



**Saint Louis University School of Medicine
Office of Continuing Medical Education**

POLICY ON FULL DISCLOSURE FOR CME ACTIVITIES

BACKGROUND

This policy on full disclosure is designed to permit the institution to pursue its academic and educational missions with regard to continuing medical education (CME) without undue influence by any individuals or groups associated with the CME activities. It is recognized that faculty and staff from Saint Louis University School of Medicine and from other institutions may enter into financial or other materially beneficial relationships with commercial organizations. It is important that CME content be based on learner needs through identified gaps and not be biased by commercial or marketing interests.

A variety of financial relationships between an individual and a commercial organization may raise the issue of conflict in a CME activity. Financial relationships are defined as those relationships in which the individual benefits by receiving a salary, royalty, intellectual property rights, consulting fee, honoraria, ownership interest (e.g. stocks, stock options, or other ownership interest, excluding diversified mutual funds), or financial benefit. Financial benefits are usually associated with roles such as employment, management position, independent contractor (including contracted research, which includes research funding where the institution gets the grant, manages the funds, and the individual is the principal or named investigator), consulting, speaking and teaching, membership on advisory committees or review panels, board membership, and other activities for which remuneration is received or expected. Relationships of the individual involved in the CME activity: (1) include those of a family member (including a spouse or partner) and (2) do not have a minimum dollar amount for them to be considered significant since inherent in any amount is the incentive to maintain or increase the value of the relationship (within 12 months prior to the activity/or planning as applicable).

Bias in CME activities may include overstating the performance of a company's product, omitting information about products of competing companies, or, more subtly, simply emphasizing a company's product so that the CME participants become most familiar with it.

Although a conflict of interest may create the potential to bias a presentation, it is accepted that most professionals associated with CME do not knowingly bias information. They recognize the conflicts of interest and put their reputations, their institutions' reputations, and their position of trust ahead of personal gain from their relationships with a commercial organization.

More difficult is the increasing concern that commercial relationships may change an individual's presentation without the presenter recognizing the bias. Hence, the appearance of bias is an equally important concern, as the mere appearance of a conflict of interest may cast doubt on the objectivity of a presentation and undermine public trust. Full disclosure of conflicting or potentially conflicting interest has been advanced as the primary and usual means to protect the integrity of CME activities.

For these reasons and to meet the requirements of the *2004 Updated Accreditation Council for Continuing Medical Education (ACCME) Standards for Commercial Support: Standards to Ensure the Independence of CME Activities*, the following policy is established.



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GUIDING PRINCIPLE:

The **perception** of a conflict of interest is as important as an actual conflict. Any relationship that exists between an individual and a commercial organization that suggests or implies a financial or contractual relationship or one that if brought to public attention would in any way diminish the reputation of the individual, the institution, or the commercial organization should be reported to the institution sponsoring the CME activity and to the audience participating in the CME activity. In addition, teachers/authors will be expected to offer education that is objective, balanced, and scientifically rigorous in compliance with the *2004 Updated ACCME Standards for Commercial Support*.

POLICY:

1. While recognizing the valuable assistance of commercial organizations in the provision of CME activities, it is understood that this support in no way entitles the supporting company to select speakers or content.
2. It is recognized that faculty and staff participation in CME activities may benefit both the individual and the institution. However, these individuals should carefully monitor their level of support from and participation in commercially-supported CME activities. Regular CME with a single commercial supporter may raise concern about the impartiality of the teacher/author, planning committee member, or activity director. Similarly, extensive participation in commercially-supported CME activities may reflect adversely on the individual's motives and impartiality and may conflict with commitment of their duties as an educational institution's employee.
3. Activity directors, planning committee members, teachers/authors, and any others planning or participating in CME activities shall disclose to the Saint Louis University School of Medicine Continuing Medical Education (SLU CME) (or its chosen educational partner) any significant, relevant financial relationships between themselves and commercial organizations. The ACCME defines "relevant" financial relationships as financial relationships in any amount occurring within the past 12 months that create a potential conflict of interest. This disclosure will be primarily accomplished by the completion of a *Full Disclosure Statement* (appended), which will be shared with the audience.
4. All *Applications for Approval of a CME Activity and AMA PRA Category 1 Credit* submitted to the SLU CME for review must include all planning committee/activity directors' completed *Disclosure Statements*. Disclosures for speakers/authors must be received at least 15 days prior to the course date for evaluation and resolution of conflicts of interest. (Optimal time for review and COI resolution is 30 days prior to the activity in order to give time for presentations to be corrected if applicable). All planners of content must disclose during the planning phase by attaching completed disclosure forms and validation of content forms to the application.
5. An individual who refuses to disclose relevant financial relationships will be disqualified from being an activity director, planning committee member, or speaker/author of CME and cannot have control of, or responsibility for, the development, management, presentation, or



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evaluation of the CME activity.

6. The content or format of a CME activity and its related materials must promote improvements or quality in healthcare and not a specific proprietary business interest/commercial interest. All CME activities must be compliant with the ACCME content validation statements which state:
 1. All the recommendations involving clinical medicine in a CME activity must be based on evidence that is accepted within the profession of medicine as adequate justification for their indications and contraindications in the care of patients.
 2. All scientific research referred to, reported or used in CME in support or justification of a patient care recommendation must conform to the generally accepted standards of experimental design, data collection and analysis.
 3. Providers are not eligible for ACCME accreditation or reaccreditation if they present activities that promote recommendations, treatment, or manners of practicing medicine that are not within the definition of CME, or known to have risks or dangers that outweigh the benefits or known to be ineffective in the treatment of patients. An organization whose program of CME is devoted to advocacy of unscientific modalities of diagnosis or therapy is not eligible to apply for ACCME accreditation.
7. Educational materials that are part of a CME activity such as slides, abstracts, and handouts cannot contain any advertising, trade names without generic names, or product-group advertising.
8. Presentations must give a balanced view of therapeutic options. Use of generic names will contribute to this impartiality.