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 FDA announced in January in a long-awaited response to last September's Institute of Medicine critique of pharmacoeconomic 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 post-marketing.
- Improving communications, especially about risk, to patients, physicians, and other interested parties.
- Improving management practices.

The IOM criticized an agency culture that saw too little focused 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 periodically scheduled reports would encompass data from the Adverse Events Reporting System (AERS), epidemiological 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 the 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 Healthcare Research and Quality, the Centers for Disease Control and Prevention, and the Veterans Affairs Department.

The VA will provide real-world data on how its patients use its prescribed medications, 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 to further overhaul the FDA's postmarketing safety program.

"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. "The first report would come 18 months after a drug's launch. The goal of the effort is "to identify potential safety concerns early in the product life cycle," the agency said."