AGA Guide for Interactions with Companies

INTRODUCTION

The AGA and AGA Institute (hereinafter, AGA) are non-profit organizations dedicated to empowering clinicians and researchers to improve digestive health. AGA has always been committed to a culture of scientific and programmatic independence, transparency and the highest ethical standards.

We believe relationships with for-profit companies in the pharmaceutical, device, technology and other sectors provide great value to AGA and its members as long as those relationships are ethically structured. AGA’s relationships with companies are, and have always been, transparent. Company support has absolutely no influence on AGA’s educational, scientific, or clinical content.

AGA has longstanding policies which govern conflicts of interest in all society-related endeavors. The AGA Institute Ethics Committee has been, and will continue to be, the gatekeeper to manage conflicts that arise. However, over the last several years new opportunities to work with Companies in ways that directly benefit our members and their patients have required additional expertise and scrutiny to assure we are managing new programs in full compliance with AGA’s Principles and Policies. In some cases, AGA’s relevant policies for interactions with companies have been decentralized or referred to programmatic staff. This Guide for Interactions with Companies (Guide), adopted by the governing board, integrates all of those policies into one document, affirms new policies where gaps in guidance existed, and allows all staff and members to have a reference document to guide them in all future endeavors with companies.

In creating this Guide, AGA has consulted with a wide variety of stakeholders within the organization (members and staff) to help critically evaluate where greater clarity was needed to assure consistency in implementation. Their perspectives have been incorporated into this Guide. It is important to acknowledge that we have also extensively relied on two existing documents, which are current benchmarks for the medical specialty community:

1. The Council on Medical Specialty Societies (CMSS) Code on Interactions with Companies
2. American College of Cardiology’s (ACC) Principles for Relationships with Industry

Please NOTE: This Guide, if adopted, can be further edited and tailored as appropriate to meet the specific and unique characteristics of AGA. The governing board should decide the best process for keeping this document current and consistent.

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1 Approved by the AGA Institute Governing Board, (11) VOTED, Nov. 2018.
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DEFINITIONS

Advertising: Advertising is a Business Transaction in which a Company pays a fee to AGA in exchange for the Society’s publication of a promotional announcement that highlights the Company or the Company’s products or services. For purposes of this Guide, Advertiser refers to a Company that purchases Advertising.

Business Transaction: A Business Transaction is an interaction between AGA and a Company in which a Company pays a fee to the Society in exchange for the Society’s event, service, or product. Examples of Business Transactions include Company payment of fees associated with subscriptions to AGA publications, exhibit space rentals, Key Opinion Leader meetings organized through the Center for GI Innovation and Technology (CGIT), advertising in AGA journals and other publications, registrations for Society meetings, and exhibit space rental.

Charitable Contribution: A Charitable Contribution is a gift, including an in-kind gift, given by a Company to a qualified tax-exempt organization (e.g., a gift to the AGA Institute to support research) for use in furthering the organization’s charitable and research purposes and in accordance with applicable tax rules and legal standards.

Clinical Practice Document: Clinical Practice Documents are systematically developed statements to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances. As used in this Guide, the term Clinical Practice Documents include AGA guidelines, clinical practice updates, medical technology assessments, quality measures, and other evidence-based clinical practice tools.

Company: A Company is a for-profit entity that develops, produces, markets, or distributes drugs, devices, services or therapies used to diagnose, treat, monitor, manage, and alleviate health conditions. This definition is not intended to include non-profit entities, entities outside of the healthcare sector, or entities through which physicians provide clinical services directly to patients.

