IOM Committee Begins Investigation of the FDA

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WASHINGTON — Acknowledging that its drug safety system is inadequate, several Food and Drug Administration officials told an Institute of Medicine panel examining the issue that the agency is ready for recommendations on how to better protect the public's health.

The IOM committee was convened at FDA's request and has been charged with examining every aspect of the agency's drug safety program, including whether it needs new powers to mandate postmarketing safety studies by pharmaceutical companies.

At its first meeting in June, the panel heard from representatives of the FDA, the pharmaceutical industry, and consumers. Each group had divergent views on how well the system works.

Janet Woodcock, M.D., acting deputy commissioner for FDA operations, said the agency had come a long way, but that it could improve on predicting, preventing, monitoring, and mitigating adverse drug events. Changes over the past decade have made it more difficult to ensure safety, Dr. Woodcock added.

Before, most drugs were marketed in other countries first, giving the agency a track record to evaluate, she said. Now, the United States is often the first avenue for sales. Huge drug company marketing campaigns aimed at physicians and consumers have led to a much quicker uptake of new drugs, which brings safety issues to a head even faster. Recalls are happening faster after a drug comes to market, but there has been no big increase in the number of withdrawals, Dr. Woodcock said.

She also said the agency was hamstrung by international agreements on how much premarket safety data could be requested; the agency can't force drug makers to conduct postmarketing safety studies.

MedWatch, FDA's postmarketing surveillance system is full of gaps, Dr. Woodcock added. Pharmaceutical makers are required to report adverse events to MedWatch, but reports from physicians, pharmacists, and other health care providers, and patients are voluntary. MedWatch receives 400,000 reports a year, but the FDA acknowledges it captures only a fraction of the events.

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Alan Goldhammer, Ph.D., associate vice president of regulatory affairs at the Pharmaceutical Research and Manufacturers of America, said, "simply increasing the number of spontaneous reports is not the answer" because it might just "increase the noise" instead of providing real signals about side effects.

He said the system was not broken. "We know more about safety profiles of drugs approved today than those approved 20 years ago," Dr. Goldhammer said, adding that "FDA's current legal authorities over drug safety are robust and do not need to be changed."

Bill Vaughan, a senior policy analyst with Consumers Union, vehemently disagreed, saying that the Washington-based nonprofit believes that "legislative action is essential to address the substantial problems in drug safety and oversight that have been highlighted over the last year."

Mr. Vaughan urged the IOM panel to make interim recommendations to Congress as early as this summer, rather than waiting until its final report, which is due out next year.

"It looks like the industry looks at the FDA like it's a paper tiger, and that needs to be addressed, and addressed soon," Mr. Vaughan said.

Steven Galson, M.D., the acting director for FDA's Center for Drug Evaluation and Research touted the FDA's new Drug Safety Oversight Board, saying it would help provide "independent" oversight and advice. The board's first meeting was in late June.

Sen. Chuck Grassley (R-Iowa), chairman of the Senate Finance Committee, said he was skeptical of the board's capabilities, noting in a letter to FDA acting commissioner Lester Crawford, D.V.M., that it does not seem independent enough.

Overall, Dr. Woodcock told the panel, "one of the questions on the table really is how much uncertainty are we willing to tolerate because we will never have total certainty." When FDA approves a drug for marketing, "that doesn't mean there are no risks, or that there are no risks to the individual patient," she said, adding that patients and doctors together should weigh benefits and risks.

The next meetings of the panel are scheduled for July 20 and October 25. ■

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