

ACCF Policies for Publication of Clinical and Scientific Content that is not Certified as CME and Excluding Clinical Documents

Introduction

The American College of Cardiology Foundation (“College” or “ACCF”) has developed *Principles for Relationships with Industry*, which serve as the organization's guide in managing our partnerships with industry in nine key areas of operation: (1) advertising, (2) charitable donations, (3) clinical document development, (4) continuing medical education, (5) exposition, (6) governance, (7) government grants and foundation support, (8) registries, and (9) sponsorships. Consistent with our *Principles for Relationships with Industry*, the College accepts sponsorships for its Web portals and other venues that support the development and dissemination of clinical and/or scientific reporting.

The goal of this document is to propose policies and processes through which the College will disseminate clinical and scientific content through its various formats, with or without commercial support, while ensuring adherence to the highest ethical standards.

Background

The College publishes clinical and scientific content and commentary in various forms through its publication channels, which include web properties, enduring print and electronic products, newsletters, and other print and electronic vehicles. The bulk of this content resides on the CardioSource and CardioSmart portals, where the College publishes a broad variety of clinical and scientific content both as part of certified CME learning activities, as well as non-certified CME content. This content largely comprises scientific reporting, where the College provides timely reports on the latest events relevant to its membership through the perspectives of experts. These reports may take the form of summaries of the journal literature, synopses of major clinical trials, and video and text-based news, including those derived from major cardiovascular meetings, and expert commentaries. Information may refer to off-label use, as in a trial using a therapy not yet approved. The College also encourages scientific discourse through online forums and discussion threads. Much of the content on the site represents the opinion or perspective of the author/user, and not that of the American College of Cardiology Foundation.

General Use Statement

We will clearly display on the CardioSource Web portals and in other venues as needed the following general use statement related to publication of clinical and scientific content:

“The views and opinions expressed are those of the contributing authors and editors and do not necessarily represent the views of the College. Specific therapies discussed may not be approved and/or specified for use as indicated. The material is not intended to present the only, or necessarily best, methods or procedures for the medical situations addressed, but rather is intended to represent an approach, view, statement, or opinion.

Some drugs, medical devices or therapies reflected in the material may not have been cleared by the Food and Drug Administration (FDA) or have been cleared for specific uses only. The FDA has stated that it is the responsibility of the physician to determine the FDA clearance status of each drug or device he or she wishes to use in clinical practice. Therefore, before prescribing any medication, please review the complete prescribing information including indications, contraindications, warnings, precautions and adverse effects.

In addition, any statements about commercial products are solely the opinion(s) of the author(s) and do not represent an ACC endorsement or evaluation of these products. These statements should not be used in advertising or for any commercial purpose.”

Principles

The following Principles for Sponsorship are set forth in our *Principles for Relationships with Industry*:

- ACC requires a written agreement with the sponsor, which reflects the purpose of the sponsorship, the amount and duration of the sponsorship, and the agreed upon method of acknowledgment of the sponsorship.
- The sponsorship complies with all applicable guidelines and regulations from the American Medical Association (AMA), Pharmaceutical Research and Manufacturers of American (PhRMA), Advanced Medical Technology Association (AdvaMed) Codes, and the Food and Drug Administration (FDA).
- ACC provides complete and timely disclosure of sponsor support at CardioSource.org and CardioSmart.org.
- Sponsorships are consistent with ACC's strategic plan and mission.
- Sponsors do not control nor are involved in any content development or 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.

Policies

In addition to the above College-wide principles, the following policies apply to the creation and publication of clinical and scientific content that is not certified for CME, with the exception of clinical documents:

