

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

**Policy on the Identification and Resolution
of Conflicts of Interest with Commercial Entities
For Educational Planners and Faculty**

Based upon financial disclosure information submitted by faculty and program directors as defined in and required by the OCME *Policy on Disclosure of Relationships between Commercial Entities and Educational Planners*, OCME will identify and resolve conflicts of interests identified for any individual³ who is in a position to control the content of an OCME-accredited CME activity.

In the event of any conflict of interest, OCME will require the following statement to be placed following the financial disclosure statement(s) for all activity faculty: *Johns Hopkins Office of CME has identified and resolved all faculty conflicts of interest regarding this educational activity.*

Identification of Conflicts of Interest

A conflict of interest is defined as when an individual who is in a position to control the content of an OCME-accredited CME activity has both a relevant¹ financial relationship with or interest in a commercial entity² **and** has the opportunity to control the activity's content relevant to the commercial entity's product(s) or service(s). For an educational planner this applies across the spectrum of activities planned as part of a CME activity whereas for the educational faculty this applies only to their specific lecture(s)/presentation(s).

The following factors are to be gauged and considered by the OCME in identifying whether an individual who is in a position to influence the content of an OCME-accredited CME activity has a conflict of interest in regards to the content of the CME activity:

- **The focus and content of the educational activity.** OCME activities that do not focus on or discuss commercial entities' products or services or make clinical recommendations regarding the use or value of those products or services do not represent a conflict of interest for individuals who have financial relationships with or interest in commercial entities. OCME activities that focus on or discuss commercial entities' products or services and/or make clinical recommendations regarding the use or value of those products or services do represent a conflict of interest for individuals who have current/ongoing financial relationships with or interest in those commercial entities whose products are discussed in the educational activity.
- **The individual's role in the educational activity.** Individuals who will be making a clinical recommendation or comparative clinical claims in the educational activity about a class/type of products or services offered by a commercial company with which they have a current/ongoing financial relationship with and/or interest in do have a conflict of interest. Individuals who will not be making a clinical recommendation or comparative claims in the educational activity about a class/type of products or services offered by a commercial company with which they have a current/ongoing financial relationship with and/or interest in do not have a conflict of interest.

- **An individual's past financial relationships with or interests in a commercial entity pertaining to content of the educational activity.** It is the OCME's assertion that an individual's past relationships that have since been discontinued prior to the last 12 months of the individual's role in the CME activity does not make the individual more likely consciously or subconsciously to influence the content of the activity in favor of the commercial entity with whom the individual had a previous relationship or interest. As such, it is OCME's policy that an individual's past financial relationships with or interests in commercial entities that have been discontinued at least a year prior to the individual's role in the CME activity and pertaining to content of the educational activity do not represent a conflict of interest.
- **An individual's past financial relationships with or interests in multiple commercial entities pertaining to the content of the educational activity.** It is OCME's assertion that the fact that an individual had past relationships (the 12 months prior to the last 12 month period) with or interests in **more than one** commercial entity whose products or services are discussed in the educational activity, rather than relationships with or interests in just one commercial company whose products or services are discussed in the activity, makes that individual less likely consciously or subconsciously to influence the content of the activity in favor of one commercial entity with whom the individual has a relationship or interest over another commercial entity with whom the individual also has a relationship or interest for fear of losing or damaging a relationship with one or more commercial companies. As such, it is OCME's policy that an individual's past financial relationships with or interests in multiple commercial entities do not predispose that individual to influence the CME activity in a negative or commercially-biased manner and consequently do not represent a conflict of interest.

The following factors are to be gauged and considered by the OCME in further identifying the level of conflict of interest an individual has and what resolution mechanism is utilized for the person who is in a position to influence the content of an OCME-accredited CME activity and has a conflict of interest in regards to the content of the CME activity.

Level 1 Conflict of Interest

- **An individual's current/ongoing financial relationships with or interests in multiple commercial entities pertaining to the content of the educational activity.** It is OCME's belief that the fact that an individual has current (during the last 12 months) relationships with or interests in more than one commercial entity whose products or services are discussed in the educational activity, rather than relationships with or interests in just one commercial company whose products or services are discussed in the activity, makes that individual less likely to consciously or subconsciously influence the content of the activity in favor of one commercial entity with whom the individual has a relationship or interest over another commercial entity with whom the individual also has a relationship or interest for fear of losing or damaging a relationship with one or more commercial companies. As such, it is OCME's policy that an individual's current/ongoing relationships with or interests in multiple commercial entities are less likely to predispose that individual to influence the CME activity in a negative or biased manner and represent a Level 1 conflict of interest that must be resolved by the Level 1 Conflict of Interest Resolution Mechanism.

An individual assessed as having a Level 1 Conflict of Interest must have that Level 1 Conflict of Interest resolved using the Level 1 Conflict of Interest Resolution Mechanism.

Level 2 Conflict of Interest

- **An individual's current financial relationships with or interests in one commercial entity pertaining to the content of the educational activity.** It is OCME's belief that the fact that an individual has current/ongoing relationships with or interests in one commercial entity whose products or services are discussed in the educational activity may make that individual more likely consciously or subconsciously to influence the content of the activity in favor of the one commercial entity with whom the individual has a relationship or interest. As such, it is OCME's policy that an individual's current/ongoing financial relationships with or interests in one commercial entity pertaining to content of the educational activity represents a Level 2 Conflict of Interest that must be resolved by the Level 2 Conflict of Interest Resolution Mechanism.