Continuing Medical Education (CME): CME consists of educational activities for which the learner may receive CME credit (e.g., American Medical Association (AMA) Physician’s Recognition Award Credit, American Academy of Family Physicians (AAFP) Prescribed or Elective Credit, American Osteopathic Association (AOA) Credit – various categories) based on accreditation awarded to the continuing education provider by a recognized accrediting body (e.g., Accreditation Council for Continuing Medical Education (ACCME), AOA, AAFP). CME activities “serve to maintain, develop, or increase the knowledge, skills, and professional performance and relationships that a physician uses to provide services for patients, the public, or the profession.” For purposes of this Code, educational activities for physicians and other health care providers that are not CME-accredited are considered Independent Medical Educational/Informational Programs (IME).

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4 These definitions have been adopted from the CMSS Code on Interactions with Companies.


**Corporate Sponsorship:** A Corporate Sponsorship is an arrangement in which a Company, typically through its marketing department, provides monetary or in-kind support for a particular Society product, service, or event, and is then acknowledged in connection with the product, service or event. Corporate Sponsorships are distinct from Educational Grants, and do not constitute Commercial Support of CME. For purposes of this Guide, Corporate Sponsor refers to a Company that provides a Corporate Sponsorship.

**Direct Financial Relationship:** A Direct Financial Relationship is a relationship held by an individual that results in wages, consulting fees, honoraria, intellectual property rights, or other compensation (in cash, in stock or stock options, or in kind), whether paid to the individual or to another entity at the direction of the individual, for the individual’s services or expertise. Stocks held as part of a mutual fund or where the individual has no direct control over the investment shall be excluded from this definition.

**Educational Grant:** An Educational Grant is a sum awarded by a Company, typically through its grants office, for the specific purpose of supporting an educational or scientific activity offered by the Society. Educational Grants awarded by a Company to support a CME activity are referred to in the ACCME Standards for Commercial Support as “Commercial Support” of CME. An Educational Grant may also be “in-kind.”

**Exhibits:** An Exhibit is a display booth within a dedicated section of an AGA meeting, such as DDW®. For the purposes of this guide, rules for exhibits, and exhibitors, are primarily for-profit companies who pay a fee in exchange for the space to showcase their products and services (although there are non-profit exhibits as well).

**Independent Medical Education (IME) Informational/Educational Program:** An IME, or Non-CME Informational/Educational Program is a program offered by AGA, a Company or other third party that provides educational or promotional information and does not offer CME credit.

**Key Society Leader:** For the purposes of this guide, Key Society Leader includes the AGA Chair, AGA Institute President, AGA Institute President-Elect, AGA Institute Vice President, and Journal Editors.

**Research Grant:** A Research Grant is an award that is given by a Society to an individual, institution, or practice to fund the conduct of scientific research. Companies may provide Societies with programmatic support (e.g., an Educational Grant or Charitable Contribution) designated for the specific purpose of funding Research Grants.

**Satellite CME Symposium:** A Satellite CME Symposium is a Company-supported CME program held as an adjunct to DDW or other AGA-sponsored meetings where CME credit for the Symposium is provided either by AGA or by a third-party CME provider, and for which the Society receives a fee.

**Society Journal:** A Society Journal is a peer-reviewed scientific journal published by AGA or by a publisher on AGA’s behalf.

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PRINCIPLES FOR INTERACTIONS WITH COMPANIES

The following Principles serve as a roadmap for all AGA interactions with companies.

➢ Independence

- AGA commits that its educational activities, scientific programs, products, services and advocacy positions are independent of any Company influence.

- Any educational grant, corporate sponsorship, charitable contribution, or support for research grants will be executed through arms-length business relationships that guarantee AGA’s independent judgement and autonomy in development of programmatic content, speakers, and policies.

- The AGA Governing Board, in consultation with the ethics committee and other relevant policy recommending bodies, is ultimately responsible for assuring all interactions with Companies meet the principles contained herein.

- No Key Society Leader (as defined herein) may have Direct Financial Relationships with Companies during his or her term of service. The ethics committee is charged with monitoring compliance with this principle during the designated terms of the Key Society Leaders.

