FDA to Sharpen Focus on Postmarketing Drug Safety

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The Food and Drug Administration has announced that it will beef up oversight of prescription drug safety, with a particular focus on risks and benefits after a product has been launched into the marketplace.

The initiatives were announced in January in a long-awaited response to last September's Institute of Medicine critique of pharmaceutic safety monitoring practices at the agency.

The agency said it had reviewed the IOM's 25 recommendations and would focus its efforts on three major areas:

► Strengthening the science used during product reviews and finding new tools to detect safety issues from preclinical testing through postmarketing.

► Improving communications, especially about risk, to patients, physicians, and other interested parties.

► Improving management practices.

The IOM criticized an agency culture that it saw as too concentrated on drug approval at the expense of product safety.

Some of the FDA initiatives are already underway. Others were published in the Federal Register as part of recommendations for the reauthorization of the Prescription Drug User Fee Act. Under the next PDUFA law, which, if enacted would begin in fiscal 2008, the FDA aims to collect $29 million from drug makers over 5 years specifically for postmarketing safety programs.

Key among the new initiatives announced in late January is a "report card" on the postmarketing safety of new molecular entities. The FDA has proposed a pilot feasibility study this year. These periodic, regularly scheduled reports would encompass data from the Adverse Events Reporting System (AERS), epidemiologic studies, postmarketing clinical trials, and from "mining" of various other databases. The first report would come 18 months after a drug's launch. The goal of this effort is "to identify potential safety concerns early in the product life cycle," the agency said.

It also proposed sharing data more often with other agencies, and said it was already collaborating with the Agency for Health Care Quality and Research, the Centers for Disease Control and Prevention, and the Veterans Affairs department. The VA will provide real-world data on how its patients use pharmaceuticals and medical devices.

To address criticism that the FDA has not done a good job of communicating what it knows about a drug's risks and on a timely basis, the agency is putting together a new advisory committee. The IOM panel had thought it would take new legislation to establish a risk communications committee, but the agency said it could—and would—move quickly to establish such a panel.

The FDA also said it would hold a public meeting in early March to explore the creation of a nationwide public-private medical product safety network. The agency envisions a network that would let both health care providers and regulators rapidly collect and exchange information about adverse events—and would do so at the point of care to help providers make better-informed treatment decisions.

American Medical Association board member Dr. Edward Langston said the AMA generally supported the proposals. "The AMA agrees that the approaches used to communicate information to patients about the risks associated with drug products need significant improvement," said Dr. Langston in a statement.

Long-time FDA critics in Congress, however, said the agency had not gone far enough.

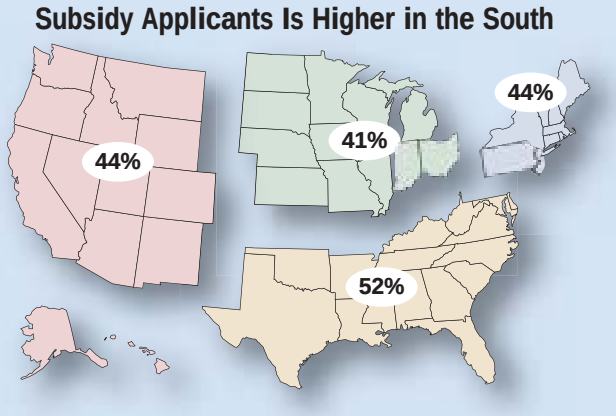
"[The report] provides important recommendations for administrative action, but only legislation can give the FDA the tools it needs to ensure that the agency is the gold standard for safety," said Sen. Edward M. Kennedy (D-Mass.), who, along with Sen. Michael Enzi (R-Wyo.) soon will introduce a bill to further overhaul the FDA's postmarketing safety program.

Sen. Christopher J. Dodd (D-Conn.) said that he and Sen. Chuck Grassley (R-Iowa) were also introducing a bill that would "revamp and prioritize the postmarket surveillance process within the Food and Drug Administration." That bill, called the Food and Drug Administration Safety Act, would establish a Center for Postmarket Evaluation and Research for Drugs and Biologics. The center would report directly to the FDA commissioner.

