HOD ACTION: Council on Medical Education Report 13 adopted as amended and the remainder of the report filed.

REPORT OF THE COUNCIL ON MEDICAL EDUCATION

CME Report 13 A-08

Subject: Financial Conflicts in CME
(Resolution 310, A-07)

Presented by: Richard J.D. Pan, MD, Chair

Referred to: Reference Committee C
(David M. Lichtman, MD, Chair)

Resolution 310 (A-07), which was introduced by the Missouri Delegation and referred to the Board of Trustees, asks that our American Medical Association work with the Accreditation Council for Continuing Medical Education (ACCME) to develop more specific disclosure criteria for financial conflicts that include a written statement, current at the time of publication of the program and included in the program, quantifying in broad categories the size of the conflict of interest in the last twelve calendar months.

Background

The ACCME Updated Standards for Commercial Support, adopted in September 2004, require accredited continuing medical education (CME) providers to: “… to show that everyone who is in a position to control the content of an education activity has disclosed all relevant financial relationships with any commercial interest to the provider (Element 2.1).” The ACCME defines a financial relationship as: “… those relationships in which the individual benefits by receiving a salary, royalty, intellectual property rights, consulting fee, honoraria, ownership interest (e.g., stocks, stock options or other ownership interest, excluding diversified mutual funds), or other financial benefit. Financial benefits are usually associated with roles such as employment, management position, independent contractor (including contracted research), consulting, speaking and teaching, membership on advisory committees or review panels, board membership, and other activities from which remuneration is received, or expected.” A “relevant” financial relationship is further defined as occurring within the past twelve months. The ACCME does not set a minimum dollar amount for a relationship to be significant as it maintains that any amount may be incentive to retain or increase the value of the relationship.

ACCME standards also require that accredited providers must disclose to learners prior to the certified educational activity information related to any financial relationship that a faculty member may have. Such disclosure must include the name of the individual, name of the commercial interest(s), and the nature of the relationship with each commercial interest (Element 6.1). Furthermore, in addition to the disclosure requirements, the ACCME also mandates that accredited providers have mechanisms to “resolve” all conflicts of interest prior to a certified activity (Element 2.3).

Discussion
The underlying principle in Resolution 310 is that the magnitude of a financial relationship should
be a critical point in disclosure; a small monetary amount would imply less of a potential for bias
than a large one. Yet, while it may seem logical to distinguish the degree of the relationship, there
is a growing body of evidence from the social sciences that shows that behavior can be influenced
regardless of the degree of the relationship. In fact, research into this subject based on 15 articles
and commentaries did not result in any findings that supported the premise that disclosing the
amount of the financial relationship would be an improvement to the process. There does not
appear to be a direct “dose-response” relationship between the amount paid and the degree of
conflict of interest (COI).

In a study examining the impact of conflicts of interest, Cain et al. found that learners may not
discount advice from biased faculty as much as they should when conflicts of interest are disclosed.
They further state that disclosure may even increase bias as it leads some faculty and authors to feel
morally licensed to exaggerate their advice. The ACCME recognizes that disclosure is one step in a
process but not the solution to assuring that educational content in a certified CME activity is valid
and free of commercial bias. To insure the integrity of the content, any conflict of interest,
regardless of size, revealed through disclosure to the CME provider, must be resolved. ACCME
guidance on resolving conflicts states that CME providers must identify safeguards to prevent the
insertion of commercial bias and this goes beyond mere disclosure. Examples of mechanisms that
may be effective in resolving conflict-of-interest include: 1) having faculty/authors content
reviewed by qualified independent reviewers to assure that content is evidence-based and not
biased; 2) limiting the content of a presentation to patho-physiology or mechanisms of disease
without therapeutic recommendations; and 3) substitution of a conflicted faculty member with
another faculty member with no COI related to the content.

Thus, while disclosure is a necessary component of a process to protect the integrity and credibility
of certified CME activities from allegations that financial conflicts are influencing content, it is the
resolution of those conflicts that provide the real safeguards to the system. Requiring additional
disclosure of the size of the financial relationship would result in greatly increasing the
documentation burden for CME providers and faculty as well as confusion on the part of learners
left to evaluate what such information would mean in terms of the content of the CME activity.
Providing an excess of information in a disclosure statement likely leads to a lesser probability that
the disclosure will be read and understood by the learner. Moreover, determining meaningful
specific dollar amounts that correspond to the levels of potential bias is not possible because of the
wide variability in physicians’ perspectives on this issue.

Summary

The ACCME has in place appropriate standards requiring that accredited CME providers not only
disclose conflicts of interest to learners but resolve those conflicts in advance of the certified CME
activity for anyone in a position to control content. It is the resolution of conflicts of interest rather
than the monetary amount that insures that educational content remains free of commercial bias.
There is no evidence to support that specifying the magnitude of conflict, and the increased
documentation that it would present for CME providers and CME faculty, would enable the learner
to better judge the integrity of the material presented.
RECOMMENDATION

Therefore, the Council on Medical Education recommends that the following be adopted in lieu of
Resolution 310 (A-07) and that the remainder of this report be filed.

That our American Medical Association continue to monitor the implementation of the
Accreditation Council for Continuing Medical Education 2004 Standards for Commercial
Support and report to the House of Delegates any major evidence that these requirements
are or are not effective in ensuring the independence of or adversely impact the availability
of continuing medical education. (Directive to Take Action)

Complete references for this report are available from the Medical Education Group.

Fiscal Note: Less than $500