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Before FDA Listening Session on Optimizing the Use of, and Processes for, Advisory Committees

June 13, 2024

Thank you for holding this listening session and providing me the opportunity to discuss actions the FDA can take to improve the functioning of its advisory committees, a system that is widely regarded as one of the most thorough in the Federal government. I am the Executive Director of the Center for Science in the Public Interest, an advocacy organization that has been working to advance public health for over 50 years. Prior to joining CSPI, I was the Associate Commissioner for Public Health Strategy and Analysis at the FDA where I managed the Transparency Task Force. I also authored a 2006 article, published in JAMA, that found a “small” relationship between certain types of conflicts-of-interest and voting behaviors. In my testimony today, I will be making four points related to the transparency and accountability of FDA advisory committees.

1. Voting should be maintained in advisory committee meetings

Much previous research on advisory committees has focused on the influence of conflicts of interest on voting and the impacts of committee votes on FDA approval decisions. A few studies, including the one conducted by my colleagues and me, have reported relationships between advisory committee members’ conflicts and votes favorable to the sponsor. Other studies have
found that FDA sometimes takes actions on drug approvals that are discordant with advisory committee votes.\textsuperscript{3,4,5,6}

For this meeting, FDA has asked if it should adjust the processes for voting to improve public understanding of how FDA receives external advice through advisory committee meetings. In a meeting last year, Commissioner Califf said that there should be less emphasis on the outcome of advisory committee votes,\textsuperscript{7} suggesting that FDA is considering eliminating voting altogether. In contrast, several senior FDA officials have argued recently that voting offers clarity on committees’ discussions and should be retained.\textsuperscript{8} I agree with this latter approach. Advisory committee voting is one way that FDA is held accountable for its actions and, importantly, it forces the committee to make the same call (approve/disapprove) the agency is being asked to make. Nothing about requiring an up or down vote precludes members from providing detailed explanations for their votes; indeed, that is the general practice at present. It is hard to escape the suspicion that the zeal for avoiding numerical tallies is rooted in a desire to avoid controversies that sometimes arise when the agency (less commonly) does not follow the committee’s recommendation. Such discordance is not necessarily a problem; it can be the result of new data arising since the advisory committee met.

2. Reasons for recusing advisory committee members due to conflicts should be made public

The Ethics and Government Act (E&G Act)\textsuperscript{9} allows federal agencies to collect confidential financial information to assist in making conflict determinations for advisory committee members. The Department of Health and Human Services and executive branch regulations require advisory committee nominees to submit this information in forms FDA-3410 and OGE-450.\textsuperscript{10,11} Based on this information, for each particular matter that might come before an Advisory Committee, FDA can either preclude a member from attending (recuse) or allow them
to attend despite the conflict (waive), if it determines that the financial interests are too distant or
minor or the need for the member’s service outweighs the potential conflict.\textsuperscript{12} Forms FDA-3410
and OGE-450 are shielded by statute from public disclosure,\textsuperscript{13} but the substance of a waived
conflict is made public by the Advisory Committee Executive Secretary at the outset of the
meeting. In contrast, details about the reasons for recusal of a conflicted Advisory Committee
member are generally not made public, though I reported a small number of cases where they
were in my 2006 article on conflicts and Advisory Committee voting patterns.\textsuperscript{1}

Each year, FDA issues a report entitled “Annual Report on FDA Advisory Committee
Vacancies and Public Disclosures,” that details the conflict experience of each committee, in
aggregated form. The report even separates those recused for conflicts from those recused for
other reasons (principally scheduling conflicts). In my experience (and the agency’s data appear
to confirm this), more advisory committee members have been recused from serving for conflicts
than have been provided waivers. One might speculate that the conflicts that led to recusals are
more severe than the waived ones. This aspect of Advisory Committee function gets little public
attention; in contrast, Advisory Committee members who are waived and allowed to serve often
create controversy. This is like evaluating the effectiveness of a sieve by the items that slipped
through. Changing the statute to permit the disclosure of these forms would be ideal, but, in the
interim, FDA should do a better job of presenting the data in its annual reports so that this point
is made. Researchers evaluating FDA’s Advisory Committee system should also take these data
into account, likely placing FDA’s Advisory Committee system in a more favorable light.

3. Advisory committee members’ section 502 conflicts should be made public

In fact, the conflicts just discussed are just a subset of the conflicts of which FDA is aware.
When FDA makes decisions about advisory committees, it reviews form FDA-3410 for direct
financial conflicts (section 208 conflicts\textsuperscript{14}) or anything that might create the appearance of
conflict (section 502 conflicts\textsuperscript{15}) related to the subject of the meeting.\textsuperscript{12} For both, FDA may either allow the member to serve or prevent the member from serving.\textsuperscript{16}

The agency publicly discloses section 208 conflicts of committee members who obtain waivers, but it does not disclose section 502 conflicts of those authorized to attend.\textsuperscript{10,17} When I was at FDA, my colleagues and I published a paper that examined the association between section 502 conflicts and voting outcomes in advisory committee meetings held between 2008 and 2014. The study was not highly powered, but we found no association between section 502 conflicts and voting outcomes, which is reassuring.\textsuperscript{18} Nonetheless, for reasons of transparency and because these 502 conflicts are often cited as undisclosed conflicts by outside parties should they discover them independently, such conflicts should be publicly disclosed. At one point, FDA even asked for input on whether to publicly disclose 502 conflicts,\textsuperscript{18} but evidently decided against doing so.

Finally, on the issue of Advisory Committee member conflicts, Open Payments has been available since 2013 as a tool for monitoring conflicts,\textsuperscript{19} yet this resource is not mentioned in FDA’s 2016 draft guidance on evaluating appearance conflicts.\textsuperscript{10} Is consulting that database a standard element of FDA’s conflict screening process?

4. The FDA and sponsor presentations should be independent

There appears to be a recent trend toward joint FDA/sponsor preparation of briefing documents. For example, FDA and Biogen prepared a joint briefing document\textsuperscript{20} for the Peripheral and Central Nervous System advisory committee meeting on aducanumab.\textsuperscript{21} After FDA approved the drug, Representatives Carolyn B. Maloney and Frank Pallone, Jr. opened an investigation into FDA’s approval process, which uncovered evidence of close collaboration between FDA and Biogen for months before the meeting.\textsuperscript{22} Indeed, FDA provided Biogen the draft text of its own review of the data and gave the company specific guidance in the
preparation of the company’s materials.

Although the FDA’s guidance for industry on preparing information for advisory committee members is silent on the issue of joint FDA/sponsor briefing materials, the agency explained to the Congressional investigators that it has generally taken the position that materials prepared by FDA and drug sponsors should be independent documents. In fact, the House investigation showed that, at the time, the agency had drafted joint briefing materials nine times. But since the publication of that report, FDA has drafted joint briefing materials for three meetings on oncology drugs that took place in March and November of last year and April of this year. FDA should update its guidance for industry and create internal guidance for FDA staff that specifically precludes joint briefing materials and affirms the independence of FDA and sponsor briefing materials. Indeed, the possibility that FDA and the sponsor may have differing interpretations of the data is one of the very reasons Advisory Committee meetings are held.

Thank you for the opportunity to address this issue. Advisory committees play an important role in FDA decision-making and measures to increase the transparency and accountability of this process will support FDA’s mission to protect public health.

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9 5 USC §13109. Confidential Reports and Other Additional Requirements.