

September 12, 2008

Murray Kopelow, MD, MSC, FRCPC
Chief Executive
Accreditation Council for Continuing Medical Education (ACCME)
515 N. State Street, Suite 1801
Chicago, IL 60654

Re: Request for Comments regarding Independence of and Commercial Support for Continuing Medical Education (CME)

Dear Dr. Kopelow:

The Biotechnology Industry Organization (BIO) appreciates the opportunity to comment on the commercial support issues raised by the ACCME in your June 11 and August 6, 2008 calls for comments.

BIO represents more than 1,200 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology technologies, thereby expanding the boundaries of science to benefit humanity by providing better healthcare, enhanced agriculture, and a cleaner and safer environment.

As an organization whose biopharmaceutical company members are committed to supporting quality CME, BIO appreciates ACCME's role in developing standards for conducting CME programs to benefit physicians, other health care providers, and their patients. We encourage the continuing dialogue on what factors and characteristics create CME that is unbiased, independent and contributes to advancing medical care.

Specifically, BIO submits these comments to fulfill the ACCME's request for comments by: (1) discussing why the current processes of attaining commercial support will not undermine the independence of CME; (2) addressing the proposal to consider the elimination of commercial support of continuing medical education activities; and (3) providing practical feedback on how to define "commercial interest" to assure that CME content provided by particular individuals does not compromise independence. These issues are addressed below.



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I. Ensuring That the Current Processes of Attaining Commercial Support Will Not Undermine the Independence of Continuing Medical Education

ACCME's Standards for Commercial Support (SCS), Standard # 1, Independence, states that a CME provider must ensure that decisions regarding the identification of CME needs, determination of educational objectives, selection and presentation of content, selection of persons/organizations in control of content, selection of educational methods, and evaluation of the activity are "*free of the control of a commercial interest.*" In the context of this standard, ACCME seeks comment on the interpretation that:

- Accredited providers may not receive communications from commercial entities announcing or prescribing any specific content that would be a topic for CME; and
- Accredited providers may not receive communications from commercial interests regarding internal criteria for providing commercial support.

BIO has concerns regarding the potential impact of such an interpretation on the ability of both providers and prospective commercial supporters to efficiently communicate areas of potential support. Without such identification, prospective providers stand to "shoot in the dark", resulting in wasted resources that properly should focus on real educational needs. BIO seeks clarity from the ACCME regarding exactly what interactions between CME providers and commercial interests would be permissible. *Is ACCME seeking to disallow all transparent communications from a commercial interest to multiple CME providers regarding general areas of interest, or only one-on-one communications regarding potential topics, or both? If such communications are permissible, is ACCME seeking to limit the format or content of such communications, or both?*

For example, a commercial entity may wish to post proposed general topics of interest on its website for potential providers to access as they wish, and to enable interested providers to respond. Such proposed topics may be very broad in nature, *e.g.* "Company X would be interested in supporting CME on depression" or may communicate interest in supporting CME in a subset of a broad therapeutic area, *e.g.*, "Company Y is interested in providing support for CME addressing treatment options for patients with advanced breast cancer." This is similar to the posting of calls for grant applications from various entities, and, as is the case here, it is not a matter of introducing bias, but rather of creating an efficient and effective system. *Is it ACCME's intent to disallow a CME provider from accessing a general communication by a commercial entity stating that it is interested in supporting CME in a general topic area? Is it ACCME's intent to disallow a communication such as this in a website posting, or in a general letter to a group of CME providers, or both?*

Additionally, a potential CME provider may wish to obtain information regarding a commercial entity's interest in or application requirements for providing commercial support. *Is it ACCME's intent to prohibit a CME provider from seeking to obtain such information by requesting it from one or more potential commercial supporters?*

In another example, a commercial entity may wish to conduct a vetting process of CME providers to determine what their compliance records and capabilities are, and to ensure high educational value, in the interest of supporting CME that is independent and fully compliant. The commercial entity may subsequently wish to send a call for grant applications or a request for proposal (RFP) to a subgroup of these CME providers, who meet its predefined criteria, identifying a general topic area of interest which they would be interested in supporting. In follow-up, a commercial entity may then wish to communicate a grant evaluation decision to an applicant, including information about the reasons for a denial, such as budgetary reasons or failure to provide an adequate needs-assessment. A commercial entity may also wish to post information regarding approved CME grants, in an effort to be more transparent. *Would communications to identify compliant/capable CME providers be permissible? Would distribution of an RFP be permissible? Would communications regarding a grant decision, or to identify grant recipients, be acceptable to the ACCME?* BIO is concerned that that without guidance from potential commercial supporters regarding information to be submitted by a CME provider seeking a grant, the process of submitting and evaluating the grants would be less efficient, and educational provider requests could potentially be denied because of failure to provide adequate information, even where the request did not lack merit.

