

A report to congressional committees.

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What GAO Found

The Food and Drug Administration (FDA) relies on more than 30 advisory committees to provide expert advice on numerous scientific topics, including opioid drugs for pain. Government-wide requirements prohibit committee members from taking part in meetings that could affect their financial interest. FDA checks for conflicts of interest by reviewing a form that committee members fill out to disclose financial interests, such as investments in drug companies. Regulations also require FDA to check for issues that could give the appearance that a committee member lacks impartiality. In some situations, FDA may grant a waiver or authorize a member to take part in a meeting, such as when the need for the member’s expertise outweighs the potential conflict. FDA also has policies to similarly review financial interests and appearance issues for guest speakers, who may be invited to meetings to present scientific information.

Examples of Financial Interests

 <p>Employment or Consulting</p>	 <p>Investments</p>	 <p>Other involvement</p>
<p>Positions (current or under negotiation) with businesses, educational institutions, governments, or nonprofits.</p>	<p>Stocks, bonds, retirement plans, trusts, partnerships, etc.</p>	<p>Any relationships that would give the appearance of a conflict (e.g., involvement in a lawsuit or research study).</p>

Source: GAO analysis of Food and Drug Administration (FDA) form 3410 and Office of Government Ethics (OGE) form 450 (information); toonsteb./stock.adobe.com (icons). | GAO-26-107877

Between June 2018 and May 2025, FDA invited an average of about 29 committee members to each of the 17 most recent meetings for committees that discuss opioids. Across these meetings, FDA’s conflict of interest review process resulted in members being recused from taking part in the meetings 15 times. FDA also granted a financial conflict of interest waiver to allow a member to participate because the agency determined their expertise was needed and that their financial interest was not substantial. In addition, FDA authorized members with appearance issues to take part in meetings seven times. These results are comparable to those of other FDA committees that GAO reviewed.

FDA uses a combination of government-wide requirements and internal policies to guide its conflict of interest review process. However, FDA does not publicly share information on how it determines whether members have financial conflicts of interest and whether they should participate in committee meetings. This is because FDA has not yet finalized required guidance on the matter more than 13 years after a law required it. In addition, FDA has not posted to its website how it makes these decisions in the interim. Further, the agency does not publicly share how it determines whether guest speakers have financial conflicts or appearance issues and whether they should participate in meetings. Publicly sharing information on how FDA makes these determinations would be consistent with the law and FDA’s own best practices. Making this information public would increase transparency and provide the public with greater assurance that FDA has steps in place to manage conflicts of interest for advisory committees, and therefore help to ensure accountability and consistency in decision making.

Why GAO Did This Study

Conflict of interest rules and guidelines are essential to ensure FDA receives independent, unbiased professional expertise from advisory committees to help its efforts to assure the safety and effectiveness of drugs, medical devices, and other products. Federal requirements for advisory committees emphasize the importance of public access, input, and accountability, including addressing conflicts of interest.

A Senate Appropriations Committee report includes a provision for GAO to review how FDA addresses conflicts of interest for advisory committee meetings, particularly for opioids.

This report (1) describes FDA’s advisory committee conflict of interest policies and review process, (2) describes the results of FDA’s review process for advisory committees related to opioids, and (3) examines the extent to which FDA publicly shares its conflict of interest policies for advisory committees.

GAO reviewed relevant federal laws and regulations, as well as FDA documentation on advisory committees. GAO also reviewed published research about the results of FDA’s conflict of interest review process and interviewed FDA officials and stakeholders familiar with advisory committee meetings.

What GAO Recommends

GAO is recommending that FDA (1) establish a time frame for issuing and publicly sharing required financial conflict of interest guidance, (2) make public how it determines these conflicts for committee members in the interim, and (3) make public how it determines conflicts and appearance issues for guest speakers.

HHS concurred with the recommendations.