

AUGS Code for Conflict of Interest
Approved April 29, 2011

Purpose and Application

Complex relationships with for-profit and non-profit organizations and entities may, by their existence, present a perceived or real conflict with the missions and values of AUGS. In as much as the existence of real or perceived conflicts of interest serves to undermine the stature, integrity, creditability and function of AUGS, AUGS must insure that its membership, leadership and the public-at-large understand the importance it places on identification and resolution of conflicts. The independence and the credibility of AUGS require implementation of a clear policy that promotes professionalism and can be enacted in a practical, fair and transparent manner. The AUGS policy has been adapted from the Council of Medical Specialty Societies Code for Interactions with Companies.¹

Conflict of interest, sometimes called duality of interest, is defined as any circumstances that create a risk that professional judgments or actions regarding a primary interest will be unduly influenced by a secondary interest. Primary interests are those associated with the stated mission of AUGS. Secondary interests may be financial or non-financial in nature (e.g. intellectual conflicts of interest, membership in other organizations, or institutional or corporate associations).

Further, the degree of permitted associations will be regulated in a fashion that is commensurate with the influence that the individual has in the creation, implementation or execution of AUGS functions. Since AUGS plays roles for advocacy for clinical care, education and research in female pelvic floor disorders, the policy shall cover all individuals who participate at any level in those functions. The definition of conflict, review and management of disclosures and the adjudication and resolution of conflicts needs to be a multi-layer effort that is charged to the Governance Committee. The policy outlined will require diligent interpretation in complex cases, with the goal of providing clarity for members as they engage in their functions. The overriding goal is to provide objective conflict management. The application of this Code is not intended to be punitive to the member nor restrict members in their roles as physicians, researchers or medical professionals. The process is by its nature fluid and ongoing reporting and review is necessary and expected.

¹ The Council of Medical Specialty Societies (CMSS) is a 501 (c) 3 organization committed to education, professionalism and quality of care. The CMSS Code was adopted on April 17, 2010.

Definitions²

The following terms are defined for the purpose of this Code:

Business Transaction: An interaction between AUGS or its Foundation and a Company in which a Company pays a fee in exchange for a service or product.

Charitable Contribution: A gift, including an in-kind gift, given by a Company to AUGS or its Foundation for use in furthering the organization's charitable purposes and in accordance with applicable tax rules and legal standards.

Clinical Practice Guideline: A guideline is a systematically developed statement to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances. Used in this code, the term Clinical Practice Guideline also refers to clinical opinions and other evidence-based clinical practice tools, as well as updates to existing Clinical Practice Guidelines (Guideline Updates).

Continuing Medical Education (CME): Continuing Medical Education (CME) consists of educational activities for which the attendee may receive CME credit based on accreditation awarded to the provider by a recognized accrediting body (ACCME). 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."³ For purposes of this code, educational activities for physicians that are not CME-accredited are considered non-CME educational/informational programs.

Company: 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 and whose interests could reasonably be seen to overlap with the interests, missions and values of AUGS. This definition is not intended to include entities outside of the health care sector, or entities through which physicians provide clinical services directly to patients.

Direct Financial Relationship: A compensated relationship with a company held by an individual that should generate an IRS Form W-2, 1099 or equivalent income report.

Educational Grant: 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 recipient. Educational grants awarded by a company to support a CME activity are

² Modified from Council of Medical Specialty Societies, 230 E Ohio St. Suite 400, Chicago, IL

³ Accreditation Council for Continuing Medical Education (ACCME): CME Content.

http://www.accme.org/index.cfm/fa/Policy.policy/Policy_id/16f1c694-d03b-4241-bd1a-44b2d072dc5e.cfm.

referred to in the ACCME Standards for Commercial Support as “Commercial Support” of CME. An educational grant may also be “in-kind.”

Gifts “in-kind”: Compensation in goods and services rather than money; non-monetary gifts of valued consideration (e.g. access to advisory or consultant services, specific resource allocation or access)

Key Society Leaders: For purposes of this Code, the Key Society Leaders are officers in the Presidential line of succession (e.g. Vice President, President-elect, President, and the Immediate Past President), the Executive Director, Scientific Program Chair and the Editor(s) of the Society’s Journal(s).

