

FDA 101: Advisory Committees

As technology changes, so do the tools we use to combat disease in the United States. Many companies use new technologies and scientific innovations to develop new generations of drugs, medical devices, and biological products such as vaccines. Some of these new medical products hold great promise. But some pose great risk.

Part of the Food and Drug Administration's (FDA) mission is to evaluate new therapies and determine which are safe and effective for their intended use. This is a complex job, often involving many areas of expertise, and sometimes FDA turns to outside experts for counsel.

FDA's advisory committees provide independent, expert advice to the agency on a range of complex scientific, technical, and policy issues. This includes questions related to the development and evaluation of products regulated by FDA.

The agency currently has 48 technical and scientific advisory committees and panels. They are a valuable resource and make an important contribution to the agency's decision-making processes. Although advisory committees provide recommendations to the agency, FDA makes the final decisions.

What is an FDA Advisory Committee?

An advisory committee lends credibility to the product review process and provides a forum for public discussion of certain controversial issues. The process helps air issues



FDA/Cathy Brown

Members of advisory committees add different perspectives and expertise that give balance to discussions.

Consumer representatives are technically qualified professionals who have specific links with consumer advocacy groups or community based organizations.

that do not have simple answers. For specific products, advisory committees consider the available evidence and provide scientific and medical advice on safety, effectiveness, and appropriate use. Committees might also advise the agency on broader regulatory and scientific issues.

Who serves on advisory committees and panels?

In general, each committee includes a chairperson, several members, a consumer representative, an industry representative, and often a patient representative. Additional experts may be added for specific meetings, as needed.

Committee membership typically includes ethnic, gender, and geographic diversity. Members have recognized expertise and judgment in a specific field. Typical members include

- Physician-scientists
- Statisticians
- Epidemiologists
- Pharmacologists
- Nutritionists
- Nurses
- Experts in animal (preclinical) studies

Representatives for industry, patients, and consumers add different perspec-

tives and expertise that give balance to the discussions and final recommendations.

What does a consumer representative do?

Consumer representatives are technically qualified professionals who have specific links with consumer advocacy groups or community based organizations.

Consumer representatives

- facilitate dialogue with the committees on scientific issues that affect consumers
- must be able to analyze scientific data
- must understand research design
- must discuss benefits and risks
- must evaluate the safety and effectiveness of products under review

How often do advisory committee meetings occur?

Advisory committee meetings can occur during any stage of a product's review process, or if appropriate, once a product is marketed. Typically, an individual committee may convene on average one to four times per year. The decision to involve an advisory committee is usually at the discretion of the Division Director of one of FDA's five product centers.

How does a person become a member of an advisory committee?

Nominations for scientific members and consumer, industry, and patient representatives typically come from professional societies, industry, consumer and patient advocacy groups, the interested individual, or from other interested people. Candidates must be willing to provide detailed information about financial holdings, employment, research grants and contracts, and other potential conflicts of interest. FDA is committed to finding qualified individuals who represent a variety of points of view to serve on advisory committees. Applications are now available on line. [FDA](#)

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FDA's Advisory Committees Web page www.fda.gov/oc/advisory/default.htm

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