacy of medications, he said.

The outpatient effort, tentatively dubbed IC3 (Improving Continuity in Cardiac Care), is in the beginning stages, with protocols, data collection tools, and reports being developed. After securing industry funding for the launch, the registry will be piloted at 100-150 physician offices across the United States next summer, Dr. Brindis said. Within a year, ACC hopes to have 400 offices enrolled and perhaps more than 1,000 in 2-3 years.

Initially, the focus will be on patients who are post discharge for acute coronary syndrome. Physicians will be asked to submit data on meeting performance goals related to prescribing evidence-based therapies such as aspirin, β-blockers, and ACE inhibitors, and how well patients and physicians do in meeting cholesterol goals.

Over time, measures will likely expand to meeting benchmarks for hypertension and heart failure treatment, and perhaps appropriateness of imaging studies, Dr. Brindis said. Eventually, the registry might be used to help physicians meet reporting needs and maintain certification through the ABIM, he said.

The registry would be voluntary. Dr. Brindis said there would be some effort to make it manageable for practices that aren't heavily invested in health information technology.

Also, Dr. Brindis said, the ACC might initially provide payments to the pilot participants, but, he added, "In the long run, hopefully, there would be so much added value that we wouldn't pay them to participate." ■

POLICY & PRACTICE

CMS Extends Form Deadline

The Centers for Medicare and Medicaid Services has extended the deadline for filing Medicare claims using its new version of claims form CMS-1500, because of formatting errors on the revised form, CMS announced. The original deadline for switching to the new form—known as CMS-1500 (08/05)—originally was April 2. But CMS said last month that contractors have been directed to continue to accept the old form until the agency notifies them to stop. Additionally, the agency advised physicians who must use the form to use legacy provider numbers, as the form cannot accommodate a National Provider Identifier (NPI) number.

New Imaging-Cut Moratorium

Several members of Congress introduced legislation last month to place a 2-year moratorium on cuts to Medicare payments for medical imaging that went into effect this year. The bill also requires a Government Accountability Office study of patient access to imaging. The bill—H.R. 1293—was introduced by Reps. Carolyn McCarthy (D-N.Y.), Gene Green (D-Tex.), and Joseph Pitts (R-Penn.), and had 49 cosponsors at press time. Rep. Pitts sponsored similar legislation in the last Congress; the cuts were mandated as part of the Deficit Reduction Act of 2005. A Senate companion bill is expected soon. Under the DRA, payments for the technical component of an imaging service are to be set at the hospital outpatient-department rate, if the payment under the Medicare physician fee schedule is higher. The Access to Medical Imaging Coalition said that a new report by the Moran Co. shows that the DRA mandate means physicians face reimbursement that's 18%-19% below that for outpatient departments. "The fact is, the DRA has decimated the imaging payments received by cardiologists, radiologists, and other providers," said Tim Trysla, executive director of the coalition.

Stroke Networks Supported

The House Energy and Commerce Committee has approved the Stroke Treatment and Ongoing Prevention Act of 2007 (H.R. 477). That bill was introduced by Rep. Lois Capps (D-Calif.) and Rep. Charles Pickering (R-Miss.), and would fund a public awareness campaign to urge Americans to seek prompt treatment. It will also provide funds for the Paul Coverdell National Acute Stroke Registry and Clearinghouse at the Centers for Disease Control and Prevention, and also $50 million in grants from fiscal year 2008 to fiscal year 2012 to promote telemedicine to broaden access to immediate and high-quality stroke care. "The STOP Stroke Act will help save lives by enhancing awareness about stroke symptoms and ensuring that those who suffer a stroke are treated as rapidly as possible with the most appropriate therapy," said Dr. Ralph Sacco, chairman of the American Stroke Association Stroke Advisory Committee.

Heart Hospitals = More Procedures

A study in the March 7 Journal of the American Medical Association found a higher volume of cardiac revascularization procedures in areas that gained specialty heart hospitals. Overall, the mean procedural volume in Medicare beneficiaries was fourfold higher at specialty hospitals than at cardiac programs at general hospitals, said the authors from the University of Michigan, Ann Arbor; the VA Ann Arbor Healthcare System; Harvard Medical School, Boston; and Yale University, New Haven. "These findings raise the concern that the opening of cardiac hospitals may lead to greater procedural utilization beyond the simple addition of capacity to a market," they wrote. The rate of percutaneous coronary interventions (PCI) was higher for patients who had not had an acute myocardial infarction, which was of concern because the benefits of PCI in this group are not clear, said the author. There are several potential explanations for the higher volume: physician owners who refer for financial gain; specialty facilities that perhaps open in markets that are predisposed to higher revascularization rates because of patient characteristics; or general hospitals that more aggressively compete with the specialty facilities, driving up overall volume. The Agency for Healthcare Research and Quality paid for the study.

Prescription Drug Sales Up

U.S. prescription drug sales grew more than 8% to $275 billion in 2006, fueled by the Medicare Part D prescription benefit, increased use of generics within new therapy classes, and new drug launches, said the pharmaceutical data firm IMS Health Inc. Total dispensed prescriptions grew at nearly a 5% pace, compared with slightly more than 3% in 2005, the firm said. Part D was a large driver of the upward trend, lifting prescription volume by an estimated 1 to 2 percentage points and pharmaceutical sales by about 1 percentage point. The benefit "increased prescription coverage to the previously uninsured and underinsured, and provided generous plan benefits to seniors," said Diana Conmy, corporate director, IMS Market Insights, in a statement. Sales of prescription drugs in the United States are expected to decline in 2007, IMS Health said.

FDA to Study DTC Risk Data

The Food and Drug Administration says it is concerned about how much risk information is disclosed to consumers in print ads and that the information is not usually in a consumer-friendly format. The agency plans to study how to improve the presentation of such information. One study will look at whether giving consumers more context—instead of a list of risks, for instance—will aid their understanding of a product's potential downside. Another will look at the usefulness of several different formats for presenting the data. Comments on the proposed testing will be accepted until mid-April.

—Alicia Ault