FDA Advisory Committees General Concepts

FDA Public Meeting
Consumer Representative Members
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Advisory Committee (AC) Goals

- To contribute credibility and integrity to FDA's mission of protecting and promoting the public health
  - obtaining outside, independent, expert advice
  - allowing for open public discussion of important health issues

General Information

- 7 Centers and 2 Offices in the Office of the Commissioner manage advisory committees
- 32 FDA ACs
  - Medical Device AC: 18 Panels
- 610 AC members
- 70 Meetings per year on average

Laws and Regulations

- Federal Advisory Committee Act (FACA - 1972)
- Government in the Sunshine Act (1976)
- FACA Final Rule on AC Management (2001)
- 21 CFR Part 14 (FDA Regulation)
- FDA Amendments Act (2007)
- Ethics Laws and Regulations

What is an Advisory Committee?

- Established with a defined membership and function
- Members do not represent any special interest (any particular organization/group)
- Utilized in the interest of obtaining consensus advice or recommendations
- Include a deliberative process – discussion with multiple experts representing an issue

AC Membership

- Academicians
- Clinicians and Practitioners
- Consumers (subject matter experts)
- Industry Representatives
- Patients and/or Patient Care Givers
- Others (unique to specific committees)

FACA Balance Requirements

- Functions performed
- Geographic distribution
- Ethnic and gender diversity
- Points of view
- Term ending date rotation

Topics Brought Before ACs

- Product approvals
- Adverse event reporting/labeling
- Product manufacturing
- Guidance documents
- Communication of risk
- Review of agency initiatives

Public Participation at Meetings

- All meeting must include an open public hearing
- Generally 1 hour per meeting day
- Participants register through an agency contact
- Participants may be questioned, but do not participate in the deliberations

Member Service

- Terms are generally 4 years
- Committees meet approximately 2 times a year
- Members are appointed as Special Government Employees (SGEs)
- Meetings are held in the Washington DC area
- Travel, lodging, per-diem, and daily pay is provided
- Members are expected to review large briefing packages before each meeting

Consumer Representative Roles

- Represent the consumer perspective
- Serve as a liaison between the committee and consumers
- Facilitate dialogue on scientific issues affecting consumers

Consumer Representative Qualifications

- Have an affiliation with and/or active participation with consumer or community-based organizations
- Be able to:
  - analyze scientific data and research design
  - understand and evaluate benefits & risks, and safety & efficacy of products

Voting and Non-Voting Membership

- 1976 Amendment to Federal Food, Drug and Cosmetics Act – general public interests would be represented on medical device advisory committees by non-voting consumer representatives
- 1996 – A Presidential policy was announced that provided for voting patient representatives on committees dealing with cancer issues
- After 1996, FDA policy made consumer representatives voting members, except where not allowed by statute

Financial Conflicts of Interest

Potential Disqualifying Interests

- Stocks and Investments
- Primary Employment
- Consulting or Advising
- Contracts or Grants
- Patents, Royalties, or Trademarks
- Serving as an Expert Witness
- Speaking or Writing

Financial Conflicts of Interest

Before Appointment

FDA must review an individual's expertise and financial information so as to reduce the likelihood that an appointed individual will later need a waiver.

- Section 712 of the Food Drug and Cosmetics Act as amended by the FDA Amendments Act of 2007

Financial Conflicts of Interest

Before Meeting Participation

All members are screened for potential financial conflicts in relation to the meeting topic.

Certain questions must be asked.

- Could the financial interest be directly and predictably affected by the discussion and outcome of the meeting?
- Could the outcome of the meeting affect the ability or willingness of the funding entity to continue its relationship with the individual?

Financial Conflicts of Interest

Waivers Allowing Participation

"participation of members with potential conflicts of interest generally would occur under narrow circumstances where the potential conflict is minimal and the member's expertise is necessary to afford the committee essential expertise"

- FDA's Guidance on Procedures for Determining Conflicts of Interest and Eligibility for Participation in FDA Advisory Committees – August 2008

Outreach

- Federal Register announcements
- Website
  - www.fda.gov/AdvisoryCommittees/default.htm
  - cv@oc.fda.gov
- Participation in professional meetings
- Direct mailings
- Brochures, flyers
- New member training

Thank You !

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