- AGA requires written agreements with Companies for all Educational Grants, Corporate Sponsorships, Charitable Contributions, Business Transactions, and support of research grants. The agreements will be reviewed by AGA General Counsel prior to execution to assure strict compliance with AGA rules.

- Volunteers are required, as part of the COI disclosure process, to certify that they have accurately reported details available on their CMS Open Payment report or other public sources.

- Disclosures of relevant conflicts of interest will be made known to the governing board, chairs of committees, key staff, and others as appropriate prior to appointments, nominations, and committee/board meetings.

➢ Transparency

- AGA will make this guide, its conflict of interest policies and relevant forms available to all members and the public by publishing them on its website.

- AGA practices full and open disclosure of industry funding, contributions, and support through standards established by AdvaMed, PhRMA, and other medical specialty societies.

- AGA will periodically review its disclosure policies for Key Society Leaders, board members, committee members, and all other volunteers who serve on behalf of the Society to be certain they are sufficient to adhere to principles of transparency, independence, and other principles within this Guide.

- Recommended changes to this guide or policies can be proposed by any committee, or any member. All proposed changes should first be reviewed by AGA Institute Ethics Committee and then sent to the governing board for approval.
Governance

AGA’s Governance Principles are applicable to all AGA and AGA Institute Governing Board members, committee members, Center boards, authors, reviewers, other volunteers, and staff. All members of these groups must be aware and adhere to the following:

- AGA requires complete and timely disclosures of all relationships with companies as part of adherence to the AGA Code of Ethics and Conduct\(^8\) and the AGA Policy on Disclosure of Potential Conflict of Interest\(^9\). All active AGA volunteers will submit their COI forms on an annual basis to assure accurate information is disclosed to the ethics committee.

- The AGA Institute Ethics Committee is charged with the responsibility to evaluate and use that disclosure information to accurately and ethically manage relationships with industry.

- Governing board and committee members are required to disclose all actual and perceived conflicts prior to, and/or during any AGA meeting.

- AGA strictly adheres to the Accreditation Council for Continuing Medical Education (ACCME) Standards for Commercial Support to ensure that CME activities are independent and free of commercial bias.

- All business relationships with industry are subject to strict contracting rules and must meet protocols established for all arms-length business transactions.

- Committee, Center, and section members and chairs, and staff are advisory to the AGA Governing Board and do not have the authority to act on behalf of or set policy unilaterally for AGA.

- Company employees will not be permitted to serve on AGA’s policy-recommending committees unless they recuse themselves (or are recused) from any discussions and votes that have any direct or perceived impact on their employer.

- Invitations for AGA’s participation in meetings, conferences, or other capacity with external organizations should be communicated to the AGA Institute President and Executive Vice President (EVP). They will determine, in consultation with relevant parties, whether AGA participation is appropriate. Neither staff nor members should participate in industry meetings as a representative of the AGA without prior knowledge and approval of the AGA EVP.

Charitable Contributions

- AGA accepts Charitable Contributions from Companies in furtherance of its mission and its established research priorities.

- AGA will decline any Contribution where the Company expects to influence Society programs or initiatives.

- AGA will adhere to all applicable tax rules and legal standards for acceptance of Charitable Contributions and management of institutional funds.


• AGA will adopt policies for consistent and appropriate recognition of donors.

Corporate Sponsorships

• AGA recognizes a Corporate Sponsorship to be an arrangement that provides financial support to AGA in exchange for value-neutral acknowledgement of the sponsor that neither endorses nor identifies a sponsor’s products or services.

• Reasonable efforts to secure multiple sponsors for programs will be made; however, sponsorships with one Company are acceptable if all principles are followed.

• AGA requires a written agreement with every sponsor, which reflects the purpose of the sponsorship, the amount of the sponsorship, and the agreed upon acknowledgement of the sponsor.

• AGA requires that any sponsorship comply with all applicable laws and regulations, including the Physician Payments Sunshine Act, and is consistent with codes from the AMA\textsuperscript{10}, PhRMA\textsuperscript{11}, and AdvaMed.

