

Standard Operating Procedures for Relationships with Industry



American
Urological
Association

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Preamble

The American Urological Association (AUA), AUA Foundation and our supporters in industry are committed to the highest ethical standards. The AUA believes relationships with members of industry provide value when such relationships are ethically structured. Moreover, the Association's relationships with industry are transparent and such industry support has no influence on educational or scientific content.

Particularly today, with public funding for continuing medical education (CME), quality initiatives and research scarce, industry support is essential to providing the high level of education and cutting-edge science that has so dramatically advanced the quality of patient care and improved outcomes in urological care in the last decade.

In 2010, the AUA signed the Council of Medical Specialty Society's (CMSS) "Code for Interactions with Companies," which reinforces the core principles that help us maintain actual and perceived independence. Adopting this code helps to ensure that the AUA's interactions with companies will be for the benefit of patients and members, and for the improvement of care in urology.

In addition to signing the CMSS Code, the AUA has developed a Standard Operating Procedure for guiding its relationships with industry. This Standard Operating Procedure has been adopted so that the AUA can self-regulate our relationships with industry in several key areas, including governance, CME, advertising, charitable donations, clinical guideline development, exposition, , government grants and foundation support, registries and sponsorship.

The AUA and its related foundation must and will continue to manage our relationships with industry responsibly, ethically and in the best interests of patient care.

AUA Practices

The AUA has developed a series of internal practices designed to facilitate transparency, ensure adherence to ethical standards and educate its membership when working with industry supporters. These ongoing practices include:

- Disclosure of all relationships with industry and other entities involved in the production, marketing, distribution or reselling of healthcare goods, services or information consumed by patients and/or physicians. (*source – “Principles, Policies and Procedures for Managing Conflicts of Interest” – Board of Directors [BOD] approved October 2009, last updated May 2011*).

Levels of Involvement:

- 1) Level I – Officers, Consultants
- 2) Level II – Committee Members
- 3) Level III – Other Members/Staff

Program Specific Requirements:

- 1) Accreditation Council for Continuing Medical Education (ACCME)-regulated activities
 - 2) *The Journal of Urology*[®]
 - 3) Clinical Guidelines
- Offering CME for physicians that is of the highest quality, timely, scientifically valid and free of bias or promotion. (*sources – “ACCME Standards for Commercial Support” & AUA Education Council “CME Content Review Policy”*).
 - Providing the best patient care possible that is independent from any undue influences of the medical device and pharmaceutical industries. (*source – “Guiding Principles for Membership Interactions with Industry – BOD approved Fall 2010*).
 - Utilizing the AUA Judicial & Ethics Committee to review and address all real or potential conflicts of interest prior to committee appointments.
 - Differentiating AUA Industry Relations & Development staff from the AUA Office of Education staff to ensure industry supporters never influence AUA educational content, programs or products.
 - File Internal Revenue Service (IRS) Form 990 “Return of Organization Exempt from Income Tax” on an annual basis disclosing financial information and sources of revenue.

Governance

These principles are applicable to the AUA and AUA Foundation Board of Directors, committee chairs, committee members, consultants and senior staff. All members of these groups must adhere to the following principles:

- Complete and timely disclosure of all relationships with industry through the AUA's Web site, www.AUAnet.org.
- The AUA's Code of Ethics, which can be found online at <http://www.AUAnet.org/content/guidelines-and-quality-care/code-of-ethics/ethics.pdf>.
- Respecting and maintaining the confidentiality of governance deliberations.
- Using disclosure information to accurately and ethically manage relationships with industry personnel in order to resolve any potential or actual conflicts of interest prior to board and committee appointments and meetings.

Development of Clinical Guidelines

- The AUA considers guideline development essential to its mission and accepts no industry funding for guideline development.
- AUA Guidelines are based on evidence based, with an explicit clinical scope and purpose.
- The AUA follows a transparent guideline process that is not subject to industry influence.
- The Chair of the AUA Practice Guidelines Committee must divest of all financial relationships that may cause a conflict of interest.
- Panel members, consultants or authors must report private or institutional interests that may compete or conflict with their objectivity in guideline development on the relevant topic. Such conflicts of interest may warrant recusal of such individuals from discussion or voting on such topic, or on a complete guideline document.
- The AUA requires a majority of guideline development panel members to be free of conflicts of interest.
- Conflicts of interest existing within 12 months prior to assuming a role with the AUA, or involving a substantial earlier relationship, or created following assumption of that role,

disclosure should include, for both the individual, his or her family, and related business and institutional interests.

