FDA's New Drug Safety Board Under Scrutiny

BY JENNIFER SILVERMAN
Associate Editor, Practice Trends

Many questions surround the authority of a new drug safety board that would oversee the management of drug safety and provide emerging information to physicians and patients about the benefits and risks of medicines on the market.

Such a board is one of several steps that

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 an independent entity, yet lawmakers and consumer groups have questioned how much independence or authority the board will actually have.

Larry Sasich, a pharmacist and research analyst for Public Citizen, noted that recommendations and concerns of the FDA's current Office of Drug Safety, which is a subunit of the Office of New Drugs, are often ignored by the agency's new drug reviewers.

If the new board reports in a similar manner, "it may be a stretch to call it an independent board," Mr. Sasich said.

Secretary Leavitt said that the new board would resolve disagreements over approaches to drug safety issues, oversee development and implementation of center-wide drug safety policies, and assess the need for MedGuides.

The safety board would be comprised of FDA officials and medical experts from other federal agencies. Outside medical experts and consumer representatives would serve as consultants.

"We hope to nominate and confirm board members within the next few months," an FDA spokeswoman said.

As another component of the oversight initiative, FDA plans to create a new "Drug Watch" Web page, a site to include emerging information for approved drugs about possible serious side effects, or other safety risks.

The Web site would also house drug safety information sheets for health care professionals and patients. Such information also would be available through MedWatch.

Through these direct communication channels, the agency plans to discuss emerging or potential safety problems with the public—even before considering a regulatory action.

Some lawmakers thought the department's new initiatives didn't go far enough to ensure drug safety.

"Consumer confidence in the FDA has been shaken to the core, and it will take more than cosmetic reforms to fix structural problems within the agency," Sen. Christopher Dodd (D-Conn.) said in a statement.

'Consumer confidence in the FDA has been shaken to the core, and it will take more than cosmetic reforms to fix structural problems within the agency.'

Sen. Dodd also expressed concern that the FDA wouldn't have the resources to adequately oversee drug safety. "The president's budget provides only a $6.5 million increase for this critically important need, and that's far short of what is needed."

Additional actions should be taken to increase FDA's resources to monitor drugs and to give it the authority to require drug companies to initiate and complete appropriate safety studies, suggested Sen. Edward M. Kennedy (D-Mass.)

The agency will eventually seek input on the quality and usefulness of this information, an FDA spokeswoman said."We are not soliciting for public comment, or treating this as a proposed rule."

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 that 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 FDA 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 PhRMA's view, the FDA has already responded "quickly and constructively" to concerns about Vioxx, Mr. Trewhitt said. ■

Consumer-Driven Health Care Will Help Quality, Expert Says

BY JOYCE FRIEDEN
Associate Editor, Practice Trends

WASHINGTON — The trend toward consumer-driven health care would ultimately improve overall health care quality, Regina Herzlinger, Ph.D., said at a consensus conference sponsored by the American Association of Clinical Endocrinologists.

Dr. Herzlinger, professor and chair of business administration at Harvard Business School, in Boston, contrasted the health care industry with the automotive industry. The automotive industry, which already is consumer-driven, is deflationary and features increasing product quality, lots of available product information, and widespread ownership.

The health care industry, on the other hand, is not consumer-driven and is characterized by inflation, unknown quality of care, and 46 million people who do not even have health insurance.

She noted that what helped the automotive industry along was the presence of entrepreneurs, who ended up being richly rewarded for their efforts. For instance, Henry Ford, founder of the Ford Motor Co., created a new, less expensive form of steel from which to make cars. "Within a decade, car ownership went from 10,000 to 1 million," Dr. Herzlinger added.

Although Mr. Ford and other automotive industry pioneers were rewarded, innovation in health care is not well-rewarded, Dr. Herzlinger continued at the meeting.

As an example, she cited the case of Ralph Snyderman, M.D., who came up with the idea of integrating the care of patients with heart failure by organizing health care teams. "In one year, he lowered the costs by 40%," Dr. Herzlinger explained.

And what was his reward for doing so? "He lost the entire savings, because the health care system does not pay for making sick people better. It pays for days in the hospital, for doctor visits, for components of care. So the healthier he made people, the fewer people went to the hospital, the fewer doctor visits there were, and the more money he lost. Right now, if you're a Henry Ford, you're punished, and we have very poor quality," she said.

With consumer-driven health care, different products would be developed to respond to the needs of different consumers, she continued. And insurers would realize they could be rewarded for considering consumers' longer-term health care needs.

"I want a 5-year insurance policy. I want my insurer to really care about my long-term health," Dr. Herzlinger commented. Switzerland has 5-year insurance policies, she noted, "and if, at the end of the 5 years, you're healthier than would have been predicted at the beginning, you get 45% of your money back. How's that for a good deal for the insurer, the provider, and the customer?"

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

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, physicians 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."

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," the sick 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." ■