

Johns Hopkins School of Medicine
OFFICE OF CONTINUING MEDICAL EDUCATION (OCME)

Appendix A

**Methods/mechanisms for the Resolution or Management
of Conflicts of Interest with Commercial Entities**

Accepted/recommended methods for resolving COI include:

A. Altering financial relationships. Individuals may change their relationships with commercial interests (e.g., discontinue contracted services). This way no duty, loyalty, or incentive remains to introduce commercial bias into the CME content. However, disclosure that such a relationship had existed within the preceding 12 months must still be made to the audience.

B. Altering control over content. An individual's control of CME content can be altered in several ways to remove the opportunity to affect content related to the products and services of a commercial interest. These include the following:

- Choosing someone else to control that part of the content. If a proposed speaker has a conflict of interest related to the content, choose someone else who does not have a relationship to the commercial interests related to the content.

- Change the focus of the CME activity. The CME provider could change the focus of the activity so that the content is not about products or services of the commercial interest that is the basis of the conflict of interest.

- Change the content of the person's assignment. The role of a person with a conflict of interest can be changed within the activity so that it is no longer about products or services of the commercial interest. For example, an individual with a conflict of interest regarding products for treatment of a condition could address the pathophysiology or diagnosis of the condition, rather than therapeutics.

- Limit the content to a report without recommendations. If an individual has been directly funded by a commercial company to perform research, the individual's presentation may be limited to the data and results of the research. Someone else can be assigned to address broader implications and recommendations.

- Limit the sources for recommendations. Rather than having a person with a conflict of interest present personal recommendations or personally select the evidence to be presented, limit the role of the person to reporting recommendations based on formal structured reviews of the literature with the inclusion and exclusion criteria stated ('evidence-based'). For example, the individual could present summaries from the systematic reviews of the Cochrane Collaboration or published guidelines from a national organization.

C. Independent Content Validation – Conflict of interest may be resolved if the CME material is peer reviewed and:

1. All the recommendations involving clinical medicine are based on evidence that is accepted within the profession of medicine as adequate justification for their indications and contraindications in the care of patients. (See Appendix B)

OR

2. All scientific research referred to, reported or used in CME in support or justification of patient care recommendations conforms to the generally accepted standards of experimental design, data collection and analysis.

D. Eliminate CME credit for that specific lecture

E. Proceeding with planned content despite recognized COI: For this to apply it must be determined that the information need exceeds the conflict.

If choice E is chosen from this list, then the Department Chair/Division chief must specifically attest to their review and agreement with that determination

Appendix B Levels of Evidence

These tables are provided as potential sources of levels of evidence. Any of these tables can be utilized at the speakers'/course directors' discretion. If an additional table is utilized, this should be so noted. The appropriate level of evidence would then be added to all slides that include recommendations or conclusions so that the learner explicitly sees the level of best evidence for that specific recommendation/conclusion. Although these tables can be utilized for all lectures/presentations, they are only required to be utilized if COI has been disclosed and this method of resolving that COI has been chosen.

Grades for quality of evidence	
Grade A	Randomized Clinical Trials (RCTs) or similar levels of evidence with consistent results
Grade B	RCTs or similar levels of evidence with inconsistent results or major methodological flaws
Grade C	Data is from observational studies or significant extrapolation is needed from study population to the target population

Grades	Clarity of R/B	Implications
1A	Clear	Strong recommendations can apply to most patients in most circumstances without reservation
1B	Clear	Strong recommendations likely to apply to many patients
1C	Clear	Intermediate strength recommendations likely to apply to many patients
2A	Unclear	Intermediate strength recommendations where action may differ based on circumstances or values
2B	Unclear	Weak recommendations
2C	Unclear	Very weak recommendations

Grade	Definition
A	Good evidence to recommend the action
B	Fair evidence to recommend the action
C	Conflicting evidence so no recommendation can really be made at this time
D	Fair evidence against a clinical action
E	Good evidence against a clinical action
I	Insufficient evidence to make a recommendation

Approved appendices on April 18, 2005 by OCME Advisory Board