POLICY & PRACTICE

Carotid Registry Opened

The Carotid Artery Revascularization and Endarterectomy (CARE) Registry, developed by the American College of Cardiology and the Society for Cardiovascular Angiography and Interventions, is open for business. As with other components of the National Cardiovascular Data Registry (NCDR), hospitals that participate will be meeting data collection requirements for Medicare payment. Data can even be retrospectively collected, going back to March 2005. Categories include device and lesion characteristics; adverse event rates, including 30-day outcomes; and patient, provider, and facility characteristics. Currently, data can be collected on paper and submitted via a complimentary data entry service offered by the registry. Beginning in January 2007, data can be submitted online at a new NCDR Web site. Participants will receive quarterly and annual benchmark reports that will give data such as comparisons between stent and endarterectomy complications, and the relative outcomes within the registry population.

CMS Incentive Payment Demo

The Center for Medicare and Medicaid Services is seeking participants for a 3-year demonstration project beginning in 2007 in which hospitals would offer incentive payments to physicians for improved quality and efficiency. CMS said it would give preference to consortiums consisting of up to 12 physician groups and their affiliated hospitals in a single geographically contiguous area. The Physician-Hospital Collaboration Demonstration will be extended to only 72 hospitals total, said CMS. The agency is looking for long-term outcomes such as mortality and readmission rates. Participants must document an episode of care from hospitalization to postdischarge and beyond. Hospitals would, for instance, offer incentive payments to surgeons for lower infection rates and fewer readmissions with complications, said CMS. Those payments would be limited to 25% of the normal pay for those cases. To apply, go to www.cms.hhs.gov/DemoProjectsEvalRpts/.

FDA Advisers: Pushovers?

A report by the Washington-based National Research Center for Women and Families claims that the Food and Drug Administration's outside advisers are pushovers when it comes to challenging drug and device applications. They analyzed voting records of a random sample of six drug advisory panels and five medical device panels from 1998 to 2005, and found a 76% approval rate for new drugs and 82% rate for new devices. The FDA does not have to follow the experts' advice, but it generally does. Of the 38 drugs recommended, all were approved by the FDA except one whose application was withdrawn by the manufacturer. The agency also approved 4 of the 11 drugs that received a negative vote. Only 50% of the reproductive health drugs were backed, compared with 100% of the products that came before the arthritis drugs advisory committee. Sixty-seven percent of microbiology devices were backed, as were 88% of ophthalmic devices. After reviewing transcripts, the researchers found that advisory panel members often expressed strong concerns about safety or efficacy, but voted to recommend approval anyway. Some committee members admitted that their votes may not have been consistent with their concerns. "Whatever the reasons, many of today's FDA drug and device advisory committees are rubber stamps for approval almost every time they meet," wrote the researchers.

Merck Executives Exonerated

Retired U.S. District Court Judge John S. Martin Jr. has determined that Merck & Co.'s executives did not knowingly mislead consumers or physicians on the cardiovascular safety of its cyclo-oxygenase-2 inhibitor, Vioxx. The judge was hired by Merck's board of directors. Over 20 months, Judge Martin and his staff reviewed the scientific literature and documents submitted in some 14,000 personal injury suits and interviewed 115 witnesses, including 100 former and present Merck employees. After talking with senior scientists, the judge said, "We are satisfied that, prior to receiving the cardiovascular results of the APPROVe trial, none of them believed that Vioxx was prothrombotic." The scientists urged that Vioxx be promptly withdrawn, which the company did, despite contrary advice from outside advisers, said the report. "This conduct is not consistent with the view that Merck's corporate culture put profits over patient safety," wrote the judge. Merck's board issued a statement that it "is reassured by the fact that, in reviewing numerous allegations of wrongdoing, the Martin Report concludes that management acted with integrity and had legitimate reasons for making the decision that it made, in light of the knowledge available at the time." The full report is available on Merck's Web site at www.merck.com/newsroom/vioxx/.

