FDA Fact Sheets:
Advisory Committees

FDA's Center for Devices and Radiological Health (CDRH) has five standing advisory committees, which provide independent professional and technical expertise on the development, safety and effectiveness, and regulation of medical devices and electronic products that produce radiation. These committees are: the Device Good Manufacturing Practice Advisory Committee, the National Mammography Quality Assurance Advisory Committee, the Technical Electronic Product Radiation Safety Standards Committee, the Patient Engagement Advisory Committee and the Medical Devices Advisory Committee.

The Medical Devices Advisory Committee (MDAC) consists of 18 panels covering all medical specialty areas. The panels, apart from the Medical Devices Dispute Resolution Panel, advise the FDA about issues related to the safety and effectiveness of medical devices, for example providing advice on a premarket approval application, classification or reclassification of a device, and general scientific issues. Panels make recommendations, but decisions are rendered by FDA.

Review of premarket approval applications for Class III devices is the most frequent panel function. Panels provide recommendations on the safety and effectiveness of the device and FDA considers those recommendations when deciding whether to approve the device. The Medical Device Dispute Resolution Panel advises the Commissioner on complex or contested scientific issues between CDRH and sponsors and manufacturers.

Panel members are not FDA employees. They are, in most cases, "special government employees," and are paid for the days they participate as panel members. There are strict conflict of interest rules governing participation on FDA advisory panels and requirements for disclosure of potential conflict of interest. When an MDAC panel reviews a device, CDRH must work to ensure that the panel has adequate expertise to assess the disease or condition that the device is intended to address, as well as the device's technology.

Panels consist of a chairperson, executive secretary (FDA), and panel members, which may include consumer, industry, and patient representatives. Consumer representatives serve as liaisons between the panel and consumers. Industry representatives act on behalf of the affected regulated industry. Patient representatives are advocates for the patients and family members affected by serious or life-threatening diseases. The consumer, industry, and patient representatives do not have voting privileges. Panel meetings are usually open to the public, but portions may be closed for the discussion of proprietary or other confidential information.