

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

Upon receipt of financial disclosure information as defined in and required by the OCME policies on planner, advisory board, and speaker disclosure of relationships with industry, OCME will utilize that information to identify and resolve conflicts of interests posed by any individual¹ who is in a position to control the content of an OCME-accredited CME activity.

Immediately following the financial disclosure statement(s) for all activity faculty, OCME will require that the following statement be placed: *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 or his/her immediate family² have both a relevant³ financial relationship with or interest in a commercial entity⁴ **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 to each of their specific lectures/presentations.

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 with 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

¹ "Individual" is defined as a person (and their spouse, partner or immediate family) who is 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.

² "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.

³ "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.

⁴ "Commercial entity" are defined as any proprietary entity producing health care goods or services used on or by patients, with the exemption of non-profit or government organizations or non-healthcare related companies.

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.

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 related to the content of the CME activity.

Conflict of Interest Scenarios and Resolution

- **An individual has never had and presently does not have a financial relationship with or interests in a commercial entity related to the content of the educational activity.** It is the OCME's assertion that no relevant conflict of interest exists
Resolution: Disclosure in advance of the learning shall be made that states that the individual has no relevant financial interest to disclose. In addition, the activity registrants will be surveyed for their perception that commercial bias existed.
- **An individual's past financial relationships with or interests in a commercial entity related 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 year 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 relationship or interest. This is true whether or not the past relationship(s) was with a single or multiple commercial entity(ies).
Resolution: Disclosure in advance of the learning shall be made that states that the individual has no relevant financial interest to disclose. In addition, the activity registrants will be surveyed for their perception that commercial bias existed.
- **An individual's current/ongoing financial relationships with or interests in multiple commercial entities related to the content of the educational activity.** It is OCME's belief that the fact that an individual has current 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 do not predispose that individual to influence the CME activity in a negative or biased manner.

Resolution: Disclosure in advance of the learning shall be made that states that the individual has relevant financial interests. The disclosure will include the name of the commercial entities and the nature of the relationships. In addition, the activity registrants will be surveyed for their perception that commercial bias existed.

- **An individual's current financial relationships with or interests in one commercial entity related 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.

Resolution: Resolution will require several processes. Disclosure in advance of the learning shall be made that states that the individual has a relevant financial interest. The disclosure will include the name of the commercial entity and the nature of the relationship. In addition, a mechanism for resolution of potential conflict must be utilized from the approved list in Appendix A. In addition, all material should be fully referenced and any and all clinical recommendations should carry a level of best evidence grade (see Appendix B). Finally, the activity registrants will be surveyed for their perception that commercial bias existed.

- **An individual is an employee of a commercial entity.** Engaging an employee of a commercial entity to speak at an accredited activity is actively discouraged. It is OCME's belief that the fact that an individual is employed by a commercial entity makes it likely, that consciously or subconsciously, the content of the activity will be influenced in favor of that commercial entity.

Resolution: Resolution will require several processes. Proposed speakers that are commercial entity employees shall submit their disclosure forms at the time of the application. Application approval will not be completed until these are reviewed and the management plan established. Disclosure in advance of the learning shall be made that states that the individual has a relevant financial interest. The disclosure will include the name of the commercial entity and the nature of the relationship. In addition, at a minimum, a mechanism for resolution of potential conflict must be utilized from the approved list in Appendix A. It is likely that several mechanisms will be required such as the speaker should not make any clinical recommendations related to the products or services provided by that commercial entity AND presentation material will receive peer review well in advance of the activity (> 30 days). In addition, all material shall be fully referenced and any and all recommendations shall carry a level of best evidence grade (see Appendix B). Finally, the activity registrants will be surveyed for their perception that commercial bias existed.

Resolution Information

- 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 believes the best way to accomplish this is not only to describe the conflict in course materials but also as a slide embedded in the lecture material. As a facilitation tool a sample slide is provided as an attachment and an electronic version is available on our web site at www.HopkinsCME.edu .
- Course director/planning committee forms for Hopkins faculty will need to be cosigned by departmental chairs. In the Department of Medicine the divisional directors can sign for the departmental chair. In signing they will attest that they do not know of any unreported COI existing for the activity as planned. If the planning committee member is not a Hopkins faculty member then the Director of CME will review the forms for conflict. The Advisory Board members (a form of peer review) that review the material will also be asked to evaluate for COI.
- 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.
- In cases where the course director, planning committee or the OCME Advisory Board remains concerned about conflict despite there being no risk of 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.
- A full list of possible means of resolving conflict is attached (Appendix A).

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.

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

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