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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

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RE: Procedures for Evaluating Appearance Issues and Granting Authorization for Participation in Food and Drug Administration Advisory Committees; Draft Guidance for the Public, Food and Drug Administration Advisory Committee Members, and Food and Drug Administration Staff; Availability (Docket No: FDA-2016-D-1399)

The Association of American Medical Colleges (AAMC), a not-for-profit association representing all 147 accredited U.S. medical schools, nearly 400 major teaching hospitals and health systems and more than 80 academic societies, appreciates the opportunity to submit comments on the *Draft Guidance on the Procedures for Evaluating Appearance Issues and Granting Authorizations for Participation in FDA Advisory Committees*, released on June 29, 2016[1] by the Food and Drug Administration (FDA). Through the AAMC's member institutions and organizations, the AAMC represents nearly 160,000 faculty members, 83,000 medical students, 115,000 resident physicians, and thousands of graduate students and post-doctoral trainees.

The AAMC appreciates FDA's commitment to ensuring that its advisory committee members have the appropriate and necessary expertise and that the process it uses to screen its members for participation is transparent and credible. A better understanding of how the FDA evaluates financial conflicts of interest and the appearance of conflict protects the integrity of advisory committee advice and advances public trust while increasing the opportunities for individuals to more accurately assess whether it is likely that they will be able to lend their expertise to particular advisory committee activities.

The AAMC is pleased that the FDA has drafted this guidance, which seeks to explain a process and application of law and regulation that is not well understood, especially by those members of the academic medicine community who seek or are asked to participate in FDA advisory committees as special government employees. In particular, the process for identifying appearances of conflict of interest, the distinction between a waiver that will allow participation despite financial conflicts and authorization to participate despite an appearance of conflict, and where the FDA has and can use discretion to allow or prohibit participation have not been adequately and clearly presented. This draft guidance would benefit from some additional clarification, as described in the following comments.

[1] 81 Federal Register 42363, June 29, 2016.

Structure and Framing of Draft Guidance and Description of Appearance of Conflicts of Interest

In 2008, the FDA published the guidance, *FDA Advisory Committee Members, and FDA Staff on Procedures for Determining Conflict of Interest and Eligibility for Participation in FDA Advisory Committees,* which describes the process for screening special government employees and regular government employees for potential financial conflicts of interest and details the standards for granting a waiver under 18 U.S.C §208(b) to allow participation under certain circumstances even if such a conflict of interest exists. Such conflicts of interest typically require recusal of the individual from participation in the FDA advisory committee.

In addition to including information about how FDA will determine whether an appearance of conflict of interest from the information reported by an individual through FDA Form 3410, the new draft guidance addresses circumstances when there is no financial conflict of interest that requires the recusal of an individual under 18 U.S.C §208(b), but when an the appearance of a conflict of interest may prevent an individual from serving on one of the FDA's advisory committees under federal regulations from the Office of Government Ethics related to personal and business relationships for government employees. The regulation, 5 CFR §2635.502, is referred to as "Section 502" in the draft guidance. A companion to rather than replacement for the 2008 guidance, this document recognizes that the "initial burden of identifying potential appearance issues" is placed on the advisory committee member and 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." [2]

The interaction of these two sets of legal requirements under which FDA is operating and the impact of each of these on the FDA's ultimate determination of whether an individual will be allowed to participate in the activities of an FDA advisory committee is opaque to most members of the committees. As an educational document meant to guide both the decision-makers and the potential advisory committee members, it seeks to clarify these decisions and processes but at times reads more like a regulation or legal treatise than guidance. Most of the text of Section 502 is included in the document, blurring the distinction between guidance and reiteration of regulation. Complicating this document is the fact that the regulation itself includes examples meant to guide government entities (not just the FDA) in making decisions about "appearance issues." What is missing from the special government employee perspective is the ability to better predict the FDA's decision in advance or better understand why a decision was made, especially when a prospective member of an advisory committee is prevented from participating because of an appearance issue. **The guidance would be strengthened in its usefulness for special government employees if it included a decision tree or other step-by-step depiction of the decision-making process that identified: what information should be provided to the FDA; what would trigger recusal, when required recusal can be waived; when and how an appearance issue would be identified; and under what circumstances an individual with and appearance issue but not financial conflict of interest would be given authorization to participate in the advisory committee or prohibited from participating.**

[2] 5 CFR §2635.502 (a).

