Principles for Relationships with Industry

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Preamble

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

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

Our 2008 Industry Forum brought together leaders from Congress, industry and medicine, and the assembled attendees determined that we must self-regulate relationships between industry and medical professionals. In addition to our best practices, the College has developed ***Principles for Relationships with Industry*** *to do just that — self-regulate our partnerships with industry in nine key areas of operation: advertising, charitable donations, clinical document development, continuing medical education, exposition, governance, government grants and foundation support, registries and sponsorship.*

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

ACC Practices

The ACC developed a series of internal practices designed to facilitate transparency and ensure adherence to ethical standards when working with our industry supporters. These ongoing practices include:

- Disclosure of all relationships with industry (RWI) [1] and other entities involved in the production, marketing, distribution or reselling of health care goods, services, or information consumed by patients and/or physicians.
- Practice funding transparency tracked at *http://www.acc.org/about/overview/overview.htm#SECS*.
- Written and verbal disclosure of RWI at the beginning of each meeting for clinical and guideline writing groups, where members are excused their voting privileges on potentially compromising issues pertaining to industry interests.
- Adherence to the Accreditation Council for Continuing Medical Education (ACCME) standards for industry support of educational content in certified CME/CE.
- Differentiating ACC industry development staff from industry education staff to ensure industry supporters never influence ACCF educational content, programs or products.

Governance Principles

These principles are applicable to ACC and ACCF trustees, committee members and senior staff. All members of these groups must adhere to the following principles:

- Complete and timely disclosure of all RWI through ACC's website, *www.acc.org.*
- Adhering to ACC's Code of Ethics which can be found at *http://www.acc.org/about/overview/ethics.html.*
- Respecting and maintaining the confidentiality of governance deliberations.
- Using disclosure information to accurately and ethically manage relationships with industry personnel to resolve any potential or actual conflicts of interest prior to board and committee meetings.

[1] The ACC defines "relationships with industry," or RWI, as all relationships with for-profit and other entities involved in the production, marketing, distribution, or selling of health care goods, services, consultation or information consumed by patients, investors and/or physicians. This may include relationships with government entities as well as not-for-profit entities, such as academic institutions.

Principles for Development of Clinical Documents

- The ACC and the American Heart Association (AHA) consider guideline development essential to their respective missions and accept no industry funding for guideline development.

- ACC requires full disclosure of all relevant RWI prior to appointment to a writing committee, covering the 12 months prior to participation.

- Full disclosure of the financial value of RWI is required. Designations of the financial relationship with industry include:

    - No monetary reimbursement

    - Modest relationship - considered to be less than $10,000

    - Significant relationship - considered to be greater or equal to $10,000

    - Type of relationship such as speaker, consultant, researcher, et cetera.

- The College reviews all disclosures to ensure a balanced group of experts prior to official commission of any writing committee. The Chair of the Committee plus greater than 50 percent of members must have no relevant relationships with industry. ACC considers "relevant" relationships to include:

    - The basis of the relationship pertains to the same or similar subject matter, intellectual property or asset, topic, or issue addressed in a document.

    - The industry relation makes a drug, drug class, or device or a competing drug or device that is addressed in a document.

    - The person or a member of the person's household, has reasonable potential for financial, professional or otherwise personal gain or loss as a result of the content addressed in a document.

- At the start of each conference call or meeting, ACC requires written and verbal disclosure by all writing committee members to ensure, and maintain, fair and balanced debate. Writing committee members with relevant RWI may not draft text or vote on recommendations. Members who abstain from voting on recommendations will be identified in a document.

- All relevant RWI for authors and peer reviewers will be published with each document. RWI are clearly identified as "significant," "modest" or "no financial benefit." In addition, a comprehensive listing of relationships with industry for authors and oversight committee members will be electronically available.

Principles for Independent Medical Education (CME/CE)

- ACC fully discloses all grants received in support of all certified and non-certified continuing medical education (CME) and continuing education (CE).

- All individuals involved in or who influence the creation of educational content must disclose RWI's relevant to their role as faculty, chairs, staff, or leadership.

- Granting organizations or commercial interests are prohibited from any involvement in decisions regarding design, development, implementation or evaluation of certified CME/CE. Contact between ACC staff, members and granting departments of pharmaceutical and device companies should be limited to discussions concerning strategic directions and capabilities of ACC.

- Every attempt is made by ACC to restrict industry funding for certified CME/CE to no more than 50 percent, consistent with the current practices of academic institutions. ACC is committed to reducing that percentage over the next several years.

- ACC CME/CE planning committees are encouraged to seek multiple grantors for all CME/CE activities and to seek funding from sources other than commercial interests, such as:

    - Foundations

    - Government

    - Non–health care commercial interest

    - Payers

    - Health care organization dues

- All certified CME/CE content is peer reviewed by experts and members of ACC or by external content review organizations or individuals who have no relevant RWI.

