

Procedures for Evaluating Appearance Issues and Granting Authorizations for Participation in FDA Advisory Committees

Guidance for the Public, FDA Advisory Committee Members, and FDA Staff

DRAFT GUIDANCE

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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

Advisory committees provide independent, expert advice to FDA on a range of issues affecting the public health.¹ To protect the credibility and integrity of advisory committee advice, FDA screens advisory committee members² carefully for two categories of potentially disqualifying interests or relationships:

- (1) current financial interests that may create a recusal obligation under Federal conflict of interest laws; and
- (2) other interests and relationships that do not create a recusal obligation under Federal conflict of interest laws but that may create the appearance that a member lacks impartiality, known as “appearance issues.”

In August 2008, FDA issued a guidance describing the process it uses to decide whether an advisory committee member has potentially disqualifying interests in the first category, *i.e.*, current financial conflicts of interest that may create a recusal obligation

¹ Advisory committees provide advice and recommendations to FDA; their recommendations are not binding on the agency. Final decisions are made by FDA. 5 USC App. 2 § 9(b); 21 CFR § 14.5.

² This guidance applies to special Government employees (SGEs) and regular Government employees (RGEs) invited to participate in FDA advisory committees subject to the Federal Advisory Committee Act (FACA) (5 USC § App. 2). For purposes of the guidance, we refer to these SGEs and RGEs as advisory committee “members.”

under Federal conflict of interest laws.³ The 2008 guidance also describes FDA's process for determining whether to grant a waiver for an advisory committee member with a financial conflict of interest to participate in an advisory committee meeting.

This draft guidance addresses FDA's process for evaluating whether an advisory committee member has potentially disqualifying interests or relationships that fall into the second category of interests: appearance issues. It also describes FDA's process for determining whether to authorize a member with an appearance issue to participate in the advisory committee meeting.

FDA's guidance documents, including this guidance, do not establish legally enforceable rights or responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

Members of FDA's advisory committees are subject to Government-wide standards of ethical conduct regulations in addition to Federal conflict of interest laws. Even where a member has no financial interests that would require her to refrain from participating in an advisory committee meeting ("recuse" herself) under Federal conflict of interest laws, the member may be disqualified from participation under the Government-wide Federal regulation at 5 CFR § 2635.502 ("section 502") if she has interests or relationships that may create the appearance that she lacks impartiality on the issue before the advisory committee.⁴ Section 502 implements the ethical principle that a Government employee should be impartial in performing her official duties, meaning that she must not give preferential treatment to any private organization or individual or use public office for private gain. To the extent that a member's performance of official duties might appear to benefit her or certain other individuals close to her, she must take appropriate steps to avoid even an appearance of violating these ethical principles.⁵

Section 502 gives FDA and other agencies significant flexibility and discretion in deciding whether a member with an appearance issue should participate in a particular

³ FDA 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, available at <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM125646.pdf>. See also FDA Guidance for the Public, FDA Advisory Committee Members, and FDA Staff: Public Availability of Advisory Committee Members' Financial Interest Information and Waivers, available at <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM295372.pdf>.

⁴ 5 CFR § 2635.502(a)-(e).

⁵ Section 502 proposed rule, 56 Fed. Reg. at 33785.

matter.⁶ Under section 502, when a member has an appearance issue, FDA may authorize the member to participate in the advisory committee meeting based on a determination, made in light of all relevant circumstances, that the interest of the Government in the member's participation outweighs the concern that a reasonable person may question the integrity of the agency's programs and operations.⁷ If FDA does not issue an authorization, the individual may not participate in the meeting or the portion of the meeting involving the particular matter relevant to the appearance issue.⁸ In determining whether to grant an authorization under section 502 to a member with an appearance issue, FDA balances the agency's interest in access to the advice of qualified experts to make important public health decisions with the need to avoid serious questions about the member's impartiality.

Section 502 places the initial burden of identifying potential appearance issues on the member.⁹ It also gives the member the initial responsibility to recuse herself where she determines that the circumstances would cause a reasonable person with knowledge of the relevant facts to question her impartiality in the matter, unless she informs FDA of the issue and receives authorization from FDA to participate.¹⁰ FDA provides assistance to members in fulfilling these duties. FDA has the discretion to make independent determinations about whether a member has an appearance issue and to decide whether to grant her an authorization to participate once an appearance issue is identified.¹¹

Sections IV and V of this guidance explain how FDA reviews potential appearance issues and grants authorizations for advisory committee members under section 502.

III. WHAT IS THE SCOPE OF THIS GUIDANCE?

This guidance applies to advisory committee meetings. Section 502 specifically describes appearance issues that arise from meetings that relate to "particular matters involving specific parties¹²." However, section 502(a)(2) also provides that "an employee who is concerned that circumstances other than those specifically described in this section would raise a question regarding her impartiality to use the process described

⁶ 56 Fed. Reg. at 33778, 33786 (July 23, 1991) ("Section 502 proposed rule").

⁷ 5 CFR § 2635.502(d).

⁸ 5 CFR § 2635.502(e).

⁹ 5 CFR § 2635.502(a).