• All sponsorships must be consistent with AGA’s strategic plan and mission.

Data Registries

• For all data registries for which AGA accepts Corporate Sponsorship, Sponsors are prohibited from participating in the direct management of the registry, unless the data registry is in part operating as a public or private medical society, device/drug manufacturer and government partnership, or for the purpose of meeting regulatory FDA objectives of device/drug surveillance and patient safety.

• AGA will oversee registry operations without Company interference; however, Corporate Sponsors and other stakeholders may be permitted to serve on registry steering groups and committees and be involved in decisions, including decisions to sell or otherwise disclose or publish registry data relating to post-marketing surveillance and patient safety.

• Under no circumstances will Sponsors or other industry representatives be allowed to have majority representation in any such group or committee.

• Registry data - TBD

• Data registry sponsorships are subject to same standards of transparency, independence and integrity as all other sponsorships.


Research Grants

- AGA does not permit Companies to select or influence the selection of recipients of Research Grants and Awards.
- AGA, through its research award process, assures its Research Award and Grant recipients are selected in a manner which preserves the standards of independence, transparency and integrity contained herein.
- Societies will not permit Companies that support Research Awards or Grants to receive intellectual property rights or royalties arising out of the recipients’ research.
- Societies will not permit Companies that support Research Grants to control or influence manuscripts that arise from the grant-funded research.
- If AGA receives programmatic support (e.g., an Educational Grant or Charitable Contribution) from a Company to support the Society’s own research, or research-related initiatives, the Society will disclose the Company support. AGA will act independently in the selection of research topics and the conduct of the research itself and resulting public release and/or publication.

Clinical Practice Documents

- AGA regularly creates and publishes evidence-based clinical guidelines, clinical practice updates, quality and performance measures, and other clinical practice documents in order to improve the quality and effectiveness of patient care.
- AGA follows a transparent, independent guideline development process that is not subject to Company influence or bias. (Reference: AGA Conflict of Interest Disclosure Policy for Clinical Practice Guidelines.)
- AGA requires all guideline, clinical practice update, and other development panel members to disclose relevant relationships prior to panel deliberations, and to update their disclosure throughout the development process.
- Companies, as well as patients, gastroenterologists and other stakeholders do have the opportunity to comment on proposed new AGA guidelines during the public comment period and those comments will be evaluated through the identical process used for all other stakeholders.
- Companies, as well as all other stakeholders, are free to submit suggestions for guidelines or other Clinical Practice Documents on new and emerging topics or updates to current guidelines for consideration by the committee. If a suggestion from a Company is pursued for a Clinical Practice Document, the Company shall have no further influence over the development of the document.
- AGA will not permit direct Company support of the development or maintenance of any Clinical Practice Documents.
- AGA will not permit direct Company support for the initial printing, publication, and distribution of Clinical Practice Documents. However, once published, it is permissible for AGA to accept Company support for the Society’s further distribution of Clinical Practice Documents, including guidelines or guideline updates, translation of the guideline or guideline updates, and repurposing of the guideline content.
- When evaluating COI’s for Clinical Practice Document writers and panels, AGA will develop
safeguards to ensure that those members selected do not have impermissible conflicts relevant to the subject matter of the guideline and to determine what is a permissible conflict; the ethics committee will work with Chairs of relevant clinical committees to determine new review procedures to implement these safeguards.

- AGA requires that the Chair of the Guideline Development Group, and a majority of Guideline (and other Clinical Practice Documents) Development Group members are free of conflicts of interest relevant to the subject matter of the guideline.

- AGA’s committees and members who are charged with creating Clinical Practice Documents can and should, as appropriate, consult with additional content experts (such as members of relevant Council Sections, or members of the CGIT) as they gather all relevant information and data necessary to accurately assess therapeutic and procedural evidence; however, all such experts must be required to disclose their conflicts prior to such consultations. A conflict under these circumstances does not disqualify the member from providing data and information, or from serving on a development panel, as long as they are not a voting member of the review panel/group or the AGA Institute Clinical Guidelines Committee.

