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BACKGROUND

Physicians, scientists, patients, and the public rely on professional organizations to provide an independent, unbiased forum for presentation of research, publications, and educational activities at their scientific sessions and in scientific publications. Attendees at educational activities sponsored by not-for-profit organizations usually incur financial and other costs. The attendees expect to gain information from leading experts that may modify their behavior and result in a change in patient care. Concerns about real or perceived conflicts of interest among organizations, physicians, scientists, patients, and educators regarding their relationships with the medical products industry have been debated in the press and in medical journals (1,2). Concerns about these relationships have been discussed extensively by the Association of American Medical Colleges (AAMC), which issued guidelines for conflict of interest in human subjects’ research based on a consensus of a committee including clinicians, scientists, legislators, ethicists, consumers, and representatives from commercial interests (3).

The Accreditation Council for Continuing Medical Education (ACCME), which accredits continuing medical education (CME) provider organizations, currently requires full disclosure of pertinent commercial relationships. The ACCME has revised the Standards for Commercial Support which were adopted on April 1, 2004. Both the American College of Cardiology Foundation (ACCF) and the American Heart Association (AHA) policies must be in compliance to maintain their accreditation (Table 1).

“Disclosure” must never include the use of a trade name or a product-group message. A provider must disclose this information to learners before beginning the educational activity. The ACCME standards allow for relationships to be disclosed verbally, and for a representative of the CME provider who was in attendance to attest in writing that verbal disclosure did occur.

Medical societies have struggled to define a significant financial relationship that poses a real or perceived conflict of interest. The American Society of Clinical Oncology recently amended its regulations to encompass any money exceeding $100 an investigator received from a firm funding a trial (5). One criticism of this regulation is that the threshold for disclosure is so low that the large number of disclosures might obscure more serious financial relationships. The New England Journal of Medicine has maintained that authors of reviews and editorials must not have any financial interest in a company or its competitor that makes a product discussed in the article. Journal editors relaxed the policy for reviewers in June 2002 because their ability to recruit individuals for review articles and editorials was constrained (6). The new policy prohibits a “significant” financial interest, which the journal defined as a lower limit of $10,000 in accordance with guidelines developed by the National Institutes of Health (7) and the AAMC (3).

The concerns of consumers and professional organizations over conflicts of interest in medical research challenge the ACCF and the AHA to review their policies on conflict of interest, acknowledgment of commercial support, and disclosure of financial relationships with the medical prod-
The CME provider must have implemented a mechanism to identify an individual who refuses to disclose relevant relationships. When commercial support is provided, the source of all support from commercial interest must be disclosed in any amount occurring within the past 12 months that create a conflict of interest.

- An individual who refuses to disclose relevant financial 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.

- The CME provider must have implemented a mechanism to identify and resolve all conflicts of interest prior to the education activity being delivered to learners. When an individual discloses to learners any relevant financial relationship(s), the information must include:
  a) The name of the individual
  b) The name of the commercial interest(s)
  c) The nature of the relationship the person has with each commercial interest

- The source of all support from commercial interest must be disclosed to learners.

- When commercial support is “in-kind,” the nature of the support must also be disclosed to learners.

Table 1. Minimum Requirements for Compliance With ACCME’s Standards for Commercial Support: Standards to Ensure the Independence of CME Activities

<table>
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<th>CME providers must be able to show that every person in a position to control the content of an educational activity has disclosed all relevant financial relationships with any commercial interest to the provider. The ACCME defines “relevant relationships” as financial relationships in any amount occurring within the past 12 months that create a conflict of interest.</th>
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<tbody>
<tr>
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Source: Excerpt from Accreditation Council for Continuing Medical Education, Standards to Ensure the Independence of CME Activities (4).

products industry. The integrity of the ACCF, the AHA, and cardiovascular subspecialty societies as well as their commitment to truth and evidence-based, unbiased scientific inquiry, provides the foundation upon which their missions depend. This fundamental tenet is critical to the validity and success of the various organizations’ annual scientific sessions, regional educational meetings, publications, and clinical guidelines.

THE DISCLOSURE POLICY

Introduction. Participants in this Consensus Conference cannot make policy for the ACCF and the AHA. However, we can offer the following for consideration by those organizations with hope they will adopt a uniform policy addressing these issues. The following is meant to demonstrate the ACCF’s and AHA’s high ethical standards and scientific integrity, and to convey a commitment to ethical behavior.

