



September 12, 2008

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Dr. Kopelow:

The Alliance for Continuing Medical Education (Alliance) is an international membership organization of more than 2,600 professionals devoted to designing and implementing continuing medical education (CME) activities for physicians. The Alliance provides professional development opportunities for CME professionals, advocates for CME and the profession, and strives to improve patient health care outcomes. The Alliance appreciates the opportunity to provide comment on issues identified in the ACCME's June and August Call for Comments issued to Accredited CME Providers.

I. The ACCME will ensure current processes of attaining commercial support will not undermine the independence of continuing medical education.

The ACCME has asked for comment on the issue of whether providers should receive "communications from commercial interests announcing or prescribing any specific content that would be preferred, or sought after, topic for commercially supported CME..." Such communication "would be considered 'direct guidance on the content of the activity'" which would place the Accredited CME Provider in non-compliance with the Standards for Commercial Support.

The Alliance supports the concept that specific content should not be communicated from commercial supporters to Accredited CME Providers. We draw a distinct line between the concept of "specific content" and "topic." In order to ensure independence of certified continuing medical education, we agree that industry should not "prescribe any specific content" for an educational activity. We recognize that this may be seen as controlling content – although we wish to note that Accredited CME Providers have the choice of whether or not to apply for the commercial support. Should they chose to apply for this commercial support, they would need to provide their own needs assessment data supporting the activity they are planning. This said, we recognize that there can easily be a blurring of the lines between acceptable and unacceptable industry input. The monitoring of this would be onerous for the ACCME.

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Mission

The Alliance for CME is a membership organization that provides professional development opportunities for CME professionals, advocates for CME and the profession, and strives to improve health care outcomes.

The Alliance does not support the concept that commercial supporters should be restricted from being allowed to communicate topics for which they are willing to provide support. Again, an Accredited CME Provider is under no obligation to seek financial or in-kind support from the commercial supporter who makes this information available. Instead, Accredited CME Providers may use this information to direct their requests for commercial support. It is unrealistic to expect individual companies to fund education outside the scope of their corporate mission. Topic parameters provided by commercial supporters will ease the work of frequently stretched CME offices. This is consistent with the fact that not-for-profit foundations post their mission and objectives to guide grant requests.

ACCME also seeks comment on whether Accredited CME Providers should receive “communications from commercial interests regarding a commercial interest’s internal criteria for providing commercial support.” ACCME states that this type of communication “would also be considered the receipt of ‘guidance, either nuanced or direct, on the content of the activity or on who should deliver that content.’” The Alliance is concerned with these statements.

We ask ACCME to clarify the definition of “internal criteria.” If, by “internal criteria” ACCME means that the commercial interests cannot provide an application form that includes information used by the commercial supporter to evaluate the request for funding, we would not support this statement. Accredited CME Providers seek support from a wide range of commercial supporters. As long as Accredited CME Providers hold true to the concept of not accepting input into the educational activity from industry, the fact that industry, in its review, knows the planned content of a proposed activity does not represent either nuanced or direct guidance. Industry can decide not to support the activity and the Accredited CME Provider is free to seek support from other companies. The only problem that could occur is if the Accredited CME Provider changed its activity based on feedback from industry in response to a completed application. In such a case, we would agree that the Accredited CME Provider would be out of compliance with the Standards for Commercial support.

If by “internal criteria” ACCME means that industry cannot make clear which specific treatment modalities/interventions must be addressed, or specific content presented in order for support to be offered, we concur with ACCME. This type of information could be perceived as crossing the bounds by influencing the content of the program. While it could be argued that Accredited CME Providers need not apply for the support if this information did not conform with their own plans, this would be considerably difficult to monitor.

II. The ACCME believes that due consideration be given to the elimination of commercial support of continuing medical education activities.

The Alliance does not support the ACCME proposal to eliminate commercial support of certified continuing medical education. There is currently no evidence available to suggest that commercial support increases or decreases bias in educational programming or negatively impacts physician decision making after attending a certified CME activity. This statement is corroborated by ACCME's own "Statement from the Accreditation Council for Continuing Medical Education (ACCME) to the Institute of Medicine Committee on Conflict of Interest in Medical Research, Education, and Practice (June 2008.)"

ACCME has been a leader in addressing the issue of conflicts of interest and commercial support. In 2004, the ACCME released the revised Standards for Commercial Support; in 2006, the ACCME released the updated criteria for accreditation; and in 2007, the ACCME clarified what it defines as a commercial supporter. These initiatives have clarified the appropriate management of commercial support and conflicts of interest. Accredited CME Providers have been actively improving their practices to conform to these updated Standards and Criteria.

Relationships with commercial interests are also guided by the Department of Health and Human Services - Office of the Inspector General (OIG), Food and Drug Administration (FDA), American Medical Association (AMA), PhRMA, and AdvaMed to help ensure independence, transparency and the integrity of commercial medical educational activities. The ACCME recommendation to eliminate commercial support completely would potentially negate the impact of all the CME components of regulations and codes that have been strengthened and enforced over the past four years.