- Guideline topic recommendations are subject to multiple levels of review and peer review by experts.
- AUA Guidelines are reviewed and approved before submission for publication to the AUA Board of Directors.
- Peer reviewers must report private or institutional interests that may impact their review of the guideline.
- Panel members and peer reviewers may not use pre-publication knowledge of the work to advance their own interests.
- At the start of each conference call or meeting, individual conflicts of interest are reviewed, and committee members are asked to comment and provide details of their relationships to the rest of the panel.
- Members who serve on AUA Guideline Panels must also complete and comply with a Non-Disclosure Agreement. As a panel member/peer reviewer and/or writer of documents produced by the relevant panel, these members are routinely exposed to certain confidential and/or proprietary information, materials or data related to the panel's work and final documentation. It is important to the integrity of the writing process and final work that this information should be kept strictly confidential and not disclosed at any time under any circumstances.

Panel members therefore agree:

- To not disclose or cause to be disclosed to anyone or any entity outside of the Guideline Panel or the appropriate AUA staff and AUA contractor any confidential and/or proprietary information, materials or data related to the Guideline Panel's work.
- To not speak publicly about a guideline or the deliberations regarding the development of the guideline until the embargo is officially lifted from any guidelines report(s).
- To keep all such confidential information in their possession or control in a safe and secure place and take all reasonable steps to protect against inadvertent disclosure or theft of the information.
- To promptly report to the AUA any potential breach of this strict confidentiality of which they are aware, by themselves or others, from whatever cause, and

assist to the extent possible in avoiding further disclosure and all possible consequences of such breach.

- Upon request from the Guideline Panel Chair or appropriate AUA staff, to promptly destroy all confidential information that they have been sent or acquired relating to the Guideline Panel. Notwithstanding the return or destruction of any confidential information, they will continue to be bound by this obligation.

Penalties/Sanctions. Panel members acknowledge that any violation or breach of this agreement on their part shall constitute grounds for termination of access to such information and the penalties described as follows:

- A letter of warning from the AUA Practice Guidelines Committee
- Removal from the panel
- Possible censure by the AUA, including possible expulsion

Independent Medical Education (including CME)

- The AUA Office of Education Chair must divest of all financial relationships that may cause a conflict of interest.
- In providing CME, the AUA will not seek support for product-specific topics.
- The AUA will make reasonable efforts to achieve a balanced portfolio of support for each CME program.
- The AUA will clearly distinguish non-CME informational/educational programs from CME activities.
- CME participants must comply strictly with the following policies for disclosure of commercial support, and the AUA must represent that:
 1. All of its educational activities are free of commercial bias for or against any product;
 2. The commercial supporters of such activities have no control over or input into the planning, content, execution or evaluation of the activity;
 3. Payment of honoraria and reimbursement of out-of-pocket expenses for faculty is reasonable, customary and proper and in accordance with the AUA Stipend and Honoraria Policy;

4. Any and all commercial support, including any “in-kind” support, is acknowledged to the learners prior to any activity;
5. All relevant financial relationships of everyone who has any control over educational content, including planners, faculty, authors, content reviewers and staff will be disclosed to the learners and will include:
 - i. The name of the individual;
 - ii. The name of the commercial interest(s) (Disclosure must never include the use of a trade name or a product-group message);
 - iii. The nature of the relationship the person has with each commercial interest;
 - iv. For an individual with no relevant financial relationship, the learners must be informed that no relevant financial relationship exists; and
 - v. An individual who refuses to disclose relevant financial relationships or fraudulently discloses such relationships will be disqualified from being a planning committee member, a teacher or an author of CME, and cannot have control of, or responsibility for, the development, management, presentation or evaluation of the CME activity.
6. No funds originating from commercial sources are used to pay travel, lodging, registration fees, honoraria or personal expenses for non-faculty attendees, and only modest meals or social events held as part of the activity are subsidized.
7. All participants in activities sponsored by the AUA Office of Education must comply also with the requirements of its Educational Content Review process.

