FDA Advisory Committees & Potential Conflicts of Interest

William A. McConagha, Esq.
Office of the Commissioner
US Food & Drug Administration

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The following materials were prepared solely for this educational discussion and do not necessarily reflect the official views of FDA or the Department of Health and Human Services.
I. Like all federal agencies, FDA’s advisory committee program must comply with several specific statutes:
   - Federal Advisory Committee Act (5 USC App. II)
   - Criminal Financial Conflicts Provisions (18 USC 208)
   - Privacy Act (5 USC 552a)
   - Trade Secrets Act (18 USC 1905)
   - FOIA (5 USC 552)

II. In addition, FDA must also comply with certain applicable provisions in the Federal Food, Drug, & Cosmetic Act (FDCA):
   - Section 712 of the FDCA (which recently replaced 505(n)(4))
   - Section 301(j) of the FDCA
Section 712 of FDCA:

With respect to potential conflicts of interest, new section 712 of the FDCA establishes three important requirements:

- When considering a term appointment to a committee, FDA shall review an individual’s expertise and financial disclosures so as to reduce the likelihood that an appointed individual will later need a conflict of interest waiver.
- A person with certain personal and/or family financial interests cannot participate in a meeting unless s/he is granted a waiver, which requires a determination by FDA/HHS that the person’s participation is “necessary to afford the advisory committee essential expertise.”
- Annual statutory cap on the number of conflict of interest waivers that can be granted by FDA
Section 712 (cont’d).

- Section 712 was enacted in late 2007.
- It signals clearly that many in Congress are concerned about persons with potential conflicts of interest participating on FDA advisory committees.
- FDA is complying with section 712 and is committed to maintaining and improving the integrity of its advisory committee program.
FDA’s Improvement Efforts:

- FDA has taken several significant steps in the last 18 months to enhance its advisory committee program:
  - Draft Guidance on Waiver Criteria
  - Draft Guidance on Disclosure of Waiver Info to the Public
  - Draft Guidance on Voting Procedures at meetings
  - Draft Guidance on Posting Briefing Materials
  - Website Improvements
- All these efforts are intended to increase transparency, refine business processes, and improve accountability