It is the opinion of the Alliance that the ACCME should take into account the valued added benefits to broaden and improve the quality and reach of certified educational programming when sufficiently funded, regardless of funding source. Funding from commercial interests has supported accredited provider's efforts to develop educational activities designed to utilize the most effective methods of instruction based upon the specific needs of the target audience. The CME provider, therefore, is better positioned to deploy the full

range of educational tools, techniques and resources to provide the best possible continuing medical education for physicians.

In addition to the above, it is important to note that advancements in medicine, both therapeutic and technologic, are not stagnant. Providers of continuing medical education rely on the financial support of industry so that they can offer ongoing education on the advancements of medical technologies and their application in the practice of medicine. Without access to viable commercial funding by providers of certified continuing medical education, industry will need to fill the educational void, thus increasing industry influence over content; a situation that would be in direct contrast to the intended goal to decrease industry influence.

To date, there is no existing evidence that supports the far-reaching premise that the elimination of commercial support for educational activities would eliminate bias in CME. Rather, the Alliance supports the ACCME's "status quo" option, whereby all commercial relationships must be disclosed and managed appropriately. It is the responsibility of Accredited CME Providers to ensure that certified educational activities are free from commercial bias and are based on the highest available level of evidence.

The Alliance shares the belief that certified continuing medical education should be independent and free of commercial bias. The Alliance has adopted its own Conflict of Interest Principles that aim to ensure transparency, thereby creating a stronger barrier between commercial interests and the content of certified continuing medical education. These principles are:

- 1. The content of CME activities must be based on evidence that is accepted by the medical profession. This evidence may be drawn from research, performance guidelines, epidemiological data, and current practice.**
- 2. All financial relationships between commercial entities and providers of certified continuing medical education must be disclosed to both the planners and the participants. The CME provider must ensure that the planning and implementation of CME activities are accomplished with no influence from commercial entities. CME providers must disclose the process by which they manage conflicts of interests with commercial entities as well as individuals and organizations.**

3. All financial relationships between commercial entities and individuals responsible for planning, implementing and presenting educational activities must be disclosed both to the accredited CME provider and to the participants of the educational activities, and managed appropriately.

The ACCME has also asked for comment with regard to a possible new paradigm for commercial support. After reviewing the proposed new paradigm, we believe the model offered is unnecessarily burdensome and will, by default, preclude most providers from qualifying for commercial support.

Rather than create a new paradigm for commercial support, the Alliance recommends that the ACCME invest resources to enhance the surveillance and enforcement of existing Essentials, Elements, Standards and Policies. We steadfastly support the need for robust, scientifically sound research investigating the impact of commercial support on educational programming and bias, and consequently on physician behavior and patient care.

III. “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 Alliance considers this a very important statement that should be openly debated. We have serious concerns with this proposed policy. Industry upholds contracts with subject matter experts to present information about their products and services. These presentations may include education on the clinical benefits and safety considerations for a marketed pharmaceutical product or device. Many times, the researchers who have conducted the clinical trials which investigated the safe and effective uses of the product are then called upon to discuss their findings in a promotional setting. This is all acceptable under the regulations set forth primarily by the Food and Drug Administration.

The Alliance is concerned that the ACCME appears to be suggesting that those contributing to the development and presentation of certified continuing medical education are not capable of fulfilling more than one role without becoming ethically and professionally compromised. The Alliance believes that when accredited providers comply with the ACCME’s Essentials, Elements, Policies, and Standards there are sufficient safeguards to ensure that certified continuing medical education activities are developed in a fair and balanced manner, upholding the standard of providing the best available evidence in a manner that will positively impact patient care. Should the

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ACCME adopt this policy, it is reasonable to believe that many excellent contributors to the advancement of clinical research and medicine would be barred from speaking as experts on the very content for which they were sought after by industry and Accredited CME Providers. Further, the Alliance is concerned by the lack of documented evidence which demonstrates a problem exists and that the ACCME's Essentials, Elements, Policies and Standards are not ensuring the highest quality of certified continuing medical education without bias being properly managed. The Alliance strongly believes that policy development should be driven by sound, evidence-based data and that change to the accreditation system should not be made in the absence of relative supporting data.

The Alliance acknowledges the ACCME's intent to improve the quality and independence of continuing medical education as the impetus for the clarifications on interactions between Accredited CME Providers and commercial supporters and the proposal to eliminate commercial support. On behalf of our membership, the Alliance offers its assistance in supporting Accredited CME Providers in meeting the ACCME's Essentials, Elements, Standards and Policies. Lastly, the Alliance supports the concept of more diligent surveillance and further study.

Sincerely,

A handwritten signature in cursive script that reads "SueAnn Capizzi".

SueAnn Capizzi, MBA
President