It would also be helpful for the guidance document to state even more clearly, that in applying the two legal standards, the FDA sees a bright line between a financial conflict of interest and an appearance issue and the two are treated distinctly for the purposes of these decisions. This is not a distinction that is regularly made in other conflict of interest regulations,[3] policies, and discussions. Certain relationships create actual or apparent conflicts of interest that need to be reviewed or managed, and are typically addressed without being labeled as one or the other. Thus, special government employees from academic communities will not be as familiar with this distinction. Clarifying the position in this draft guidance would improve understanding both of what needs to be disclosed to the FDA and why final determinations or authorizations were made.

Authorization of Participation Despite Identified Appearance Issues

Under section 502, FDA has broad discretion to determine whether a member's participation in an advisory meeting should be authorized even where an appearance issue has been identified. This requires an evaluation of the circumstances and an assessment of "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."[4] Section 502 provides six factors any agency should take into consideration to decide whether to authorize participation if the agency concludes that an appearance issue exists. The examples that the draft guidance provides to demonstrate how this more general agency regulation would be applied to the FDA's decision-making are helpful, and highlight the flexibility and broad discretion afforded by section 502.

From the perspective of a special government employee who is authorized to participate in one advisory committee and prevented from participating in another, this may contribute to negative external perceptions of a process that has been described to us as feeling "arbitrary," "inconsistent," and "vague" by faculty members and academic leaders who have been prevented from participating in an advisory committee because of an appearance issue after an exhaustive and time-consuming disclosure process.[5] This may be the result of the need for the guidance for FDA decision makers or may instead be the consistent application of criteria that are not apparent from outside the agency. For example, as stated in the guidance, "[i]n 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." **Absent from the draft guidance is an indication of what if any of the decision-making process will be documented by the FDA and communicated to the member, who may not understand why authorizations were granted in some cases and not in others.** Both application of the flexibility afforded by section 502 and better communication with members about the reason for the decisions can help FDA increase its trust from academic communities and committee participation by qualified experts.

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[3] *See, e.g.*, the Public Health Service regulations on Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought at 42 C.F.R. Part 50, Subpart F, which distinguishes between "significant financial interests" that need to be disclosed and interests or relationships that do not, but does not distinguish between an actual conflict of interest and an apparent conflict.

[4] 5 CFR §2635.502 (d).

[5] It should be noted that in anecdotal discussions with faculty and academic leaders, the time required to complete the FDA Form 3410 and associated disclosure process is the primary reason for a lack of interest in participating in FDA advisory committees as special government employees.

Voluntary Disclosure of Participation Through Authorization

FDA has asked specifically for comment on whether its advisory committee members should voluntarily disclose if they are participating in an activity after having been authorized to participate under the agency's authority to allow such participation under section 502. In many cases, disclosure can improve transparency and trust in an objective process. However, **voluntary disclosure of such authorizations should not be recommended through this draft guidance or in FDA policy at this time without a clear and consistent process for its adoption.**

The AAMC is concerned that the discussion of voluntary disclosure in this context is likely to be seen as a requirement without standards or consistent application. That the disclosure would be about an authorization following determination of an appearance of conflict, not a financial conflict of interest requiring recusal under 18 U.S.C §208(b) makes the disclosure of an authorization less meaningful. Further, given the broad flexibility granted to the FDA for issuing these authorizations, the disclosure of an authorization on its own provides little useful information to other members of the advisory committee or the public. Consider an advisory committee meeting where three members have been granted authorization to participate despite having appearance issues, and one member voluntarily discloses an authorization that was granted because the particular matter could have no impact on his own financial interests, another member voluntarily discloses an authorization that was granted because she was one of the few experts available who could provide the necessary expertise, and a third chooses not to disclose that his participation is authorized based on the fact that the FDA would not be required to follow the advice he provide. On balance the disclosure process has not resulted in what disclosure should do – better inform the committee and the public about potential biases that may exist in the advice that FDA is receiving.

We appreciate FDA's efforts to ensure objectivity and accountability in its conflict of interest screening process and the opportunity to comment on this important issue. We would be happy to answer any questions or provide additional input. Please feel free to contact Heather Pierce, Senior Director and Regulatory Counsel at hpierce@aamc.org or (202) 478-9926.

Sincerely,

Ross E. McKinney, Jr, MD

Chief Scientific Officer