FDA Tells IOM Drug Safety Panel Changes Needed

WASHINGTON — Acknowledging that its drug safety system is inadequate, several FDA officials told an Institute of Medicine panel examining the issue that the agency needs 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 the panel meeting in June, the panel heard from representatives of the FDA, the pharmaceutical industry, and consumers. Each 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 said. Before drugs were marketed in other countries, first, the United States was the first to approve an agency track record to evaluate, she said. Now, the United States is often the first avenue for sales.

Drug company marketing campaigns aimed at physicians and consumers have led to a quicker uptake of new drugs, which brings safety issues to a head even faster. Recalls are happening faster after a drug comes to market because of there being a 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 was forced 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 patients are voluntary.

MedWatch records 1,107,000 reports a year, but the FDA acknowledges it captures only a fraction of the events.

Alan Goldhammer, Ph.D., associate vice president, health care policy for 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, "and legal authorities over drug safety are robust and do not need to be changed."

Bill Vaughan, a senior policy analyst with Consumers Union, disagreed. "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 before the panel issues its final report, due out next year.

Steven Galson, M.D., the acting director of the 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 June.

Sen. Chuck Grassley (R-Iowa) 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.

Dr. Woodcock told the panel, "One of the things that are on the table really is how much uncertainty are we willing to tolerate," adding that patients and doctors should demand better information.

The panel's next meeting is scheduled for October 25.

By Alicia Ault

Summary Brief of Prescribing Information

Please see full Prescribing Information. 

INDICATIONS AND USAGE Raptiva is indicated for the treatment of moderate to severe chronic plaque psoriasis in adults who have failed to respond to previous systemic therapy or phototherapy, and who have a disease course that is consistent with a diagnosis of plaque psoriasis in adults (see CLINICAL STUDIES).

HOW SUPPLIED Raptiva® (efalizumab) is supplied in a single-use vial containing 123 mg (100 mg of efalizumab (protein) and 23 mg of sucrose) as a lyophilized powder for reconstitution. Each vial is for single use only. 

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