



ACG FDA RELATED MATTERS COMMITTEE:

Guidance for Membership

FDA ADVISORY COMMITTEES: ITS ROLE AND HOW TO CONTRIBUTE

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ACG FDA Related Matters Committee

INTRODUCTION

FDA Advisory committees play a crucial role in advising the Agency on the safety and efficacy of medicines and devices marketed in the U.S., and thereby impact how we practice medicine and the treatment options available. ACG members are encouraged to serve on the FDA Advisory Committee and use their expertise to advise the FDA on Gastroenterology medications and devices. This manuscript provides information on the advisory committees and how ACG members can get involved. It includes a discussion on the role of advisory committees, how they work, and how to get involved in an advisory committee.

PURPOSE OF THE FDA ADVISORY COMMITTEE

The mission of the U.S. Food and Drug Administration (FDA) is to protect public health by ensuring the safety of medical drugs and devices. FDA Advisory committees play a crucial role in advising the Agency on the safety and efficacy of medicines and devices marketed in the U.S., and thereby impact how we practice medicine and the treatment options available. Committees consist of a panel of independent experts who provide recommendations on products regulated by the Agency.



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The FDA has more than 30 technical and scientific advisory committees, one of which is the Medical Devices Advisory Committee (MDAC) which has 18 panels. The Committee or panel of interest for Gastroenterologists are the Gastrointestinal Drug Advisory Committee and the Gastroenterology and Urology Devices Panel.

The Gastroenterology and Urology Devices Panel reviews and evaluates data on the safety and effectiveness of marketed and investigational gastroenterology devices. For example, the Gastroenterology and Urology Devices Panel met on July 14th, 2021, to discuss the premarket approval application for the Organ Care System (OCS) Liver System by TransMedics, Inc. The discussion on OCS included indications for use, clinical trial results, primary and secondary effectiveness endpoints, and device malfunction.

The Gastrointestinal Drug Advisory Committee advises FDA on medications used in Gastroenterology. For example, the Committee met on March 8th, 2018, to discuss approval of Tofacitinib for the treatment of adults with moderately to severely active ulcerative colitis (UC) who failed other therapies. During the advisory committee meeting, the regulatory history of the drug, currently approved UC therapies, clinical pharmacology, and efficacy of Tofacitinib were discussed.

Our members are encouraged to serve on the FDA Advisory Committee and use their expertise to advise the FDA on Gastroenterology medications and devices.

FDA ADVISORY COMMITTEE MEMBERSHIP AND TRAINING

A committee consists of core members appointed by the Commissioner and members who could be called upon to participate on an ad hoc basis. Committee size ranges from 10-15 members. The core members are appointed based on their scientific or technical expertise and serve the duration of their term of 1-4 years, unless they resign or are removed by the Commissioner. Scientific experts appointed as core members may include researchers, statisticians, engineers, medical faculty, chemists, biologists, and other science-oriented professionals. All core members are eligible to vote regardless of conflicts of interest.



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The ad hoc members may include representation from consumer and patient interests, industry, and at least 2 members who are experts in the field. Ad hoc members cannot vote if they have conflicts of interest or do not have content expertise. Hence, representatives from the drug manufacturing industry are considered non-voting members.

Sometimes committees need to invite experts who are unrelated to the expertise defined in the committee charter, if the medical product calls for a specific need for a particular expert. For example, a hepatologist may be involved in evaluating a medication for a neurological condition that could cause adverse effects on the liver.

The committee should have representation from all geographic locations and be balanced in regard to gender and ethnicity. The FDA regularly reaches out the ACG and other societies when looking for experts. However, anyone can nominate an individual for committee membership, with the nominee's awareness. An individual may also self-nominate.

New members of the committee are provided education and training on advisory committee service. Members are also provided written educational material, videos, as well as one on one discussions with FDA staff, and training sessions. They are also given the opportunity to attend at least one advisory committee meeting prior to their appointment.

HOW DOES AN ADVISORY COMMITTEE WORK?

The Federal Advisory Committee Act of 1972 established guidelines on how the FDA committee operates. While these committees provide recommendations, final decisions are made by the FDA.

The chairperson of the advisory committee presides over a meeting and ensures that meetings are conducted in a manner that allows for balanced presentations of the issues by both the FDA and the sponsor. Other important roles of the chairperson include protecting committee discussion time, providing sufficient coverage of relevant issues, ensuring that the committee provides clear and scientifically valid advice to the FDA in a timely manner, and ensuring that public hearing is properly conducted.



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The FDA selects a federal employee to serve as a Designated Federal Officer (DFO) to ensure that all procedures are conducted within applicable statutory, regulatory, and administrative directives. The DFO is the primary point of contact for the Agency, the public, and the Committee.

Committee meetings are scheduled within 60 days of the matter being ready for review. A matter is deemed ready for review when the Agency and the applicants have completed all preparatory work for presentation to the Committee. Meetings typically occur twice a year in the Washington D.C. area and usually last for 2 days. Travel and hotel expenses are reimbursed at the government rate and a modest fee is provided for the service.

A satisfactory quorum should be present to hold an FDA committee meeting. Generally, all voting members must be present for the quorum to be considered sufficient. However, in some cases, FDA may specify that a quorum is reached when the majority of voting members who are experts in the field are present. Committees are required to dedicate a minimum of 60 minutes of each meeting for open public comment.

The primary "Agency decision-maker" should provide the FDA's decision within 90 days of the committee's recommendations. The Primary Agency decision-maker is also required to notify the affected parties if no decision was made as well as the rationale (must be documented).

Each FDA committee must be renewed by the Agency every two years, or its charter automatically expires. Besides providing recommendations to the FDA, advisory committee meetings also serve as the FDA's first public discussion of a new medical product. It can be a valuable source of information for patients, health care providers, and others who are interested in the product.

GET INVOLVED

Contact the ACG apply for membership through the FDA Advisory Committee Membership Application portal.



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REFERENCES

The Federal Advisory Committee Act with Annotations and Amendments. House version. The Federal Advisory Committee Act | GSA. <https://www.gsa.gov/policy-regulations/policy/federal-advisory-committee-management/legislation-and-regulations/the-federal-advisory-committee-act>

Guidance for industry. Advisory Committees: Implementing Section 120 of the Food and Drug Administration Modernization Act of 1997. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/implementation-section-120-food-and-drug-administration-modernization-act-1997-advisory-committees>

Learn About FDA Advisory Committees | FDA. <https://www.fda.gov/patients/about-office-patient-affairs/learn-about-fda-advisory-committees>

FDA advisory committees: their purpose, how they work, and how you can become a member. Charles Brady. *Am J Gastroenterol*. 2006 Apr;101(4):689-91. <https://pubmed.ncbi.nlm.nih.gov/16635215/>

Transcripts of FDA advisory committee discussions are posted on a website: www.fda.gov/ohrms/dockets/ac/acmenu.htm.