FDA to Sharpen Drug Safety Focus

The agency proposes a pilot feasibility study this year on gathering early postmarketing safety data.

BY ALICIA AULT
Associate Editor, Practice T rends

The Food and Drug Administration said it will beef up oversight of prescription drug safety, with a particular focus on risks and benefits once 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 pharmaceutical safety monitoring practices at the agency.

The FDA said it had taken a close look at the IOM's 25 recommendations, and that it would focus its efforts on three major areas:

1. Strengthening the science used during product reviews and finding new tools to detect safety issues from preclinical testing through postmarketing.
2. Improving communications, especially about risk, to patients, physicians, and other interested parties.
3. 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," according to the FDA.

The FDA 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.

The FDA says it can and will move quickly to form a new committee to help communicate what it knows about a drug's risks on a more timely basis.

To address criticism that the FDA has not done a good job of communicating what it knows about a drug's risks 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 FDA's 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.

However, longtime FDA critics in Congress said the agency had not gone far enough.

"Today's report is thoughtful, and 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 agency'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.

"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. ■

FYI

Free Asthma Screenings in May

The American College of Allergy, Asthma, and Immunology is offering free asthma screenings through its 11th annual Nationwide Asthma Screening Program. Starting in May, the screenings will be held in more than 300 communities nationwide. The program is supported by AstraZeneca. For more information, including dates, sites, and online asthma self-tests for adults and children, visit www.acaai.org/public/lifeQuality/nasp. htm.

Pediatric Emergency Preparedness

"Pediatric Terrorism and Disaster Preparedness: A Resource for Pediatricians" summarizes the role of national, regional, and local emergency response systems before, during, and after disasters and terrorism events. Information is available on triage, supportive care, and referral of children affected by different types of terrorist and disaster events. To access the resource, visit www.ahrq.gov/research/pedprep/resource.htm.

Fact Sheet on Pain Management

The Substance Abuse and Mental Health Services Administration has published a new fact sheet on providing pain management while avoiding psychological dependence on opioids. To order free copies of "Pain Management Without Psychological Dependence: A Guide for Healthcare Providers," contact the National Clearinghouse for Alcohol and Drug Information by calling 800-729-6686.

Feds Launch AIDS Web Site

The U.S. Department of Health and Human Services has launched AIDS.gov, a searchable Web site for the public that provides information on HIV and AIDS prevention, testing, treatment, research programs, and federal policies and resources. The site has links to information on federal funding and financial assistance for AIDS organizations. For more information, visit www.aids.gov.