

# Continuing Medical Education (CME) & Ethical Concerns for Orthopaedic Review Course

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Notes

During the 1990's there has been much discussion and debate concerning conflicts of interest and ethics in medicine. This debate has moved into the area of continuing medical education. So much so, the FDA has investigated CME activities and drafted concept papers concerning commercial support with regards to educational and scientific medical meetings.

As a response to the FDA concerns the Accreditation Council for Continuing Medical Education (ACCME) adopted standards for all accredited sponsors in 1992.

Since 1992 all CME activities must meet the standards established. It is the opinion of this author that most orthopaedic CME courses not only do not meet these standards, but they do not even understand them.

## Standards

### 1. General Responsibilities of Accredited Sponsors

Accredited sponsors are responsible for the content, quality and scientific integrity of all CME activities certified for credit. Identification of continuing medical education needs, determination of educational objectives, and selection of content, faculty, educational methods and materials is the responsibility of the accredited sponsor. Similarly, evaluation must be designed and performed by the accredited sponsor.

#### *a. Basic Design Requirements for CME Activities*

In designing educational activities, the accredited sponsor must assure that the activities have the following characteristics: They must be free of commercial bias for or against any product; If the activities are concerned with commercial products, they must present objective information about those products, based on scientific methods generally accepted in the medical community.

#### *b. Independence of Accredited Sponsors*

The design and production of educational activities shall be the ultimate responsibility of the accredited sponsor. Commercial supporters of such activities shall not control the planning, content or execution of the activity. To assure compliance with this standard, the following requirements must be adhered to.

##### *(1) Assistance with Preparation of Educational Materials*

The content of slides and reference materials must remain the ultimate responsibility of the faculty selected by the accredited sponsor. A commercial supporter may be asked to help with the preparation of conference related educational materials, but these materials shall not, by their content or format, advance the specific proprietary interests of the commercial supporter.

##### *(2) Assistance with Educational Planning*

An accredited sponsor may obtain information that will assist in planning and an educational activity from any outside source whether commercial or not. However, acceptance by an accredited sponsor of advice or services concerning speakers, invitees or other educational matters, including content, shall not be among the conditions of providing support by a commercial organization.



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## Notes

### (3) *Marketing CME Activities*

Only the accredited sponsor may authorize a commercial supporter to disseminate information about a CME activity to the medical community. However, the content of such information is the responsibility of the accredited sponsor, and any such information must identify the educational activity as produced by the accredited sponsor.

### (4) *Activities Repeated Many Times*

Accredited sponsors that offer commercially supported educational activities that repeat essentially the same information each time they are given, must demonstrate that every iteration of that activity meets all of the Essentials and Standards.

### (5) *Educational Activities or Materials Prepared by Proprietary Entities*

When accredited sponsors offer educational activities consisting of concepts or materials prepared by proprietary entities, such activities must adhere to the Essentials and Standards in all respects, especially with regard to the provisions concerning the independence of the accredited sponsor in planning, designing, delivering, and evaluating such activities.

## 2. Enduring Materials

The accredited sponsor is responsible for the quality, content, and use of enduring materials for purposes of CME credit. (For the definition, see ACCME “Standards for Enduring Materials.”)

## 3. Identifying Products, Reporting on Research, and Discussing Unlabeled Uses of Products

### a. *Generic and Trade Names*

Presentations must give a balanced view of therapeutic options. Faculty use of generic names will contribute to this impartiality. If trade names are used, those of several companies should be used rather than only that of a single supporting company.

### b. *Reporting Scientific Research*

Objective rigorous, scientific research conducted by commercial companies is an essential part of the process of developing new pharmaceutical or other medical products or devices. It is desirable that direct reports of such research be communicated to the medical community. An offer by a commercial entity to provide a presentation reporting the results of scientific research shall be accompanied by a detailed outline of the presentation which shall be used by the accredited sponsor to confirm the scientific objectivity of the presentation. Such information must conform to the generally accepted standards of experimental design, data collection and analysis.

### c. *Unlabeled Uses of Products*

When an unlabeled use of a commercial product, or an investigational use not yet approved for any purpose is discussed during an educational activity, the accredited sponsor shall require the speaker to disclose that the product is not labeled for the use under discussion or that the product is still investigational.

## 4. Exhibits and Other Commercial Activities

### a. *Exhibits*

When commercial exhibits are part of the overall program, arrangements for these should not influence planning or interfere with the presentation of CME activities. Exhibit placement should not be a condition of support for a CME activity.



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## Notes

*b. Commercial Activities During Educational Activities*

No commercial promotional materials shall be displayed or distributed in the same room immediately before, during, or immediately after an educational activity certified for credit.