¹⁰ *Id.*

¹¹ 5 CFR § 2635.502(c).

¹² Office of Government Ethics (OGE) regulations define a "particular matter involving specific parties" to include "any judicial or other proceeding, application, request for a ruling or other determination, contract, claim, controversy, investigation, charge, accusation, arrest or other particular matter involving a specific party or parties. The term typically involves a specific proceeding affecting the legal rights of the parties, or an isolatable transaction or related set of transactions between identified parties." 5 CFR §§ 2640.102(1) and 2635.502.

in this section to determine whether she should or should not participate in a particular matter.” This guidance will address those circumstances specifically described as well as other circumstances that could raise appearance issues, as contemplated by section 502.

The principal focus of section 502 is on “particular matters involving specific parties.” These are proceedings that affect the legal rights of specific companies, organizations, or individuals. Advisory committee meetings involving review of a product approval application or the safety of, or labeling changes for, a specific product are particular matters involving specific parties. If a committee reviews two or more specific products in a single meeting, each constitutes a separate particular matter involving a specific party.

This guidance applies only to special government employees (SGEs) and regular government employees (RGEs), referred to collectively in this guidance as “members”¹³ invited to participate in FDA advisory committees subject to the Federal Advisory Committee Act (FACA)(5 USC § App.2) engaged in activities involving a particular matter. It does not apply to members serving on a FDA advisory committee who are not SGEs or RGEs.¹⁴

This guidance addresses only appearance issues under section 502. This guidance does not address financial conflicts of interest that disqualify members from participation under 18 USC § 208.¹⁵

IV. DETERMINING WHETHER AN APPEARANCE ISSUE EXISTS

A. What is the Screening Process to Identify Possible Appearance Issues?

In preparation for an advisory committee meeting involving a particular matter, members report to FDA any interests related to the subject matter of the meeting.¹⁶ These interests are reported on the Confidential Financial Disclosure Report (also known as the Form FDA 3410, an alternate form approved by OGE to be used in lieu of the OGE confidential financial disclosure report, Form OGE-

¹³ Most FDA advisory committee members are appointed as SGEs. However, advisory committee members may also be RGEs. For example, FDA may request participation by employees of the United States Department of Agriculture, the Centers for Disease Control and Prevention, or other Federal agencies where these employees’ expertise is needed.

¹⁴ Some participants at advisory committee meetings are neither SGEs nor RGEs. Industry representatives, for example, are not SGEs and are appointed to advisory committees to provide the point of view of the industry they represent. Industry representatives are not subject to federal conflict of interest laws or standards of ethical conduct regulations.

¹⁵ As noted, FDA has issued guidance on these financial conflicts of interest, *supra* note 4.

¹⁶ <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM125646.pdf>

450). The Form FDA 3410 is specifically tailored to meet the needs of FDA’s advisory committees.^{17, 18} Although the Confidential Financial Disclosure Report Form FDA 3410 primarily focuses on current financial interests, it also asks for information about past financial interests that directly relate to the products or issues to be considered at the meeting, and any other interests or relationships that might give rise to an appearance issue.¹⁹ A member may seek assistance from FDA in completing this form. In completing this form, a member is required to report anything that would create an appearance issue not otherwise disclosed on the Form. The member may make a threshold judgment as to whether the information would cause a reasonable person to question her participation, and so inform the agency.

FDA reviews the completed Confidential Financial Disclosure Report for each member in advance of every committee meeting to determine whether an appearance issue exists. As part of this review, FDA may ask for clarification about reported interests or about interests not reported but of which FDA may otherwise be aware.

B. What Circumstances May Create an Appearance Issue?

Section 502 specifically lists certain interests and relationships that could create an appearance issue, described below in subsections 1 and 2. It also includes a “catch-all” provision, described in subsection 3, which covers any other circumstances that may cause a reasonable person to question the member’s impartiality. Once these circumstances described in this section raise a concern regarding the impartiality of the member, FDA considers the totality of the circumstances when determining to grant an authorization, as described in section V.

1. “Direct and Predictable Effect” on the Current Financial Interest of a Member of the Advisory Committee Member’s Household

Under section 502, the following scenario would raise a potential appearance issue: *where the particular matter coming before the advisory committee is likely to have a “direct and predictable effect” on the current financial interest of a member of the advisory committee member’s household.*

¹⁷ In some rare instances where the particular matter before the committee is broad and far-reaching and will affect a class of non-federal entities without reference to a specific product or type of product, the agency may decide to use the Form OGE-450 for members to report their financial interests.

¹⁸ Form FDA 3410 asks members to identify anything that would give an “appearance” of a conflict where Form OGE-450 does not specify appearance issues.

¹⁹ See 5 CFR § 2635.502(a).

