FDA Proposes New Conflict-of-Interest Limits

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The Food and Drug Administration is proposing to beef up its conflict-of-interest guidelines for experts who serve on its advisory committees, the agency announced in a teleconference.

Proposed guidelines would bar experts with stock or other financial interests worth more than $50,000 in a particular company from reviewing that manufacturer's product, and ban voting by those who receive or own less than $50,000.

The $50,000 rule would be applied to any holdings or interest within 12 months of an advisory panel meeting.

The proposal was billed by FDA officials as an upgrade of guidelines that have been in effect since 2000 and were made partly in response to public demands for more accountability, according to Randall Lutter, FDA acting deputy commissioner for policy.

The new guidance attempts to balance the quest for transparency with the need for qualified experts; as in the past, the guidelines are not legally binding.

"[The] FDA is committed to making the advisory committee process more rigorous and transparent so that the public has confidence in the integrity of the recommendations made by its advisory committees," said Mr. Lutter in a statement issued by the agency.

However, in the briefing, he said the FDA "was not aware of any instances where decision making has been adversely affected by conflicts members might have." The new guidance attempts to balance the quest for transparency with the need for qualified experts, said Mr. Lutter.

As in the past, the guidelines are not legally binding. They are offered as suggestions to staff evaluating potential conflicts of interest by both government and nongovernment employees.

It is rare for staff to make decisions that fall outside of the guidance, though, and waivers will likely only rarely be granted, said Mr. Lutter.

For instance, if a panel member has received an individual grant or other fee of less than $50,000 from a company for work in the hematology area, but is reviewing the company's cardiology drug or device, that person might be allowed to participate in the panel meeting.

Mr. Lutter and other agency officials would not say how they came up with the $50,000 threshold or how many current advisory panel members might be disqualified based on that figure.

However, said Mr. Lutter, "our judgment is, it is a significant number."

The restriction applies to stocks and investments, primary employment, consulting work, contracts and grants, royalties, expert witness work, and speaking and writing fees. It does not apply to mutual funds.

The $50,000 figure will be increased each year in line with the consumer price index, according to the proposal.

A critic of the FDA's conflict-of-interest policies said the new guidance is a significant step forward in part because it will bar participants from voting if they have a financial conflict. They "will be identified as committee members with a taint," said Peter Lurie, deputy director of Public Citizen's Health Research Group.

In the past, even nonvoting members could influence a panel's decision, he said, adding that the new proposal will act as a "countermeasure."

The proposed rules also could "drive the conflict rate lower," said Mr. Lurie, noting that when it comes to recruiting new advisory committee members, "there's going to be a premium on finding those who don't have conflicts."

The guidance document was posted on the FDA's Web site on March 21. Once it is published in the Federal Register, it will be open for public comment for 60 days. The agency expects to incorporate suggestions and issue the final guidance shortly after that time, said Mr. Lutter.

To submit electronic comments on the draft guidance, visit www.regulations.gov or www.fda.gov/dockets/ecomments. Written comments may be sent to: Division of Dockets Management (HFA-305), U.S. Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD, 20852. Comments must include the docket number 2007D-0101. ■