IOM Report Calls for Change in Emphasis at FDA

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The Food and Drug Administration should shift its emphasis from the preapproval period to postmarketing, when new drugs pose the greatest risk of safety problems, a sweeping report from the Institute of Medicine recommends.

Numerous safety-related issues over the past few years—including the widely publicized recall of Vioxx (rofecoxib), and struggles over labeling changes for antidepressants—have led to a lack of confidence in drug development and regulation, according to the 15 experts impaneled by the IOM.

"The credibility of FDA, the industry, the academic research enterprise, and health care providers has become seriously diminished in recent years," the committee said in its report.

The FDA, in particular, has floundered, hampered by a lack of funding and mismanagement that has led to internecine strife and miscues that may have resulted in delays in addressing safety issues, said the panel, which was made up of academicians, ethicists, and the head of the U.K. Medicines and Healthcare Products Regulatory Agency.

"FDA's reputation has been hurt by a perceived lack of transparency and accountability to the public, a legacy of organizational changes that have not been completed or sustained, and an apparent slowness in addressing lack of sponsor compliance," according to the report, "The Future of Drug Safety: Promoting and Protecting the Health of the Public."

The committee recommended that FDA should consider requiring new molecular entities to carry a special caution that the products' true risks and benefits are unknown. FDA also should consider restricting or banning direct-to-consumer advertising of those products during that early marketing period, said the committee.

After 5 years, the FDA should formally review all the available data on those products and publicize the findings, said the panel.

In addition, results of any phase II-IV clinical trials that are submitted to the FDA should be published on the Web site www.clinicaltrials.gov.

Given that most label changes are voluntary and that many companies have not conducted the requested postmarketing studies, the FDA needs more power to enforce regulations, including the ability to more quickly and directly levy fines or secure injunctions against companies that do not comply, the committee said.

The FDA should not be given unilateral authority, however, said the panel. "We understand that offering discretion does not mean offering dictatorial power," said R. Alta Charo, a bioethicist at the University of Wisconsin Law School.

Among the panel's other recommendations:

▶ FDA funding and staff should be vastly increased.

▶ FDA commissioners should be appointed to a 6-year term in order to bring stability to the agency's leadership.

▶ Staff from the FDA's Office of Surveillance and Epidemiology should join the teams that review new drugs, to increase the safety focus from the start.

▶ At least 60% of the membership of each FDA advisory committee should have no significant financial involvement with the sponsors of the products being reviewed.

Some of these changes—such as a shift in resources from the preapproval to the postapproval side—could be done administratively. Others, however, such as giving the agency new enforcement authority, would require an act of Congress.

In a press briefing after the report was released, FDA officials acknowledged that there have been some difficulties, but they largely deflected the criticism by instead discussing initiatives the agency has undertaken in the last 2 years to shore up postmarketing safety efforts.

"The FDA has led an aggressive effort, which includes developing new tools for communicating information to patients and new resources for drug safety, to improve the management of the process for how we uncover and communicate important drug safety issues," said acting FDA Commissioner Andrew von Eschenbach at the briefing.

The Pharmaceutical Research and Manufacturers of America also defended FDA's recent strides and the industry's safety record. ■