

Officers 2009-2010

June 12, 2009

President

Lois Colburn
University of Nebraska
Medical Center

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 North State Street
Chicago, IL 60610

Past-President

Melinda Steele, M.Ed.
Texas Tech University
Health Sciences Center

Re: CEJA Report (1-A-09)

Dear Drs. Benjamin and Van Heeckeren:

President-Elect

Todd Dorman, M.D.
Johns Hopkins School
of Medicine

The Society for Academic CME (SACME) appreciates the opportunity to comment on the CEJA Report and Recommendations (1-A-09) "Financial Relationships with Industry in Continuing Medical Education". The mission of SACME is to promote the research, scholarship, evaluation and development of CME/CPD (continuing medical education/continuing professional development) that helps to enhance the performance of physicians and other healthcare professionals practicing in the United States, Canada, and elsewhere for purposes of improving individual and population health.

Vice President

Gabrielle Kane, M.B., Ed.D.
University of Washington School
of Medicine

The current CEJA report, though much improved over previous versions, proposes an ethical framework to guide the practice of CME. SACME is concerned that the underpinning for the recommended ethical framework is guided by research findings during a different regulatory period, did not consider current evidence-based research on bias in CME, nor the impact of the current regulatory environment on continuing medical education.

Treasurer

Deborah Sutherland, Ph.D.
University of South Florida
Continuing Professional
Development

First, much of the discussion on bias in CME and the influence of CME on a physician's prescribing patterns is drawn from analyses of CME activities that occurred prior to significant changes in the regulatory landscape of CME. Further analysis of the articles cited would find that the Bowman⁽¹⁾ article does not definitively conclude that industry support of CME activities led to increased prescribing of a commercial supporter's

Secretary

Susan Tyler, M.Ed., C.M.P.
University of Cincinnati
College of Medicine

product. In fact, the authors point out that a variety of external factors can lead to a change in prescribing patterns. Confusing the discussion further is the inclusion of data related to physician participation in industry sponsored non-CME activities.⁽²⁾ While inclusion of data from this latter article appears to strengthen the CEJA argument, in reality it is misleading and only serves to further blur the distinction between certified CME and FDA-regulated programming.

Second, there is no mention of the June 2008 report commissioned by the ACCME, *The Relationship between Commercial Support and Bias in Continuing Medical Education Activities: A Review of the Literature*⁽³⁾, which found that “there is no empirical evidence to support or refute the hypothesis that CME activities are biased”. This is an important report that should be included when framing any discussion on commercial support and bias in CME.

Third, there is no discussion of how the field of CME has evolved. The very issues cited by the outdated research led to the implementation of the first ACCME Standards of Commercial Support in 1992⁽⁴⁾ and development of the CEJA Opinion 8.061 Gifts to Physicians from Industry⁽⁵⁾. Since then, the current ACCME Standards for Commercial SupportTM (SCS)⁽⁶⁾, coupled with FDA restrictions⁽⁷⁾, guidance from the OIG⁽⁸⁾, the new codes of conduct from PhRMA⁽⁹⁾, AdvaMed⁽¹⁰⁾, and stricter institutional policies on faculty interaction with industry, have further strengthened the environment in which CME is produced.

Based on the issues raised above, the CEJA recommendation of a framework of “ethically preferable” and “ethically permissible” continuing medical education activities creates a false dichotomy between providers that accept commercial support and those who do not. Implicit in this dichotomy is the perception that commercially supported CME is inherently biased.

In addition, Item 3b of the section on CME that is “ethically permissible” is in error. The 2004 SCS, Standard 3 indicates that a provider “cannot be required to by a commercial interest to accept advice or services concerning teachers, authors, or participants or other education matters, including content, from a commercial interest as conditions of contributing funds or services.” If there is any language in a LOA that even suggests industry input or control of content, accredited providers are prohibited from signing that LOA. Further elaboration by the ACCME has indicated that CME providers may not even solicit suggestions on content or speakers from a commercial supporter nor ask a supporter to verify whether scientific content in a CME activity is accurate.⁽¹¹⁾

Council on Ethical and Judicial Affairs
American Medical Association
June 12, 2009
Page 3

Additionally, within the recommendation of what is "ethically permissible", there is language that is vague and confusing. For instance, how can a physician determine which CME provider is "overly reliant" on commercial support and which is not?

In Item 4, the term "modest financial interests" is likewise vague. The current ACCME SCS states that a relevant financial relationship of *any* amount creates a conflict of interest. Since accredited providers are required to comply with the SCS to maintain accreditation, the steps identified in Items 4 and 5 are part of the current practice of CME.

In light of the concerns noted above, SACME recommends that Report 1-A-09 be referred back to the Council of Ethical and Judicial Affairs.

Sincerely,



Lois Colburn
President

References

1. Orlowski JP, Wateska L. *The effects of pharmaceutical firm enticements on physician prescribing patterns: There's no such thing as a free lunch.* 1992;102:, Chest, pp. 270-273.
2. Cervero RM, He J. *The Relationship between Commercial Support and Bias in Continuing Medical Education Activities: A Review of the Literature.* June 2008. Commissioned Report by the Accreditation Council on Continuing Medical Education.
3. ACCME. *Standards for Commercial Support.* March 20, 1992.
4. AMA. *Gifts to physicians from industry.* Issued June 1992.
5. ACCME. *ACCME Standards for Commercial Support.* 2004.
6. Bowman MA, Pearle DL. *Changes in drug prescribing patterns related to commercial company funding of continuing medical education.* 1988;8, The Journal of Continuing Education in the Health Professions, pp. 13-20.
7. ACCME. "Ask ACCME, Standards for Commercial Support -- Independence, Item #4". [Accessed: June 11, 2009.] http://www.accme.org/index.cfm/fa/faq.detail/category_id/667b72cf-6277-4317-99f9-1e476b621e76.cfm.
8. U.S. Food and Drug Administration. *Guidance for industry: Industry-supported scientific and educational activities.* *Federal Register.* 1997, Vol. 62 (232), pp. 64093-64100.
9. Cf. Office of Inspector General. *Compliance Program Guidance for Pharmaceutical Manufacturers.* Washington, DC : Department of Health and Human Services, 2003.
10. Pharmaceutical Research and Manufacturers of America. *PhRMA Code on Interaction with Health Professionals.* Washington, DC : s.n., Revised 2008.
11. Advanced Medical Technology Association. *AdvaMed Code on Interactions with Health Care Professionals, Revised and Restated Code of Ethics.* Effective July 1, 2009.