

# The Ethics of the CEJA Report 2009

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## **“Financial Relationships with Industry in Continuing Medical Education”**

Lewis A. Miller, MS, CCMEP

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The Council on Ethical and Judicial Affairs (CEJA) of the American Medical Association (AMA) has recently submitted its above-titled report to a reference committee of the AMA, to be considered for submission to the AMA House of Delegates in mid-June. The report has moved from the stand of CEJA a year ago -- which called for a ban on industry support of CME – but not very far. The essence of the 2009 recommendations:

1. “It is ***ethically preferable*** that CME providers accept funding only from sources that have no direct financial interest in a physician’s clinical recommendations and that those involved in CME have no ... direct financial interest in the subject matter ...”
2. “It is ***ethically permissible*** that CME providers accept funding from industry sources ***if*** the educational activity is planned by the provider based on needs identified independent of and prior to solicitation or acceptance of the funding; the use if funding is not restricted in any way; the source ... is clearly disclosed; and the CME provider is not overly reliant on funding from industry sources...”
3. “CME activities that involve financial relationships that cannot be addressed through any of these mechanisms are ***“ethically prohibited.”***”

We have several issues to raise about the research, conclusions and recommendations of this report, namely:

1. Is the report itself ethical, based on the biased level of research reported?
2. Do the conclusions warrant the recommendations?
3. Is there sufficient justification for describing actions as ethically preferable vs. ethically permissible?

### **The Quality of Research and Ethics of the Report**

Ethics is often defined as “basic principles of right action”, and involves the determination of right and wrong. The principles of right action call for fair balance and avoidance of bias. Determination of right from wrong depends on full reporting of known data and analysis thereof. The report fails to live up to these criteria.

The section titled “Industry Support for CME”, while indicating that “industry support now accounts for more than half of all income” to accredited CME providers, suggests that such support exists because of “uncertain funding from other sources”. The report ignores the real reasons for the growth of industry funding. Industry sees results that benefit companies, physicians and their patients, e.g.:

- a. disseminating research findings that benefit patient care;
- b. identifying best practices in diagnosis and treatment in therapeutic areas of interest to supporters;
- c. informing physicians of off-label uses<sup>1</sup>, and,
- d. in some cases, discharging a social responsibility.

Later paragraphs in the same section deal with studies from 17-23 years ago<sup>2,3,4</sup> that “offer some insight”. There is disclosure that these studies predate the Standards for Commercial Support of the Accreditation Council for CME (ACCME)<sup>5</sup>; however, the standard themselves are not described in any detail, nor is evidence presented regarding their effectiveness. The section on “Disclosure” mentions the ACCME requirement to disclose conflict of interest, goes on to criticize the value of disclosure itself, and yet fails to disclose that the ACCME standards require resolution of the conflict. Further, the value of the ACCME standards on independence is apparently dismissed in one sentence under “Firewalls”, because CEJA believes they are insufficiently specific.

CEJA states that “evidence also indicates that industry support can influence the overall topics, speakers and educational content of CME”. There is no definition of the level of evidence, which appears to be “expert opinion” of the authors rather than randomized trials, non-randomized trials or meta-analyses. Furthermore, one of the most important papers not referenced is that by Cervero and He<sup>6</sup>. This study, commissioned by the ACCME, could find no evidence that commercial support did -- or did not -- influence doctors inappropriately, nor could they find any evidentiary link between commercial support of CME and patient care outcomes.

One more omission: There is no reference to updated industry standards<sup>7</sup> on gifts to physicians, venues for meetings supported by industry, and awareness of the need for independence of CME.

This discussion identifies a major gap between the level of CEJA research and that of thorough research on the impact of industry support of CME. There is a lack of fair balance. There is sufficient evidence to show that, by its acts of commission and omission, the report reflects a bias against industry support of CME. We therefore believe that it is reasonable to challenge both the quality of research and the ethics of the report.

### **The Gap Between Results, Conclusions and Recommendations**

In the Results section of the Executive Summary, CEJA states that “the profession must safeguard the independence and integrity of continuing medical education by ensuring that control of the educational enterprise remains in the hands of the profession.”

