

More Postmarketing Drug Information to Go Online

BY ALICIA AULT

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WASHINGTON — Food and Drug Administration officials said in March they have started several new initiatives in response to the Institute of Medicine's call to upgrade and overhaul its drug safety efforts.

The projects, including a pilot project 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 that lambasted the 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, the FDA's associate director for medical policy. The Center for Drug Evaluation and Research (CDER) has begun a pilot project with four new molecular entities to gather data at 1, 2, and 3 years after launch, he said. He declined to name the drugs.

The agency also plans to publish a newsletter on its Web site to provide up-to-date information on a drug's postmarketing experience, said Dr. Ellis Unger, acting deputy director for science at CDER's Office of Surveillance and Epidemiology.

The IOM report also urged Congress to give the FDA greater and more precise enforcement powers, partly to compel drug manufacturers to fulfill their commitments to gather postmarketing data.

Peter Barton Hutt, a former FDA general counsel and now senior counsel with Covington & Burling in Washington, said the agency already has all the enforcement power it needs, but that it needs more funding outside of the user fees it collects.

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

In a report to Congress (fiscal 2006), 63% of postmarketing studies had not been started. The agency needs a better hammer to get those studies done, she said. ■

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POLICY & PRACTICE

Ex-FDA Chief Fined

Former Food and Drug Administration Commissioner Lester Crawford, D.V.M., Ph.D., has been sentenced to 3 years of supervised probation and fines of slightly less than \$90,000 for charges stemming from his ownership of stock in companies regulated by the FDA. The penalty exceeded a \$50,000 fine in a plea agreement Dr. Crawford and federal prosecutors struck last year but still spared the former FDA chief jail time. U.S. Magistrate Judge Deborah Robinson of the District Court for the District of Columbia also ordered Dr. Crawford to perform 50 hours of community service. Dr. Crawford resigned his FDA administrator post in September 2005 after just 2 months and did not give a reason for his resignation. In October 2006, he pleaded guilty to charges of having a conflict of interest and false reporting of information about stocks that he and his wife owned. Prosecutors said that Dr. Crawford filed seven incorrect financial reports with a government ethics office and Congress beginning in 2002.

Insurance Cost Sharing

Fewer than 24% of private sector employees covered by employer-sponsored health insurance do not pay a portion of their own premium, down from 35% in 1998, according to a report from the Agency for Healthcare Research and Quality. In both years, employers were more likely to offer no-contribution single coverage than no-contribution family coverage; 18% of employees eligible for health insurance from their employer in 1998 worked in a firm that offered at least one family coverage plan that required no employee contribution, but by 2004, that rate had fallen to 13%, the report said.

Majority Want Access Guarantee

Nearly two-thirds of Americans believe the federal government should guarantee access to health care, and 60% are willing to pay more in taxes for that guarantee, according to a poll released last month by the New York Times and CBS News. Half of those polled said they would be willing to pay as much as \$500 a year in additional taxes, while nearly 8 in 10 said they thought it was more important to provide universal access to health insurance than to extend the Bush administration's tax cuts. In addition, a quarter of those with insurance said that they or someone in their household had gone without a medical test or treatment because insurance would not cover it; 60% of those without insurance reported the same situation. The nationwide telephone poll of 1,281 adults was conducted in late February 2007.

Hospital Demonstration Extended

The Centers for Medicare and Medicaid Services has approved a 3-year extension of the Premier Hospital Quality Incentive Demonstration (HQID), a value-based purchasing project involving

more than 260 hospitals across the country. Recently released second-year results of the demonstration show "substantial improvement" in quality of care across five clinical focus areas, including acute myocardial infarction, heart failure, coronary artery bypass graft, pneumonia, and hip and knee replacement, with total gains in quality over the first 2 years of 11.8 percentage points, CMS said in a statement. The hospitals involved have received incentive payments for providing high-quality care. During the first 3 years of the project, only top-performing hospitals have been eligible for incentive payments, but the 3-year extension will test the effectiveness of offering incentive payments to hospitals achieving a defined level of quality (or quality threshold) or achieving the greatest improvement in quality and a quality threshold.

Medicaid Growth Sustainable

Expected growth in government revenues is likely to be large enough to sustain Medicaid spending increases over the next 40 years while still allowing substantial real growth in spending for other public services, according to a study published in the Feb. 23 edition of the journal *Health Affairs*. The analysis by the Kaiser Family Foundation's Commission on Medicaid and the Uninsured looked at both potential long-term Medicaid spending and the availability of government revenues to support it. "While a substantial component of state government spending, Medicaid is not likely to be the financial burden squeezing out other public priorities that some policy makers fear," said study coauthor Richard Kronick of the University of California, San Diego, in a statement. After accounting for demographic and health coverage trends such as an aging population and declines in employer-sponsored insurance, the study found that Medicaid's share (17% in 2005) of national health expenditures is expected to remain about the same until 2025 and then rise slowly to 19% by 2045. "Efforts to reduce the growth in Medicaid by shifting costs or threatening coverage will ultimately require better controlling the rate of growth of health spending overall," Diane Rowland, executive director of KFF's commission said in a statement.

Hospitals Embrace IT

Nearly half of all community hospitals reported moderate or high use of health information technology (IT) in 2006, compared with 37% in 2005, according to recent survey results from the American Hospital Association. Hospitals also reported dramatic increases in the use of computerized alerts to prevent negative drug interactions; in 2006, 51% of hospitals were using real-time drug interaction alerts, up from 23% in 2005. Larger hospitals were more likely than smaller hospitals were to have heavy use of health IT, AHA said.

—Jane Anderson