

CardioSmart National Health Initiative A National Campaign from the American College of Cardiology To Promote Everyday Strategies for Heart Health

Executive Summary

Heart disease remains the number one killer and disabler of individuals in the United States and much of the western world.

The American College of Cardiology (ACC) is the primary non-profit, professional association of practicing cardiologists in the United States. It is composed of more than 37,000 members include cardiologists, nurses, and other members of the cardiovascular care team, and it is actively engaged in member and patient education, scientific guideline development, and advocacy.

To help stem the tide of heart disease in our country, the ACC has launched the *CardioSmart* National Health Initiative, aimed at assisting people in making better and more thoughtful choices in their everyday lives. The program points the way to a healthier approach to the choices available. These everyday strategies give people with and at risk for heart disease tools, not rules, to improve their heart health.

There is an abundance of heart health and disease prevention information available, but this information is not necessarily translating into healthier lifestyles and risk reduction. Massive overhauls in behavior - especially if attempted all at once - are often too difficult for individuals to maintain, making them ultimately unsustainable. The goal of the *CardioSmart* National Health Initiative is to point out small, attainable, practical changes which, taken as a whole, will positively impact health.

There are two key principles in the *CardioSmart* initiative:

- ▶ Engaging people in the active management of their own heart health.
- ▶ Empowering individuals to make better, heart-healthier lifestyle choices.

These principles will be delivered through four elements:

- ▶ Strengthening the doctor/patient relationship to improve health outcomes for people with heart disease by delivering patient-centered tools to doctors' offices.
- ▶ Providing a comprehensive, web-based platform with information and smart, practical tools to improve heart health and help people with heart disease become active participants in their health.
- ▶ Sponsoring community-based events to provide everyday strategies to improve heart health
- ▶ Working with national consumer products companies to help deliver CardioSmart strategies to people at risk for heart disease.

It's time to be *CardioSmart*. Because small changes add up to big results over time.

The Importance of Being *CardioSmart*

The ACC has been a major contributor to the remarkable progress made over the past 50 years in the diagnosis and management of patients with cardiovascular disease (CVD): a nearly 50% reduction in age-adjusted mortality. This progress has reduced the rate of growth in heart disease but, unfortunately, it has not eliminated heart disease as the major cause of death in the U.S. To the contrary, the absolute number of deaths from cardiovascular disease is on the rise.

From an economic standpoint, the impact is undeniable: the care of people affected by cardiovascular disease (including the care of hypertension and vascular disease) accounts for nearly one fifth health care expenditures in our country, with further increases projected. The annual economic burden of cardiovascular disease and stroke currently is estimated to be \$500 billion. Despite major gains in reducing cardiovascular mortality, clear challenges still remain in areas of cardiovascular disease prevention, treatment, and management of chronic heart conditions.

While clinicians have developed guidelines that recommend standards of care for common cardiovascular and related diseases, an enormous gap remains between prescribed targets and the ability to attain them. Recent studies indicate that:

- 65% of people with hypertension have poor blood pressure control;
- 54% of diabetics have Hemoglobin A1c levels above 7%, the guideline-based goal for this measure;
- 27% of people with high LDL cholesterol have not attained lipid-lowering goals in accordance with ACC/AHA guideline measures.

There is a growing body of evidence that suggests these outcomes can be vastly improved when people become more knowledgeable and engaged in their own health management and care. Studies indicate that individuals are more likely to be active participants in their care when their physicians and health care team encourage such participation.

These are the fundamental drivers for the ACC's *CardioSmart* National Health Initiative. We believe that active enrollment of people by their physicians and cardiac care team into sustainable, effective heart health management programs (which provide education, tools and resources for making better decisions) will result in better individual health outcomes.

The goal of the CardioSmart campaign is not necessarily to effect drastic changes in behaviors overnight; the goal is to support small, immediate changes that over time, can have a big impact on health outcomes.

Our success will be measured by our ability to “move the needle” in care outcomes by providing education, direction and support leading to greater guideline compliance, and better health management decisions, actions, and lifestyle choices.

ACC Policies for CardioSmart National Health Initiative Corporate Partnerships

The American College of Cardiology recognizes the important role that partnerships with a variety of corporations and organizations can play in supporting *CardioSmart* awareness and individual decision-making, and in disseminating *CardioSmart* health information to people with heart disease and those at risk for it. The ACC's *CardioSmart* National Health Initiative has established partnership development as a key strategy for reaching our target audiences.

