

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)

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

7 8 Background

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

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

32 33 Discussion

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1 The underlying principle in Resolution 310 is that the magnitude of a financial relationship should
2 be a critical point in disclosure; a small monetary amount would imply less of a potential for bias
3 than a large one. Yet, while it may seem logical to distinguish the degree of the relationship, there
4 is a growing body of evidence from the social sciences that shows that behavior can be influenced
5 regardless of the degree of the relationship.¹ In fact, research into this subject based on 15 articles
6 and commentaries did not result in any findings that supported the premise that disclosing the
7 amount of the financial relationship would be an improvement to the process. There does not
8 appear to be a direct “dose-response” relationship between the amount paid and the degree of
9 conflict of interest (COI).

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

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

36 37 Summary

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

1 RECOMMENDATION

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

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6 That our American Medical Association continue to monitor the implementation of the
7 Accreditation Council for Continuing Medical Education 2004 Standards for Commercial
8 Support and report to the House of Delegates any major evidence that these requirements
9 are or are not effective in ensuring the independence of or adversely impact the availability
10 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