The phrase “direct and predictable effect,” as used in section 502, has the same meaning as under the Federal financial conflict of interest statutes.²⁰ Specifically, a particular matter will have a “direct” effect on a financial interest if there is a close causal link between any decision or action to be taken in the matter and any expected effect of the matter on the financial interest.²¹ A particular matter will have a “predictable” effect if there is a real, as opposed to a speculative, possibility that the matter will affect the financial interest.²²

In applying this “direct and predictable effect” standard for purposes of section 502, FDA considers the interests of “member[s] of [the individual’s] household.”²³ In this respect, section 502 is broader than the Federal financial conflict of interest statutes, which direct FDA to consider the financial interests of a member or the member’s spouse and minor children only, not other potential household members.²⁴ As used in section 502, the phrase “member of [the individual’s] household” is construed broadly to include, for example, adult children and parents living with the member, as well as others sharing the member’s house, whether or not related to her (although it would not include a houseguest who lives in the house for a month or less).²⁵ FDA evaluates each set of the circumstances in determining whether a reasonable person would consider an individual to be part of the member’s household for purposes of section 502.²⁶

2. A Person or Entity with Whom the Member has a “Covered Relationship” is or Represents a “Party to the Matter”

Under section 502, the following scenario would also raise a potential appearance issue: *where a person (or entity) with whom the advisory committee member has a “covered relationship” is or*

²⁰ See 5 CFR § 2635.402(b)(1), 18 USC § 208.

²¹ 5 CFR § 2640.103(a)(3)(i).

²² 5 CFR § 2640.103(a)(3)(ii). For more information on how FDA evaluates whether a meeting will have a “direct and predictable effect” on an member’s current financial interest, please refer to FDA’s guidance on financial conflicts of interest, FDA 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 Committee Meetings, available at <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM125646.pdf>.

²³ 5 CFR § 2635.502(a).

²⁴ Compare 18 USC § 208(a) with 5 CFR § 2635.502(a).

²⁵ 57 Fed. Reg. at 35006, 35026 (Aug. 7, 1992) (“Section 502 final rule”).

²⁶ *Id.*

represents a “party to the matter” coming before the advisory committee. Both “covered relationship” and “party to the matter” are described below.

“Covered Relationship”: Section 502(b)(1) provides that a member has a “covered relationship” with the following people and entities:

- (i) A person with whom the member has or is seeking a business, contractual, or other financial relationship other than a routine consumer transaction;²⁷
- (ii) A person who is a member of her household or a relative with whom she has a close personal relationship;
- (iii) A person or entity for which the member has, within the last year,²⁸ served as an employee, officer, director, consultant, agent, attorney, trustee, contractor, or general partner;
- (iv) A person or entity for which the member’s spouse, parent, or dependent child currently serves or is seeking to serve as an employee, officer, director, consultant, contractor, agent, attorney, trustee, or general partner; and
- (v) An organization, other than a political party, in which the member is an “active participant.” Mere membership in an organization, payment of dues, or the donation or solicitation of financial support does not, by itself, constitute active participation.

Section 502’s “covered relationship” prong requires consideration of a broader set of relationships and interests than under the Federal financial conflict of interest statutes. For example:

- ***Household Members and Relatives:*** Section 502 provides for consideration of situations where: the member’s household (discussed above in Section IV.B.1); or (b) relatives with whom the member has a close personal relationship (e.g., adult children, parents, in-laws), whether or not they reside in the member’s household, are a party or party representative to the particular matter before the committee. (As noted, Federal conflict of interest laws cover the financial interests of the member, her spouse, and minor children, not adult children or other household members.)

²⁷ This paragraph specifically excludes situations in which the relationship is with a “prospective employer” as defined in 5 CFR § 2635.603(c). The latter type of relationship is governed by the financial conflict of interest analysis under 18 USC § 208.

²⁸ “Within the last year” means within the 12 months preceding the date of the advisory committee meeting.

- ***Certain Past Financial Interests:*** Section 502 covers certain *past* financial relationships. For example, if the member, in the previous year, has served as a consultant to a sponsor of a product before the committee, she has a covered relationship with a party to the particular matter before the committee. (The financial conflict of interest analysis applies only to the member’s *current* financial interests and those under negotiation or for which she has an agreement.)
- ***Certain Current Financial Interests:*** Even where a member’s current financial relationship has been determined not to create a recusal obligation under Federal financial conflict of interest laws, it could present an appearance issue under section 502. For example, if a member has a current consulting contract with a sponsor of a product being reviewed by the advisory committee, but the member’s contract is not related to the product or issue being considered by the committee, FDA may conclude that the particular matter before the committee is unlikely to have a “direct and predictable effect” on the member’s financial interest under Federal financial conflict of interest statutes (depending on the particular circumstances). However, the member’s contractual relationship with the sponsor would constitute a “covered relationship” under section 502 and could present an appearance issue.
- ***Certain Relationships that Exist through the Member’s Role with an Employer or Organization:*** Even where there is no recusal obligation under Federal financial conflict of interest laws, FDA’s practice is to consider that the member could still have an appearance issue under section 502 if: (1) she holds a leadership position with her employer, or is an “active participant” in an organization, and; (2) that employer or organization has a financial relationship with the sponsor whose product is coming before the advisory committee. This appearance issue may exist even if the employer’s or organization’s relationship is unrelated to the products or issues before the committee and the member was not personally involved in the funded activity. Leadership responsibilities could include managerial or supervisory duties or any fiduciary duties. “Active participation” could include service as an official of the organization or otherwise directing the activities

of the organization.²⁹ Because of this broad coverage of section 502, FDA’s practice is that a member that holds a leadership position with her employer, or is an “active participant” in an organization, should report any financial relationships that are known to the member between her employer and the party or parties to the particular matter before the committee. This reporting applies even when the financial relationship is unrelated to the products or issues before the committee, the member has not been personally involved in the funded activity, and the financial interest has ended within the past 12 months.³⁰

“Party to the Matter”: The determination of who is a party to the matter depends on the specific facts of each case, in particular whose legal rights or obligations will be affected by the particular matter before the committee. Generally, FDA considers a party to include any sponsor of the product(s) coming before the advisory committee. Other entities with certain types of financial relationships related to the product(s), such as licensees, may also be parties to the matter.