Corporate Partnership Evaluation Criteria

Corporations and organizations interested in partnering with ACC on the *CardioSmart* National Health Initiative must meet all of the following criteria:

- Show a substantial and credible commitment to the ACC's *CardioSmart* National Health Initiative goals and objectives, and to raising awareness about the education, resources, and toolkits among the program's key audiences.
- Offer products, services, or communications materials that relate to encouraging heart healthy behaviors, including (but not limited to) improved nutritional intake, promotion of physical activity, achievement or maintenance of a healthy weight and smoking cessation. The products, services, or communications materials may be applicable to all individuals or may speak specifically to subsets of people with established cardiovascular disease.
- Are not associated with products or services that are not in the public interest or that are in any other way inconsistent with the mission and vision of the ACC.
- Are interested in providing resources, supporting campaign/program activities, and developing materials through services such as printing program materials, disseminating campaign/program messages through existing organizational channels (such as commercial outlets, Web sites, newsletters, direct mailings, advertising, product packaging), sponsoring events, and/or producing multimedia materials.
- Do not require or expect any endorsement by the ACC, either actual or implied, of any product or service.
- Proposed partners must be willing to comply with a communications strategy that allows for member outreach, education and consensus building prior to public communications.
- Proposed partners must be approved through the ACC's review process, which includes initial approval by the College's Patient-Centered Care Committee followed by approval by the Executive Committee of the Board of Trustees.

ACC Requirements for Corporate Partners

Approved corporate partners must agree to:

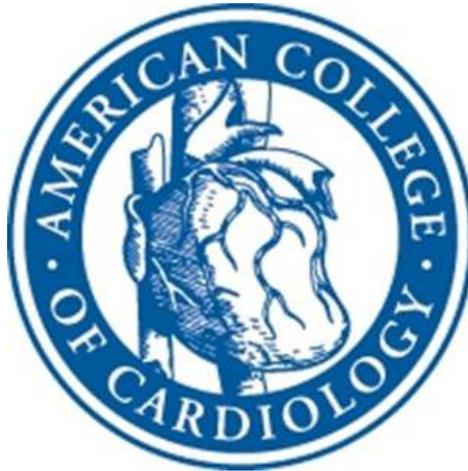
- Work with ACC physician members and staff and to develop a written, signed Memorandum of Understanding (MOU) or contract document that outlines each party's activities and responsibilities. This must include terms for use of the ACC and *CardioSmart* logo(s) and/or word marks. In addition, this MOU must include these engagement guidelines as part of the official documentation.
- Commit to the complete editorial independence of the ACC.
- Abide by the ACC's overarching Principles of Relationships with Industry with particular attention to the principles of sponsorship (Appendix 1).
- Commit to developing promotional materials and activities, including product packaging, that neither suggest nor imply an endorsement of any product or service by ACC and are directly related and narrowly focused to the dissemination of health information and support of the campaign/program. Partners must provide such materials and activity plans to the ACC for review and approval prior to their use and/or dissemination.
- Use the disclaimer statement below when using an ACC program logo. The statements must appear at least once on each primary collateral item (e.g. Web site, brochure, ad) produced as part of a partnership program. Mice type/fine print is acceptable.
 - **Disclaimer Language:** Participation by [company name] does not imply endorsement by the American College of Cardiology.
- Use all program materials without any changes to the content and with an attribution to ACC as the source and with the above disclaimer language as necessary. In addition, partners must obtain appropriate permissions from owners of content licensed to but not owned by ACC.
- Invest in the creation of health education activities and promotions that extend the dissemination of program messages, e.g., special events and promotions, Web promotions, customer mailings, on-package inclusion of campaign messages, health fairs/screenings, editorial content, inclusion of campaign messages in paid advertising, and airing of campaign public service announcements. Partners are asked to work with the ACC to determine appropriate use and obtain review and approval of each material prior to use.
- Provide the ACC with information about the nutritional value of any food products and the product packaging language.
- Ensure that food products and over-the-counter medications that make scientific claims related to health (including heart health) are substantiated by the appropriate Federal governing body (such as the FDA or USDA).

ACC Acknowledgment of Corporate Partners

As a minimum, the ACC offers the following ways to acknowledge the support of its corporate partners:

- On the ACC's *CardioSmart.org* Web pages, such as those featuring program partners or sponsored keynote events. This is reserved for partners who have made a commitment that is:
 - Long-term (more than 3 months in duration);
 - Confirmed through a signed MOU or contract document;
 - Directly supporting the ACC *CardioSmart* campaign rather than with a community group associated with the campaign; and
 - A multi-faceted effort supported by the ACC.
- With a linked URL for a corporate site on a *CardioSmart.org* Web page.
- With appropriate acknowledgement of corporate partners on member communications, event materials, signage, and advertising for ACC events and promotional collateral.
- With the provision of exhibition space at the ACC annual meeting.
- With Press Releases and other collaborative activities to promote the relationship.
- With periodic inclusion in the ACC's video news productions.
- With exclusivity in certain well-defined product categories.