An individual assessed as having a Level 2 Conflict of Interest must have that Level 2 Conflict of Interest resolved using the Level 2 Conflict of Interest Resolution Mechanism.

Resolution of Conflicts of Interest

An individual assessed as having a Level 1 Conflict of Interest must have that Level 1 Conflict of Interest resolved using the Level 1 Conflict of Interest Resolution Mechanisms below:

Mechanisms to Resolve Level 1 Conflict of Interest

- All relevant financial disclosure information regarding individuals in a position to influence the content of the educational activity will be disclosed to participants at the beginning of the CME activity. The OCME believe the best way to accomplish this is not only to describe the conflict in course materials but also as a slide (or other visual) embedded in the lecture material. As a facilitation tool a sample slide is provided as an attachment, the conference coordinators have access to the slide set and an electronic version is available on our web site at www.hopkinscme.net.
- The Advisory Board members who peer review the materials will be asked to evaluate for COI. They may subsequently recommend corrective action if deemed appropriate (see Appendix A).
- In cases where the course director, planning committee or the OCME Advisory Board remains concerned about the Level 1 conflict, the individual in a position to control the content of the educational activity may be instructed to reference the best available evidence when planning, preparing, presenting, authoring or reviewing CME activity content. Although any table of levels of best evidence may be utilized Appendix B provides several commonly utilized examples.
- All CME activity participants will be requested to complete an evaluation assessment questionnaire following the activity that contains a question asking them whether they perceived any commercial bias in the activity and, if so, to explain their perception of bias.

An individual assessed as having a Level 2 Conflict of Interest must have that Level 2 Conflict of Interest resolved using the Level 2 Conflict of Interest Resolution Mechanism below:

Level 2 Conflict of Interest Resolution Mechanism

- All relevant financial disclosure information regarding individuals in a position to influence the content of the educational activity will be disclosed to participants at the beginning of the CME activity. The OCME believe the best way to accomplish this is to not only describe the conflict in course materials but also as a slide (or other visual) embedded in the lecture material. As a facilitation tool a sample slide is provided as an attachment and a electronic version is available on our web site at www.hopkinscme.net
- A mechanism for COI resolution taken from the list attached must be utilized and documented (Appendix A).
- All educational activity content planned or prepared by an individual who has been identified as having a conflict of interest, if not already resolved by a mechanism cited in this policy, must be peer-reviewed by two “commercially-disinterested” physicians utilizing a clearly delineated or established peer-review system/process. All requested revisions and alterations to the activity content recommended or requested by the peer-reviewers in order to ensure that the content is accurate, fair & balanced and unbiased must be incorporated into the content. The OCME recognizes that it would rarely be practical for this step to apply to live presentations.
- OCME may request that the course director/planning committee forms for Hopkins faculty be co-signed by departmental chairs. (In the Department of Medicine the divisional directors may sign for the departmental chair.) In signing they will attest that they are not aware of any unreported COI existing for the activity as planned.
- All CME activity participants will be requested to complete an evaluation assessment questionnaire at the conclusion of the activity. The questionnaires must contain questions asking the participants whether they perceived any commercial bias in the activity and, if so, to explain their perception of bias.

The purpose of this policy is not to prevent an individual with relationships with or interests in commercial entities from participating in an educational activity, but to ensure that OCME-accredited CME activities are in the best interest of the public. Deviations from the above policy will be considered on a case-by-case basis by the OCME only in emergent situations or special circumstances.

Definitions

1. “Relevant” financial interests or relationships are defined as receipt of funds (money, gifts, travel, directly purchased stock, etc) by the individual (and his/her spouse, partner or immediate family) in any amount over the last 12 months directly from a commercial interest whose products or services are discussed in or pertain to the content of the educational activity. For purposes of OCME identification and resolution of conflicts of interests, disclosure of “relevant” financial interests or relationships will be further delineated as “past” (any interests or relationships in the 12 months prior to the last 12 months) and “current” (any interests or relationships in place and/or active at the time of the individual’s involvement in the CME activity or in place during the last 12 months) and will be requested from individuals on the Financial Disclosure form.

2. “Commercial interests” are defined as any proprietary entity producing health care goods or services, with the exemption of non-profit or government organizations or non-health care related companies.
3. “Individuals” are defined as persons (and their spouse, partner or immediate family) who are in a position to control the content of the educational activity. Such individuals include, but are not limited to: Editorial positions for CME activities, Planning Committee member, freelance writer, author, JHM employee, contributor, joint sponsor personnel, and vendor.
4. “Direct Grant/Research Funding” is defined as funds that are directly received from a commercial entity by an individual for research or clinical trials and/or educational purposes. Grant/research funds received from commercial entities by a medical institution or medical university/school will not be considered “direct grant/research funding”. Even if these funds are in turn used to pay individuals for research or clinical trials that are part of the individual’s employment with the medical institution or medical university/school. As these will not be considered “direct” funding, they will not need to be disclosed by the individual or to activity participants.
5. Immediate family is defined at a minimum by minor children. The individual filling out the report is permitted to be more encompassing if they believe a potential relevant conflict exists.

Policy approved on April 18, 2005 by OCME Advisory Board.

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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