3. Other Circumstances that May Raise a Question about the Member’s Impartiality

Section 502 provides a “catch-all” for other circumstances that may create an appearance issue: *where circumstances other than those specifically described may raise a question about the member’s impartiality.*³¹ In FDA’s experience section 502, such circumstances could include:

- ***Particular Matters of General Applicability:*** Generally, section 2635.502 focuses on particular matters involving specific parties. However, section 2635.502(a)(2) provides a mechanism for SGEs to determine whether they should recuse

²⁹ For example, a member may have an appearance issue if she is an officer in a nonprofit organization that has received funding from the sponsor within the past year, whether or not that funding relates to the product or issues before the committee and even if all monies have been paid and all services rendered. A member also may have an appearance issue if she has a leadership role at a university (e.g., dean) that has funding from the sponsor to carry out clinical trials on products that are unrelated to the products before the committee, even if the member has no personal involvement with the clinical trials.

³⁰ For example, the Chair of a clinical division at a hospital should report any grants or contracts that have been awarded to her division by the sponsor even if the grant has been completed in the past year and all monies have been paid and all services rendered. Likewise, a president or director of an organization is expected to report any funds the sponsor has given to the organization in the past year.

³¹ 5 CFR § 2635.502(a)(2).

themselves from other “particular matters” that are not described elsewhere in the rule. “Particular matters of general applicability” involve potential changes to regulations or agency guidance, or other broad topics such as policy-making and decisions that affect an entire class of products, such as reviewing labeling changes for an entire class of products³². Particular matters of general applicability tend to raise fewer appearance issues than particular matters involving specific parties³³. However, the agency may require members to recuse from particular matters that do not involve specific parties, based on the concern that the member’s impartiality reasonably may be questioned under the circumstances.

- ***Relationships that are Not Technically “Covered Relationships”***: Professional, social, or other relationships that are not technically a “covered relationship” under section 502 could still raise concerns about the member’s impartiality. For example, an appearance issue may arise if the member has a close personal relationship (but not technically a “covered relationship”) with someone who is a party or party representative, such as if the member is a close friend with the patent holder on the product at issue. Additionally, if the member has a close personal relationship with an officer of the sponsor, these scenarios may raise appearance concerns.³⁴
- ***Past Financial Interests Ending More Than One Year Before the Meeting that Suggest a Close Relationship with the Sponsor or Involvement with the Product(s) before the Committee***: Although interests or relationships more than a year old do not generally give rise to appearance issues, there may be exceptions when these involvements suggest close ties to the sponsor or product(s). These include:
 - Past relationships with the sponsor that were long-term and of substantial value.
 - Past involvement with the product(s) at issue.
- ***Other Relationships or Interests, Whether Current or Past, that May Raise Questions about the Member’s Impartiality***:

³² A “particular matter of general applicability means a particular matter that is focused on the interests of a discrete and identifiable class of persons, but does not involve specific parties.” 5 CFR § 2640.102(m).

³³ Section 502 proposed rule, 56 Fed. Reg. at 33786.

³⁴ Section 502, final rule, 57 Fed. Reg. at 35026.

These relationships or interests involving the member (or a member of her household) may include:

- Past involvement in a lawsuit related to the product(s) or issues before the committee or otherwise involving the sponsor.
- Involvement as a subject in a clinical trial of one of the products at issue.

V. DETERMINING WHETHER TO GRANT A SECTION 502 AUTHORIZATION

A. Whether a Reasonable Person Would Question the Member's Impartiality

Determining whether to grant a section 502 authorization requires evaluating the circumstances described above and then assessing whether these interests, relationships, or circumstances would cause a “reasonable person with knowledge of the relevant facts” to question the member’s impartiality in the particular matter.³⁵ This question assumes the perspective of reasonable person who knows the circumstances, not the perspective of “the unreasonable, uninformed, or overly zealous.”³⁶ As discussed in Section IV.A, a member, under section 502, may make a threshold judgment on whether a reasonable person would question her impartiality and may disqualify herself from participation.

If FDA concludes that a reasonable person would not question the member’s impartiality, there is no appearance issue and the member may participate in the meeting.³⁷ If FDA concludes that an appearance issue exists and is still interested in having that member participate, FDA then asks whether the Government’s interest in the member’s participation outweighs the concern that a reasonable person may question the integrity of the agency’s programs and operations. If so, FDA may grant an authorization before the meeting to allow the member to participate. If FDA does not grant an authorization, the member may not participate in the meeting.

