FDA Advisory Panel Voices Persistent Safety Concerns

The U.S. Food and Drug Administration has not done enough to improve oversight of the drug approval and surveillance process, according to a panel of safety experts that advises the agency.

At the February meeting of the FDA’s Drug Safety and Risk Management Advisory Committee, members sharply questioned officials over the seeming lack of independence of the new Drug Safety Oversight Board appointed last May that is made up almost entirely of agency employees, holds closed meetings, and considers much of the decision-making process proprietary. The board was created as one part of a larger initiative to improve openness and oversight at the FDA.

The board may be misnamed if it gives the public the impression that it operates like the National Transportation Safety Board, an independent agency that is in a position to fault the government and/or industry, said committee member Arthur Levin, director of the Center for Medical Consumers in New York. More public input is needed to bring transparency into this process, he said.

Members also questioned the effectiveness of the FDA in communicating emerging threats to physicians and the public in general as well as the adequacy of current funding levels. To do those things, however, the agency may need more money and more authority, said Curt Furberg, M.D., Ph.D., a professor at Wake Forest University in Winston-Salem, N.C.

“It currently can take months to publish a black box warning. It should be a quicker process,” he said.

The FDA does move very quickly once it decides to warn the public about a drug safety problem, said Susan Cummins, M.D., executive director of the agency’s oversight board. However, before that can happen, the agency has to consider the perspective of all stakeholders, and that takes time.

“The mix of science, politics, and policy creates a lot of room for honest disagreement,” she said.

The committee also heard the concerns of dermatologists that the iPLEDGE risk management program, which as of March 1 restricts distribution of the teratogen isotretinoin (Accutane) because of its history of causing birth defects, creates too many barriers to appropriate use of the acne drug.

FDA officials said that they are aware of concerns within the cancer community that the restricted distribution mechanism could interfere with off-label use of the drug in young children with neuroblastoma.

FDA officials acknowledged the committee’s concerns and recommended that members convey them to the Institute of Medicine’s ad hoc committee, a panel formed last year to assess the current system for monitoring drug safety. It is due to submit a report on its findings in July.

—Joel B. Finkelstein