Independent Satellite Symposia

- The AUA recognizes the value of collaboration with other organizations to sponsor CME educational activities for members and other urological healthcare professionals.
- Medical education providers are required to certify independent satellite symposia for CME credit ensuring all aspects of the activity adhere to the guidelines and policies of the Accreditation Council for Continuing Medical Education (ACCME).
- Approval of all independent satellite symposia applications must be reviewed and approved by the AUA Secretary, who in serving on the Board of Directors, has no conflicts of interest as defined by the AUA Level I policy.
- Applications are reviewed for medical education provider validity and education program learning objectives and needs assessment.
- Faculty serving on independent satellite symposia may not duplicate content being presented as part of the official AUA Annual Meeting.

- Independent satellite symposia must complement and not compete with AUA activities.
- Third party organizers must use appropriate disclaimers to distinguish the independent satellite symposia from AUA CME in advertising and promotional materials.
- The AUA will ensure that independent satellite symposia are clearly distinguished from AUA CME programs.

Government Grants/Foundation Support

- A written agreement with the grantor that reflects the purpose and amount of the grant is required.
- Grant support complies with all applicable laws and regulations, including those from the American Medical Association (AMA), Pharmaceutical Research and Manufacturers of America (PhRMA) and Advanced Medical Technology Association (AdvaMed) codes.
- The AUA and AUA Foundation provide complete and timely disclosure of grant support on www.AUAnet.org.
- Grant support is used in a manner consistent with the AUA's and AUA Foundation's strategic plans and missions, and controlled by the AUA and AUA Foundation. Legitimate grantor restrictions or conditions are permissible.

Charitable Donations

- Charitable donations are used in a manner that is consistent with the AUA's and AUA Foundation's strategic plans and missions, and controlled by the AUA and AUA Foundation. Legitimate donor-advised or restricted donations are permissible.
- The AUA and AUA Foundation will decline charitable contributions where the company expects to influence AUA and AUA Foundation programs or advocacy positions, or where company restrictions would influence AUA and AUA Foundation programs or advocacy positions in a manner that is not aligned with our missions.
- Charitable donations are managed and reported in compliance with all applicable state/federal laws and regulations, including the IRS Code.
- The AUA and AUA Foundation adopted policies for consistent and appropriate recognition of donors.

Sponsorships

These principles are applicable to all AUA and AUA Foundation sponsorship activities. We recognize a sponsorship to be an arrangement with industry, a company or organization that provides financial support to the AUA or AUA Foundation in exchange for value-neutral acknowledgement that neither endorses nor identifies a sponsor's products or services.

- The AUA and AUA Foundation require a written agreement with the sponsor, which reflects the purpose of the sponsorship, the amount of the sponsorship and the agreed upon acknowledgment of the sponsorship.
- The sponsorship complies with all applicable laws and regulations from the American Medical Association (AMA), Pharmaceutical Research and Manufacturers of America (PhRMA) and Advanced Medical Technology Association (AdvaMed) codes.
- The AUA and AUA Foundation provide complete and timely disclosure of sponsor support at www.AUAnet.org.
- Sponsorships are consistent with the AUA's and AUA Foundation's strategic plans and missions.
- Sponsors are not involved in tactical execution of the sponsored activity.
- Reasonable efforts will be made to seek multiple sponsors for items and programs whenever appropriate.
- The AUA will require non-CME educational programs to be clearly distinguished from its CME programs.
- The AUA and AUA Foundation independently determine how to acknowledge the sponsor in a value-neutral manner so as to not endorse or promote a sponsor's product or service.
- Acceptance of sponsorship is not an endorsement of any product or service by the AUA or AUA Foundation.

Advertising

- Advertising content must be easily distinguished from editorial content.
- Advertising should not be placed adjacent to any editorial content that is relevant to the product or company of said advertisement.

