



**Testimony of Peter Lurie, MD, MPH**  
**President, Center for Science in the Public Interest**  
**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.<sup>1</sup> 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.<sup>1,2</sup> Other studies have

found that FDA sometimes takes actions on drug approvals that are discordant with advisory committee votes.<sup>3,4,5,6</sup>

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,<sup>7</sup> 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.<sup>8</sup> 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)<sup>9</sup> 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.<sup>10,11</sup> 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.<sup>12</sup> Forms FDA-3410 and OGE-450 are shielded by statute from public disclosure,<sup>13</sup> 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.<sup>1</sup>

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<sup>14</sup>) or anything that might create the appearance of

conflict (section 502 conflicts<sup>15</sup>) related to the subject of the meeting.<sup>12</sup> For both, FDA may either allow the member to serve or prevent the member from serving.<sup>16</sup>

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.<sup>10,17</sup> 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.<sup>18</sup> 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,<sup>18</sup> 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,<sup>19</sup> yet this resource is not mentioned in FDA's 2016 draft guidance on evaluating appearance conflicts.<sup>10</sup> 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<sup>20</sup> for the Peripheral and Central Nervous System advisory committee meeting on aducanumab.<sup>21</sup> 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.<sup>22</sup> 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,<sup>23</sup> 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.<sup>22</sup> In fact, the House investigation showed that, at the time, the agency had drafted joint briefing materials nine times.<sup>22</sup> 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.<sup>24,25,26</sup> 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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<sup>1</sup> Lurie P, et al. Financial Conflict of Interest Disclosure and Voting Patterns at Food and Drug Administration Drug Advisory Committee Meetings. *JAMA*. 2006;295(16):1921-1928.

<sup>2</sup> Pham-Kanter G. Revisiting Financial Conflicts of Interest in FDA Advisory Committees. *Milbank Q*. 2014;92(3):446-470.

<sup>3</sup> Tapley AL, Lurie P, Wolfe SM. Suboptimum Use of FDA Drug Advisory Committees. *Lancet*. 2006;368(9554):2210.

<sup>4</sup> Haslam A, Gill J, Prasad V. Oncology Drug Advisory Committee Recommendations and the US Food and Drug Administration's Actions. *Mayo Clin Proc*. 2020;95(2):424-426.

<sup>5</sup> Daval CJR, Sarpatwari A, Kesselheim AS. Unwanted Advice? Frequency, Characteristics, And Outcomes Of Negative Advisory Committee Votes For FDA-Approved Drugs. *Health Aff (Millwood)*. 2022;41(5):713-721.

<sup>6</sup> Zhang AD, Schwartz JL, Ross JS. Association Between Food and Drug Administration Advisory Committee Recommendations and Agency Actions, 2008-2015. *Milbank Q*. 2019;97(3):796-819.

<sup>7</sup> Eglavitch JS. Calif: Advisory Committee Meeting Structure Needs an Overhaul. *Regulatory Affairs Professional Society*. February 14, 2023. <https://www.raps.org/news-and-articles/news-articles/2023/2/califf-advisory-committee-meeting-structure-needs>. Accessed June 10, 2024.

<sup>8</sup> Eglavitch JS. FDA Officials Argue for Retaining Advisory Committee Votes, Welcome Return to Face-to-Face Meetings. *Regulatory Affairs Professional Society*. February 27, 2024. <https://www.raps.org/news-and-articles/news-articles/2024/2/fda-officials-argue-for-retaining-advisory-committ>. Accessed May 28, 2024.

<sup>9</sup> 5 USC §13109. Confidential Reports and Other Additional Requirements.