Policy statement. Audiences for any of the ACCF and the AHA programs, products, policies, services, and scientific publications are to be informed, prior to their participation, of relevant relationships with commercial interests with any proprietary entity producing health care goods or services (with the exception of non-profit or government organizations and non-health care-related companies) on the part of the ACCF and the AHA as organizations and by individual ACCF and AHA contributors (including directors, planners, reviewers, moderators, speakers, faculty, and authors of programs, products, services, and publications). The policy should apply to authors of book chapters and editors of journals. Members of the ACCF and the AHA are expected to adhere to these policies when they participate in “satellite sessions” around the time of local or national scientific sessions and that are not sponsored or endorsed by the ACCF and the AHA.

These policies also should apply to members who participate in other educational activities such as live case demonstrations, which may serve to disseminate knowledge, management strategies, or advances in technology, but they should not be used primarily to promote a product. The use of the demonstrated technology always should be put in proper clinical perspective. The provision of money by a commercial interest to support a demonstration course must not influence the content of the program.

Finally, it is the current policy of the ACCF and the AHA to comply with the following:

2. The ACCME’s “Standards for Commercial Support” (10).
3. The Accreditation Council for Graduate Medical Education’s (ACGME) “Principles to Guide the Relationship Between Graduate Medical Education and Industry” (11).

Individual financial relationships to disclose. The following relevant relationships with commercial interests with any proprietary entity producing health care goods or services (with the exception of non-profit or government organizations and non-health care-related companies) supporting a program, product, service, or document, including financial interest for individual contributors (and his or her spouse and dependent children) or for any foundation or entity controlled or directed by the individual or his or her spouse, must be disclosed before an individual contributor’s participation in an ACCF or an AHA activity. The levels recommended in this document were influenced by policies previously established by the National Institutes of Health (7) and by the Food and Drug Administration (12).

The Consensus Conference recommends that relevant relationships be defined in terms of levels and nature of support. The levels are as follows:

- None
- Modest: less than or equal to $10,000
- Significant: greater than $10,000

The categories of support are defined as follows:

1. Consulting fees, honoraria (including honoraria from a third party, if the original source is a financially interested company), gifts or other emoluments, or “in kind” compensation from a financially interested company (or entitlement to the same), whether for consulting, lecturing, travel, service on an advisory board,
Table 2. Disclosure of Financial Relationships

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<tr>
<th>Nature of Support</th>
<th>Level of Support</th>
<th>Commercial Entity</th>
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</thead>
<tbody>
<tr>
<td>Personal Income/Investments</td>
<td>Specify</td>
<td>Specify</td>
</tr>
<tr>
<td>Royalties/Stock Options</td>
<td>Yes or No</td>
<td>Specify</td>
</tr>
<tr>
<td>Programmatic Support</td>
<td>Specify</td>
<td>Specify</td>
</tr>
<tr>
<td>Cumulative/Total Support</td>
<td>Specify</td>
<td>Specify</td>
</tr>
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legal testimony or consultation, or for any other similar purpose in the prior calendar year.

2. Equity interests (or entitlement to the same), including stock options, of any amount in a non-publicly traded and financially related company.

3. Equity interests (or entitlement to the same) in a publicly traded and financially related company (see the examples in the following text).

4. Royalty income or the right to receive future royalties under a patent license or copyright, where the topic is directly related to the licensed technology or work under discussion.

5. Any non-royalty payments or entitlements to payments in connection with the activity that are not directly related to the reasonable costs of that activity.

6. Service as an officer, director, or in any other fiduciary role for a financially interested company, whether or not remuneration is received for such service.

7. Sole ownership, partnership, or principal of an enterprise.

*Exceptions: interests of any amount in financially interested company(ies) by virtue of ownership of publicly traded, diversified mutual funds.

Programmatic Support

8. Research grants from a financially interested company.

9. Fellowship support.

10. Funding of a salary or position (partial or full) or “in-kind” support of the program.

A potential conflict of interest level should reflect a cumulative value of personal income/investments and programmatic support. All royalties or stock options should be acknowledged because their value could become significant, and having such arrangements implies a vested interest in the future of the related commercial interest. Full disclosure of relationships with commercial interests should be available to the learner prior to the activity. The speaker must acknowledge whether specific categories and the cumulative value of relationships is none, modest (less than or equal to $10,000), or significant (greater than $10,000). The name(s) of the commercial interest(s) must be printed in the syllabus and should be presented verbally or visually on a slide at the time of presentation. The introductory slides should include the information in Table 2.

Both the ACCF and the AHA should develop a uniform secure database, updated yearly, containing full disclosure of relationships with commercial interests for individuals (including planners and reviewers of programs and publications) participating in ACCF and AHA educational activities, products, policies, services, and scientific publications.