B. Whether the Government's Interest in the Member's Participation Outweighs the Concern that a Reasonable

³⁵ 5 CFR § 2635.502(a).

³⁶ Section 502, final rule, 57 Fed Reg. at 35008. This test does not depend on whether the public has actual knowledge of the appearance issue.

³⁷ 5 CFR § 2635.502(c)(2).

Person May Question the Integrity of the Agency's Programs and Operations

According to OGE, section 502 is intended to give an agency “broad discretion” to determine whether a member’s possible appearance issue “is so significant that it should disqualify them from participation.”³⁸ As OGE has explained, section 502 authorizations “call for the agency [decision maker’s] exercise of judgment and not the application of [a] precise [formula] from which only one correct conclusion can be reached.”³⁹

Even so, the regulation provides a non-exclusive list of factors that an agency may take into consideration in deciding whether to grant a section 502 authorization. In general, these factors are intended to provide greater flexibility and discretion to the agency than those that apply to granting waivers from disqualifying conflicts of interest under 18 USC § 208.⁴⁰ The factors that may be taken into consideration are:

- (1) The nature of the relationship involved;
- (2) The effect that resolution of the matter would have upon the financial interests of the person involved in the relationship;
- (3) The nature and importance of the member’s role in the matter, including the extent to which the member is called upon to exercise discretion in the matter;
- (4) The sensitivity of the matter;
- (5) The difficulty of reassigning the matter to another expert; and
- (6) Adjustments that may be made in the member’s duties that would reduce or eliminate the likelihood that a reasonable person would question her impartiality.⁴¹

(1) The Nature of the Relationship Involved: As noted, appearance issues may arise from: (1) a personal relationship between the member and another individual, e.g., a household member whose financial interests may be affected or close relative, who may be a party to the particular matter that is the subject of the advisory committee meeting; or (2) a past or present professional or other relationship between the member and a company, person, or organization that is a party or party representative to the matter before the advisory committee. Relationships with the party to the matter that have been determined to be unrelated to the particular matter before the committee might, depending on the circumstances, present lesser appearance concerns than relationships more

³⁸ Section 502 proposed rule, 56 Fed Reg at 33786.

³⁹ Section 502 final rule, 57 Fed. Reg. at 35027.

⁴⁰ Section 502 proposed rule, 56 Fed Reg at 33786.

⁴¹ 5 CFR § 2635.502(d)(1)-(6).

directly related to the particular matter. For other types of relationships, in analyzing the nature of a particular relationship to determine whether a section 502 authorization may be warranted, FDA considers the totality of the circumstances, such as:

- Whether the relationship is current or past (past relationships weigh more in favor of participation);
- If a past relationship existed within the prior 12 months (relationships that have not existed within the prior 12 months weigh more in favor of participation);
- Whether the relationship is, or was, related to the product before the committee (relationships not related to the product, e.g., a contractual relationship not related to the product, weigh more in favor of participation than related relationships);
- The magnitude of the financial interest created by the relationship (small interests weigh more in favor to participation); and
- If the member conducted or was otherwise involved with past research on the product, whether that research will be reviewed by the committee (the general principle is that a member should not review her own work).

(2) The Effect that Resolution of the Matter Would Have Upon the Financial Interests of the Person Involved in the Relationship: FDA considers whether the outcome of the particular matter before the advisory committee may have an effect on the current financial interests of a household member or relative with whom the member has a close personal relationship because the household member or relative is employed by or otherwise has a financial relationship with the company (or other party) whose product is before the advisory committee. In these rare cases, FDA may take into account:

- Whether the company is small or large (interests in a company with a wide range of products weigh more in favor of granting a section 502 authorization because of the greater likelihood that the outcome of the meeting will not affect the financial stability of the company and, therefore, the continuing viability of the household member or relative's employment or other relationship with the sponsor).
- Whether the financial interest is related to a product before the committee (interests not related to the product weigh more in favor of participation);
- Whether a household member's or relative's employment with a party is related to the product or is in a division of the company that is

- responsible for the product (employment in the company that is not related to the product can weigh more in favor of participation; and
- The magnitude of the interest (small interests weigh more in favor of participation).

(3) *The Nature and Importance of the Member's Role in the Matter, Including the Extent to which the Member is Called upon to Exercise Discretion in the Matter:* Advisory committees provide only recommendations to FDA; final decisions are made by FDA.⁴² The fact that the member's recommendations are solely advisory in nature, and are not made individually but as only one member of a committee of experts, might weigh in favor of granting a section 502 authorization, depending on the circumstances.

(4) *The Sensitivity of the Matter:* At the time that FDA screens members for appearance issues, it may be difficult to predict whether the matter to be addressed by the committee will be considered sensitive or controversial. FDA nonetheless considers whether the issue coming before the committee is likely to generate significant public interest or the potential for litigation. In highly sensitive cases, FDA may be less likely to grant a section 502 authorization, depending on the analysis of the other factors.