- Members of the CardioSource Science and Quality Editorial Board, CardioSmart Editorial Board, guest editors for specific programs, members of the Clinical Quality Committee, and members of the CardioSource Steering Committee will all be clearly displayed on the ACC Web Portals. These members will all have their Relationship with Industry (RWI) available for review on CardioSource.org and CardioSmart.org.
- All contributors to clinical and scientific content and programs published on the ACC Web portals will be required to disclose RWI, and to identify those relationships that they believe are relevant to the activity. These RWI will be available for public review on the ACC Web portals and the ACC reserves the right to highlight relevant relationships.
- Sponsorships for specific sections of the site will be acknowledged appropriately on the specific section. The ACC Web portals may provide a link to the sponsors' corporate site, with an appropriate interstitial page that informs the user they are leaving the ACC Web portal.
- Whenever possible and feasible, ACCF seeks sponsorship from multiple supporters. It is understood, however, that occasions may arise where sole-support of a specific area may occur, and in these circumstances, ACCF will ensure that no conflict of interest with the supporter exists by maintaining independent and objective control of the sponsored content. Acknowledgement of the sponsor's support will be reflected clearly and appropriately.
- All clinical and scientific content and programs published on the the ACC Web portals will undergo appropriate editorial review to ensure freedom from industry or sponsor bias, including documentation of the review and its relevance. In cases where sponsorship has been secured, the editors assigned oversight of an area will have no RWI with the sponsor(s). The editors will also be responsible for reviewing the content contributors' RWI. Editors assigned oversight and review of content areas will be identified, along with their RWI statements, on the ACC Web portal sites.
- ACC Web portal sites' scientific reports often include an interpretation and/or an expert opinion of the author or editor. The following statement will be made visible as part of every clinical and scientific reporting activity: "Statements or opinions expressed herein reflect the views of the contributor, and do not reflect the official views of the ACCF, unless otherwise noted."

- In areas that are judged to be biased or not fair and balanced by the editorial board and/or any of the ACC Web portals oversight groups, the editors may, at their discretion, choose to present a contrasting view that will serve to provide a fair and balanced approach to the presentation of the issue(s).
- ACCF will encourage scientific discourse on the ACC Web portals by permitting discussion around scientific reporting through the use of social media tools, including comments, evaluations and user ratings. Participation is open to members of industry and other individuals who may have commercial interests. As such, the following statement will be included in all online forums and discussion groups: “Statements or opinions expressed herein reflect the views of the contributor, and do not reflect the official views of the ACCF, unless otherwise noted.”
- ACCF will endeavor to avoid use of brand names in the presentation of clinical and scientific content on its Web portals.
- ACCF may collaborate with appropriate third-party organizations to create programs and activities that contain clinical and scientific content. In these instances, the ACCF must have a written agreement with the third party that outlines the terms of any sponsorship agreement. These *Principles* and *Policies* will apply to all third-party collaborations.

In addition to these policies, the ACCF will follow the FDA’s *Guidance for Industry-Supported Scientific and Educational Activities* appended to the end of this document, and located at <http://www.gwumc.edu/cehp/pdf/CMEPolicies/FDAguidance.pdf>. Where possible, the ACCF will follow the 12 principles addressed in this document, including editorial independence, full disclosure of funding and relationships, how the information is disseminated, and other factors listed in the document below.

CardioSource Oversight

Science and Quality Editorial Board

Oversight for the development of Science and Quality content on CardioSource and CardioSmart is the responsibility of the CardioSource Science and Quality editorial board, consisting of an Editor-in-Chief (“E-i-C”) and several Associate Editors and Team Leaders. The E-i-C is chosen by a national search, and all of the editors are chosen for their knowledge in cardiovascular medicine and expertise in web delivery mechanisms. If there is a specific new section of the site that is appropriate to add and expertise is not available on the current board, CardioSource will hire a “guest editor” for that specific section. The E-i-C is responsible for all of the content that is published on the Science and Quality portion of CardioSource.

Clinical Quality Committee

The Clinical Quality Committee governs all of the content that is published in the Science and Quality arena. This committee is responsible for evaluating the CardioSource Science and Quality Editor-in-chief and for making recommendations on the selection of the E-i-C, determining new clinical areas and services that need to be added to the site in consideration of competing priorities, and evaluating proposals for new sponsored areas.

CardioSource Steering Committee

This Committee governs the policies and procedures for material on the CardioSource Web site, including advertising, functionality, service offerings, and exploring new business models and partnerships.