"Congress will act on FDA-related legislation this year, and meaningful structural reforms to the agency need to be a part of what Congress does with regard to drug safety," said Sen. Grassley in a statement. ■

DATA WATCH

Eligibility for Medicare Drug Benefit for Low-Income Subsidy Applicants Is Higher in the South



Note: Percentage of applicants determined eligible based on Social Security Administration data as of Nov. 17, 2006.
Source: The Kaiser Family Foundation

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POLICY & PRACTICE

Missed Opportunities for Prevention

Two new reports from the Agency for Healthcare Research and Quality find that physicians often miss opportunities to offer patients preventive and counseling services. It is the fourth consecutive year in which AHRQ has compiled data on 40 core quality measures for the National Healthcare Quality Report. Among the agency's findings: Only 52% of adults reported undergoing recommended colorectal cancer screening, and fewer than half of obese adults reported that they had received diet counseling. Only 48% of patients with diabetes received blood sugar screens or foot and eye exams. The overall quality of care improved by almost 8% in hospitals, but by only 3% in ambulatory settings and by 1% in nursing homes and home health settings, according to AHRQ. The agency attributed quality improvement in hospitals to initiatives established by the Centers for Medicare and Medicaid Services. In a separate study—the National Healthcare Disparities Report—AHRQ found that blacks received poorer quality care than did whites in 73% of the core measures. Furthermore, Hispanics received poorer quality of care in 77% of the measures, and low-income people in 77% of the measures.

Drug Ads Play On Emotions

A new study shows that prescription drug advertising on television is rarely educational, and mostly uses emotional appeals to entice consumers. Dominick Frosch, Ph.D., of the University of California, Los Angeles, and colleagues analyzed ads shown during prime time and evening news hours over 4 consecutive weeks on four major broadcast networks. The sample included ads for 7 of the top 10 best-selling prescription drugs for 2004, and included reminder ads (the "ask your doctor" ads, which do not have to be factual) and product claim ads (which must include product risks). A positive emotional appeal—such as a character who's happy after taking the product—was used by 95% of the claim ads and 100% of the reminder ads. The claim ads did provide some educational information, such as detailing how to use the drug or enumerating some of the potential risks and benefits, said the authors. But, they concluded, direct-to-consumer advertising "often presents best-case scenarios that can distort and inflate consumers' expectations about what prescription drugs can accomplish." Their analysis appeared in the January/February issue of the Annals of Family Medicine. In an editorial accompanying the study, former Food and Drug Commissioner David Kessler said that "although none of these findings are surprising, they should be disturbing."

Back Pain Program to Begin

Physicians and chiropractors who provide high-quality back pain care will soon be able to be recognized under a program sponsored by the National Committee for Quality Assurance (NCQA). The program will identify physicians and chiropractors who follow 16 evidence-based criteria, including performing a thorough patient assessment, offering recommendations for appropriate physical activity, and avoiding unnecessary imaging. Criteria also include patient education and shared decision making about surgery and alternatives with the patient. "How back pain is treated varies tremendously from practice to practice, [such that] where you go for your care is as important as what is causing your problem," NCQA President Margaret E. O'Kane, said in a statement. The program was designed with input from experts in orthopedics, neurosurgery, primary care, and public health, as well as from health plans and employers. NCQA will begin accepting applications for the program in April.

Antidepressant Side Effects Vary

Second-generation antidepressants generally have similar rates of effectiveness but have variable side effects, according to an AHRQ analysis. On average, about 61% of patients will experience at least one side effect from taking a selective serotonin reuptake inhibitor (SSRI) or a serotonin norepinephrine reuptake inhibitor (SNRI), according to the analysis. However, the type of side effect varies by drug. For example, the SNRI venlafaxine (Effexor) is associated with more reports of nausea and vomiting than are SSRIs, according to AHRQ. The antidepressant trazodone (Desyrel), on the other hand, is associated with higher rates of somnolence than are some similar drugs. Researchers at AHRQ analyzed 293 published studies to compare the risks and benefits of second-generation antidepressants in the treatment of major depressive disorder, dysthymia, and subsyndromal depression. "Second-generation antidepressants provide hope for many of the millions of Americans who struggle with depression," Dr. Carolyn Clancy, AHRQ director, said in a statement. "But often, trying to find the right drug is trial and error, and in many cases relief is temporary or comes with serious side effects. It's clear we need more evidence to help patients and their doctors make the best choices." The study is available at http://effectivehealthcare.ahrq.gov.

New Medical School to Open

The Touro College of Osteopathic Medicine will open this fall in New York's Harlem neighborhood. The new school's mission is to serve minorities in the area, and school officials also plan to recruit medical students from among minority populations. The new facility is in the final stages of construction and is expected to be completed in April. School officials have already received 800 applications for the first class of 125 students. Officials also plan to hire 40 full-time faculty and 100 part-time faculty, as well as 200 physicians from New York City–area hospitals as adjunct faculty members.

—Alicia Ault