FDA's New Drug Safety Board Under Scrutiny

Critics say board may lack independence and authority and may not have sufficient resources.

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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 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 composed 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.

The FDA's goal is to improve response 'to possible adverse health consequences that may arise regarding drugs that have been approved.'

As another component of the new 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 that the department's new initiatives did not 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.

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. Physicians and patients should have a solid and comprehensive basis for their discussions and decisions," 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. At a hearing last December, Senate Finance Committee Chairman Charles Grassley (R-Iowa) asserted that the FDA needed a more efficient, streamlined process for postmarketing drug safety

In PhRMA's view, the FDA has already responded "quickly and constructively" to concerns about Vioxx, asking the Institute of Medicine to conduct a thorough exam of the drug safety system, Mr. Trewhitt said. The oversight initiative "is one more step in that process." ■

For more information about the new FDA oversight initiative, see www.fda.gov/cder/drugsafety.htm.

'Face-to-Face' DME Prescribing Proposal Annoys Neurologists

BY JOYCE FRIEDEN
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WASHINGTON — Medicare's proposal to require a face-to-face visit before a physician can prescribe a wheelchair or other durable medical equipment to a patient is annoying and inconvenient, several physicians said at a meeting of the program's Practicing Physicians Advisory Council.

"How is a face-to-face visit a step forward?" said Laura Powers, M.D., a Knoxville, Tenn., neurologist and member of the council, which advises Medicare on issues of interest to physicians. "If I take care of stroke patients in the hospital and they leave with a walker, then progress to a cane, do they have to come back for a face-to-face visit before I can prescribe a cane?"

Herb Kuhn, director of the Center for Medicare Management at the Centers for Medicare and Medicaid Services, said that the idea behind the regulation was to deter durable medical equipment (DME) supplier fraud in the wake of the recent scandal in the power wheelchair industry.

"We're looking for continuity of care," Mr. Kuhn said.

"If a person had a relationship with a physician and had seen that physician over a period of time and the physician knew they were ultimately going to need a power wheelchair, they could make that prescription before then. We wanted to try to avoid a situation where people are popping in for one time, getting a wheelchair, and moving on."

Council chair Michael Rapp, M.D., said he could understand why the agency was concerned about wheelchair fraud. "Power wheelchairs are one thing," said Dr. Rapp, an emergency physician. "But [other] DME—I don't even know what it all includes, but a lot of stuff could be involved here."

Under the proposed rule, a face-to-face examination would be required "to determine the medical necessity of durable medical equipment, orthotics, and prosthetics."

However, the exam must be "for the purpose of evaluating and treating the patient's medical condition and not for the sole purpose of obtaining the prescribing physician's or practitioner's order for the [equipment]."

Don Thompson, director of the division of ambulatory services at CMS, told the council members that the agency "doesn't want to create an unnecessary burden for physicians," even as it is trying to combat DME fraud.

Dr. Rapp expressed concern that Medicare would not pay for evaluations performed solely to determine whether the patient needed a power wheelchair, despite the fact that "that might be an extensive evaluation." Mr. Kuhn responded that he did not think the agency would want to get out of paying for such an extended visit, "but it perhaps requires some clarification and comment," he added.

Although wheelchair fraud is at the heart of the agency's fraud concerns, the CMS Physician Regulatory Issues Team (PRIT) is looking at expanding the categories of specialists permitted to prescribe power wheelchairs.

Currently only physiatrists, orthopedic surgeons, neurologists, or rheumatologists can prescribe power wheelchairs, and primary care physicians and other specialists can prescribe them only if one of those specialists is not readily available—that is, if they are located more than a day's round trip from the beneficiary's home—or if the patient is too sick to travel to a specialist.

"I think we're coming to a good resolution on this with our proposal to allow physicians of any specialty to prescribe them, and that's in the final approval process now," said William Rogers, M.D., director of PRIT. "It really wasn't the best time to be broadening the number of specialties that can do it, but it is the right thing to do." ■

A face-to-face exam would be required to determine the medical necessity of DME.