Research Grant: For purposes of this Code, a Research Grant is an award that is given by a Company or other funding agency to an individual, institution, or practice to fund the conduct of scientific research. Companies may provide an individual, institution, or practice with programmatic support (e.g., an Educational Grant) designated for the specific purpose of funding Research Grants.

AUGS/Society: For purposes of this document, the use of the term “Society” or the abbreviations AUGS encompasses all Committees and programs that fall within the AUGS governance structure (for example, the AUGS Foundation).

Principles and Practice

1. Independence

AUGS will develop all educational activities, scientific programs, products, services and advocacy positions aligned with the mission of the Society, independent of external influence, and will develop and adopt policies and procedures that foster this independence. AUGS will separate their efforts to seek Educational Grants, Corporate Sponsorships, Charitable Contributions and support for Research Grants from their programmatic decisions. The initial step in program development is the independent assessment by AUGS that a program is needed (e.g. to address gaps in care or knowledge). Once AUGS determines that a program is needed, it is permissible to assess the availability of funds.

- a. The Governance Committee will be responsible for evaluating and adjudicating conflicts of interest and guiding the interactions of AUGS, and its Members, and monitoring compliance with this Code by the covered individuals.
- b. Key Society Leaders may not have Direct Financial Relationships with Companies during his/her term of service. Financial Relationships from entities whose sole purpose is medical education (e.g. book and journal publishers, UptoDate, ACGME approved CME, etc) is allowed but must be disclosed and if the relationship could reasonably be seen to overlap with the interests, missions, and values of AUGS may require management.
- c. Other AUGS Members are permitted to have Direct Financial Relationships with Companies but must disclose any such Relationship and indicate whether it is in excess of \$5,000 per year when requested.
- d. Nominees for Key Leadership positions will be notified that they will be required to terminate any Direct Financial Relationship with Companies prior to the start of their term.
- e. Key Society Leaders may provide uncompensated service to Companies and accept reasonable travel reimbursement in connection with those services. Research support is acceptable as long as the money is paid to the institution or practice where the research is conducted, not to the individual. Direct financial compensation for CME by Companies is not permitted, however support for CME activities from hospitals or health care systems (both for-profit and non-for profit), medical education companies, and non-for-profit entities such as medical societies is allowed. Research support, uncompensated services or other permitted relationships must be disclosed to AUGS, regardless of monetary value or its equivalent.
- f. Key Society Leaders and the Board of Directors cannot serve as officers or members of the governing board of related professional associations during their term of office. Related professional societies include national and international professional societies whose principal interests include Female Pelvic Medicine and Reconstructive Surgery including but not

limited to Society for Female Urology and Urodynamics (SUFU), International Continence Society (ICS), International Urogynecological Association (IUGA), Society of Gynecologic Surgeons (SGS), American Association of Gynecologic Laparoscopists (AAGL). It does not include national specialty organizations like American College of Obstetrics and Gynecology (ACOG), American Board of Obstetrics and Gynecology (ABOG), American Board of Urology (ABU), and the American Urological Association (AUA).

- g. Key Society Leaders and the Board of Directors who are elected or appointed prior to the time AUGS approves this Code have until October 1, 2012 to end their relationships/conflicts related to service on other governing boards and Direct Financial Relationships with Companies. These relationships should be disclosed in accordance with Principle 2a and b.
- h. AUGS will use written agreements with Companies for Educational Grants, Corporate Sponsorships, Charitable Contributions, Business Transactions and support of Research Grants. Written agreements should specify what the funds are for, the amount given, and the roles of the Company and the Covered Individual. These agreements may be reviewed by the Executive Director or other designated body.

2. Transparency

AUGS will make their conflict of interest policies available to their members and the public. AUGS, through the Governance Committee, will manage conflicts of interest in a variety of ways. This may include disclosure alone, or other conflict of interest management mechanisms such as recusal, divestiture or AUGS-independent review. The Governance Committee will select conflict of interest management mechanisms that are appropriate for the activity, the type of relationship and role of the individual under consideration.

