FEDERATION OF AMERICAN SCIENTISTS

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Advisory Committees for the 21st Century

Toolkit for policy reformers

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About FAS

The **Federation of American Scientists (FAS)** is an independent, nonpartisan think tank that brings together members of the science and policy communities to collaborate on mitigating global catastrophic threats. Founded in November 1945 as the Federation of Atomic Scientists by scientists who built the first atomic bombs during the Manhattan Project, FAS is devoted to the belief that scientists, engineers, and other technically trained people have the ethical obligation to ensure that the technological fruits of their intellect and labor are applied to the benefit of humankind. In 1946, FAS rebranded as the Federation of American Scientists to broaden its focus to prevent global catastrophes.

FAS believes that society benefits from a federal government that harnesses science, technology, and innovation to meet ambitious policy goals and deliver impact to the public. FAS is a catalytic, non-partisan, and nonprofit organization committed to using science and technology to benefit humanity through national security transparency, policy agenda-setting, and delivering on the promise of equitable and impactful policy.

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About this toolkit

From January 2024 to July 2024, The Federation of American Scientists interviewed 30 current and former Advisory Committee (AdComm) members. Based on these discussions, we were able to source potential policy recommendations for the executive level that may assist with enhancing the FDA's ability to obtain valuable advice for evidence-based decision-making. In this toolkit, we build off of those discussions by providing you with actionable policy reform recommendations. We hope that these recommendations catapult the Advisory Committee structure into one best suited to equip all AdComms with the necessary tools needed to continue providing the government with the best advice.

FOR QUESTIONS RELATED TO THIS TOOLKIT, PLEASE CONTACT:

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Acronyms

AdComm	Advisory Committee
COI	Conflict of Interest
FDA	United States Food and Drug Administration
NOA	Notice of Availability
OMB	Office of Management and Budget
PC	Public Comment
PFDD	Patient-Focused Drug Development

Voting for FDA Advisory Committees

UPDATE TYPE: **PROCESS** | REGULATORY

- Maintain voting as an integral function, allowing FDA Advisory Committee members to convey their collective expertise and advice, aiding the FDA in informed decision-making on scientific and regulatory matters
- Revise the guidance for FDA Advisory Committee Members and FDA Staff to explicitly define circumstances for which voting should occur and eliminate sequential voting

Best Practices for Implementation

The United States Food and Drug Administration can uphold their voting mechanism by updating their document entitled, "Guidance for FDA Advisory Committee members and FDA staff: Voting Procedures for Advisory Committee Meetings" to include language that clearly states a vote should be taken at all Advisory Committee meetings where a medical product is being reviewed. This guidance should also indicate that the absence of voting should only occur if an Advisory Committee meeting has been convened to discuss issues of policy. Further, this guidance should be considered a level 2 guidance as it falls into the category of addressing a "controversial issue". To effectuate these changes, a notice of availability (NOA) may be submitted to the Federal Register for public input (public input is not a requirement before implementation).

Potential Language to be Utilized for Guidance

In an effort to continue to allow Advisory Committee members to provide unbiased, evidence-based feedback and uphold such an integral part of the Advisory Committee process, voting is hereby mandatory for all Advisory Committee meetings that are convened where the purpose is to review and assess the safety and efficacy of medical products.

Involved Stakeholders

In order for this process to successfully occur, the FDA will need to amend their guidance with the aforementioned updates. Consideration should be given to incurred costs for personnel required to complete these updates. Personnel needed for these amendments may include, but are not limited to, the

- (a) Office of the Commissioner, Office of Clinical Policy and Programs, Office of Clinical Policy,
- (b) Center for Devices and Radiological Health,
- (c) Center for Biologics Evaluation and Research, and
- (d) Center for Drug Evaluation and Research

FDA Staff, Leadership, and AdComm Disagreements

UPDATE TYPE: **PROCESS** | REGULATORY

- Ensure that all FDA staff and leadership are fully cognizant of the existence and details of the *Scientific Dispute Resolution at FDA* guidance and the process for submitting disputes for review
- Develop guidance that clearly explains a transparent process to communicate effectively with AdComm members regarding decision making when parties have opposing viewpoints

Best Practices for Implementation

Implementing these recommendations will improve conflict resolution internally and between the Agency and Advisory Committee members. Best practices for implementation include