(5) *The Difficulty of Reassigning the Matter to Another Expert:* Members of FDA advisory committees are scientific experts who are leaders in their respective disciplines. Depending on the nature of the matter before the committee, and the needs of the agency for experts with a background in a highly specialized area or sub-specialty, the pool of individuals with the required expertise may be very limited. Scheduling conflicts may further limit the available pool of experts who are able to participate in a committee meeting. FDA evaluates each situation to determine what is best to uphold public confidence in the scientific integrity of the advisory committee process while ensuring that the committee has the necessary expertise. Where a member has particular expertise or experience that is very important to the committee's work, or where others with comparable expertise have conflicts or appearance issues more extensive than the member's, FDA is more likely to grant a section 502 authorization. Where there are alternate experts who possess comparable expertise and have fewer conflicts and appearance issues, FDA is less likely to grant a section 502 authorization. In situations where there is a need for a diversity of expert opinion and there is a limited pool of experts on a particular matter, FDA is more likely to grant a section 502 authorization.

⁴² 5 USC App. 2 § 9(b); 21 CFR § 14.5.

(6) Adjustments that May be Made in the Member's Duties that Would Reduce or Eliminate the Likelihood that a Reasonable Person Would Question the Member's Impartiality: In situations where the appearance concern is significant, the agency may consider adjusting the scope of the member's participation to minimize the concern while allowing the agency to obtain relevant expertise. If adjustments can be made to a member's role to reduce or eliminate the likelihood that a reasonable person would question the integrity of the agency's programs or operations, FDA is more likely to grant a section 502 authorization. Such adjustments may include limiting the member's participation to engaging in committee discussions but not voting, or allowing the member only to give a presentation on a select topic and respond to questions directly related to that presentation but not to participate in committee discussions or voting.

* * *

In deciding whether to grant an authorization, FDA may take into account all of these six factors. To help explain this decision-making process, the **Appendix** contains examples of appearance issues and factors FDA would consider in deciding whether to grant a section 502 authorization for the member to participate in the advisory committee meeting.

VI. APPENDIX: EXAMPLES OF APPEARANCE ISSUES AND FACTORS FDA WOULD CONSIDER IN DETERMINING WHETHER TO GRANT A SECTION 502 AUTHORIZATION

Where a member has an appearance issue under section 502 with respect to the particular matter that is the subject of an advisory committee meeting, FDA evaluates whether, in light of all the relevant circumstances, the agency's interest in the member's participation in the meeting outweighs the concern that a reasonable person may question the integrity of the agency's programs and operations. This evaluation is fact-specific and is conducted on a case-by-case basis. This Appendix describes three examples in which a member would be considered to have an appearance issue under section 502. There are several factors FDA considers relevant in determining whether to grant a section 502 authorization for the member to participate in the meeting. These factors can exhibit various degrees of weight in the authorization decision depending upon the specific conditions and scenario regarding the member. The examples below are intended only to illustrate how some of these factors could be applied. Each situation is evaluated on its own merits and facts considering multiple factors.

Scenario: The advisory committee is reviewing the safety and efficacy of a product. The meeting is a particular matter involving specific parties with one party to the matter (“the sponsor”).

Example #1: *The member's primary employment is as a dean of the medical school at a large university. The member reported that her employer has a multi-year grant from the product sponsor (i.e., the sponsor of the product that will be reviewed and evaluated at the advisory committee meeting) and the grant is not related to the product before the committee. This is an interest or relationship that could cause a reasonable person to question the member's impartiality.*

Factors FDA Would Consider in Determining Whether or Not to Grant a Section 502 Authorization For the Member to Participate in the Meeting:

- Whether the member receives any personal funding or remuneration from the grant (if not, this would weigh in favor of a section 502 authorization);
- Size and diversity of the range of products made or under development by the sponsor providing the grant funding to the employer (the larger and more diverse the range of products the more this would weigh in favor of a section 502 authorization);
- Whether the member's employer relies solely, or principally, on this grant from the sponsor (if not, this would weigh in favor of a section 502 authorization);

- Whether the matter before the committee is considered sensitive or controversial (matters that are typical and routine without controversy would weigh in favor of a section 502 authorization);
- Whether the member has expertise that is important to the committee’s work and others with comparable expertise have conflicts or appearance issues more extensive than the member’s (if so, this would weigh in favor of a section 502 authorization);
- If there is a need for multiple experts in a field (if so, this would weigh in favor of a section 502 authorization).

Example #2: *The member serves on the board of directors of a nonprofit organization that receives donations from the sponsor. This is an interest or relationship that could cause a reasonable person to question the member’s impartiality.*

Factors FDA Would Consider in Determining Whether or Not to Grant a Section 502 Authorization For the Member to Participate in the Meeting:

- Whether the nonprofit organization has taken a position on the product or the meeting topic (if not, this would weigh in favor of a section 502 authorization);
- Whether the member receives any personal funding or remuneration from the donations given to the nonprofit by the sponsor (if not, this would weigh in favor of a section 502 authorization);
- Size and diversity of the range of products made or under development by the sponsor providing donations to the nonprofit organization (the larger and more diverse the range of products the more this would weigh in favor of a section 502 authorization);
- Whether the matter before the committee is considered sensitive or controversial (if not, this would weigh in favor of a section 502 authorization);
- Whether the member has expertise that is very important to the committee’s work and others with comparable expertise have conflicts or appearance issues more extensive than the member’s (if so, this would weigh in favor of a section 502 authorization);
- If there is a need for multiple experts in the field (if so, this would weigh in favor of a section 502 authorization).