—Alicia Ault

Sales of Generic Clopidogrel Halted Pending Trial Outcome

BY ELIZABETH MECHCATIE
Senior Writer

A federal judge has ordered the manufacturer of generic clopidogrel to stop selling the product but not to recall the stock that remains in pharmacies, which, according to the ruling, had been used to fill almost 80% of clopidogrel prescriptions.

On Aug. 31, the U.S. District Court for the Southern District of New York granted the motion filed by Sanofi-Aventis requesting a preliminary injunction that prohibits the Canadian generic manufacturer, Apotex Inc., from selling its generic formulation of clopidogrel, until a patent infringement case filed against Apotex is resolved. The court, however, did not order Apotex to recall the generic clopidogrel product that has already been distributed.

In early August, Apotex launched its generic clopidogrel amid patent litigation with marketers of clopidogrel (Plavix), Bristol-Myers Squibb Co. (BMS) and Sanofi-Aventis, and a federal investigation of the latter companies.

The generic clopidogrel was used to fill most prescriptions. BMS and Sanofi-Aventis moved for a preliminary injunction in U.S. District Court for the Southern District of New York ordering Apotex to halt sales and recall existing inventory, and a hearing was held on Aug. 18.

The court's opinion stated that Sanofi had "adequately demonstrated" that questions Apotex raised about the validity and enforceability of the clopidogrel patent were "without substantial merit" based on the evidence to date, and that Sanofi had "demonstrated a likelihood of success on the merits at trial." The Court also ordered Sanofi and BMS to post a $400 million bond, as security for Apotex in case the final ruling favored the generic company. A trial date has been set for Jan. 22, 2007.

At the time of the hearing, one generic clopidogrel pill cost $1.10 less than the price of one Plavix pill before Apotex launched the generic, and 78.4% of all clopidogrel prescriptions were being filled with the generic product, according to the opinion. The document refers to testimony made at the hearing that there were 48 million people who used clopidogrel daily. ■

CMS Awaits McClellan Successor

With the fight underway to avoid a proposed 5.1% physician payment cut under Medicare slated to take effect in January, it's unclear who will be leading the agency responsible for administering Medicare.

Dr. Mark B. McClellan resigned as administrator of the Centers for Medicare and Medicaid Services in early September after a 2½-year tenure with the agency. At press time, no acting or permanent replacement had been named by the White House.

Dr. McClellan, who previously served as commissioner of the Food and Drug Administration and as an economic adviser to President Bush, said that he is considering a move to a Washington-area think tank in the short term. He is also on leave from Stanford (Calif.) University, where he holds teaching posts in medicine and economics.

In a press briefing announcing his resignation, Dr. McClellan said he will stay on at CMS for the next few weeks to aid in the transition, which he expects to be wrapped up by early October.

Dr. McClellan said that after several years in government service, he wanted to spend less time on the road and more time with his family. "This kind of decision is never easy, and there's never a great time for it," he said.

He took the reins at CMS just months after the passage of the Medicare Modernization Act and has presided over the transition to the Medicare Part D drug benefit.

There has been momentum on all new initiatives at CMS, including the Part D benefit, he said. Dr. McClellan touted the progress of the Part D program, including lower-than-forecast beneficiary costs and an overall high rate of participation and beneficiary satisfaction. And regardless of the outcomes of this year's midterm congressional elections, Dr. McClellan said he expects to see continued congressional oversight of the program. "We should keep looking closely at it," he said.

The American Medical Association praised Dr. McClellan's expertise and experience as a physician and called for a replacement who would bring similar qualifications to the job. "It is our hope, that before leaving CMS, Dr. McClellan will intensify his efforts to help physicians provide the best possible care to Medicare patients by supporting congressional efforts to ensure that the 2007 Medicare physician payment update will reflect the increase in physicians' practice costs," Dr. Cecil B. Wilson, AMA board chair, said in a statement.

Dr. McClellan is board certified in internal medicine and earned a PhD in economics from the Massachusetts Institute of Technology. In addition to his work in the Bush administration, Dr. McClellan served in the Treasury Department under President Clinton. Before working in the federal government, Dr. McClellan was an associate professor of economics and medicine at Stanford University.

—Mary Ellen Schneider

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