Comments: Optimizing the Food and Drug Administration's Use of and Processes for Advisory Committees

Robert Steinbrook, M.D.
Director
Public Citizen's Health Research Group
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I write as the Director of Public Citizen's Health Research Group. We have no financial conflicts of interest. These written comments follow my oral comments at the virtual listening session on this topic on June 13, 2024.

As Public Citizen frequently participates in Food and Drug Administration (FDA) advisory committees and makes oral presentations during the open public hearings, we share the agency's goal of improving the public perception and understanding of these meetings.

These comments address three topics: (1) The importance of maintaining or perhaps even expanding voting questions as a central feature of advisory committee meetings; (2) Releasing both the sponsor's and the agency's publicly available briefing materials 5 to 7 business days before the date of the advisory committee meeting, not—as is typically the current practice—no later than 2 full business days before the meeting; and (3) Reducing to zero, with rare exceptions, the number of voting members of advisory committees who are granted waivers to participate, despite having an otherwise disqualifying financial interest. All these recommendations, if adopted, would improve the public perception and understanding of advisory committees.

Comments from FDA officials raise concerns that advisory committees will be asked to vote less frequently on central questions, such as whether a drug is effective for the treatment of a disease, whether the benefits of a drug outweigh its risks, and whether the drug should be approved. Although we understand that a committee vote may be mistakenly viewed as an agency decision, it is the FDA's responsibility to explain as needed that advisory committees, as the name indicates, are advisory, and the agency makes the final decision. Discussion questions and voting questions complement each other. Voting is an integral part of the process, because it allows committee members to record their overall view after a long and detailed discussion of the pluses and minuses of a drug or device. Importantly, without a vote, it would be easier for the FDA or the sponsor of a marketing application to spin the discussion as they wish and to disregard the committee's advice. Moreover, a vote, particularly in instances when the FDA does

not follow the committee's recommendations, increases the chances that the agency will clearly and publicly state why it reached a different decision.

At present, the publicly available materials for an advisory committee are usually released 2 business days before the meeting. The materials are complex, totaling dozens if not hundreds of pages, and require careful study. When slides are included in the oral presentation, they often must be submitted to the FDA on the same day that the briefing materials become available. As the materials are finalized earlier, the FDA should release them 5 to 7 full business days before the meeting and provide speakers at the open public hearing with a minimum of 2 full business days to prepare slides.

Granting waivers to participate to voting members of advisory committees despite their having an otherwise disqualifying financial interest makes it easier to find voting members. Nonetheless, granting a waiver based on the FDA's determination that the "financial interests are not so substantial as to be deemed likely to affect the integrity of …the services"[1] is inherently a subjective judgment. The essential point about financial conflicts of interest, which is often ignored or misunderstood, was by made by Dennis Thompson in a 1993 article in the *New England Journal of Medicine*: "the rules do not assume that most physician researchers let financial gain influence their judgment. They assume only that it is often difficult if not impossible to distinguish cases in which financial gain does have improper influence from those in which it does not."[2] Reducing to zero, with rare exceptions, the number of voting members of advisory committees who are granted waivers to participate would be an important step forward for the integrity of the advisory committee process.

Thank you for the opportunity to comment.

[1] Office of Government Ethics. 5 C.F.R. 2640.301 Waivers issued pursuant to 18 U.S.C. 208(b)(1). https://www.govinfo.gov/content/pkg/CFR-2010-title5-vol3/pdf/CFR-2010-title5-vol3-sec2640-301.pdf Accessed June 12, 2024.

[2] Thompson DF. Understanding financial conflicts of interest. N Engl J Med. 1993;329(8):573-576. doi:10.1056/NEJM199308193290812.