Disclosure of Financial Relationships to Audiences

The need to disclose specific financial involvement only applies if it is germane to the content of the CME activity or related to commercial supporters of the educational activity. All audiences and readers will be informed, prior to or as an integral part of the activity, whether the contributor: 1) has no individual relationships to disclose as previously described, or 2) has individual relationships to disclose as previously described. It is incumbent on the speaker to provide full disclosure of germane relationships to commercial interests. It is the responsibility of the moderator to request this information at the time of presentation if it has not been provided. Non-compliance, which includes willful refusal or incomplete disclosure, should prohibit future participation by that individual in ACCF and AHA activities.

The ACCF and AHA organizational financial relationships to disclose should be acknowledged before or as an integral part of the activity by indicating the corporate name of the supporter and the level of financial support as previously defined.

MECHANISMS FOR DISCLOSURE

Participants in educational activities. The content or format of a CME activity or its related materials must promote improvements or quality in health care and not specific proprietary business or commercial interests. Presentations must offer a balanced view of therapeutic options. Use of generic names will contribute to impartiality. If the CME educational material or content includes trade names, where available, trade names of products from several companies should be used, not just trade names from a single company. The program syllabus and/or a slide should disclose relationships with commercial interests to identify a potential conflict of interest of both planners and reviewers.

Authors of original articles. The ACCF and AHA journal editors should obtain information regarding relationships with industry at the time of submission of an original manuscript and before inviting an editorial submission from an expert. When feasible, an additional expert opinion may be sought from another peer without a potential conflict of interest. Transparency concerning potential conflict of interest for authors of original publications and editorialists is sufficiently important to warrant a more in-depth statement specifying the nature and magnitude of the relevant relationship with a commercial entity. The information disclosed should include: 1) the name of the individual, 2) the name of the company/enterprise, 3) the nature of the contract with industry (e.g., data handling, statistics, censorship of results, ability to report adverse findings), and 4) the level of financial support.
Members of the writing groups of the ACCF and the AHA scientific statements and practice guidelines. The potential conflict of interest of the writing group should be provided in detail. The ACC/AHA Task Force on Practice Guidelines developed a policy for the guideline process that incorporates several unique elements (8). The Consensus Conference endorses this approach. Each writing committee member is required to make full oral disclosure at the initial writing committee meeting of any potential conflict of interest. At each subsequent meeting, a written summary of disclosure is provided to the entire committee, and each member is asked to update his or her information regarding any new potential conflict of interest. Full disclosure is thought to be critical to the credibility of the process, and it is carefully monitored by the Task Force. Those members of the writing committee who have disclosed a relationship with industry are invited to supply information on the topic for which they provided a disclosed relationship, but they are excused from the room for the vote on guideline recommendations pertaining to the disclosed conflict. Information on relationships with commercial interests for each writing group member and peer reviewer of a practice guideline is published with the document. Finally, members of the writing committee are prohibited from sharing information pertinent to the writing effort with commercial interests until the document has been posted on the ACC and/or AHA web sites.

CONSEQUENCES FOR NONCOMPLIANCE

Personal and professional. Consequences for refusal or failure to disclose a relationship with industry or to be willfully out of compliance with the ACCF and the AHA policies need to be substantial enough to ensure the integrity of the policies. The policies and potential sanctions should be fully disclosed to all participants in educational activities, products and services, and publications. The ACC/AACC Ethics and Discipline Committee and the AHA Conflict of Interest Review Committee should be responsible for administering and enforcing appropriate sanctions. The ACCF and the AHA should create a mechanism to randomly audit disclosures and to create a process where ACCF and AHA members and attendees of educational activities can report potential violations, including partial disclosure or non-disclosure, for further investigation.

Refusal by an individual to provide adequate disclosure consistent with the conflict of interest policy should prohibit participation by that individual in ACCF and AHA activities. As a further safeguard, violations may also be reported to the individual’s academic institution or entity with whom he or she is professionally affiliated.

A mechanism should be established for disqualification of individuals with a conflict of interest that cannot be adequately dispelled with disclosure. Such matters might be placed under the jurisdiction of the ACC/AACC Ethics and Discipline Committee and the AHA Conflict of Interest Review Committee.

Potential legal risks. The Office of the Inspector General of the U.S. Department of Health and Human Services (HHS) has published a Compliance Program Guidance (13) relevant to this subject. Because HHS is responsible for proper use of Medicare and other government programs, it is vigilant to prevent improper use of the program funds. The Guidance speaks to support provided by pharmaceutical manufacturers in Section B: “Key Areas of Potential Risk.” With regard to educational grants, the Guidance addresses the issue that, to the extent the medical product manufacturer has any influence over the substance of an educational program or the speaker, there is a risk that the educational program may be used for inappropriate marketing purposes.

