Sweeping Changes Sought at FDA

Panel Recommends FDA Be Given More Control Over Drug Approval, Marketing, Reviews

By RYAN STANTON, M.D.

Sept. 22, 2006 — Sweeping changes would be made in the way drug companies operate and in the power of the Food and Drug Administration to oversee them if Congress and the FDA adopt new recommendations from the Institute of Medicine, a nonprofit organization created by Congress to advise the federal government on health issues.

If the recommendations in the 200-plus-page report are adopted:

- New types of drugs could not be advertised in the media.
- They would be re-evaluated for approval after five years and reviewed constantly for safety.
- Any new drug would have a clear marker letting patients know it was new and that the overall safety cannot be guaranteed.

In addition to those recommendations, the IOM report said the FDA suffers from a lack of regulatory authority, organizational problems and a chronic lack of funds and staff. The report calls for increased funding and staffing at the FDA, and more public access to drug studies and safety data. The FDA should be given more authority to fine drug companies, as well as to file injunctions against them and regulate how they do business. It should also be given the power to order withdrawals of drugs. No more "all-or-nothing approach," according to the report.

"We want to provide a tool kit of regulatory options," said Sheila Burke, chairwoman of the IOM Committee on the Assessment of the U.S. Drug Safety System.

The report recommends that the FDA tightly regulate drug advertising on new medications and continue to review new safety data on drugs even after they are approved.

"We want to establish restrictions on direct-to-consumer advertising until safety can be established," said Alto Charo, a member of the IOM committee.

Other experts agree that pushing new drugs on consumers before safety can be firmly established is a bad idea.

"Since the medication is not yet known to be safe, direct-to-consumer advertising should be forbidden," said Alan Sager, professor of health services at the Boston University School of Public Health. "This should be legislated and then defended in court."

Although the report criticizes the agency, the FDA actually asked for the critique. The FDA itself
commissioned the report from the IOM in light of the concerns that were raised when Merck withdrew the painkiller Vioxx in 2004.

"We want to ensure access of Americans to safe medications," said Steven Galson, director of the Center for Drug Evaluation and Research at the FDA.

This 15-month review ended with 25 different recommendations for FDA officials.

The overall theme of the IOM's findings and recommendations are to improve the balance between the time before a drug is approved and the time after a drug hits the market. Some experts criticize the FDA for not paying enough attention to drug safety after it approves a drug. "There is clearly an imbalance in the preapproval and postapproval evaluations, and the goal of our recommendations is to bring the strength of the preapproval setting to the postapproval setting," Burke said. "Real life use of prescription drugs is much different than preapproval trials."

Since one job of the FDA is to bring new and safe medications to the public, the FDA is encouraged to bring drugs quickly to the market while accurately establishing the risks of the new medication.

That balance can be tough. While studies might do an adequate job of showing whether a drug works, those same studies cannot always pick up on all of the side effects that a drug might cause.

"All drugs have risks. Our job is to uncover these risks as quickly as possible," said Dr. Andrew C. von Eshenbach, acting director of the FDA.

The pharmaceutical industry questioned some of the conclusions of the report.

"It would be a mistake to accept the notion that the FDA drug safety system is seriously flawed," said Caroline Loew, senior vice president of the Pharmaceutical Research and Manufacturers of America.

"After all, fewer than 3 percent of approved prescription drugs have been withdrawn from the American market for safety reasons over the last 20 years," Loew said.

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