- (a) building the Scientific Dispute Resolution at FDA guidance into the official FDA onboarding process for new hires to raise awareness,
- (b) provide annual employee trainings in an effort to stay up-to-date with dispute resolution processes and procedures, and
- (c) develop a guidance that delineates the process for resolving conflicts between the Agency and Advisory Committees when there are differing opinions

Note: Guidance for resolving disputes between the Agency and Advisory Committees should be submitted to the Federal Register for public comment. Guidance should also include plain language that designates the avenue to be used for official decision notifications, the timeliness of these notifications after convenings have concluded, and circumstances in which the FDA cannot notify Advisory Committees that their decision is in direct opposition of the Committee's vote (e.g., if this notification would breach a confidentiality agreement with the applicant). Implementing a transparent process to communicate with AdComm members regarding differences between the Agency and the AdComm will assist in improving morale between both parties, but also encourage continued support of the AdComm.

Involved Stakeholders

Successful implementation of these recommendations will require the capacity of human resources personnel and individual center leadership.

UPDATE TYPE: PROCESS | **REGULATORY**

- Incorporate the *Scientific Dispute Resolution at FDA* guidance into FDA regulations
- Amend the *Scientific Dispute Resolution at FDA* guidance to dictate the mandatory execution of best practices within the dispute resolution process
- This guidance should identify additional non-biased parties (that may not be government-affiliated) to provide impartial guidance on complex scientific matters affecting public safety

Best Practices for Implementation

Center leadership can assign FDA staff to make the necessary guidance amendments which should include the requirements for inclusion in the onboarding of all FDA employees. Staff should also be responsible for obtaining

feedback on amendments from all necessary internal parties and submitting proposed amendments to OMB for review and addition to the Federal Register. Federal register comments will then be reviewed by FDA staff, guidance will be updated accordingly, and a final draft submitted to OMB for review. If approved, the final regulation will be published in the Code of Federal Regulations. Congressional involvement should not be necessary.

FDA Center leadership should delegate the task of creating an annual mandatory training program for all FDA employees to review this guidance in an effort to stay abreast of the procedures for dispute resolution.

Quotes from AdComm experts

> "FDA leadership needs to make is clear what data was used and why they're moving forward when there is opposition"
>
> "Disagreements should be addressed by a non-biased source because it affects the public safety."
>
> "There will be times where there are disagreements between staff and leadership. However, there's a critical need for transparency within the FDA about why decisions are made. These are not decisions about evidence only. Ever."
>
> "Disagreements should be a matter of public scrutiny. There should be transparency that doesn't jeopardize confidentiality."

Involved Stakeholders

FDA Center leadership, FDA staff, and the Office of Management and Budget (OMB) are the intended stakeholders for implementation of these recommendations. To incorporate this guidance into FDA regulations, Center leadership will need to assign FDA staff to amend guidance and submit to OMB.

Leveraging AdComm Membership

UPDATE TYPE: **PROCESS** | REGULATORY

Expanding Committee Representation

If there is flexibility and committee composition is not bound by law, include a patient representative and pharmacist and/or pharmacologist on each Committee

- Patient representatives provide a needed perspective due to lived experiences and understanding of how specific drugs and devices affect their day-to-day life
- Drugs and devices will usually pass through the hands of pharmacists and pharmacologists. Therefore, they should have the opportunity to serve on these Committees and provide feedback. Pharmacologists also understand the clinical application of drugs
- Have a roster of temporary members that can be used when additional expertise is needed for Committee meetings or when there is a conflict of interest (COI)

Amplifying the Role of the Chair

Expand the role of the Committee chair that will encompass the task of recruiting both standing and ad hoc members, as well as identifying prominent issues and products for Committee consideration, thereby allowing for specialized input from their Committee

Establishing Training and Regulatory Procedures for Incoming Members

- Institute a basic 101 training for all newly appointed Advisory Committee members that covers statistical analysis, clinical trial design, and elucidates the partnership between the FDA and AdComm
- Include an overview of the regulatory process and how the FDA's decision-making process is performed

Best Practices for Implementation

With respect to Committee composition, the FDA should consider adding patient representatives to all Committees that review medical products. The addition of a patient representative will ensure that the voice of the population who the medical product affects is heard. The FDA can select individuals best suited to fill these roles through connecting with patient advocacy organizations. If patient representatives are selected, the FDA should develop an onboarding program to familiarize the patient representative with basic knowledge of the federal regulation process. This program should educate the patient representative on

