FDA's New Drug Safety Board Under Scrutiny

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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.

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 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.

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 explained 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.

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.

Now Boarded: Pediatric Dermatology a Recognized Subspecialty

BY DOUG BRUNK
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When Kenneth E. Bloom, M.D., sat down in front of a computer monitor and keyboard to take the first-ever pediatric dermatology board certification exam in October, he felt a sense of accomplishment before he entered a single keystroke.

After all, the test was his idea, which he first proposed at a meeting of the Society of Pediatric Dermatology in 1997.

"When I first mentioned this, the idea of physicians taking another test did not go over very well," recalled Dr. Bloom, a dermatologist in private practice in Minneapolis. "There are a host of reasons why I think this subspecialty needed to take place. One is to recognize a true subspecialty field and to give credibility and recognition to the major advances in the care of children. Plus, while I am formally trained in both pediatrics and dermatology, there are a whole host of pediatric dermatologists who never had formal pediatrics training, who never had any true licensure or board specialty that identified them. This exam makes them unique."

The exam is also meant to give pediatric dermatologists certain clout with managed care providers, added Elaine Siegfried, M.D., of St. Louis University. When managed care began to flourish in the 1990s, she said, "board certification became not only important for training, but it started becoming economically important. If you didn't have a board-certified specialty, then payers didn't recognize that you existed, so it wouldn't become necessary to include your services for patients."

Today, Dr. Siegfried calls Dr. Bloom's idea for the exam visionary. But back in 1997, "most of us were busy defining diseases and taking care of sick children, and we didn't really think about what was up ahead," said Dr. Siegfried, also in private practice in St. Louis. "Ken thought about it from a private practice perspective. He was being shut out of managed care. He had just left the university [setting], so all of these kids he was previously taking care of had limited access to care by a pediatric dermatologist."

With help and cooperation from the American Board of Dermatology, Dr. Siegfried, as well as Ilona Frieden, M.D., of the University of California, San Francisco, and several other pediatric dermatologists—all members of the Society for Pediatric Dermatology—created a proposal that was submitted to the Committee on Certification. (SKIN & ALLERGY NEWS, March 2004, p. 1).

The test marked another milestone for the American Board of Dermatology: its first computer-based exam. Minor technical glitches with some computers created a tense atmosphere early on. "There was a little more anxiety than I thought there would be," said Dr. Siegfried, vice chair of the committee that assembled the test questions. "Even a few very experienced people who are bright and widely published seemed a little anxious."

Of the 92 examinees, only 4 failed, for a pass rate of 96%. And 15 of the 200 items on the test were answered correctly by all examinees. An additional 44 items were answered correctly by 95%-99% of examinees.

Susan Bayliss Mallory, M.D., a member of the Society for Pediatric Dermatology since 1980, opted against taking the exam because her daughter was expecting a baby at the time. "But I think it's a great idea," said Dr. Mallory, director of pediatric dermatology at Washington University in St. Louis. "It's probably more applicable to people coming out of training right now, as opposed to somebody like me, who's older and established in my training. I may indeed take it next time. If I take the exam, it will be because I think it is a good [way to be a] role model for the younger attendings."

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DR. BLOOM

Some of her peers, she added, chose not to take the test because of its $1,600 price tag, and others wondered how it would benefit their practice. That was not the case for Seth J. Orlow, M.D., who began to be squeezed out of managed care physician panels in the late 1990s because many did not recognize pediatric dermatology as a subspecialty.

"They'd say, 'We have enough dermatologists,' " said Dr. Orlow, professor of pediatric dermatology at New York University Medical Center. "I would say to them, 'You don't have any pediatric dermatologists on your panel.' They'd say, 'There's no such thing.' "

He added that for physicians who practice in academic medical centers, the exam "adds an additional level of certification, so you can say, 'I'm actually certified in pediatric dermatology.' I think that's valuable."

Dr. Orlow said that members of the test committee made "a real effort to be inclusive as to who got to take the exam, rather than be exclusive. It was not meant to restrict people from practicing pediatric dermatology but, rather, to add an independent measure of ability in pediatric dermatology."

Dr. Bloom added that creation of the exam "opened the door for communications between the American Board of Pediatrics and the American Board of Dermatology to create joint training programs."

Dr. Orlow, who was the first to complete the test—it took him 90 minutes—described the exam as a good measure of "walking-around knowledge" of pediatric dermatology. The next exam takes place in 2006. For more information, visit the American Board of Dermatology Web site, at www.abderm.org. ■