If it is ACCME's interpretation/intent to disallow these exchanges, BIO is concerned that such limitations on information dissemination would adversely impact realization of the value and purpose of CME programming. Such prohibitions would effectively banish an efficient method of matching accredited CME providers with potential CME supporters, and matching independently-identified educational needs with appropriate and compliant sources of funding. This would likely result in the inefficient use of resources by providers and commercial interests, as well as missed opportunities to positively impact patient care.

BIO believes that general communications announcing interest in a general topic/area, without any suggestion of specific content, presenters, or products are appropriate and acceptable. Such communications do not interfere with the independence of CME, as the mere suggestion of a general topic or criteria for support or application need not influence the outcome and educational value of a program or activity. There are numerous other controls in place to assure that CME activities remain independent, objective and educational. For example, SCS Standard #5, "Content and Format without Commercial Bias", requires that CME programs promote improvements or quality in healthcare by providing education on a full range of treatment options, rather than focusing on a particular medicine. Also, pursuant to SCS Standard#1, "Independence", it is the responsibility of CME providers to identify CME needs and education objectives, and select the content for a CME program, without control of a commercial interest. *What concerns does the ACCME have regarding general communications from potential commercial supporters to CME providers?* BIO believes that a limitation on general communications intended to identify potential sponsors would serve only as an impediment while adding no real benefit to the quality or independence of CME.

We further note that the newly issued PhRMA Code on Interactions with Healthcare Professionals

(http://www.phrma.org/code_on_interactions_with_healthcare_professionals/) states that “a company may communicate to multiple CME providers or the public a general topic for a CME program that might be of interest to physicians.” (See PhRMA code, Q. 21) BIO agrees that such communications are appropriate and useful, and can contribute to the development of CME that can meet the needs of the medical community and benefit patients.

Finally, BIO also seeks clarification on whether ACCME’s interpretation of SCS #1 would impact logistical discussions between commercial supporters and CME providers. Logistical discussions may include communications about potential types of educational design (e.g., live activity versus web-based activity), timing of educational initiatives, budget for educational initiatives, geographical location, status updates regarding a grant budget, and other matters unrelated to the content of or audience or faculty for the activity. *Given that such discussions do not involve the content of a CME program, or the selection of faculty/presenters, does ACCME agree that such logistical communications are acceptable and do not interfere with the independence of a CME activity?*

II. Consideration of the Proposal To Eliminate Commercial Support of Continuing Medical Education Activities

ACCME seeks comment on whether commercial support of CME activities should continue or should be eliminated, and requests that stakeholders, including the medical community, education community, and the public weigh in on and debate the subject. ACCME further seeks comment on whether a new paradigm should be created as an alternative to the current structure of commercial support for CME.

If such changes to the current model of CME are being considered, a broad gathering of input and information and full debate is warranted. This is a very complex and significant issue for stakeholders, including BIO members. Creating a new paradigm would have a major impact on how CME is conducted and how opportunities for medical education are created. In turn, BIO is concerned that if health care providers have less access to quality CME, this could have a negative impact on patient outcomes. Without any evidence that commercial support for CME results in programming that is inherently biased, a change in the current ACCME standards may be unwarranted. In fact, a report commissioned by the ACCME concludes that there is no empirical scientific evidence that industry support of CME results in bias¹:

¹ Ronald M. Cervero PhD and Jiang He, MPA, “The Relationship Between Commercial Support and Bias in Continuing Medical Education Activities: A review of the Literature” (June 2008) http://www.accme.org/dir_docs/doc_upload/aae6ecc3-ae64-40c0-99c6-4c4c0c3b23ec_uploaddocument.pdf

“With the widespread concern about the impact of industry support on medical research, practice, and education, the question of whether this support produces bias in accredited CME activities is critically important. The ACCME Standards for Commercial Support are designed to assure that CME activities are not biased toward the commercial interest supporting the activity. However, to date, there is no empirical evidence to support or refute the hypothesis that CME activities are biased.”²

Further, as noted previously, there are numerous other controls in place to assure that CME activities remain independent, objective and educational. In addition to the PhRMA Code, FDA’s 1997 “Guidance for Industry: Industry Supported Scientific and Educational Activities” addresses company funding, disclosure of relationships, and other aspects of CME programs to ensure that commercially supported CME is not considered promotional.