Guidance for Industry-Supported Scientific and Educational Activities ¹

U.S. Department of Health and Human Services
Food and Drug Administration
Office of Policy

November 1997

Two important sources of information on therapeutic products (human and animal drugs, biological products, and medical devices regulated by the Food and Drug Administration (FDA) for health care professionals are: (1) Activities (programs and materials) performed by, or on behalf of, the companies that market the products; and (2) activities, supported by companies, that are otherwise independent from the promotional influence of the supporting company. Although both provide valuable and sometimes vital information to health care professionals, the programs and materials performed and disseminated by companies are subject to the labeling and advertising provisions of the Federal Food, Drug, and Cosmetic Act (the act), whereas the truly independent and non-promotional industry-supported activities have not been subject to FDA regulation.²

This jurisdictional line is important because the constraints on advertising and labeling³ when applied to scientific and educational activities, can restrict the freedom of participants to discuss their data or express their views. In particular, discussions of unapproved uses, which can be an important component of scientific and educational activities, are not permissible in programs that are or can be (because the provider is not functionally independent) subject to substantive influence by companies that market products related to the discussion. Thus, the agency, has traditionally sought to avoid regulating activities that are produced independently from the influence of companies marketing the products. The agency recognizes that industry-supported activities can be both non-promotional and educational.

Demarcating the line between activities that are performed by or on behalf of the company, and thus, subject to regulation, and activities that are essentially independent of their influence has become more difficult due to the increasing role industry has played in supporting postgraduate and continuing education for health care professionals.

The agency traditionally has recognized the important public policy reasons not to regulate all industry-supported activities as advertising or labeling. To permit industry support for the full exchange of views in scientific and educational discussions, including discussions of unapproved uses, FDA has distinguished between those activities supported by companies that are non-promotional and otherwise independent from the substantive influence of the supporting company and those that are not. Those activities that have been deemed by the agency to be independent from influence by the supporting company and non-promotional have not been treated as advertising or labeling, and have not been subjected to the agency's regulatory scrutiny.

¹ This guidance has been prepared by FDA's Intra-Agency Working Group on Advertising and Promotion. This guidance represents the Agency's current thinking on industry-supported scientific and educational activities. It does not create or confer any rights for or on any person and does not operate to bind FDA or the industry. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

² In this context, the terms "independent" and "non-promotional" are not mutually exclusive. The agency views independence as an indication of whether an activity is non-promotional.

³ These provisions require the company to ensure that the content does not promote unapproved uses, and that discussions of the company's products are not false or misleading and do not lack fair balance.

In determining whether an activity is independent of the substantive influence of a company, the agency examines whether and to what extent the company is in a position to influence the presentation of information related to its products or otherwise transform an ostensibly independent program into a promotional vehicle. FDA is concerned that companies may influence the content of educational programs both directly and indirectly. Directly, by being involved in the selection of speakers or in the treatment of topics. Indirectly, through the nature of the relationship between the company and the provider (e.g., if the provider has reason to believe that future financial support from the company depends upon producing programs that promote the company's products.)

FDA is responsible for seeing that scientific and educational activities that are not intended to be promotional are designed to be truly independent from substantive influence by the marketers of regulated products. The agency recognizes, however, that the primary responsibility for overseeing the process of postgraduate and continuing professional education and scientific exchange lies with the scientific and health care communities and accrediting organizations. Accordingly, FDA will work closely with scientific and professional health care communities and accrediting organizations to help ensure that provider activities are independent.

The agency is providing this guidance to describe the agency's enforcement policy with regard to scientific and educational activities supported by industry. The guidance seeks to clarify the distinction drawn by the agency between scientific and educational activities that FDA considers non-promotional and those that the agency considers promotional, and to provide guidance on how industry may support such activities without subjection to regulation under the labeling and advertising provisions of the act.

This guidance applies only to those company-supported activities that relate to the supporting company's products or to competing products. A company-supported educational activity or part thereof that does not relate to the company's products or a competing product, or suggest a use for the company's products, would not be considered a promotional activity under this guidance.

FDA has not regulated and does not intend to regulate, under the labeling and advertising provisions of the act, industry-supported scientific and educational activities that are independent of the influence of the supporting company. Companies and providers who wish to ensure that their activities will not be subject to regulation should design and carry out their activities free from the supporting company's influence and bias, based on the factors considered in evaluating activities and determining independence, as described below. These factors are provided to furnish guidance on the design and conduct of such activities, so that they will be educational and non-promotional in nature. These factors will be considered as part of an overall evaluation of an activity; no individual factor is likely by itself to stimulate an action based on lack of independence.