- (a) the types of questions presented to Advisory Committees,
- (b) how the FDA views the role of the patient representative in the process,
- (c) the internal review process for data that is submitted, and
- (d) other pertinent topics related to medical product regulation

Leveraging the role of the Advisory Committee Chair can help the FDA fully optimize the use of their Committee. "Chairs possess extensive networks that could support the identification of permanent or temporary expert participants for AdComms" (Banks, 2024). Allowing Chairs the ability to identify relevant issues or products for their respective committees to review can provide an additional layer for the FDA to keep abreast of critical public concerns via appropriate committee evaluation (Banks, 2024).

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their respective committees to review can provide an additional layer for the FDA to keep abreast of critical public concerns via appropriate committee evaluation (Banks, 2024).

Finally, while Committee members may be experts in their own right, training should be provided for all. The FDA should provide basic 101 training courses that can cater to the needs of members with various knowledge bases. Training should include information on the relationship between the FDA and Advisory Committee members, best practices for understanding statistical analysis, and the different types of clinical trial designs. Training should provide real-world examples of statistical analysis and trial design in use (this can be done by providing examples from prior medical product review).

Involved Stakeholders

FDA Center staff (including statisticians and scientists for the development of training programs).

Conflict of Interest (COI) Auditing

UPDATE TYPE: **PROCESS** | REGULATORY

- Develop a process that can quickly replace individuals who have a known conflict of interest
- Clearly delineate criteria for committee service acceptance regarding individuals with potential or actual conflicts of interest

Best Practices for Implementation

To prevent recurring COIs, the FDA should develop a database of experts for various categories of expertise that can be selected to replace those with known COIs. This database should include names, contact information, credentials, all areas of expertise for each expert, and should link to public financial interest databases that can serve as a source for identifying conflicts (e.g., Open Payments, Dollars for Docs).

To prevent public confusion, the FDA should amend their *Guidance for the Public, FDA Advisory Committee Members, and FDA Staff: Public Availability of Advisory Committee Members' Financial Interest Information and Waivers* to specify circumstances that warrant a COI waiver being administered. This will increase transparency and help Advisory Committee members and the public understand the reasoning in allowing members with conflicts to participate in meetings. This guidance can then be submitted to the Federal Register for public comment

UPDATE TYPE: **PROCESS** | **REGULATORY**

- Streamline the COI process to prevent duplicative work that may act as a deterrent to experts volunteering to serve on the AdComm (work with GSA on this matter if necessary)

Best Practices for Implementation

Streamlining the COI process will assist the FDA with retention efforts for Advisory Committees while maintaining compliance with conflict of interest regulations. A digital system should be developed that allows Advisory Committee members to select whether their financial information has changed through the use of a dropdown or check box. This will prevent duplicative work and also contribute to a sustainable (green) process.

Involved Stakeholders

The Office of the Commissioner, Office of Clinical Policy and Programs, Office of Clinical Policy would be the interested stakeholder to issue updates to the COI policy and would work with the General Services Administration if necessary.

The Role of Patient Advocacy in the AdComm Process

UPDATE TYPE: **PROCESS** | REGULATORY

Dedicate staff to identifying crucial public comments from patient advocates that should be considered for regulatory decision-making

- Include a patient representative on all committees that are reviewing medical products
- If possible, ensure that patient representatives selected have basic knowledge of the federal regulation process

Establish criteria for which all public comments must abide by

- This can be done by creating a checklist for the public to review and consider before forming their comment and that clearly delineates the mandatory criteria that a medical product must meet to be considered for approval
- A disclaimer can also be added to state that there is a specific threshold or sample size of a population who must benefit from the medical product

Promote patient focused medical product development through the use of incorporating patient perspectives into the life cycle of the regulatory process

- This can be done through hosting patient town hall discussions for areas such as rare diseases and expanding initiatives such as the Patient Focused Drug Development (PFDD) public meetings
- Make patient engagement ongoing, rather than only allowing patient engagement quarterly or annually as done with most FDA-led programs and initiatives

Best Practices for Implementation

Public comments are a crucial part of the regulatory process. The FDA should focus on increasing participation in this process, as well as notifying participants of what should be expected from the public comment period. By law, the FDA must allow a public comment period for all Advisory Committee convenings. To increase participation, the FDA should allow public comments to be vocalized in-person and virtually, in addition to the submission of public comments to the docket.