Given the significance of such a major potential policy change, BIO recommends that ACCME should proceed deliberatively. It would be premature to reach a conclusion regarding support for CME without further assessment of the need for a change, evidence that there is, indeed a concern to be addressed, and what the impact of specific changes is likely to be.

In assessing commercial support for CME, there are a number of questions to be considered, including:

- whether commercial support for CME compromises the independence and scientific quality of CME programs;
- whether the existence of commercially supported CME has a detrimental impact on medical education and patient care;
- whether the process of CME sponsorship will be consistent for all types of CME providers, including for profit-providers, university and hospital providers, and professional medical societies;
- whether existing controls and standards, such as disclosure of commercial support and financial relationships, are sufficient to achieve the goals of independence, non-bias, and educational quality; and
- whether elimination of commercial support would impact the quality and availability of CME activities.

BIO recommends that these and other data points should be studied and assessed before any major change is proposed or implemented. A paradigm shift such as this should not be undertaken without evidence of potential benefits to medical education and public health.

² Id at p. 8.

Given that there have been a number of recent developments in this area, including issuance of the revised PhRMA Code, and that governmental and commercial entities are currently assessing and re-assessing these issues, ACCME should also take these other efforts into consideration prior to reaching any conclusions.

If, following such an assessment, ACCME determines that an alternative paradigm would be beneficial, it would then be appropriate to launch a pilot project, to test the impact of any new program prior to it adopting it more broadly.

III. How to Define “Commercial Interest” To Assure That CME Content Provided by Particular Individuals Does Not Compromise Independence

ACCME’s Standards for Commercial Support, Standard #1, Independence, states that a CME provider must ensure that decisions regarding selection of CME presentation and content, and the persons in a position to control the content must be free of the control of a commercial interest. In this context, the ACCME seeks comment on whether individuals who are not employees of a commercial interest, but who are involved in the promotion of that company’s products and services, should be excluded from controlling CME content. For example, the ACCME asks whether physicians who are paid by commercial entities to deliver promotional content to other physicians may also teach in independent CME activities. ACCME seeks comment on the following policy:

- Persons paid to create, or present, promotional materials on behalf of commercial interests cannot control the content of accredited continuing medical education on the same content.

The ACCME expands on this proposal, stating that not every financial relationship between an individual and industry would implicate this policy.—*e.g.*, persons conducting research funded by industry, or reporting on the results of industry-funded research, would not be affected unless they also participate in promotional activities on the same content.

BIO appreciates the ACCME’s efforts to define the appropriate methods of assuring that education is separate from promotional activities, and that CME programs are conducted independently. However, BIO is concerned that a policy excluding certain persons from CME participation may only address a perception of bias, and would not serve the primary goal of providing high quality independent CME.

Physicians involved in research and clinical trials on innovative therapies are generally the most knowledgeable about important advances in science and treatments, by virtue of both their background in a therapeutic area and participation in the research.

Biopharmaceutical companies engage these experts to participate in research because of their specific expertise, and, following that research may also determine that these experts are the most informed and proficient to conduct training or educational sessions on the therapy for their colleagues, as consultants to a company. And again, when a CME provider is seeking experts to present at a CME program, these same physician experts may be the

most qualified, particularly in a niche therapeutic area, where the number of experts or specialists may be very limited.

BIO believes that such experts should not be prohibited from presenting CME content, solely because of a consulting relationship with a commercial interest in that content area. Exclusion of such experts could deprive CME program attendees of hearing from and learning from the best and the brightest in particular therapeutic areas. As stated previously, the existing ACCME Standards, including the requirements for disclosure of all relevant financial relationships with any commercial interest, and the provision of a balanced view of therapeutic options, are sufficient to produce CME programs that are independent and unbiased. The ACCME's proposal appears to assume that physicians with recognized expertise in an area would not be capable of presenting unbiased scientific/medical information, an assumption that we do not accept. Further, physicians who would attend such CME programs are sufficiently educated and sophisticated to assess the nature of the information presented and the relevant disclosures.

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BIO appreciates your consideration of these comments and looks forward to ACCME's clarifications on the issues we have raised. If you have any questions, please contact me at 202-962-6673.

Sincerely,



Sandra J.P. Dennis
Deputy General Counsel for Healthcare