

# FDA Drafts New Conflict Rules for Advisers

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The Food and Drug Administration said that it wants to require more public disclosure of advisory committee members' conflicts of interest and that the information will be available on a new and improved Web site.

The agency also said it will post more data in advance of upcoming meetings.

The changes were announced in November in a draft guidance, which does not carry the weight of a rule, but is generally followed by most companies that have products regulated by the FDA. A draft guidance represents the agency's "current thinking on the topic."

According to the FDA, the new emphasis on disclosure is a response to recommendations made by the Institute of Medicine in its 2006 report, "The Future of Drug Safety: Promoting and Protecting the Health of the Public."

The draft guidance will apply to all members of the 31 current advisory panels. Committee members are either government employees or outsiders who are designated as special government employees. The FDA will ask panelists to state publicly the type, nature, and magnitude of any "disqualifying financial interests."

Panel members will be required to complete a waiver request when they have a financial conflict. As part of that document, they'll list the nature of the interest (for instance, whether it's a stock holding, or if they've been a paid consultant or an expert witness); whether the conflicting relationship is with the sponsor or a competitor; and the value of the remuneration, up to \$50,000.

These requirements are only slightly different from what is currently requested, but the waiver forms are clearer and will be made available to the public sooner. At least 15 days before an advisory committee meeting, any disclosures from panelists

will be posted on the Web site, along with the agency's waiver decision.

Currently, waivers may or may not be posted a few days in advance of a committee meeting, and are read aloud at the start of the proceedings. Critics have charged that panel reviews of products have become less rigorous because so many committee members have conflicts of interest. Essentially, the panels are biased in favor of approval, critics contend.

The National Research Center for Women and Families, a consumer advocacy group, issued a report in 2006 showing that advisory panels backed approval for 76% of new drugs and 82% of new medical devices, and that 96% of those products were later approved by the FDA.

The new guidance "focuses on disclosure, not on change," Diana Zuckerman, Ph.D., the president of the National Research Center, said in an interview. "Although disclosure is nice, it doesn't solve the problems."

A recent report commissioned by the FDA concluded that creating conflict-free panels would require higher recruiting and screening costs, and would take much more time than the current process, potentially delaying important decisions. Eastern Research Group, a consulting firm in Lexington, Mass., studied 16 advisory committee meetings that involved 124 panel members. Of the 124, 32 (26%) required waivers for at least one meeting. Almost the same number required waivers for multiple meetings. An equal number of standing members and consumer representatives required waivers (29%). More than half of patient representatives required waivers.

Dr. Zuckerman questioned the study's validity, noting that the consulting company used literature searches to form the basis of its conclusions on panelists' conflicts. The FDA would be more proactive in searching for conflict-free advisers, she suggested. ■

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