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- <sup>10</sup> U.S. Food and Drug Administration. *Procedures for Evaluating Appearance Issues and Granting Authorizations for Participation in FDA Advisory Committees: [Draft] Guidance for the Public, FDA Advisory Committee Members, and FDA Staff*. 2016. <https://www.fda.gov/media/98852/download>. Accessed May 28, 2024.
- <sup>11</sup> 5 CFR §2634, subpart I. Confidential Financial Disclosure Reports.
- <sup>12</sup> U.S. Food and Drug Administration. *FDA Advisory Committees: Financial Conflicts of Interest Overview*. n.d. <https://www.fda.gov/media/87421/download#:~:text=In%20the%20FDA%20Form%203410,it%20to%20FDA%20for%20review>. Accessed May 28, 2024.
- <sup>13</sup> 5a USC §107. Confidential Reports and Other Additional Requirements.
- <sup>14</sup> 18 USC §208. Acts Affecting a Personal Financial Interest.
- <sup>15</sup> 5 CFR §2635.502. Personal and Business Relationships.
- <sup>16</sup> 18 USC §208. Acts Affecting a Personal Financial Interest.
- <sup>17</sup> U.S. Food and Drug Administration. *Guidance for the Public, FDA Advisory Committee Members, and FDA Staff: Public Availability of Advisory Committee Members' Financial Interest Information and Waivers: Final Guidance*. 2014. <https://www.fda.gov/media/83188/download>. Accessed May 28, 2024.
- <sup>18</sup> Xu J, et al. Association of Appearance of Conflicts of Interest With Voting Behavior at FDA Advisory Committee Meetings-A Cross-sectional Study. *JAMA Intern Med*. 2017;177(7):1038-1040.
- <sup>19</sup> U.S. Centers for Medicare & Medicaid Services. *Program Overview*. n.d. <https://openpaymentsdata.cms.gov/about>. Accessed June 10, 2024.
- <sup>20</sup> U.S. Food and Drug Administration, Biogen. *Combined FDA and Applicant PCNS Drugs Advisory Committee Briefing Document*. 2020. [https://fda.report/media/143503/PCNS-20201106-CombinedFDABiogenBackgrounder\\_0.pdf](https://fda.report/media/143503/PCNS-20201106-CombinedFDABiogenBackgrounder_0.pdf). Accessed May 28, 2024.
- <sup>21</sup> 85 FR 61013. Peripheral and Central Nervous System Drugs Advisory Committee: Notice of Meeting; Establishment of a Public Docket; Request for Comments.
- <sup>22</sup> U.S. House Committee on Oversight and Reform and Committee on Energy and Commerce. *The High Price of Aduhelm's Approval: An Investigation into FDA's Atypical Review Process and Biogen's Aggressive Launch Plans*. 2022. <https://oversightdemocrats.house.gov/sites/evo-subsites/democrats-oversight.house.gov/files/2022-12-29.COR%20%26%20E%26%20Joint%20Staff%20Report%20re.%20Aduhelm.pdf>. Accessed May 28, 2024.
- <sup>23</sup> U.S. Food and Drug Administration. *Guidance for Industry: Advisory Committee Meetings – Preparation and Public Availability of Information Given to Advisory Committee Members*. 2008. <https://www.fda.gov/media/75436/download>. Accessed May 28, 2024.
- <sup>24</sup> U.S. Food and Drug Administration. *April 12, 2024 Meeting of the Oncologic Drugs Advisory Committee Meeting Announcement*. 2024. <https://www.fda.gov/advisory-committees/advisory-committee-calendar/april-12-2024-meeting-oncologic-drugs-advisory-committee-meeting-announcement-04122024>. Accessed June 10, 2024.
- <sup>25</sup> U.S. Food and Drug Administration. *November 16, 2023: Meeting of the Oncologic Drugs Advisory Committee Meeting Announcement*. 2023. <https://www.fda.gov/advisory-committees/advisory-committee-calendar/november-16-2023-meeting-oncologic-drugs-advisory-committee-meeting-announcement-11162023>. Accessed June 10, 2024.
- <sup>26</sup> U.S. Food and Drug Administration. *March 9, 2023: Meeting of the Oncologic Drugs Advisory Committee Meeting Announcement*. 2023. <https://www.fda.gov/advisory-committees/advisory-committee-calendar/march-9-2023-meeting-oncologic-drugs-advisory-committee-meeting-announcement-03092023>. Accessed June 10, 2024.