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FDA Puts Stricter Limits on Advisory Committees

The FDA is imposing stricter rules on the management of its advisory committee meetings, including caps on the amount of money members can receive, streamlined voting procedures, improved ways committees release pre-meeting information, and new voting procedures.

FDA deputy commissioner for policy Randall Lutter PhD told reporters that while the FDA wants the best expert advice it can find, the actions are designed to make decision making simpler and more transparent, saying that the new policies "are well beyond the legal requirements enacted recently by Congress…These improvements will help ensure that the FDA is getting the highest (quality advice)… while preserving public confidence."

The actions include:

- A $50,000 cap on personal financial interest received by an advisory committee member, spouse, and children.
- A requirement to post all briefing documents at least 48 hours before a meeting.
- FDA website simplification.
- Implementing simultaneous voting by members, instead of going around the panel individually.

Conflicts of Interest

Dr. Lutter said that unless the FDA grants a waiver, advisory committee members who receive more than $50,000 in personal financial interest, such as stocks, will not be allowed to serve on the committee. He added that if a potential adviser's financial conflict is less than $50,000 but he or she is the chief investigator of a drug that is the subject of a meeting, then the potential adviser will be disqualified. University grants are not included in the $50,000.

Waivers may be given to advisers who exceed the cap if they add essential expertise to the committee meeting. FDA senior policy adviser and counselor Jill Hartzler Warner said, "There are some waivers that require us to do a sort of balancing test as to whether the financial interest that poses a potential conflict is outweighed by a need for that (person) to participate. Is this adviser needed? Is he so essential that we need him on our advisory committee in order to provide the committee with essential expertise? We will apply that (criteria) to every waiver now."

Asked if the rules will create a problem with recruiting new advisory committee members, FDA officials said that they have been successfully recruiting for the past year. Warner said, "We certainly (consider) recruitment of those advisers with minimal or no conflicts as a very important primary goal, and we have stepped up recruitment to a significant degree. We've contacted in the past year almost 280 professional organizations to recruit new members, published six Federal Register notices…and emailed almost 400 (emails) seeking new nominees, and we've attended professional meetings. We have many CVs (curricula vitae) submitted – 350 at this point – so we are looking at recruitment as a way to meet our goals in order to reduce the number of waivers we grant…We have in the guidance enumerated certain circumstances where the contribution is significant. We have (also) incorporated a cap on the number of waivers that we would grant, and that is in accordance with the new FDA Act…An expert has to be very essential to the needs of the committee to receive a waiver."

Asked what the FDA will do if there are only a few experts on a given device who are also involved in the clinical trials of that device, Warner said, "How do we reconcile these strict standards with getting experts we need? We feel that we've struck that balance by looking at expertise. We feel that this balance will give us the expertise we need while maintaining the public trust…Our recruitment is really across the board, and we are recruiting in all the (committee meeting) areas." Michael Ortwerth PhD, director of the FDA's advisory committee oversight and management staff, said, "We are getting responses from all centers…We are keeping in contact with a number of organizations in the device area – professional organizations – to make sure that we have a finger on what the interest is in the community."

The new criteria regarding conflicts of interest will be implemented in 120 days. Dr. Lutter said, "There are analyses that go into conflict of interest, and we need a period of time to start fresh with decisions."

Streamlining and Simplifying Procedures

The FDA will also have new computer templates for waivers and financial disclosure aimed at making them clear and more consistent. Dr. Lutter said that the FDA's website will be simplified, "For example, you will be able to find briefing materials in two clicks from the advisory committee website instead of eight clicks that you used to need." The FDA is also asking consumers for feedback and will post summaries of the feedback on its website.

The FDA intends to post advisory committee briefing materials at least 48 hours prior to the meeting. The agency also is providing new guidance details on preparing submitting documents to the FDA for inclusion in the panel's briefing materials as well as a timetable for document submission.

Voting

The FDA is now recommending that advisory committees use simultaneous voting, in which all members vote at once. Previously, advisory committees sometimes voted sequentially, with the committee chair calling on each member individually and asking members to announce their vote aloud one-by-one. Simultaneous voting, the FDA claims, will avoid "voting momentum" in which some voters may be influenced, even subconsciously, by the votes of those who preceded them. Dr. Lutter said that this is designed to "eliminate any perception that they may influence each others' votes." Warner added, "On voting, we decided not to restrict all waivers to non-voting (as written in draft guidance). Waivers may be voting or non-voting at the discretion of the agency."

The FDA also recommended that the results of votes be announced immediately in the meeting. The FDA plans to post a list on its website that indicates how each member voted.

The FDA has proposed new criteria to clarify when the Agency should refer a matter to an advisory committee. In some instances, the FDA is required by law to refer a matter to an advisory committee. In other instances, the FDA would consider these new criteria when deciding whether to refer a matter to an advisory committee. Dr. Lutter said that for first-in-class products for human use, the FDA will either refer the product to a panel or provide an action letter with a summary of the reasons why the agency didn't refer it to a panel before approval.

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