- AGA will not permit Guideline Development Group members, expert consultants, or staff to discuss details of a guideline’s development with Company employees or representatives, will not accept unpublished data from Companies, and will not permit Companies to review guidelines in draft form, except as part of public comment periods.

- In the event that new, evidence-based relevant data emerges after the public comment period has expired, there will be an appeals process established to consider edits and addendum to guidelines and other documents.

**Society Journals**

- AGA Journals shall maintain editorial independence through a firewall that separates the editorial decisions from Society governance and operations and from Advertisers.

- Editorial independence of the Journals will be consistent with accepted standards for medical publishing, such as those established by the International Committee of Medical Journal Editors (ICMJE) and the World Association of Medical Editors (WAME).

- Society Journals will require all authors to disclose financial and other relationships with Companies, as well as all other relevant COI’s that could create an actual or perceived conflict.

- Authors’ disclosure information will be considered by Society Journal editors in evaluating an article for publication. If the article is published, Society Journals will publish the authors’ disclosure information with the article or issue.

- Society Journals will require editors and reviewers to disclose financial and other relationships with Companies, and those disclosures will be published on the Journal’s website.

- The Editor-in-Chief of each Society Journal will have the ultimate responsibility for determining when a conflict of interest should disqualify an editor or reviewer from reviewing a manuscript, according to established policies.

- Society Journals will adopt policies prohibiting the submission of “ghost-written” manuscripts prepared by or on behalf of Companies.
Advertising

- AGA maintains an advertising policy for its journals, which, is adhered to by the organization’s publishing partner, Elsevier. AGA is developing an overarching policy that would apply to all advertising, regardless of where it is placed.
- Advertising content must be easily distinguished from editorial content.
- Advertising is subject to review and AGA reserves the right to refuse any advertising.
- Acceptance of advertising is not an endorsement of any product or service by AGA.

AGA Meetings and Education (CME/IME)

- When providing CME, AGA is in full compliance with ACCME Standards for Commercial Support, and has policies and procedures designed to identify and manage conflicts of interest in Company-supported CME programs.
- AGA will not seek or accept support for product-specific topics.
- AGA will retain control over the use of Educational Grants and will implement safeguards designed to ensure that educational programs are non-promotional and free from commercial influence and bias.
- AGA’s CME subcommittee has responsibility to select the objectives, content, faculty and format of educational activities to assure they are consistent with AGA’s mission and strategic plan.
- AGA and Companies can engage in dialogue about topics, potential experts, and emerging issues in science and development. However, the ultimate decision about program content, tactics, etc. remains with AGA and its planning committees.
- AGA has responsibility of assuring that speakers do not use company-controlled presentations and/or slides with company logos.
- AGA will clearly distinguish Non-CME Programs from CME Programs.
- If the purpose of an AGA CME or IME session is to demonstrate or train attendees in the safe and effective use of a particular drug, device, service or therapy, AGA may accept in-kind support from Companies that develop, produce or distribute them. In accordance with ACCME Standards, AGA may accept in-kind support from a single Company when other equal but competing products are not available for inclusion.
- AGA will accept sponsorship for surveys of health care providers and patients. AGA owns the resulting data and decides if/how to release the information.
- AGA appoints medical advisors to oversee sponsored patient education programs. These medical advisors should not have independent relationships with the program’s sponsor. Medical advisors have final control over program content.
- When working on a sponsored education program, AGA will not contract with subcontractors (e.g. public relations firms, education development companies) that conduct related branded work for the corporate sponsor.
CME-Accredited Satellite Symposia

- AGA, both at DDW and other Society meetings, requires Companies that seek to hold Satellite CME Symposia to undergo an application and selection process.
- AGA, both at DDW and other Society meetings, will ensure that Satellite CME Symposia are clearly distinguished from Society CME in meeting programs and promotional materials.
- Societies will require third party organizers of Satellite CME Symposia to use appropriate disclaimers to distinguish the Symposia from Society CME programs in Symposia advertising and program materials.
- Societies will not permit Key Society Leaders to participate in Satellite CME Symposia as faculty members, presenters, chairs, consultants, or in any other role besides that of an attendee who receives no honoraria or reimbursement.

