Doctors: FDA must keep public trust without losing best experts

NOV 17, 2020

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There is a widespread consensus that conflict-of-interest (COI) waivers the Food and Drug Administration (FDA) grants to some advisory committee members are appropriate and necessary, but there's also concern that an overzealous approach to such waivers will undermine the actual or perceived quality of these committee's recommendations, according to an AMA Board of Trustees report.

The FDA has about 550 people on its 50 advisory committees and panels that provide independent expert advice and recommendations on scientific, technical and policy matters for the products the agency regulates. And federal laws outline what constitutes a conflict of interest and when a waiver is allowed.

"Despite long-standing federal laws governing conflict of interest and waivers applicable to FDA advisory committee members, there have remained persistent concerns in the general public that waivers of conflict of interest negatively impact the trustworthiness and independence of advisory committee recommendations," according to the report adopted at the November 2020 AMA Special Meeting.

The report notes, however, that researchers have found that "the perverse exclusion of 'financially conflicted members resulted in a sharp drop in average member expertise."

Streamlining the COI waiver process

So, while “ensuring conflicts of interests do not compromise the integrity of the FDA advisory committee is paramount,” the report also says “there is an ongoing pressing need to fill FDA advisory committee vacancies” and that the FDA should “streamline the conflict of interest process to reduce any unnecessary documentation, administrative barriers or delays that might hinder the participationof qualified physicians on FDA advisory committees.”

Delegates adopted policy saying the FDA’s decisions must be “trustworthy” and that “patients, the public, physicians, other health care professionals and health administrators, and policymakers must have confidence that FDA decisions and the recommendations of FDA advisory committees are ethically and scientifically credible and derived through a process that is rigorous, independent, transparent, and accountable. Rigorous policies and procedures should be in place to minimize the potential for financial or other interests to influence the process at all key steps.”

Such policies and procedures should include:

- Required disclosure of all relevant actual or potential conflicts of interest, both financial and personal.
- A mechanism to independently audit disclosures when warranted.
- Clearly defined criteria for identifying and assessing the magnitude and materiality of conflicts of interest.
- Clearly defined processes for preventing or terminating the participation of a conflicted member, and mitigating the influence of identified conflicts of interest, such as prohibiting individuals from participating in deliberations, drafting or voting on recommendations on which they have conflicts, in those limited circumstances when an individual’s participation cannot be terminated due to the individual’s unique or rare skillset or background that is deemed highly valuable to the process.

In addition, the new AMA policy says:

- Clear statements of COI policy and procedures, and disclosures of FDA advisory committee members’ conflicts of interest relating to specific recommendations should be published or otherwise made public.
- Participation on advisory committees should be facilitated through appropriate balancing of the relative scarcity or uniqueness of an individual’s expertise and ability to contribute to the process, as compared to the feasibility and effectiveness of mitigation measures.
- The FDA should streamline the COI process to the greatest extent possible, thereby eliminating any unnecessary documentation, delays, or administrative barriers to qualified physicians’ participation on FDA advisory committees.

Addressing future conflicts

The FDA's safeguards against COI are not designed to prevent future financial ties that may be seen as a conflict of interest to something the advisory committee member worked on previously, the AMA Board of Trustees report says.

To address that, delegates also adopted a new policy saying "the FDA should undertake an evaluation of pay-later conflicts of interest (e.g., where a FDA advisory committee member develops a financial conflict of interest only after his or her initial appointment on the advisory committee has expired) to assess whether these undermine the independence of advisory committee recommendations and whether policies should be adopted to address this issue."