

# CAPITOL STREET

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## FDA AdComm Reform is Not Coming Any Time Soon

### Califf Lays Out Six Key Focus Areas

Relevant Industries

Biopharma, MedTech & Diagnostics

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### »» Our Take & Next Up

**FDA Commissioner Robert Califf is keeping alive the topic of reforming advisory committee meetings, but we don't see fundamental changes happening in the near future.** In a Sept. 30 commentary published in *Nature* ([link](#)), Califf and Deputy Commissioner Namandjé Bumpus discussed ways the FDA's advisory committee process could be optimized to reduce burdens and improve public understanding. Despite AdComm reform being a high priority for exiting Commissioner Califf, the next steps are watered down, and won't change the process near-term.

### »» Key Points

**The newly-unveiled FDA focus areas are watered down and administrative, indicating no near-term AdComm reform. The FDA is continuing to consider how advisory committee policies and practices can be optimized and engaging the public and advisory committee members throughout that process.** Califf and Bumpus identified the following focus areas for the optimization of FDA advisory committees:

1. Modernize systems to reduce paperwork burden and streamline processes, including by updating forms for expedited digital signature and processing and exploring system improvements for special government employee onboarding and internal processes.
2. Explore how to improve the utility of the advice the FDA receives from Advisory Committees, including by evaluating the composition of existing committees and considering how to best solicit useful feedback from committees.
3. Improve recruitment of SGEs, possibly by increasing dedicated staff and engaging existing committee members.
4. Share and standardize certain practices and procedures across the agency and ensure that internal resources are up to date and easily accessible.
5. Improve public understanding of ACs and the role they have, including through external communications and publications.
6. Obtain input on FDA use of ACs from all interested parties through a public listening session and docket for public comment.

**Recall, the FDA held a June 13 meeting ([here](#)) to obtain feedback to improve the advisory committee (AdComm) system of 50-ish years (see our analysis [here](#)).** The all day meeting focused on three major

areas: (1) the composition of advisory committees, (2) administrative and other challenges for committee members, and (3) public perception of AdComms. A major overhaul is unlikely near-term given the current regulatory burden at the agency, staffing, and a potential administration change. We note that the majority of the thousands of decisions the FDA makes every year do not go to an advisory committee but given important science & public health issues the debate is relevant.

**Califf who has said he won't remain as Commissioner for a potential Harris term, since February 2023 has called for AdComm reform due to a need to combat misinformation and reduce confusion.** Link to opening remarks [here](#). Specifically, many wonder whether AdComm votes are the FDA's decision as well. Most don't understand the difference. Current (2024) efforts to reform the committee process were announced in January and are being led by Namandjé Bumpus, FDA's newly appointed Deputy Commissioner (bio [here](#)). The agency has begun internal change and received formal feedback from different interest groups (stakeholder recommendations [here](#)).

**We note the FDA AdComm reform discussion comes at a time of FDA bipartisan scrutiny, so stay tuned for reform in the coming years (regardless of election outcome, but this may take time).** Recall former GOP presidential candidate Vivek Ramaswamy's call to "gut" the FDA. Lawmakers have criticized the FDA over its handling of e-cigarettes, response to the infant formula shortage, and ongoing drug shortages. The FDA also approved COVID therapies and vaccines as well as tests quickly (EUA), without much follow-through. The FDA has also overruled AdComms in approving medicines based on patient experience and real-world evidence (RWE) (think DMD).

## **FDA PUBLIC MEETING HIGHLIGHTS**

**Expert recommendations to FDA fall into several buckets: maintain FDA AdComm voting, provide more transparency, and allow public feedback.** Speakers included patient advocacy groups, trade associations, scientists, former AdComm representatives and members, and former FDA Associate Commissioner Peter Lurie. Main points are below. More and better consumer/patient representation: Speakers asked for more consumer representatives on committees, assurance that consumer representatives do not have industry ties and can analyze and critique scientific data, and that patient representatives are patients of the disease in question. Conflicts of interests: A divisive topic with some presenters arguing they need to be relaxed, others pushing for tightened restrictions. New guidelines to implement public testimony: As a reminder, AdComm members do not have guidelines on how to integrate public testimony from clinical trial participants with lived experiences that contradict clinical data. Maintain the voting process: See bullet below for more detail. Increased transparency and communication: On the purpose of and discussion during advisory committee meetings.

**FDA AdComm voting is likely to remain in place for the foreseeable future.** In response to past [discussions](#) by Califf to conduct fewer advisory votes, speakers unanimously supported keeping the vote system consistent. Peter Lurie, the former Associate Commissioner of the FDA, was a vocal supporter of the current voting system and maintained that "it's hard to escape the suspicion that the desire to abolish the vote is a way to avoid accountability when the FDA votes differently." Other supporters of the current voting system include Reshma Ramachandran (chair of the Doctors for America's FDA Task force), Aaron Kesselheim (professor of medicine at Harvard and former AdComm member), patient advocacy groups, and nonprofit policy think tanks (Federation of American Scientists and the Alliance for Aging Research).

**Conflicts of interest (COI) is a divisive topic; particularly as the most relevant experts typically have industry ties or funding.** Barriers for expert advisors included strict conflict of interest and hefty paperwork. Notably, one of the goals of the meeting was to reduce the administrative burden of advisors to increase broader participation. Steve Berman, Deputy Vice President of Regulatory Affairs at BIO, argued that the FDA needs to balance COI rules with real experts. Speakers argued for:

- Relaxation of COI rules, arguing they exclude the foremost experts and frontline clinicians in a disease (especially rare diseases), who often receive financial support and are involved in therapeutic development research.
- Other speakers argued that any financial conflict of interest should preclude the ability of an advisory committee member to serve due to impact on public trust and sound scientific assessment.

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