Appendix 1. The ACC’s Principles for Relationships with Industry



Principles for Relationships with Industry

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Preamble

The American College of Cardiology (ACC), American College of Cardiology Foundation and our supporters in industry are committed to the highest ethical standards. ACC believes relationships with members of industry provide value provided 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.

ACC's ongoing practices include —

- ACC requires the disclosure of *all* relationships with industry (RWI) and other entities involved in the production, marketing, and distribution or reselling of health care goods, services or information consumed by patients and/or physicians. This may include relationships with government entities as well as not-for-profit entities, such as academic institutions.
- ACC adheres to the Accreditation Council for Continuing Medical Education standards for industry support of educational content in certified CME/CE.
- ACC discloses all industry funding sources on its Web site (<http://www.acc.org/about/overview/overview.htm#SECS>) in a unique transparency effort.
- Members of guidelines and other clinical document writing groups disclose any relevant RWI in writing and verbally at the beginning of each and every meeting. They reclude themselves from votes on issues involving their relationships.
- There is a strict separation between ACC development staff (who work directly with industry) and education staff (who seeks industry funding for CME/CE and develop educational content). Industry supporters *never* influence the content of ACCF educational programs or products.

Our 2008 Industry Forum brought together leaders from Congress, industry and the house of medicine, and the assembled attendees determined that we *must* self-regulate relationships between industry and medical professionals. In addition to the above 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.

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

Governance Principles

These principles are applicable to ACC and ACC Foundation Trustees, Committee Members, and Senior Staff.

- ✚ Trustees, ACC/F committee members and senior staff disclose all relationships with industry^[1] in a complete and timely fashion via the College's publicly accessible Web site.
- ✚ Trustees, committee members and senior staff adhere to the College's Code of Ethics.
- ✚ Trustees, committee members and senior staff respect and maintain the confidentiality of governance deliberations.
- ✚ Trustees, committee members and senior staff use disclosure information to manage relationships with industry and any resulting potential or actual conflicts of interest prior to board and committee meetings.

^[1] The ACC defines “relationships with industry” as *all* relationships with for-profit and other entities involved in the production, marketing, distribution, or selling of health care goods, services advice 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

- ✚ ACC and the American Heart Association consider guideline development essential to their missions and accept no industry funding for guideline development.
- ✚ ACC requires full disclosure of all relevant relationships with industry and other entities (up to 12 months prior to participation on a writing committee) in advance of formal appointment to such a committee. The ACC requires disclosure not only of the relationship, but also of the financial value, *i.e.*, relationship with no monetary reimbursement, modest relationship (<\$10,000), or significant relationship (≥ \$10,000) and type of relationship, *e.g.*, speaker, consultant, researcher, *etc.*
 - The College reviews all disclosures to ensure a balanced group of experts prior to official commission of the Writing Committee. (The Chair of the Committee and greater than 50 percent of members must have no “relevant” relationships with industry.) “Relevant” relationships mean: (1) The *relationship or interest* relates to the same or similar subject matter, intellectual property or asset, topic, or issue addressed in the *document*; or (2) The *company/entity* (with whom the relationship exists) makes a drug, drug class, or device addressed in the *document*, or makes a competing drug or device addressed in the *document*; or (3) The *person or a member of the person’s household*, has a reasonable potential for financial, professional or other personal gain or loss as a result of the issues/content addressed in the *document*.
 - ACC requires ongoing disclosure by all Writing Committee members verbally and in writing at every Committee conference call and meeting to ensure awareness and inform the debate.
- ✚ Writing Committee members with relevant relationships with industry may not draft text or vote on recommendations. Members who abstain from voting on recommendations are prominently identified in the document.
- ✚ All relevant relationships with industry for authors and peer reviewers are published along with each document in table format. Relationships with industry are labeled in the table as significant/modest/no financial benefit and the category of each relationship is clearly designated. A comprehensive listing of relationships with industry for authors and oversight committee members is available electronically.

Principles for Independent Medical Education (CME/CE)

- ✚ ACC fully and completely 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 could influence) the creation of educational content disclose their relationships with industry relevant to their role as faculty, chairs, staff, or leadership.
- ✚ Granting organizations or any commercial interests have absolutely no involvement in any decisions regarding design, development, implementation or evaluation of certified CME/CE. Contact between ACC staff and members and granting departments of pharmaceutical and device companies is 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 either peer reviewed by non-conflicted content expert members of ACC or by external content review organizations/individuals.
- ✚ 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.
- ✚ Responsibility for managing conflicts of interest is given to chairs of planning committees for development of all certified CME/CE content and requires use of all relevant disclosure forms (process overseen by leadership committees of the College).

