

FDA RELATED MATTERS COMMITTEE

MEMBERS

Amanda K. Cartee, MD, FACC, Chair
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James B. Canavan, MD, PhD
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George Salem, MD, FACC
Tilak U. Shah, MD, MHS, FACC
Adam F. Steinlauf, MD
Nyree K. Thorne, MD
Chung Sang Tse, MD
Shivakumar Vignesh, MD, FACC



Amanda K. Cartee, MD, FACC

RESPONSIBILITIES AS STATED IN THE ACG BYLAWS

This Committee shall be responsible for maintaining and strengthening the College's relationship with the Food and Drug Administration (FDA), as well as providing topical information to *The American Journal of Gastroenterology* and other ACG publications and meetings regarding GI drugs and devices that have been reviewed and/or approved by the FDA.

OBJECTIVES

1. Maintain and enhance an ongoing relationship with the U.S. Food and Drug Administration (FDA):
 - To serve in an advisory role concerning gastroenterology products.
 - To assess impact of FDA decisions regarding drugs/devices and to inform ACG leadership and members.
 - To provide suggestions for the FDA GI Drug Advisory Committee.
 - To develop and maintain collaborative programs with the FDA.
2. Provide updates, via *The American Journal of Gastroenterology*, SmartBrief, the ACG website, other media, and workshops or symposia, for our members on key issues stemming from FDA policies or decisions.
3. Serve as a resource for members to report adverse events (AEs) more easily.

COMMITTEE REPORT

The FDA Related Matters Committee in 2025 is under the leadership of Amanda Cartee, MD, FACC.

FDA and Innovation Technology Committee Joint-Committee Workshop at ACG 2025

The Committee is planning a joint workshop with the Innovation & Technology Committee during the 2025 annual meeting.

FDA Committee Manuscripts

The Committee routinely drafts manuscripts related to FDA and clinical gastroenterology. These manuscripts are published in the Red Section of *The American Journal of Gastroenterology (AJG)* or hosted on the FDA Committee section of the ACG website.

FDA Network of Experts

The College is also a member-organization of the FDA's "Network of Experts." This program allows the FDA rapid access to expertise when it is needed to supplement existing knowledge and expertise within the Center for Devices and Radiological Health (CDRH) and the Center for Drug Evaluation and Research (CDER).

FDA Safety Alerts & Meetings

The Committee continues to highlight and notify ACG members when the FDA publishes safety alerts and other regulatory updates pertaining to clinical gastroenterology. ACG notifies membership through various communication tools and social media. The ACG FDA Related Matters Committee continues to host these safety alerts and recalls on ACG's website.

Committee members continue to monitor and attend important hearings at the FDA on behalf of the College (when possible).

FDA Employees Participating in Committee Activities

The Committee will still invite FDA employees to participate in committee calls and meetings, helping to serve as a special-advisor role to provide guidance and recommend committee activities.