



FDA Advisory Committees: Financial Conflicts of Interest Overview

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What is a “conflict of interest”?

- A conflict of interest, for the purposes of FDA Advisory Committees, occurs when an individual selected to serve on an advisory committee has financial interests that may be impacted by the individual’s work on the advisory committee.
- 18 U.S.C. 208(a) prohibits all employees, including Special Government Employees (SGEs) serving on advisory committees, from participating in any particular Government matter that will have a “direct and predictable effect” on their financial interests.

What is a “conflict of interest”? (cont.)

- Financial interests include anything currently held that can financially impact the SGE or the interests of others with whom the SGE has a certain relationship, including the SGE’s spouse, minor children, business partners, employer, and organizations in which the individual serves as officer, director, or trustee.
 - *Examples include:*
 - *Stocks;*
 - *Bonds;*
 - *Interests through ownership, partnership, LLC;*
 - *Consulting arrangements;*
 - *Grants or contracts; and*
 - *Employment.*

How does the FDA determine if there is a conflict of interest?

- Prior to an advisory committee meeting, SGEs selected to serve on the advisory committee complete the FDA Form 3410, which identifies potential conflicting financial interests with the meeting topic(s). In the FDA Form 3410, SGEs list their financial interests that may create a conflict, and submit it to FDA for review.

How does the FDA determine if there is a conflict of interest? (cont.)

- Based on information obtained during this screening process, the FDA follows the procedures outlined in “Guidance for the Public, FDA Advisory Committee Members, and FDA Staff on Procedures for Determining Conflict of Interest and Eligibility for Participation in FDA Advisory Committees” to determine whether an advisory committee member has a potential conflict of interest and whether participation in an advisory committee meeting is appropriate.

What types of financial interests create a potential conflict?

- Prior to an advisory committee meeting, FDA identifies entities (including companies or other organizations) that could be affected by the outcome of the advisory committee proceedings and any FDA decision based on the committee's recommendations and screens SGEs for interests with these entities.
 - Example: The sponsor of a new drug application that is being presented to an advisory committee and sponsors of drugs that closely compete with the subject drug would all be "potentially affected organizations" for which the financial interest of the SGE in the organization would need to be considered for potential conflicts of interest.

What types of financial interests create a potential conflict?

- For each financial interest held by the SGE, FDA examines if there is a close (“direct”) causal link between any decision or action to be taken in the matter and any expected effect of the matter on the financial interest, and if there is a real (“predictable”), as opposed to a speculative, possibility that the matter will affect the financial interest.

What if a potential conflict of interest exists?

- If a particular matter will not have a “direct and predictable effect” on a SGE’s financial interests, the SGE, absent any “appearance” concerns*, **can** serve on the FDA Advisory Committee for that particular matter.
- If a particular matter will have a “direct and predictable effect” on a SGE’s financial interests, the SGE, absent the provisions outlined in 18 U.S.C. 208(b), **cannot** serve on the FDA Advisory Committee for that particular matter.

*Circumstances related to relationships that a SGE has outside the SGE’s service on an advisory committee might lead to questions of whether the SGE has an “appearance of a lack of impartiality.” Under 5 CFR 2635.502, the key question is whether a reasonable person who is familiar with the facts would question the SGE’s impartiality to serve on an advisory committee for a particular matter.

What if a potential conflict of interest exists?

- **18 U.S.C. 208(b) Applicable Provisions:**
 - **18 U.S.C. 208(b)(2):** The SGE can serve on a FDA Advisory Committee if the FDA determines that the SGE's financial interest falls within an applicable regulatory exemption, listed at 5 C.F.R. 2640, for certain financial interests which are too remote or too inconsequential to affect the integrity of the services of the SGE.
 - **18 U.S.C. 208(b)(3):** The FDA can grant an SGE a waiver to serve on a FDA Advisory Committee if the FDA certifies in writing that the need for the SGE's services outweighs the potential for a conflict of interest posed by the financial interest involved.

What can be done to prevent conflicts of interest?

- Because of the variety of topics that come before a particular FDA Advisory Committee, many different interests can create conflicts. An interest may create a potential conflict for one meeting, but not for another.
- The best thing SGEs, or potential SGEs, can do is to keep track of their interests. SGEs must be mindful of not only their personal interests, but those of their employer and any organizations in which they have a leadership role. Keeping updated, easily accessible records will help ensure accurate disclosure and allow for a full evaluation of any potential conflicts of interest prior to service on an FDA Advisory Committee.