FDA Issues Conflict of Interest Rules for Advisers

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Experts serving on the Food and Drug Administration's advisory committees are now subject to new rules aimed at ensuring that they do not have conflicts of interest that could bias their decisions.

In early August, the FDA issued four final guidance documents and a draft guidance outlining how it plans to handle conflicts of interest among members of advisory committees, which review the safety and efficacy of drugs, medical devices, diagnostic tests, and other products and ingredients that the agency regulates.

In a separate move, the agency said that it plans to make it easier to find documents before and after advisory committee meetings by improving how it posts meeting information on its Web site.

Guidance documents represent the agency's current thinking on a topic, but carry less weight than does a regulation. The FDA has no power to enforce guidance documents, which manufacturers and the agency generally use as rules of thumb.

The newest guidance documents will help ensure that the FDA "is getting the highest quality scientific advice, while at the same time preserving public trust in our decisions," Randall Lutter, Ph.D., the FDA's deputy commissioner for policy, said in a teleconference briefing with reporters.

In the past, the agency has asked advisers to disclose potential conflicts of interest, but there was no monetary limit. Each potential conflict was weighed individually, and waivers were granted based on whether the adviser's expertise was considered necessary for a particular meeting.

With the new guidance, the agency sets a dollar limit on advisers' financial interests. If an adviser—or his or her spouse or minor child—has interests of at least $50,000 in an entity that would be directly or indirectly affected by the outcome of a particular meeting, the adviser would be barred from participating. Advisers with interests less than $50,000 will be allowed to participate and vote, unless they are found to have a significant conflict of interest.

An advocate who has been critical of the FDA's conflict of interest policy for advisers said that the $50,000 cap is too high.

"The FDA wants us to believe that an advisory committee member can receive $49,999 from a company and still make an unbiased decision. I don't buy it and the research doesn't support it," said Diana Zuckerman, Ph.D., president of the National Research Center for Women and Families, an advocacy organization in Washington.

Advisers would be barred from participating in a meeting if they had interests of at least $50,000 in an entity that would be affected by the outcome of the meeting.

She and another agency critic, Dr. Sidney Wolfe, director of Public Citizen's Health Research Group, both expressed concern that the new guidance would still allow advisers with conflicts to vote. Those advisers will be granted waivers if they are determined to provide essential expertise. This is not much of a change from current policy, according to Dr. Wolfe and Dr. Zuckerman.

But the FDA said that the Food and Drug Administration Amendments Act of 2007, which was signed into law last year, limits the number of waivers it is allowed to grant.

In another guidance, the agency said that it will require simultaneous voting by all committee members. Advisers at some meetings have begun using an electronic voting system to ensure that panel members don't influence the votes of those who succeed them in voting; the votes are conducted privately, and then broadcast immediately afterward on a screen. Dr. Wolfe said that when he has seen the voting system in action, "it worked well and served the stated purpose."

He also praised the agency's proposed guidance to set out a more definitive policy on when a product should be referred to an advisory committee for review.

The FDA also is changing the administrative process for advisory committee meetings. The agency will formally notify a sponsoring company 55 days in advance that a meeting has been scheduled. Also, the FDA will post materials relating to the meeting on its Web site no later than 2 full days in advance of the meeting. ■