- Advertising is subject to review and the AUA and AUA Foundation reserve the right to refuse any advertising.
- Advertising must comply with all applicable laws and regulations.
- Acceptance of advertising is not an endorsement of any product or service by the AUA or AUA Foundation.
- *The Journal of Urology*® will maintain editorial independence from advertisers.

Expositions and Exhibitors

Industry expositions and related activities have merit and provide value to physicians and other members of the urological care team.

- A written agreement with exhibitors reflects all exhibitor activities undertaken during the exposition activity.
- Exhibitors must comply with all applicable laws and regulations, including those from the American Medical Association (AMA), Pharmaceutical Research and Manufacturers of America (PhRMA) and Advanced Medical Technology Association (AdvaMed) codes, as well as those related to the exhibition venue.
- The AUA provides complete and timely disclosure of exhibit revenues at www.AUANet.org.
- The sale of exhibit space and related activities is independent of sponsor, advertising, charitable, grant or other financial support.
- The AUA Board of Directors, Plenary session participants, program moderators, course directors and course faculty shall not participate in any marketing or promotional activities held in the exposition space.
- Exposition and exhibitor activities shall be physically segregated from all CME activities.

Research Funding

- No funding shall be solicited or accepted by the AUA/AUA Foundation from any private industry, commercial supporter or related source, under express conditions or attendant circumstances whereby the source of funds retains an inappropriate control over use of the funds.

- More specifically, no AUA/AUA Foundation funding source may impose restrictions on content or publication of research, nor dictate:
 - the procedures, protocols or identity of individual researchers or institutions by whom or where the research will be conducted;
 - conditions of confidentiality or prepublication review; or
 - ownership of intellectual property or patentable results of the research.
- No individual making a presentation using materials prepared by industry shall do so without disclosing the nature and origin of such materials. Donor-restricted grants will be accepted only after careful scrutiny to avoid imbalance between competing interests, and to avoid the fact or appearance of bias.
- Independent committees will be appointed to select recipients of research grants based on peer review of grant applications.
- The AUA/AUA Foundation will not require recipients of research grants to meet with company supporters.
- The AUA/AUA Foundation will disclose company-supported research and act independently in the selection of research projects and the conduct of the research itself.

Registry Sponsorship

The goal of the Clinical Data Registries is to measure and improve the quality of urological care, and is operated and governed independently of any outside industry involvement or support.

- A written agreement with the sponsor reflects the purpose, amount and the agreed upon acknowledgment of the sponsorship by the registry.
- The AUA provides complete and timely disclosure of sponsor support of the registries at www.AUAnet.org.
- Sponsor support is used in a manner consistent with the AUA's strategic plan and mission, and is controlled by the AUA.
- Industry may support the registry operations through sponsorships in:
 - Participant enrollment
 - Marketing
 - Product development

- Sponsorships shall not be drug class exclusive, which could prohibit the AUA from seeking additional sponsorships from device and/or drug manufactures in the same class.
- Industry sponsors may serve on a registry in an advisory industry liaison group to provide external stakeholder input on registry activities.
- The advisory industry liaison group’s primary functions include:
 - Receiving communication and updates on registry progress;
 - Providing insights on pertinent clinical and scientific topics; and
 - Promoting the adoption of the registry among their organizations’ constituents.
- Industry may request registry data analysis and research using the registry standard application. Requests being considered will follow standard registry processes and procedures.
- The AUA must review and approve any sponsor communication or materials related to its sponsorship of the registry prior to publication.
- Registry data shall not be propriety or exclusive to any participating sponsors.

Licensing

- The AUA and AUA Foundation logos, as well as the names “AUA,” “American Urological Association, Inc.,” and “American Urological Association Foundation” are registered trademarks owned by the American Urological Association Education and Research, Inc. Use of any of these trademarks by affiliated or unaffiliated entities or persons (other than the American Urological Association Education and Research, Inc.) is prohibited, without the express written permission of authorized representatives of the American Urological Association Education and Research, Inc.
- Neither the AUA, nor the AUA Foundation nor any official, representative or employee identified with either organization, may endorse any commercial product related to the specialty of urology.