Example #3: *The member had a consulting contract⁴³ with the sponsor that ended four months ago.⁴⁴ The consulting contract and relationship with the sponsor has ended and all monies received. This is an interest or relationship that could cause a reasonable person to question the member’s impartiality.*

⁴³ Consulting contracts do not ordinarily constitute “employment” and therefore do not usually implicate 18 U.S.C. 208. However, in this example the member still has a covered relationship with the sponsor and therefore the agency analyzes the interest under 5 CFR 2635.502.

⁴⁴ In instances where the contract is completed and all monies paid, the member will still have a covered relationship under section 502 with the entity for a period of 12 months.

Factors FDA Would Consider in Determining Whether or Not to Grant a Section 502 Authorization For the Member to Participate in the Meeting:

- Whether the member's contract with the sponsor was related to the product before the committee (if not, this would weigh in favor of a section 502 authorization);
- The magnitude of the financial payments to the member under the contract (a small amount would weigh in favor of a section 502 authorization);
- Size and diversity of the range of products made or under development by the sponsor (the larger and more diverse the range of products the more this would weigh in favor of a section 502 authorization);
- Whether the work done under the contract will be a focus of the discussions of the meeting (if not, this would weigh in favor of a section 502 authorization);
- Whether the matter before the committee is considered sensitive or controversial (if not, this would weigh in favor of a section 502 authorization);
- Whether the member has expertise that is very important to the committee's work and others with comparable expertise have conflicts or appearance issues more extensive than the member's (if so, this would weigh in favor of a section 502 authorization);
- If there is a need for multiple experts in a given field (if so, this would weigh in favor of a section 502 authorization).

ATTACHMENT: [FORM FDA 3410](#)

Use the list of products/firms/issues in the cover memorandum to complete this form. Interests relating to these firms must be reported even if unrelated to products/indications listed.

Please answer all questions below to the best of your knowledge. If you are employed by a university or other research institution, you may have little or no personal knowledge about certain financial interests of your employer (e.g., the details of certain research grants in which you are not personally involved). In those cases, you are required to report only what you actually know about the interest, and you have no duty to inquire about further details from your employer. In some situations, however, you may hold a position (such as department chair) in which you exercise some authority with respect to research projects in which you are not personally involved as an investigator or researcher. In those cases, inquiry into additional information about the interest could be helpful in preventing unintentional conflicts of interest or appearances of impropriety.

1. CURRENT FINANCIAL INTERESTS

To your knowledge, do 1) you, your spouse, minor child, general partner, 2) organization in which you serve as an officer, director, trustee, general partner or employee, and/or 3) entity with whom you are negotiating or have any arrangement concerning prospective employment have any current involvement or financial link with the meeting/task issues (including competing companies)?

a. **INVESTMENTS** (e.g., stocks, bonds, retirement plans, trusts, partnerships, sector funds, etc.) **NONE** (If "none," skip to Item b.)

FIRM	TYPE OF INVESTMENT	OWNER (self, spouse, etc.)	NUMBER OF SHARES	CURRENT VALUE	CHECK PERCENTAGE OF NET WORTH		
					LESS THAN 5%	5 - 15%	MORE THAN 15%
					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

b. **EMPLOYMENT** (Full or Part Time) (Current or Under Negotiation) **NONE** (If "none," skip to Item c.)

FIRM	RELATIONSHIP (self, spouse, etc.)	POSITION IN FIRM	DATE EMPLOYMENT OR NEGOTIATIONS BEGAN

c. **CONSULTANT/ADVISOR** (Current or Under Negotiation) **NONE** (If "none," skip to Item d.)

FIRM	TOPIC/ISSUE	AMOUNT RECEIVED	DATE FROM	DATE TO	RELATED TO LISTED PRODUCTS/INDICATIONS/ISSUES
					<input type="checkbox"/> YES <input type="checkbox"/> NO
					<input type="checkbox"/> YES <input type="checkbox"/> NO
					<input type="checkbox"/> YES <input type="checkbox"/> NO

d. **CONTRACTS/GRANTS/CRADAS** (Current or Under Negotiation) **NONE** (If "none," skip to Item e, next page.)

TYPE OF AGREEMENT (contract, grant, CRADA)	PRODUCT UNDER STUDY AND INDICATIONS	AMOUNT OF REMUNERATION TO		TIME PERIOD	SPONSOR *	YOUR ROLE †	AWARDEE	RELATED TO LISTED PRODUCTS/INDICATIONS/ISSUES
		INSTITUTION	YOU					
								<input type="checkbox"/> YES <input type="checkbox"/> NO
								<input type="checkbox"/> YES <input type="checkbox"/> NO
								<input type="checkbox"/> YES <input type="checkbox"/> NO
								<input type="checkbox"/> YES <input type="checkbox"/> NO

* Government, Firm, Institution, Individual

† Site Investigator, Principal Investigator, Co-Investigator, Employee, Partner, No Involvement, or Other

IF MORE SPACE IS NEEDED, COPY AND ATTACH AS ADDITIONAL PAGES

1. CURRENT FINANCIAL INTERESTS (Continued)

e. PATENTS/ROYALTIES/TRADEMARKS

NONE (If "none," skip to Item f.)