- a. AUGS, through its Governance Committee, will provide written disclosure forms individuals who serve on behalf of AUGS and will use the disclosed information to manage conflicts of interest in decision-making. AUGS will require volunteers to update disclosure information at least annually and when material changes occur.
- b. AUGS will disclose all Direct Financial Relationships and uncompensated relationships held by the Key Society Leaders and Board of Directors, making this information available to their members and the public.

3. AUGS and its Relationships with Industry

To support its mission-related activities, the Society solicits restricted and unrestricted contributions from organizations, corporations and foundations. The Society enters into corporate relationships to:

- a. Increase the dissemination of scientific, medical and health information and education.
- b. Help develop, produce and implement Society/Foundation mission-related programs, materials and activities.
- c. Provide a new means of raising funds and increasing public awareness for the Society's mission-related activities.

In accepting donations from corporations with vested interests in how the public regards their products, the Society is determined to avoid conflict of interest, or even its appearance. Therefore, the Society enters into corporate relationships thoughtfully, with careful consideration given to the possible unintended effects, especially regarding the organization's public trust.

- a. AUGS will decline charitable contributions where the donor expects to influence Society programs or advocacy positions, or where donor restrictions would influence Society programs or positions in a manner that is not aligned with the Society's mission.
- b. Reasonable restrictions on the purposes for which Charitable Contributions will be used are acceptable, as are reasonable requirements for reporting on the uses of the donated funds.
- c. AUGS will disclose Company Support (Educational Grants, Corporate Sponsorships, Charitable contributions and support of research grants) making this information available to their members and the public.

4. Corporate Support

- a. Advertising: Advertising in all Society publications should be easily distinguishable from editorial content. Advertising should not be designed to look like scientific articles. Placement of advertising adjacent to articles or editorial content discussing the Company or product that is the subject of the ad is prohibited. All advertisements are subject to review by the Editor-in-Chief and overseen by the Society. Advertisements placed in publications that pertain to CME must comply with ACCME requirements, which state that advertisements must remain separate from educational content.
- b. AUGS will not place the names or logos of Companies or products on Society-distributed, non-educational "reminder" items (e.g. tote bags, lanyards, highlighters, notebooks and luggage tags) that Companies are not permitted to give directly to healthcare professionals under generally accepted standards for ethical interactions. (i.e. PhRMA Code, AdvaMed Code).
- c. Sponsorship: AUGS will only accept sponsorship of items or programs that are aligned with the Society's strategic plan and mission.
- d. Exhibits: A code of exhibitor conduct will be developed and shared with all companies participating in any Society meeting. The purpose of this

code is to ensure that the tone of the exhibit hall is professional in nature and follows existing PhRMA, AdvaMed and ACCME guidelines. Members of the Board of Directors may not participate as leaders or presenters in a Company promotional/marketing event held in the exhibit hall. This includes the exhibit booth and industry expert theater.

5. Education

In accordance with ACCME policy educational content shall promote health care, and not a specific proprietary business interest. The content shall offer a balanced view, and should use generic names in place of product trade names whenever possible. Live case demonstrations shall not be used to promote a product and shall provide a proper clinical perspective. This policy applies to the organization as a whole, and to all educational activities, including satellite symposia not sponsored or endorsed by the Society.

- a. The educational content of all programs will not be directed or influenced by the provision of financial support.
- b. Individuals affected by this policy include course directors, planners, reviewers, moderators, speakers, faculty; and individuals who influence the content of other educational products, services and publications.
- c. AUGS will not solicit supporters' suggestions about program topics, speakers or content.
- d. AUGS staff will retain control over the submission of educational grants and implement safeguards to ensure educational programs are non-promotional and free from commercial influence and bias.
- e. Presenters will not be allowed to use company-controlled presentation materials and from using slides with company logos.
- f. Satellite CME Symposia: These programs are planned by a third-party provider and must comply with ACCME standards and be clearly distinguished as separate from the Society's CME programs in all promotional materials and on-site. Key Society Leaders and the Board of Directors are not permitted to participate as faculty, presenter, chair or consultant or in any role other than attendee.
- g. Industry Expert Theaters: These programs are planned independent from any Society educational efforts and must be clearly distinguished as separate from the Society's CME programs in all promotional materials and on-site. Key Society Leaders and the Board of Directors are not permitted to participate as faculty, presenter, chair or consultant or in any role other than attendee.

