FDA’s New Drug Safety Board Under Scrutiny

By Jennifer Silverman
Associate Editor, Practice Trends

The board will resolve disagreements over approaches to drug safety issues.

Sec. Leavitt

Health and Human Services Secretary Mike Leavitt is taking to improve oversight and “openness” at the Food and Drug Administration. “Our goal is to prepare the agency for these new demands by improving the way we monitor and respond to possible adverse health consequences that may arise regarding drugs that have been approved for sale to U.S. consumers,” said acting FDA Commissioner Lester Crawford, D.V.M., Ph.D.

The drug safety board is being touted as a major initiative that will help the agency meet the challenge of monitoring the safety of drugs already on the market. The board will serve as an advisory group to the FDA, reviewing and responding to new drug safety information and emerging or potential safety problems within the agency.

The agency does plan on issuing draft guidance on procedures and criteria for identifying drugs and information for the Web page. A spokesman for the Pharmaceutical Research and Manufacturers of America said that such an organization supports any effort to address the quality of information used by the agency.

For health care professionals and patients, it is important that regulatory decisions and communications be based on sound science and reflect carefully considered judgments regarding both benefit and risk,” said Jeff Trewhitt, adding that PhRMA would study the initiatives and respond to the FDA’s request for input.

But Public Citizen’s Mr. Sasich said the effort to step up monitoring of drugs seems like an attempt to deflect recent criticisms that PhRMA hasn’t been meeting its charge as a public safety agency.

In particular, FDA has been criticized for not acting quickly enough to inform physicians and patients about the possible health repercussions of cyclooxygenase-2 (COX-2) inhibitor Vioxx (rofecoxib), which was withdrawn from the market last September 2004. In PPRMAs view, the FDA has already responded “quickly and constructively” to concerns about Vioxx, Mr. Trewhitt said.

Washington — The trend toward consumer-driven health care would ultimately improve overall health care quality, according to Regina Herzlinger, Ph.D., professor and chair of health care policy at the Harvard Business School, in Boston, who treats sick people well. But if you go to the patient’s point of view, you find that the insurer is the provider, and the patient is the customer.

Consumer-Driven Health Care Will Help Quality, Expert Says

By Joyce Frieden
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The idea that this group isn’t going to get what it wants, that’s fantasy. They want [doctors] to integrate themselves, seize control of the system, and help patients care for their chronic diseases.”

Dr. Herzlinger took issue with the notion that consumer-driven health care plans would be disadvantageous to sick people. “Quite the contrary. It will finally focus attention on sick people. Right now it’s in the incentive of the insurers to get rid of sick people and not to pay people who treat sick people well. But if you go to a consumer-driven system with risk-adjusted prices, that would be ‘very attractive kinds of entities.’

Dr. Herzlinger also challenged the notion that only those individuals who could afford high-cost health plans would receive the highest quality of health care.

In the automobile industry, “What is the best car in the U.S.? Toyota,” she said. However, as Dr. Herzlinger pointed out, Toyota is not the highest-cost car. “Not by a long shot.” Instead, it’s the best quality car “because that’s where all the money is. That’s the mass market.”

Aging baby boomers are a big driver behind the trend toward consumer-driven health care, which will pay physicians based on outcomes.

“I want a 5 year insurance policy. I want my insurer to really care about my long-term health,” Dr. Herzlinger continued. Switzerland has 5-year insurance policies, she noted, and if, at the end of the 5 years, you’re healthier than when you started, you get 45% of your money back. Is that a good deal for the insurer, the provider, and the customer?”

Dr. Herzlinger predicted that it will become commonplace for insurers to offer integrated team care for chronic diseases. The teams will be wired, they’ll be focused, and they’re going to be paid for the fact that they’re dealing with sicker people,” she said.

Offering such teams would be a matter of “simple economics,” she continued. “You’re the insurer; 80% of your money goes for sick people. If you want to make it cheaper and better, how better to make it cheaper and better than to go to these organizations?”

Under a consumer-driven health care system, “what people would be paid based on outcomes, and there would be ‘long-term contracts so you don’t look at your patients in a 1-year kind of window,’” she said. “Investments in self-care early on” would be rewarded.

One big driver behind consumer-driven health care are the aging baby boomers, a group that Dr. Herzlinger called ‘the most narcissistic, self-centered, empowered, and effective cohort we’ve ever had in the United States. The idea that this group isn’t going to get what it wants, that’s fantasy. They want [doctors] to integrate themselves, seize control of the system, and help patients care for their chronic diseases.”

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