FOR	FIRM	RELATED TO LISTED PRODUCTS/ INDICATIONS/ISSUES	IF "YES," EXPLAIN BELOW AND INDICATE INCOME RECEIVED
		<input type="checkbox"/> YES <input type="checkbox"/> NO	
		<input type="checkbox"/> YES <input type="checkbox"/> NO	
		<input type="checkbox"/> YES <input type="checkbox"/> NO	

f. EXPERT WITNESS (Last 12 months or under negotiation)

NONE (If "none," skip to Item g.)

I appeared for or against the following listed firm(s) and issue(s).

FIRM AND ISSUE	AMOUNT RECEIVED	RELATED TO LISTED PRODUCTS/ INDICATIONS/ISSUES	IF "YES," EXPLAIN BELOW
		<input type="checkbox"/> YES <input type="checkbox"/> NO	
		<input type="checkbox"/> YES <input type="checkbox"/> NO	
		<input type="checkbox"/> YES <input type="checkbox"/> NO	

g. SPEAKING/WRITING (Last 12 months or under negotiation)

NONE (If "none," skip to Item 2.)

FIRM	TOPIC/ISSUE	AMOUNT RECEIVED		DATES	RELATED TO LISTED PRODUCTS/ INDICATIONS/ISSUES
		HONORARIUM	TRAVEL		
					<input type="checkbox"/> YES <input type="checkbox"/> NO
					<input type="checkbox"/> YES <input type="checkbox"/> NO
					<input type="checkbox"/> YES <input type="checkbox"/> NO

2. PAST FINANCIAL INTERESTS

a. To your knowledge, do any of the following persons have any past involvement with the meeting/task issues: **You, your spouse, minor child, general partner, organization in which you serve as an officer, director, trustee, general partner, or employee.**

YES NO NOT TO MY KNOWLEDGE

b. If "Yes," describe involvement.

FIRM/PRODUCT	FINANCIAL INVOLVEMENT (e.g., contract/consultant)	ROLE	DATES	RELATED TO LISTED PRODUCTS/ INDICATIONS/ISSUES
				<input type="checkbox"/> YES <input type="checkbox"/> NO
				<input type="checkbox"/> YES <input type="checkbox"/> NO
				<input type="checkbox"/> YES <input type="checkbox"/> NO
				<input type="checkbox"/> YES <input type="checkbox"/> NO

IF MORE SPACE IS NEEDED, COPY AND ATTACH AS ADDITIONAL PAGES

3. OTHER INVOLVEMENTS (Other Kinds of Relationships)

NONE (If "none," skip to Item 4.)

Using the list of products/firms/issues in the cover memorandum, identify anything that would give an "appearance" of a conflict, which has not been disclosed above (e.g., involvement in a lawsuit, researcher initiated study, gift of research materials, etc.).

4. CERTIFICATION STATEMENT

The above information is true and complete to the best of my knowledge. I have read and I understand the policies relating to my obligations as a special Government employee. If there are any changes, I will notify you before the meeting/task. My response contains _____ pages.

SIGNATURE

DATE

PLEASE RETURN BY:

TO: COMMITTEE MANAGEMENT CONTACT

ADDRESS

TELEPHONE

()

FAX

()

PRIVACY ACT STATEMENT

Title I of the Ethics in Government Act of 1978 (5 U.S.C. App.), Executive Order 12674, and 5 CFR Part 2634, Subpart I, of the Office of Government Ethics regulations require the reporting of this information. The primary use of the information on this form is for review by Government officials of your agency, to determine compliance with applicable Federal conflict of interest laws and regulations. Additional disclosures on the information on this report may be made:

- (1) to a Federal, State, or local law enforcement agency if the disclosing agency becomes aware of a violation or potential violation of law or regulation;
- (2) to a court or party in a court or Federal administrative proceeding if the Government is a party or in order to comply with a subpoena;
- (3) to a source when necessary to obtain information relevant to a conflict of interest investigation or decision;
- (4) to the National Archives and Records Administration or the General Services Administration in records management inspections;
- (5) to the Office of Management and Budget during legislative coordination on private relief legislation; and
- (6) in response to a request for discovery or for the appearance of a witness in a judicial or administrative proceeding, if the information is relevant to the subject matter.

This confidential report will not be disclosed to any requesting person unless authorized by law.

Falsification of information or failure to file or report information required to be reported may subject you to disciplinary action by your employing agency or other appropriate authority. Knowing and willful falsification of information required to be reported may also subject you to criminal prosecution.

FOR FDA USE ONLY

SIGNATURE OF REVIEWING OFFICIAL

DATE

COMMENTS OF REVIEWING OFFICIAL

IF MORE SPACE IS NEEDED, COPY AND ATTACH AS ADDITIONAL PAGES