To reduce the risks that a program supported by a grant is used improperly to induce or reward product purchases or to market products inappropriately, manufacturers are advised to separate their grant-making function from the sales and marketing function. Effective separation of these functions should help ensure that grant funding is not inappropriately influenced by sales or marketing motivations and that the educational purposes of the grant are legitimate. With regard to research funding, the Guidance advises clear separation of research contracts from marketing.

The HHS Guidance also states that manufacturers, providers, and suppliers of health care products and services frequently cultivate relationships with physicians in a position to generate business for them through a variety of practices, including gifts, entertainment, and personal services compensation arrangements. The activities have a potential for fraud and abuse and, historically, have generated a substantial number of anti-kickback convictions (see the Task Force 4 report). The Guidance speaks to consulting and advisory payments and conveys concern about compensation relationships with physicians for services connected directly or indirectly to a manufacturer’s marketing sales activities, such as speaking, certain research, or preceptor or “shadowing” services. These may pose a risk of fraud and abuse. It is important to note that the Guidance is advisory in intent; nonetheless, it does have the legal authority of federal anti-kickback statute, which poses risk of prosecution by the U.S. Attorney General’s office.

RECOMMENDATIONS

The Consensus Conference believes the policies proposed herein would represent the ACCF, the AHA, and cardiovascular subspecialty societies’ commitment and dedication to the highest levels of professionalism and ethical behavior in educational activities and publications. Therefore, the Consensus Conference proposes the following recommendations:

1. Disclosure of financial relationships with commercial interests should be mandatory for educational activities and publications (original articles, policy statements, editorials, texts, and guidelines). The policy and disclosure guidance
discussed in this document should be adopted by the ACCF, the AHA, and cardiovascular subspecialty societies using as uniform a mechanism as possible.

2. The ACCF, the AHA, and cardiovascular subspecialty societies should develop a secure uniform database containing full disclosure of relationships with commercial interests for individuals (including planners and reviewers of programs and publications) participating in ACCF and AHA educational activities, products, policies, services, and scientific publications. The database should be updated yearly.

3. The ACCF, the AHA, and cardiovascular subspecialty societies should educate their members and promote compliance with: the AMA’s policy on “Gifts to Physicians from Industry” (8); the ACCME’s “Standards for Commercial Support” (10); and the ACGME’s “Principles to Guide the Relationship Between Graduate Medical Education and Industry” (11).

**TASK FORCE 3 REFERENCES**


**Task Force 4: Appropriate Clinical Care and Issues of “Self-Referral”**

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**Participants:** Timothy J. Gardner, MD, FACC, FAHA, Harry R. Kimball, MD, Richard L. Popp, MD, MACC, FAHA, Lynn Smaha, MD, PtdD, FACC, FAHA, Sidney C. Smith, Jr, MD, FACC, FAHA, L. Samuel Wann, MD, MACC, FAHA

**INTRODUCTION**

“Professionalism is the basis of medicine’s contract with society. It demands placing the interests of patients above those of the physician, setting and maintaining standards of competence and integrity, and providing expert advice to society on matters of health . . . . Essential to this contract is public trust in physicians, which depends on the integrity of both individual physicians and the whole profession” (1). Cardiovascular specialists support the fundamental principles of primacy of patient welfare, patient autonomy, and the promotion of social justice.

For the purposes of this document, “self-referral” occurs when a physician recommends a patient intervention from which the physician may benefit personally. Such recommendations usually facilitate the provision of efficient, effective, and high-quality care, but may also afford the potential for abuse. As former JACC Editor-in-Chief William Parmley stated so clearly: “At issue is the question of intent; if the intent is to provide excellent medical care, the practice is laudable. If the intent is to subjugate medical decision-making, then the practice is unethical” (2). Those few physicians who are publicized for violating our trust do not reflect the rank and file of cardiovascular specialists.

The cardiovascular specialist’s primary duty is to the patient. His or her role is to promote patient welfare in an increasingly complex health care environment, one that has been made even more complex by the anti-kickback statutes and Stark laws (see the following sections). Having entered into a physician-patient relationship, physicians must counsel their patients regardless of individual financial or medical care delivery system considerations or other factors, such as socio-economic status, race, gender, or sexual orientation (3). The physician’s clinical judgment must not be influenced by financial incentives from a fee-for-service system.