Exhibits

- AGA, both for DDW and for other meetings, has written policies that govern the nature of exhibits and require exhibitors to comply with applicable laws, regulations, and guidance; these policies are public and transparent.
- AGA will only permit for-profit exhibitor giveaways that are educational, modest in value, and consistent with established standards for ethical interactions.
- AGA will make reasonable efforts to place exhibit booths out of attendees’ required path to Society CME sessions.
- Key Society Leaders may not participate as leaders or presenters in Company promotional/marketing events held in exhibit space.

AGA Centers

- From time to time, AGA has and shall create Centers, which are special, centralized initiatives with multi-purpose objectives. There are currently two Centers, The Center for GI Innovation and Technology (CGIT) and the Center for Gut Microbiome Research and Education.
- All the provisions within the Governance Section of this Guideline are applicable to AGA Centers.
- Unlike other Centers or AGA committees, CGIT volunteers and staff have routine and significant interaction with Companies, in order to fulfill its objective of supporting innovation and the development of new technology which will be used by AGA members and benefit their patients.
- Due to the nature of information sharing that occurs between CGIT, Companies and regulatory bodies, such as FDA, about specific technologies, the CGIT may serve as an objective resource to other AGA committee's and activities.
- AGA must assure that CGIT’s services, including those services provided to Companies are handled in a manner wholly consistent with the Principles contained throughout this Guide;
- AGA must assure that all Centers that engage in Business Transactions (e.g., Key Opinion Leader meetings, clinical study design and development, etc.) and Corporate Sponsorships (e.g., Tech Summit support) are held to same standards as all other AGA initiatives with Industry.
Advocacy, Coding, Coverage and Reimbursement

**Advocacy Initiatives**
AGA does not permit Companies to influence or impact AGA’s legislative and regulatory policies and positions.

- All policies are developed through established processes by the AGA Government Affairs Committee and/or other policy recommending bodies within AGA; the governing board must review and approve all policy decisions before implementation by government affairs members and staff.
- Potential conflicts of interest of all committee members are disclosed through AGA’s COI process. Company representatives will not be permitted to serve on AGA’s policy-recommending committees unless they recuse themselves (or are recused) from any discussions and votes that have any direct or perceived impact on their employer.
- AGA does work with Companies, as appropriate, on shared legislative and regulatory priorities and through approved Coalitions that further the mission and strategic plan of AGA.

**Coding, Coverage and Reimbursement Initiatives**

- AGA, along with the American College of Gastroenterology (ACG) and the American Society for Gastrointestinal Endoscopy (ASGE), has played a significant role at the AMA Current Procedural Terminology (CPT) Editorial Panel Meetings to develop coding recommendations and create/revise CPT codes and with AMA/Specialty Society Relative Value Scale Update Committee (RUC) in identifying the physician work and resources required to provide services. This important work has an impact on reimbursement by Medicare, Medicaid and commercial payors.
- AGA, ACG and ASGE have established a process for assisting Companies on CPT coding applications to help facilitate bringing new technology to market and improve the lives of patients.
- AGA’s process for assisting Companies on CPT coding applications is consistent with the rules established by the CPT Editorial Panel Process\(^{12}\) and the RVS Update Committee of the American Medical Association.
- AGA recognizes that there are circumstances where the required expertise to represent AGA at the CPT, RUC and other related bodies may include interactions with Companies. It is essential that those conflicts are disclosed, evaluated, and transparent to members and the public.