

Joint Implant Surgery and Research Foundation

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Timothy McTighe, Ph.D. (hc), Executive Director, Chagrin Falls, OH
Guy T. Vise Jr., M.D., Chairman, Jackson, MS
Charles O. Bechtol, M.D., Founder. Los Angeles, CA

Recently there has been much discussion and debate concerning conflicts of interest and ethics in medicine. This debate has now moved into the area of continuing medical education. So much so that the FDA was seriously investigating CME activities and drafted a concept paper concerning commercial support activities in scientific or educational context in October 1991 and more recently November of 1992.

The Accreditation Council for Continuing Medical Education (ACCME) intervened and was successful in pointing out to the FDA that a governing body was already in place concerning CME activities. However, the FDA did instruct the ACCME that if they change their guidelines concerning commercial support of CME activities to standards they would basically back-off from and official involvement.

Effective May 4, 1992 the Accreditation Council for Continuing Medical Education has adopted new standards for all ACCME accredited sponsors.

The Joint Implant Surgery and Research Foundation is an accredited sponsor and has conducted continuing education activities since its formation in 1971.

Accredited sponsors often receive financial and other support from non-accredited organizations. Such support can contribute significantly to the quality of CME activities. The purpose of these new standards is to describe appropriate behavior of accredited sponsors in planning, designing, implementing and evaluating certified CME activities for which commercial support is received.

The following topics will be highlighted in this paper:

1. General Responsibilities of Accredited Sponsors – The accredited sponsors are responsible for the content, quality, and scientific integrity of all ME 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.

2. Enduring Materials – The accredited sponsors are responsible for the quality, content, and use of enduring materials for purposes of CME credit.

3. Identifying Products, Reporting on Research and Discussing Un-Labeled Use of Products – Presentations must give a balanced view of options. Faculty use of generic names will contribute to the impartiality. If trade names are used, those of several companies should be used rather than only that of a single supporting company. Reporting scientific research offered by a commercial entity to provide a presentation reporting the results of scientific research shall be accompanied by a detailed outline in the presentation which shall be used by the accredited sponsor to confirm the scientific objectivity of the presentation. Concerning unlabeled uses of products or an investigational use not yet approved for any purpose is discussed during the 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 – When commercial exhibits are part of the overall program, arrangements for these should not influence planning or interfere with presentation of CME activities. Exhibit placement should not be a condition of support for CME activity. No commercial, promotional material shall be displayed or distributed in the same room immediately before, during, or immediately after an educational activity certified for credit. Representatives of commercial supporters may attend an educational activity but not engage in sales activities while in the room where the activity takes place.

5. Management of Funds from Commercial Sources – 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 single agreement between the commercial supporter and the accredited sponsor. No other funds from a chimerical source shall be paid to the director of the selectivity. Payment of reasonable honoraria and reimbursement of out of pocket expenses for faculty is customary and proper. Commercial support must be acknowledged in printed announcements and brochures. However, reference must not be made to specific products.

6. Commercially Supported Social Event – Should not compete with nor take precedence over the educational events.

7. Policy On Disclosure of Faculty and Sponsor Relationships – An accredited sponsor shall have a policy disclosure of the existence of any significant financial interest or other relationship a faculty member or a sponsor has with the manufacturer of any commercial products discussed in an educational presentation.

8. Financial Support for Participants in Educational Activities – 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. Scholarships 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.

Conclusion: there is no question that commercial support can contribute significantly to the quality of CME activities. However, there have been abuses in the past and the ACCME new standards will help to assure scientific integrity of all CME activities that receive certification for credit.