In the Conclusions section, CEJA states that “commercial funding for professional education can pose significant ethical challenges to medicine’s ability to focus primarily on the needs of patients and ensure quality education for physicians”.

There is no evidence presented that commercial support prevents the profession from safeguarding the independence of CME. As the ACCME Standards for Commercial Support demonstrate, the profession is capable of taking steps to protect the independence and integrity of CME. There is no evidence that control of the educational enterprise has passed from the hands of the profession to the hands of industry. If, as the conclusion suggests, industry support raises significant ethical challenges to doctors’ ability to provide good patient care, has the profession failed to deal with these challenges? There is no evidence to support this contention. And if evidence does exist, should it not be forwarded to the ACCME for consideration in strengthening its safeguards?

ACCME faced this issue of industry support recently and decided not to make any recommendations for its termination. The Executive Committee stated<sup>8</sup>:

The ACCME believes that the CME system’s internal controls provided by the ACCME® Standards for Commercial Support, and associated ACCME policies, support the development of independent continuing medical education that **a)** is free of commercial bias and **b)** does not result in an inclination by professionals to direct care that is unwarranted or unnecessary. The ACCME is committed to providing oversight of accredited continuing medical education that is developed in compliance with the ACCME® Standards for Commercial Support and that includes commercial support and/or teachers and authors who have financial relationships with ACCME-defined commercial interests.

### Ethically Right or Wrong?

Finally, some explanation is required for the dichotomy of ethics presented in the recommendations. It would appear that it is unethical for CME providers to accept funding from industry and for faculty, organizers and participants who have a financial interest in the subject matter to avoid taking part in such CME. However, it also appears that it is ethical for providers to accept such support, and for individuals to take part, if certain conditions are met.

We find it difficult to determine that one position is more right than another.

If the best ethical behavior on the part of a CME provider or a physician is to avoid any risk of influence from financial support, that determines right action. Is it fair to ask physicians and CME providers to decide that a degree of risk is almost as right as no risk?

CEJA seems to be saying: Don't eat the poisonous mushrooms – unless they are properly seasoned!

We recommend that the report be referred back to CEJA by the reference committee for further examination.

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- 1 Miller LA, Examining the Value of Commercially Supported CME”, J Contin Ed Health Prof. 2009; 29(1):68-70.
- 2 Bowman MA, Pearle DL. Changes in Drug Prescribing Patterns Related to Commercial Company Funding of Continuing Medical Education. J Contin Ed Health Prof. 1988;8:13-20.
- 3 Orłowski JP, Wateska L. The Effects of Pharmaceutical Firm Enticements on Physician Prescribing Patterns. Chest. 1992;102:270-273.
- 4 Bowman MA. Impact of Drug Company Funding on the Content of Continuing Medical Education. Moebius. 1986;6(1):66-69.
- 5 Standards for Commercial Support. Accreditation Council for CME. 2004-2007. Accessed at [http://www.accme.org/dir\\_docs/doc\\_upload/68b2902a-fb73-44d1-8725-80a1504e520c\\_uploaddocument.pdf](http://www.accme.org/dir_docs/doc_upload/68b2902a-fb73-44d1-8725-80a1504e520c_uploaddocument.pdf) on May 27, 2009.
- 6 Cervero RM, He J. The Relationship between Commercial Support and Bias in Continuing Medical Education Activities: A Review of the Literature. Accreditation Council for CME. June 2008. Available at [http://www.accme.org/dir\\_docs/](http://www.accme.org/dir_docs/)
- 7 Code on Interactions with Healthcare Professionals. Pharmaceutical Research Manufacturers Assn. 2009. Accessed at <http://www.phrma.org/files/PhRMA%20Marketing%20Code%202008.pdf> on May 27, 2009.
- 8 Executive Summary of the March 2009 Meetings of the ACCME Board Of Directors. Accessed at [http://www.accme.org/dir\\_docs/whats\\_new/21c470b8-3a3c-4ea9-b0af-3d03e29e96fb\\_uploadfile.pdf](http://www.accme.org/dir_docs/whats_new/21c470b8-3a3c-4ea9-b0af-3d03e29e96fb_uploadfile.pdf) on May 27, 2009.