6. Charitable Contributions

Both AUGS and the AUGS Foundation are the benefactor of charitable contributions. It is acceptable for both entities to accept contributions that are designated to support a specific program allowing for reasonable restrictions.

- a. All contributions will be used in a manner that is aligned with the Society's strategic plan and mission.
- b. No contributions will be accepted where the donor expects to influence programs or positions, or where donor restrictions would influence programs or positions.
- c. All donors will be recognized in a consistent and appropriate manner. Donor recognition typically includes: Web site listing, signage, walk-in slides, from a podium and in printed materials.

7. Research Grants and Endowed Lectures

Through contributions from individual donors, Companies and foundations the Society is able to award annual research grants and select Endowed Lecturers.

- a. Companies are not permitted to select (or influence the selection of) recipients of Research Grants or Lectures. Companies have no control or influence over manuscripts that arise from grant-funded research.
- b. AUGS will appoint an independent review committee to select lecturers or the recipients of research grants, based on a peer review process.
- c. AUGS will not name a research grant or endowment after a corporate entity. Instead recognition will be provided to all corporate/foundation donors to the grant or lecture programs.
- d. AUGS will not permit Companies that support Research Grants to receive intellectual property rights or royalties arising out of the grant-funded research

8. Clinical Practice Guidelines/Clinical Review Documents

The credibility and authority of guidelines/review documents depend on a common understanding that they are developed through a rigorous independent process, based on the best scientific evidence.

- a. The Chair of the Guidelines Committee (or any committee tasked with developing a guideline/clinical review) must be free of conflicts of interest and remain free of conflicts of interest for at least one year after publication.
- b. Committee members are required to complete an annual disclosure form and disclose all relationships prior to panel deliberations, as well as update their disclosures throughout the development process. All disclosure information will be posted along with the published document. It is recommended that at least 50% of the committee members will be free of conflicts of interest.
- c. Committee members or staff may not discuss 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.

- d. Committee members are not permitted to speak on behalf of any Guideline at a Company meeting or Company-sponsored meeting for a period of one year after publication.
- e. All contributors, including expert advisors or reviewers who are not officially part of the committee, are required to disclose financial or other substantive relationships that may constitute a conflict of interest.
- f. Individuals who are employed by or engaged to represent a Company are not eligible to serve on a guideline development committee or serve as an expert advisor or reviewer.

Since health care providers, payors and patients look to clinical guidelines as an important resource from experts in the field, it is important that they are free from commercial bias and influence.

- g. A transparent development process that is free of company influence will be followed in the development of all guideline and guideline related products.
- h. Direct company support of the development of clinical practice guidelines will not be permitted.
- i. Corporate support may be solicited to assist with the distribution of clinical guidelines to AUGS members and other interested parties.

Prior to publication guideline recommendations will be subject to multiple levels of review, including rigorous peer-review by a range of experts. The AUGS Board of Directors will review and approve all documents prior to being submitted to the journal, *Female Pelvic Medicine and Reconstructive Surgery*. It is expected that the Journal will submit the guideline document to an independent editorial review like any other manuscript submitted for publication.

9. *Female Pelvic Medicine and Reconstructive Surgery*

The Society's Journal (s) shall maintain editorial independence from the Society and its advertisers. In general, a firewall exists between the editorial policies and decisions of the Journal from the Society's governance and operations. The Journal may have its own conflict of interest policy, which should at a minimum include:

- a. All authors are required to disclose financial and other relationships with Companies for the past year. This disclosure information will be published with the article/issue.
- b. All editors and reviewers are also required to disclose financial and other relationships with Companies. These disclosures will be published on the Journal's Web site.
- c. The Editor-in-Chief has the ultimate responsibility for determining when a conflict of interest should disqualify an editor or reviewer from reviewing a manuscript, according to established policies.

10. Adherence to the Code

Adherence to this Code will be promulgated by AUGS. All Members of AUGS will be encouraged to adopt the principles of this Code and their application.