

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.