- ACC CME/CE planning committees are required to use physician competence and performance gaps as the basis of all program planning activities and for assessment of outcomes. All activities are designed to enhance competence, performance or patient care outcomes consistent with established quality guidelines and not in the interest of commercial companies.

- Chairs of planning committees are responsible for managing conflicts of interest, pertaining to all certified CME/CE content development and require access to all relevant disclosure forms. This process is overseen by leadership committees at ACC.

- ACC is committed to the ethical management all content developed for certified CME/CE to reduce and prevent commercial bias. In addition to ACC's full disclosure policy, the American College of Cardiology will perform alternate measures to ensure appropriate handling of certified CME/CE including but not limited to:
    - Peer review
    - Full disclosure to participants
    - Public disclosure
    - Disclosure of highest level of evidence for patient care diagnosis or treatment recommendations
    - Attestation forms completed by all involved in planning and implementing certified CME/CE
    - Evaluation of potential commercial bias by participants in certified CME/CE

- Action required if more than 10 percent of learners indicate potential bias in any CME/CE content

- ACC maintains strict separation between staff members who solicit and administer commercial support fundraising efforts for CME/CE versus staff who solicit funds for marketing, sponsorships and/or other promotional or non-CME/CE activities.

- ACC ensures full compliance with all regulatory policies and guidelines from organizations including but not limited to: the Accreditation Council for Continuing Medical Education, American Nurses Credentialing Center (ANCC) Standards for Commercial Support, Pharmaceutical Research and Manufacturers of America (PhRMA), Advanced Medical Technology Association (AdvaMed) Codes, American Medical Association (AMA), Gifts to Physicians, Office of the Inspector General (OIG), and Food and Drug Administration (FDA).

CME/CE-Certified Satellite Symposia and Co-sponsored Activities

- ACC recognizes the value of collaboration with other organizations to sponsor CME/CE-certified educational activities for members and other cardiovascular health care professionals. Co-sponsorship during the Annual Scientific Session and other venues conferences is determined by shared vision and strategic plan for education and all quality guidelines and at the discretion of the ACC.

- Approval of all satellite symposia and co-sponsored activity proposals, whether solicited by ACC or unsolicited, must undergo the same rigorous approval process for ACC-owned activities.

- Satellite symposia and co-sponsored activities must enhance ACC's educational platform and therefore must complement, not compete with, ACC-owned activities.

- Design, development and implementation of satellite symposia and co-sponsored activities are subject to the guiding principles for independent medical education (CME/CE) as referenced above, as well as principles and policies related to:

    - Disclosure and resolution of conflict of interest for faculty, planners and staff

    - Independence from commercial influence

    - Content based on competence and performance gaps of learners

Principles for 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.

- ACC provides complete and timely disclosure of grant support on *www.acc.org*.

- Grant support is used in a manner consistent with ACC's strategic plan and mission, and controlled by ACC. Legitimate grantor restrictions or conditions are permissible.

Principles for Charitable Donations

- Charitable donations are used in a manner that is consistent with ACC's strategic plan and mission, and controlled by ACC. Legitimate donor-advised or restricted donations are permissible.

- Charitable donations are managed and reported in compliance with all applicable state and federal laws and regulations, including the Internal Revenue Service (IRS) Code.

Principles for Sponsorships

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

- ACC requires 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.

- ACC provides complete and timely disclosure of sponsor support at *www.acc.org*.

- Sponsorships are consistent with ACC's strategic plan and mission

- Sponsors are not involved in tactical execution of the sponsored activity.

- ACC independently determines how to acknowledge the sponsor in a value-neutral manner so as to not endorse or promote a sponsor's product or service.

Principles for 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 ACC reserves 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 ACC.

Principles for Expositions and Exhibitors

Industry expositions and related activities have merit and provide value to physicians and other members of the cardiovascular 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.
- ACC provides complete and timely disclosure of exhibit revenues at *www.acc.org*.
- The sale of exhibit space and related activities is independent of sponsor, advertising, charitable, grant or other financial support.
- Trustees and Annual Scientific Session Planning Committee members 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.
- Promotional and product presentations shall not be held at the same time as scheduled CME activities.

Principles for Registry Sponsorship and Research

The goal of the registries is to measure and improve the quality of cardiovascular 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.

- ACC provides complete and timely disclosure of sponsor support of the registries at *www.acc.org*.

- Sponsor support is used in a manner consistent with ACC's strategic plan and mission and is controlled by ACC.

- Industry may support the registry operations through sponsorships in:
    - Participant enrollment
    - Marketing
    - Product development

- Sponsorships shall not be drug class exclusive which could prohibit ACC 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:
    - Receive communication and updates on registry progress.
    - Provide insights on pertinent clinical and scientific topics to the Registry Steering Committee.
    - Promote 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.

- ACC 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.