Principles for Independent Medical Education (CME/CE)

- ✚ ACC is committed to a process for managing all content developed for certified CME/CE to prevent any commercial bias. That process includes previously described full disclosure and some or all of the following procedures:
 - 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 who solicits and administer commercial support fundraising efforts for CME/CE and 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, including, but not limited to the Accreditation Council for Continuing Medical Education (ACCME) and American Nurses Credentialing Center (ANCC) Standards for Commercial Support, Pharmaceutical Research and Manufacturers of America (PhRMA) and 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 during the Annual Scientific Session and in other venues, as long as these activities are aligned with the College's vision and strategic plan for education and all quality guidelines.
- ✚ 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) listed above, as applicable, including 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
 - Full compliance with all regulatory policies and guidelines, including, but not limited to ACCME and ANCC Standards for Commercial Support, AMA Gifts to Physicians, OIG, and FDA.

Principles for Government Grants/Foundation Support

- ✚ There is a written agreement with the grantor that reflects the purpose and amount of the grant.
- ✚ Grant support complies with all applicable laws and regulations, including 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 ACC's publicly accessible Web site.
- ✚ Grant support is used in a manner consistent with ACC's strategic plan and mission and controlled by ACC, although 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, although 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 Code.

Principles for Sponsorships

These principles are applicable to all ACC sponsorship activities. ACC recognizes a sponsorship to be an arrangement with industry that provides financial support to ACC in exchange for which ACC may acknowledge the sponsorship support in a value-neutral manner that acknowledges but does not promote or endorse a particular industry sponsor or its products or services nor identify a particular product or service.

- ✚ There is 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 by the College.
- ✚ The sponsorship complies with all applicable laws and regulations, including 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 on ACC's publicly accessible Web site.
- ✚ Sponsorships are consistent with ACC's strategic plan and mission.
- ✚ Sponsors are not involved in the tactical execution of the sponsored activity.
- ✚ ACC independently determines how to acknowledge the sponsor in a value-neutral manner that does not imply special access, influence or endorsement.

Principles for Advertising

- ✚ Advertising should be easily distinguishable from editorial content.
- ✚ Advertising should not be placed adjacent to any editorial content that is relevant to the product or company that is the subject of the advertisement.
- ✚ Advertising is subject to review by ACC, 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.
- ✚ There is a written agreement with exhibitors that reflects all exhibitor activities undertaken during the exposition activity.
- ✚ Exhibitors must comply with all applicable laws and regulations, including the American Medical Association (AMA), Pharmaceutical Research and Manufacturers of America (PhRMA), and Advanced Medical Technology Association (AdvaMed) Codes, as well as the rules and regulations related to the particular exhibit space or venue.
- ✚ ACC provides complete and timely disclosure of exhibit revenues on ACC's publicly accessible web site.
- ✚ The sale of exhibit space and related activities is independent of other support that may otherwise be provided to ACC by exhibitors, *e.g.*, educational grants, charitable donations, advertising, *etc.*
- ✚ 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.
- ✚ Registry governance and science operate absolutely independent of any industry involvement or support.
- ✚ There is 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 by the registry.
- ✚ ACC provides complete and timely disclosure of sponsor support of the registries on ACC's publicly accessible Web site.
- ✚ Sponsorship support is used in a manner consistent with ACC's strategic plan and mission and controlled by ACC.
- ✚ Industry may support the registry operations through sponsorships, such as:
 - Participant enrollment
 - Marketing
 - Product development
- ✚ Sponsorships shall not be drug class exclusive prohibiting the College from seeking additional sponsorships from device and/or drug manufactures in the same class.
- ✚ Industry sponsors may serve on registry 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 to the Registry Steering Committee insights on pertinent clinical and scientific topics.
 - Promote the adoption of the Registry among their organizations' constituents.
- ✚ Industry may request registry data analysis and research using the registry standard application. Requests will be considered on their own merit and will follow standard registry processes and procedures.
- ✚ If an industry sponsor desires to publish, distribute or use any aggregate registry data or reports, the sponsor first must obtain prior written approval from ACC.
- ✚ ACC must review and approve any sponsor communications or materials related to its sponsorship of the registry prior to publication.



- ✚ Sponsors do not receive any data that have not been provided to other registry participants or other registry stakeholders.