

Johns Hopkins University 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**

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

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 or in the upcoming 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, marketing, re-selling, or distributing health care goods or services used on or by patients, with the exemption of non-profit or government organizations or non-healthcare related companies.

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.

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. Please note that this resolution guideline does not apply if all of the commercial entities are the only financial supporters of the activity (see example below).

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's current financial relationships with and only with or interests in and only in all commercial entities supporting the CME activity 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 all the commercial entities 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 commercial entities 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 relevant financial interests. The disclosure will include the names of the commercial entities and the nature of the relationships. 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.

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 CME content. However, disclosure that such a relationship had existed within the preceding 12 months must still be made.
- 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:
 - a. 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.
 - b. 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.
 - c. 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.
 - d. 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.
 - e. 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:
 - a. 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
 - b. 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.
 - a. The Department Chair/Division chief must specifically attest to their review and agreement with this 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