

FDA To Tighten Up Conflict Of Interest Rules For Advisory Panels – Finally, but is it enough?

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FDA To Tighten Up Conflict Of Interest Rules For Advisory Panels
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The US Food and Drug Administration (FDA) announced new draft guidelines on Wednesday to tighten up conflict of interest rules for members to its advisory panels. They are inviting public comments for the next 60 days before they move to finalize the guidelines.

The FDA's acting deputy commissioner for policy, Randall Lutter said, "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".

He added that, "Today's draft guidance document should provide more consistency in the consideration of who is eligible to participate in advisory committee meetings and would simplify the process".

All prospective FDA advisory committee members are screened before each meeting to assess potential financial conflict of interest.

The draft guidelines would replace the current FDA Waiver Criteria issued in 2000 and which the FDA feels is too complex. At the moment it is the only guide they have to help them assess whether the FDA's need for an individual's expertise outweighs the potential for a conflict of interest.

The main benefit of the new conflict of interest guidelines is that it would reduce the differences in how they reach a decision for each meeting.

The FDA also wants to clarify the rules on financial interests. If a potential adviser, after allowing for certain exemptions, has disqualifying financial interests in excess of 50,000 US dollars, then he or she would not qualify to participate, regardless of how valuable their expertise might be.

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However, if the financial interests turn out to be less than the 50,000 US dollar threshold, then that person might be recommended to take part but only as a non-voting panel member.

This would mean that full panel members with full voting rights would only be drawn from those with no potential conflicts.

The FDA defines financial interest as the "potential for gain or loss to a person (or their family and outside affiliations) as a result of the government's action on a particular topic". This could include but is not limited to "stock ownership, related research and consulting arrangements".

The purpose of advisory committees is to give the FDA external independent advice on: food, human and veterinary drugs, biological products, and medical devices. Their recommendations are considered by the FDA but they are not binding. The FDA itself makes the final decision.

An advisory committee generally comprises: chairperson, members, plus consumer and industry representatives and sometimes a patient representative. They may also bring in other experts as required.

The FDA has launched a new website on recruitment of advisory committee members which it hopes will increase public participation in the process.

A notice on the proposed rules is to appear in the Federal Register in the next few days.

To submit electronic comments visit www.regulations.gov or www.fda.gov/dockets/ecomments. To submit written comments send them to Division of Dockets Management (HFA-305), U.S. Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD, 20852. In all instances use docket number 2007D-0101 to search for the proposed rules or reference your comments.

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