Regarding Committee composition, please refer to Best Practices for Implementation under **Leveraging AdComm Membership** for information on the addition of patient representatives to Advisory Committees.

Patient engagement in the regulatory process is necessary to inform evidence-based decisions. While the FDA currently has ways to engage these communities through the use of public comment and initiatives such as Patient Focused Drug Development (PFDD), engagement should be an ongoing process. As mentioned, the FDA can develop and leverage existing relationships with public health agencies and advocacy organizations who can then serve as the liaison of feedback to the FDA. The FDA can also consider expanding their current initiatives and programs to engage communities twice a quarter instead of quarterly or annually. Consistent engagement in this form will help to establish trust between the FDA and the public who they serve, as well as give them the needed information from the communities who are most impacted from their decisions.

Involved Stakeholders

Implementation of these recommendations and expansion of current initiatives will require the involvement of FDA Center leadership and Center staff.

Improving Public Awareness and Understanding of Advisory Committees

UPDATE TYPE: **PROCESS** | REGULATORY

FDA can leverage social media platforms to increase awareness and understanding of AdComms through the use of disseminating information (engagement, ads, etc.)

- FDA should include a disclaimer on **all** communications and marketing materials regarding AdComms
- These disclaimers should also be made at all public meetings
- Disclaimers should emphasize the purpose of AdComm votes (disclaimer should state that votes allow AdComm members to provide an official stance to the FDA as experts, but those votes are also non-binding)
- Develop a webpage that allows people to be placed on listserv regarding upcoming meetings
- Partner w/state and local public health agencies and advocacy organizations to spread awareness

Best Practices for Implementation

The FDA should develop a monthly content plan to utilize its current interactive and social media outlets and disseminate information related to the role of Advisory Committees and their convenings, while also maintaining compliance with the FDA's social media policy. The social media content plan should be centered around

- (a) what an Advisory Committee is,
- (b) how members are selected,
- (c) information regarding votes of Advisory Committees and how they are specific to safety and efficacy, but are not voting on the approval of a medical product,
- (d) discussing upcoming Advisory Committee meetings, their location, and inviting the public to participate via public comment,
- (e) sharing information about what a public comment is, requirements for making public comments, and how the FDA reviews them, and
- (f) sharing a webpage where the general public can input their personal email to be notified of upcoming Advisory Committee meetings

FDA staff should develop a plain language disclaimer to be placed on all social media posts, meeting materials, and websites related to Advisory Committees. This disclaimer should illustrate that Advisory Committee members will provide unbiased expertise to assist the FDA with their decision. However, while the Committee's vote is included in consideration for the decision, their vote is non-binding which leaves the FDA as the final decision maker for approval.

use social media for widespread dissemination of AdComm information	develop informational disclaimers for AdComm material	partner with public health agencies to spread awareness	increase in engagement and decrease spread of misinformation

Finally, the FDA should identify state/local public health agencies, as well as advocacy organizations that they can potentially partner with to disseminate information more broadly. These agencies and advocacy organizations have strong relationships with various communities who should be engaged in the regulatory process. Developing a relationship with these agencies and organizations in an attempt to engage the community will assist the FDA with

building connections and trust, as well as mutual understanding of Advisory Committee roles. Potential partners can be identified using the linked list under involved stakeholders.

Involved Stakeholders

Implementation of these recommendations and expansion of current initiatives will require the involvement of FDA Center leadership, Center staff, Office of External Affairs (OEA) Web and Digital Media staff, Office of Information Management and Technology (OIMT), state/local public health departments, and advocacy organizations.

Note: These listings of state/local public health departments and advocacy organizations are intended to be used as a starting point in the identification of potential partners and not to be considered an exhaustive list.

FAS FEDERATION OF AMERICAN SCIENTISTS

About the Federation of American Scientists

The Federation of American Scientists' is dedicated to democratizing the policymaking process by working with new and expert voices across the science and technology community, helping to develop actionable policies that can improve the lives of all Americans. For more about the Federation of American Scientists, visit **FAS.org.**