More Postmarketing Data to Be Shared on FDA Web Site

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WASHINGTON — Food and Drug Administration officials said in March that 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.

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In a September 2006 report that lambasted 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.

"I think 5 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 (CDER) 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 particular 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 a newsletter on its Web site that will 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.

He promised a full accounting but noted that the agency will not disclose any proprietary information.

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

Peter Barton Hutt, a former FDA general counsel and now senior counsel with Covington and Burling in Washington said that most companies comply with FDA requests because "industry is terrified of FDA." Mr. Hutt said FDA had all the enforcement power it needed already. He argued that the agency did, however, need more funding outside of the user fees it collects.

FDA critics have said the agency is unduly beholden to industry because of user fees. Former FDA Deputy Commissioner Mary Pendergast noted that 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 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 most recent report to Congress (fiscal 2006), 63% of those studies had not been started, she said. The agency needs a better hammer to get those studies done, said Ms. Pendergast. ■

May 23 Deadline Coming to Sign Up for National Provider Identifier

The clock is ticking for physicians to sign up for a National Provider Identifier, the new 10-digit number that will be used by Medicare, Medicaid, and many private health plans to process claims.

The deadline for registering for an NPI number is May 23. Physicians who are not using an NPI number after that date could experience cash flow disruptions, according to the Centers for Medicare and Medicaid Services.

Most health care plans and all health care clearinghouses must begin using NPIs to process physicians' claims in standard transactions by May 23. Small health care plans have another year to become compliant.

"The NPI is the new standard identifying number for all health care billing transactions, not just for billing Medicare or Medicaid," said Aaron Hase, a CMS spokesman. As of Jan. 29, more than 1.6 million NPIs had been assigned, according to CMS.

Physicians and other providers can apply for an NPI online or by using a paper application. Hospitals or professional associations can submit applications for several physicians in an electronic file.

A physician who submits a properly completed electronic application could have his or her NPI in 10 days. However, it can take 120 days to do the remaining work to use it, Mr. Hase said.

One thing to be aware of is that you may already have an NPI, because some large employers may have already registered their providers, Mr. Whitman said.

The next question is how widely CMS plans to disseminate the NPIs. CMS officials have said they are considering creating some type of directory of NPIs that could be available to physicians and office staff.

—Mary Ellen Schneider

Physicians can apply for an NPI online at https://nppes.cms.hhs.gov or call 800-465-3203 to request a paper application.

POLICY & PRACTICE

Obesity Ups Workers' Comp Costs

Obesity can have a negative effect on workers' compensation costs for employers, according to a study by Duke University researchers. The study looked at records of nearly 12,000 Duke employees over a 7-year period and found that obese workers filed twice as many workers' compensation claims and had medical costs seven times higher than those of nonobese workers. They also lost 13 times more work days because of work-related injuries and illnesses. "Given the strong link between obesity and workers' compensation, maintaining healthy weight is not only important to workers but should also be a high priority for employers," said Dr. Truls Ostbye, professor of community and family medicine at the university and lead author of the study. "Work-based programs designed to target healthful eating and physical activity should be developed and then evaluated as part of a strategy to make all workplaces healthier and safer." The study appeared in the April 23 issue of Archives of Internal Medicine.

Osteoporosis Audit in the Works

European experts are planning an audit to determine the status of osteoporosis in Europe. Current estimates are that in the European Union, an osteoporosis-related fracture occurs every 30 seconds, and with an aging population, the number of osteoporosis-related hip fractures is expected to double from about 500,000 to 1 million annually over the next 50 years, according to the International Osteoporosis Foundation (IOF). The IOF supports the EU Osteoporosis Consultation Panel, the group planning the audit. "We need this new [audit] to evaluate current standards of osteoporosis management in Europe," said Juliet Compston, chair of the consultation panel. "This comprehensive snapshot will enable members to assess developments over the years, and identify areas that require more attention."

ADA Launches 'CheckUp America'

The American Diabetes Association has launched a campaign to help Americans learn how to lower their risks of type 2 diabetes and heart disease. The "CheckUp America" campaign, which is funded by several pharmaceutical companies, includes an online risk assessment called My Health Advisor. Based on an individual's self-reported health status, the tool will assess the person's risk for type 2 diabetes, heart attack, stroke, and death, and will also suggest simple things the person can do to lower his or her risk. "Our major goal is to dispel the myth that disease prevention requires an extraordinary effort," said Dr. John Buse, president-elect, medicine and science, at the ADA. "Helping individuals understand and apply this information could mean the difference between life and death."

Group Receives $35 Million Grant

The Sumner M. Redstone Charitable Foundation has awarded a $35 million, 5-year grant to FasterCures/The Center for Accelerating Medical Solutions. FasterCures, founded 4 years ago, formed the Research Acceleration and Innovation Network to bring together disease research organizations that are focused on innovative research on diseases such as diabetes, heart disease, AIDS, and breast cancer. "One of our goals is to remove many of the bureaucratic and regulatory barriers that researchers face in pursuing better treatments and cures for all life-threatening conditions," said FasterCures chairman Michael Milken. The grant also will be used to support FasterCures' Patients Helping Doctors program, which works to speed recruitment of patients for clinical trials.

Chicago Employers Tackle Diabetes

The Midwest Business Group on Health, a Chicago-based group of employers, has established an employer-based diabetes self-management program endorsed by the Institute of Medicine of Chicago. In the Taking Control of Your Health program, which is funded by Novo Nordisk Inc. and Novartis, employers will waive or lower copays for diabetes medications as an incentive to get patients to adhere to their medication regimens. Patients will also meet regularly with a pharmacist coach who is specially trained in diabetes education and monitoring. The program is modeled after several successful programs, including the Asheville Project in North Carolina. "The pharmacist's role is to be an educator and motivator, ensuring the patient follows their physician's orders and understands how to manage and monitor their diabetes and medications," said MBGH president and CEO Larry Boress. MBGH is one of the groups participating in the Diabetes Ten-City Challenge, a national diabetes self-management program conducted by the American Pharmaceutical Association and funded by GlaxoSmithKline Inc.

Juries Side With MDs

Contrary to popular belief, juries in malpractice cases actually sympathize more with physicians and less with their patients, according to a law professor who performed an extensive review of studies involving malpractice cases from 1989 to 2006. Philip Peters, professor of law at the University of Missouri–Columbia, found that plaintiffs rarely win weak cases, although they have more success in cases viewed as a "toss-up" and better outcomes in cases with strong evidence of medical negligence. Mr. Peters, whose study appeared in the May edition of the Michigan Law Review, said that several factors systematically favor medical defendants in the courtroom, including the defendants' superior resources, physicians' social standing, social norms against "profiting" by injury, and the jury's willingness to give physicians the benefit of the doubt when evidence conflicts.

—Joyce Frieden