*c. Commercial Supporters at Educational Activities*

Representatives of commercial supporters may attend an educational activity, but may not engage in sales activities while in the room where the activity takes place.

## 5. Management of Funds from Commercial Sources

*a. Independence of the Accredited Sponsor in the Use of Contributed Funds*

The ultimate decision regarding funding arrangements for CME activities must be the responsibility of the accredited sponsor. Funds from a commercial source should be in the form of an educational grant made payable to the accredited sponsor for the support of programming. The terms, conditions and purposes of such grants must be documented by a signed agreement between the commercial supporter and the accredited sponsor. All support associated with a CME activity, whether in the form of an educational grant or not, must be given with the full knowledge and approval of the accredited sponsor. No other funds from a commercial source shall be paid to the director of the activity, faculty, or others involved with the supported activity.

*b. Payments to Faculty*

Payment of reasonable honoraria and reimbursement of out-of-pocket expenses for faculty is customary and proper.

*c. Acknowledgment of Commercial Support*

Commercial support must be acknowledged in printed announcements and brochures, however, reference must not be made to specific products.

*d. Accountability for Commercial Support*

Following the CME activity, upon request, the accredited sponsor should be prepared to report to each commercial supporter, and other relevant parties, information concerning the expenditure of funds each has provided. Likewise, each commercial supporter should report to the accredited sponsor information concerning their expenditures in support of the activity.

## 6. Commercially Supported Social Events

Commercially supported social events at CME activities should not compete with, nor take precedence over the educational events.

## 7. Policy on Disclosure of Faculty and Sponsor Relationships

*a. Disclosure Policy for All CME Activities*

An accredited sponsor shall have a policy requiring disclosure of the existence of any significant financial interest or other relationship a faculty member or the sponsor has with the manufacturer(s) of any commercial product(s) discussed in an educational presentation. All certified CME activities shall conform to this policy.

*b. Disclosure in Conference Materials*

CME faculty or sponsor relationships with commercial supporters shall be disclosed to participants prior to educational activities in brief statements in conference materials such as brochures, syllabi, exhibits, poster sessions, and also in post-meeting publications.



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## Notes

### *c. Disclosure for Regularly Scheduled Activities*

In the case of regularly scheduled events, such as grand rounds, disclosure shall be made by the moderator of the activity after consultation with the faculty member or a representative of the supporter. Written documentation that disclosure information was given to participants shall be entered in the file for that activity.

## **8. Financial Support for Participants in Educational Activities**

### *a. Expenses of Non-Faculty Attendees*

In connection with an educational activity offered by an accredited sponsor, the sponsor may not use funds originating from a commercial source to pay travel, lodging, registration fees, honoraria, or personal expenses for non-faculty attendees. Subsidies for hospitality should not be provided outside of modest meals or social events that are held as part of the activity.

### *b. Scholarships for Medical Students, Residents and Fellows*

Scholarship or other special funding to permit medical students, residents, or fellows to attend selected educational conferences may be provided, as long as the selection of students, residents or fellows who will receive the funds is made either by the academic or training institution, or by the accredited sponsor with the full concurrence of the academic or training institution.

In addition to CME activities there is growing concern with regards to the selection of total joint implants. Currently there are a variety of implants on the market, some with excellent results, others with unacceptable short term failure rates. Failed total joint arthroplasty has significant consequences, particularly for the patient, but also for the healthcare community in terms of economic costs.

There are many factors that affect the selection of one implant over another. We are seeing pressure by hospital purchasing departments to use products on contracts regardless of clinical outcomes or surgeon support.

Industry has established patient/implant matching guidelines without any clinical outcomes to support these marketing activities.

Increased competition has activated questionable practices like offering surgeons the opportunity to take trips to recreational locations often paid for by local sales agents. There are also reports of surgeons being paid per case by these agents. Often surgical experience and implant design features are at the bottom of the list of items influencing the product selection of implants used.

There is concern with current practices of the orthopaedic industry directly sponsoring non-CME courses. Such courses are regarded by the FDA as promotional programs and as such are subject to the same labeling laws as all medical device promotional material.

This means that only approved medical indications may be promoted (discussed, presented). CME sponsored courses are allowed to discuss off-labeled indications, as long as there is disclosure of status. Increased non-CME sponsored courses by industry could bring about increased FDA monitoring and regulations.

In addition to FDA concerns, the Internal Revenue Service has taken a dim view on deductions by surgeons attending NON-CME courses, especially courses located at resort settings. One should be very careful in declaring business deductions for these type of meetings.

Conclusion: There is no question that the individual medical societies (AMA, AAOS, ACCME) are establishing ethical guidelines for their members. However, there are no established ethical guidelines for the orthopaedic industry. The best standard to use is disclosure. Reluctancy to disclose a relationship would suggest it is questionable.