A. Factors Considered in Evaluating Activities and Determining Independence

FDA will consider the following factors in evaluating programs and activities and determining independence:

(1) Control of Content and Selection of Presenters and Moderators

The agency will consider whether the provider has maintained full control over the content of the program, planning of the program's content, and over the selection of speakers and moderators. In so doing, the agency will look at whether the supporting company has engaged in scripting, targeting points for emphasis, or other actions designed to influence the program's content. In addition, the agency will consider if the company has suggested speakers who are or were actively involved in promoting the company's products or who have been the subject of complaints or objections with regard to presentations that were viewed as misleading or biased in favor of the company's products.

(2) Disclosures

The agency will consider whether there was meaningful disclosure, at the time of the program, to the audience of: (1) The company's funding of the program; (2) any significant relationship between the provider, presenters or moderators, and the supporting company (e.g., employee, grant recipient, owner of significant interest or stock); and (3) whether any unapproved uses of products will be discussed;

(3) The Focus of the Program

The agency will consider whether the intent of the company and the provider is to produce an independent and non-promotional activity that is focused on educational content and free from commercial influence or bias. The agency will also consider whether the title of the activity fairly and accurately represents the scope of the presentation.

The agency also will look at the focus of the activity to determine if the central theme is based on a single product marketed by the company or a competing product, except when existing treatment options are so limited as to preclude any meaningful discussion of alternative therapies. This is not to suggest that each treatment option must be discussed with precisely equal emphasis. However, emphasis on a newer or, in the view of the presenter, more beneficial treatment modality should be provided in the context of a discussion of all reasonable and relevant options.

(4) Relationship Between Provider and Supporting Company

The agency will consider whether there are legal, business or other relationships between the company and the provider that could place the company in a position whereby it may exert influence over the content of the activity (e.g., a provider that is owned by, or is not viable without the support of, the company supporting the activity).

(5) Provider Involvement in Sales or Marketing

The agency will consider whether individuals employed by the provider and involved in designing or conducting scientific or educational activities are also involved in advising or otherwise assisting the company with respect to sales or marketing of the company's product.

(6) Provider's Demonstrated Failure to Meet Standards

The agency will consider whether the provider has a history of conducting programs that fail to meet standards of independence, balance, objectivity, or scientific rigor when putting on ostensibly independent educational programs.⁴

(7) Multiple Presentations

The agency will consider whether multiple presentations of the same program are held.

⁴FDA recognizes that some repeat programs can serve public health interests. The Department of Health and Human Services sometimes actively encourages multiple presentations on selected urgent topics.

(8) Audience Selection

The agency will consider whether invitations or mailing lists for supported activities are generated by the sales or marketing departments of the supporting company, or are intended to reflect sales or marketing goals (e.g., to reward high prescribers of the company's products, or to influence "opinion leaders").

(9) Opportunities for Discussion

In the case of a live presentation, the agency will consider whether there was an opportunity for meaningful discussion or questioning provided during the program.

(10) Dissemination

The agency will consider whether information about the supporting company's product presented in the scientific or educational activity is further disseminated after the initial program, by or at the behest of the company, other than in response to an unsolicited request or through an independent provider as discussed herein.

(11) Ancillary Promotional Activities

The agency will consider whether there are promotional activities, such as presentations by sales representatives or promotional exhibits, taking place in the meeting room.

(12) Complaints

The agency will consider whether any complaints have been raised by the provider, presenters, or attendees regarding attempts by the supporting company to influence content.

B. Additional Considerations

The foregoing list of factors is not intended to be exhaustive and other factors may be appropriate for consideration in a particular case.

One means of documenting the measures taken to ensure independence of an activity is to have a written agreement between the provider and the supporting company. This document should reflect that the provider will be solely responsible for designing and conducting the activity, and that the activity will be educational, non-promotional, and free from commercial bias. While not required, a written agreement, coupled with the factors described above, can provide valuable evidence as to whether an activity is independent and nonpromotional.

FDA recognizes the important role accrediting organizations can play in ensuring that industry sponsored educational activities are independent and non-promotional. The agency also recognizes the importance of avoiding undue Government interference in postgraduate and continuing education for health care professionals, as the agency seeks to ensure that company promotional activities meet applicable legal requirements. Thus, the agency will continue to work with major accrediting organizations to monitor company-supported educational activities conducted by their accredited providers.