Strengthening the Advisory Committee Process

FDA/Cathy Brown

The Food and Drug Administration (FDA) is strengthening and improving the workings of one of its most valuable resources—advisory committees.

Advisory committees are groups of experts from outside the agency that FDA sometimes turns to for help on complex scientific, technical, and policy issues. Advisory committees provide independent, professional expertise related to the development and evaluation of products regulated by FDA, such as human and animal drugs, blood and other biological products, medical devices, and foods. For example, an advisory committee may provide advice to help FDA weigh the risks and benefits of a new potential treatment for a disease.

HOW ADVISORY COMMITTEES WORK

FDA may pose questions to an advisory committee about a specific product. The committee discusses the questions after looking at briefing materials, which contain background information such as available studies on the product, and then votes on the questions. Although the committee makes recommendations to FDA, the agency makes the final decisions.

FDA currently has 48 technical and scientific advisory committees. A committee generally includes a chairperson, several scientists and health professionals, an industry representative, a consumer representative, and sometimes a patient representative.

IMPROVEMENTS

Improvements to strengthen the advisory committee process were released on August 4, 2008, in a set of four final guidances and a draft guidance. In preparing the final guidances, FDA considered public comments on previously issued draft guidances. Guidances are not legally enforceable, but instead are recommendations that describe FDA's current thinking on a topic. The five guidances and their main purposes are described below.

1. Final Guidance: Procedures for Determining Conflict of Interest and Eligibility for Participation in FDA Advisory Committees

Purpose: To strengthen the transparency and consistency of the process FDA uses to assess advisor potential conflicts of interest

FDA laws and regulations require that the financial interests of advisory committee members be scrutinized for their potential to create a conflict of interest. For example, an advisor who has a contract with a company whose product is being discussed in the meeting may have a potential conflict of interest. This guidance sets out a clear, streamlined approach for determining who may be eligible to participate on an advisory commit-

Advisory committees make an important contribution to FDA's decision-making processes

tee. The approach makes the review of conflicts of interest more stringent—beyond that required by law.

2. Final Guidance: Public Availability of Advisory Committee Members' Financial Interest Information and Waivers

Purpose: To be transparent and open to the public

This guidance describes FDA's policy for public disclosure of information when an advisory committee member has a potential conflict of interest. Advisory committee members who have been granted a waiver by FDA to participate in a meeting will be asked to publicly disclose their potentially conflicting financial interests, and FDA will then make this information publicly available. FDA will also make publicly available waivers that the agency grants allowing participation in advisory committee meetings.

3. Final Guidance: Voting Procedures at Advisory Committee Meetings

Purpose: To help ensure the integrity and meaning of the voting results

In the past, during advisory committee meetings, members have often voted sequentially—aloud, one right after the other. This new guidance recommends voting at the same time to prevent some voters from being potentially influenced by the votes of those who precede them. Simultaneous voting may be done by a show of hands, by written vote, or other method decided by the committee chairperson.

4. Final Guidance: Public Availability of Briefing Materials

Purpose: To help prepare briefing materials and to be open and transparent to the public

This guidance presents tools, such as timelines, to help product sponsors develop, organize, and submit briefing materials for FDA to pass on to committee members before a meeting occurs. The guidance also discusses when FDA intends to make these materials available to the public by posting them on FDA's Advisory Committee Web site.

5. Draft Guidance: When FDA Convenes Advisory Committee Meetings

Purpose: To clarify when FDA should refer a matter to an advisory committee

In some instances, FDA is required by law to refer an issue to an advisory committee. In others, the agency can choose whether or not to refer an issue. The draft guidance proposes that FDA consider several specific factors when making this choice. FDA believes that prioritizing according to these factors would help ensure that the limited resources of the advisory committee program are devoted to consideration of those matters in which the agency would most benefit from the advice of outside, independent experts.

In addition to the guidances, another improvement is the redesign of FDA's Advisory Committee Web site. The redesign makes it easier for viewers to locate previously hard-to-find information, for example, meeting announcements and meeting materials. The redesign was based on feedback from usability testing and other scientific methods. The Web site also gives users an opportunity to provide feedback on the site to FDA.

WHAT THE IMPROVEMENTS MEAN TO CONSUMERS

FDA often seeks the advice of advisory committee members before it makes decisions such as whether or not to approve a product, extend a product's use to more people or for another indication, or add a warning to a product's label. Advisory committees make an important contribution to FDA's decision-making processes, which ultimately determine what treatments and other products are available to consumers.

Each advisory committee usually has a consumer representative, who may be a health professional with links to consumer advocacy groups or community-based organizations. FDA may also invite a patient representative to participate in a committee. A patient representative is knowledgeable about, or may even have, the disease or condition under discussion by the committee. While contributing to the scientific discussion, consumer and patient representatives bring to the committees an awareness of concerns of patients and family members directly affected by a serious disease.

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