FDA RELATED MATTERS COMMITTEE

MEMBERS

Amanda K. Cartee, MD, FACG, Chair
Teminioluwa A. Ajayi, MD
Kalyan R. Bhamidimarri, MD, MPH, FACG
Jacqueline N. Chu, MD
Lawrence Goldkind, MD
Omar K. Jamil, MD
Madhu Mathew, MD
Fazia A. Mir, MD
Daphne Moutsoglou, MD, PhD
Sunhee (Sandra) Park, MD, FACG
Harini Rathinamanickam, MD
K. Gautham Reddy, MD, FACG
George Salem, MD, FACG
Tilak U. Shah, MD, MHS, FACG
Debra G. Silberg, MD, PhD, FACG
Ahmed S. Telbany, MD
Nyree K. Thorne, MD
Chung Sang Tse, MD

Amanda K. Cartee, MD, FACG

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 2026 is under the leadership of Amanda Cartee, MD, FACG.

FDA Committee Workshop at ACG 2026

The Committee plans to host a workshop during ACG 2026. The topic for the ACG 2026 Annual Meeting will be, "We Are What We Eat: An Overview of U.S. Food Policy, Supply, and Advocacy."

Committee Comments- FDA Draft Guidance on Clinical Trials

In January 2026, the committee provided comments on the FDA Draft Guidance: "Scientific Considerations in Demonstrating Biosimilarity to a Reference Product: Updated Recommendations for Assessing the Need for Comparative Efficacy Studies." The draft guidance describes considerations regarding comparative clinical study or studies with efficacy endpoints intended to support a demonstration that a proposed therapeutic protein product is biosimilar to a reference product.

In November 2025, the committee provided comments on the FDA's draft guidance entitled "Erosive Esophagitis: Developing Drugs for Treatment." The draft guidance solicited recommendations on clinical trials for drugs being developed for erosive esophagitis (EE) and maintenance of healed EE in adults, including considerations for eligibility criteria, trial design features, efficacy evaluations, as well as safety assessments. The committee also provided comment on the FDA's draft guidance entitled "Symptomatic Nonerosive Gastroesophageal Reflux Disease: Developing Drugs for Treatment." The draft guidance details FDA's recommendations for drugs being developed for the treatment of symptomatic nonerosive gastroesophageal reflux disease (sGERD) in adults, including considerations for eligibility criteria, trial design features, efficacy evaluations, as well as safety assessments.

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.