



Southcrest Building, Suite 105
1025 Montgomery Highway
Birmingham, Alabama 35216-2856
Phone: 205/824-1355
Fax: 205/824-1357
Email: acme@acme-assn.org
Website: www.acme-assn.org

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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.

June 8, 2009

Regina M. Benjamin, MD, MBA, Chair
Council on Ethical and Judicial Affairs
Daniel W. Van Heeckeren, MD, Chair
Reference Committee on Constitution and Bylaws
American Medical Association
515 N. State Street
Chicago, IL 60610

RE: CEJA Report (I-A-09)

Dear Drs. Benjamin and Van Heeckeren:

The Alliance for Continuing Medical Education (Alliance) is an international membership organization comprised of more than 2,500 professionals from medical schools, hospitals, medical specialty societies, state medical societies, medical education communication companies, pharmaceutical and medical device companies, and related organizations 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 applauds the Council on Ethical and Judicial Affairs (CEJA)'s well meaning intent "To provide ethical guidance for physicians and the profession with respect to industry support for continuing medical education..." The Alliance also agrees with the CEJA's conclusion that "pharmaceutical, biotechnology, and medical device companies—can offer enormous benefit to the profession and the patients it serves." We agree further that relationships with these companies must be transparent and managed in a manner that identifies and resolves potential conflicts to prevent bias.

Despite the laudable objective of the CEJA report, the specific ethical guidance provided to physicians and the profession on pages 8 & 9 of the report is vague and open to multiple interpretations. The Alliance strongly recommends that this report be referred back to CEJA for reconsideration and clarification.

The Alliance offers the following comments concerning CEJA's proposed "ethical framework to guide professional practice with respect to financial relationships in the context of continuing medical education."

The Differentiation Between Ethically Preferable and Ethically Permissible

- The distinction presented between ethically preferable and ethically permissible implies a value judgment that educational activities with commercial support or speakers with financial relationships with industry are somehow less evidence-based or less ethical than activities with no commercial support or speakers with no financial relationships. The report from CEJA provides no current data to support this potential judgment. Indeed, the report fails to acknowledge the one current study by Cervero that found no evidence in support for or against this premise¹. Further research needs to be conducted in this area before new ethical standards are established.
- The delineations between ethically preferable and ethically permissible can be subjective and confusing and will be interpreted differently by physicians and the public alike. We believe there is no value in suggesting shades of gray as to whether or not a practice is ethical. Both “ethically preferable” and “ethically permissible” are, in fact, ethical.
- Ethically preferable CME, as defined by this document, places undue pressure on all organizations that provide continuing medical education to eliminate commercial support. Business models may well have been established that rely upon industry support. As long as these models comply with the ACCME Essentials, Standards, and Policies there is no evidence that industry support represents an ethical issue.
- There are circumstances when individuals having relationships with industry are the best potential faculty for a CME activity. This is particularly true when a new pharmaceutical product or device is made available either in clinical trials or after FDA approval. The Alliance would argue that it is ethically preferable to have knowledgeable faculty with a financial relationship with industry in this instance rather than the CME provider selecting a “good enough” speaker simply because he/she lacks a relationship with industry.
- In its effort to clarify how a program can be ethically permissible while accepting commercial support or utilizing speakers with relationships with industry, the report specifies several conditions that lack clarity. The report should:
 - Define what “overly reliant” means in regards to CME provider dependence on funding from industry sources.
 - Define “modest financial interests” with regard to individuals involved in programming for, developing content for, and teaching in CME activities. Note that the ACCME’s Standards for Commercial Support require that any amount of financial interest must be disclosed and managed. Does CEJA propose that CME providers collect information on specific financial amounts? If so, CEJA should clearly state where the tipping point is between “modest financial interests” and unacceptable financial interests.

¹ Cervero, R., & He, J. The Relationship between Commercial Support and Bias in Continuing Medical Education Activities: A Review of the Literature. 2008. Commissioned and Funded by Accreditation Council on Continuing Medical Education

- Define “demonstrably uniquely qualified” as it relates to the involvement of individuals with significant, unavoidable financial interest. This is a subjective description that would be very hard to defend or prove if the uniquely qualified expert had a “substantial” financial interest in the educational recommendations or content. Providing evidence of such a selection could become onerous. A focus on the overall process of faculty selection and evidence of the process for the CME provider’s management of conflict of interest policy is more appropriate.
- Finally, we note that the report does not recognize the value of the safeguards that are currently in place to address conflicts of interest. Accredited CME providers must uphold the ACCME’s Standards for Commercial Support and already adhere to the conditions being recommended in the description of ethically permissible, so we contend that there is no ethical dilemma to be addressed. Furthermore, there are no data available to suggest that the Standards for Commercial Support are not effectively mitigating potential conflicts of interest.

Alliance Conflicts of Interest Principles

The Alliance shares the belief expressed in the CEJA report that certified continuing medical education must be independent and free of commercial bias. The Alliance recently established its position on conflicts of interest and 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 interest 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.

Thank you for the opportunity to comment.

Sincerely,



Jann Balmer, PhD
President
Alliance for Continuing Medical Education