

CME BRIEFING

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UNDERSTANDING CONTINUING MEDICAL EDUCATION: THE ROLE OF THE PHARMACEUTICAL COMPANY REPRESENTATIVE

Recently, there has been some discussion among accredited providers about the appropriate involvement and conduct of pharmaceutical company representatives in certified continuing medical education (CME) activities.

This article will try to simplify the sometimes complex issues.

Independent CME Versus Promotional Education: Some Definitions

Although independent CME programs and promotional education share a common goal—to improve the quality of medical care and patient health via physician education—they employ different strategies. The following definitions will help you distinguish between the two types of activities:

Promotional education is medical communication designed to market approved products. Promotional activities are used to describe product features and benefits, create interest in ongoing phase IV trials, and promote wider acceptance and increased prescriptions by physicians. Promotional programs are not “certified,” that is, physicians who participate cannot obtain CME credit. The content of promotional education must be reviewed by the underwriting company for accuracy and fair balance and is limited by FDA regulations that prohibit discussion of off-label use.

An independent CME activity is medical education that may be certified and designed to keep physicians informed of clinically relevant issues. CME activities serve the purpose of medical training through dissemination of new medical information—specifically topics that will expand the physician’s

clinical understanding and skills. Independent CME programs often provide participating physicians with credit hours that satisfy certain professional or hospital requirements. Unlike product-based promotion, CME content is broader and more balanced, and it may include discussion of off-label use for approved and unapproved products.

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Recognizing the Potential of CME
Despite all the resources available in our information-saturated society, ensuring that doctors fulfill their professional commitment to a “lifetime of learning” is not an easy task. Scientifically rigorous medical education that meets the stringent

guidelines set forth by the Accreditation Council for Continuing Medical Education (ACCME), other accrediting bodies, and the FDA fills a great need. By funding such programs, pharmaceutical companies are contributing to a physician’s “lifetime of learning.”

It is important for the representatives of a pharmaceutical company to understand their roles with respect to both types of activities. Violations of CME rules and restrictions can have very serious consequences for pharmaceutical companies and CME providers, as well as for the hospitals and physicians being served.

The Representative’s Role and What to Expect
Although some of the guidelines regulating CME activity may seem arbitrary, they have been established by the ACCME to protect the quality and integrity of independent learning and to allow CME to be funded by pharmaceutical firms, yet not be regulated as promotion and advertising.

ing events or a play. Moreover, any social activities connected with CME must be planned, approved, and paid for by the CME sponsor. The grantors cannot organize separate social events in conjunction with CME meetings.

Q: Can pharmaceutical company representatives be the sole source of audience generation for a certified CME activity?

A: No. However, the accredited provider often will provide grantor representatives the opportunity to *assist* in audience generation. Care must be taken, and any audience generation devices (invitational brochures or posters) must be approved by the accredited provider prior to use.

Q: May pharmaceutical company representatives pay the registration fee so physicians can attend a CME event “free of charge”?

A: No. Payment of a physician’s fee violates the FDA Draft Policy Statement and the ACCME Standards for Commercial Support, and it would place the individual physician in the position of violating the AMA’s Opinions on Gifts to Physicians from Industry and Ethical Issues in Medical Education.

Q: May pharmaceutical company representatives obtain the names and addresses of physicians who attend a CME event?

A: The FDA Draft Policy Statement prohibits drug manufacturers from mailing unsolicited materials to participants in CME events. Physicians attending a CME event do not expect, and may not want, a sales call as a result of their attendance at a conference. Collecting names and addresses for future marketing campaigns undermines the

independence and purpose of the CME activity in question. Although requesting a physician’s name or address following a meeting is not technically a violation of the regulations, it certainly violates the intent of a CME program and may dampen a physician’s enthusiasm for attending future CME events funded by the grantor company. ~

The resources used for this article are:

- FDA Draft Policy Statement on Industry Supported Scientific and Educational Activities (November 1992)
- ACCME Standards for Commercial Support of Continuing Medical Education
- Hypothetical Questions and Answers on the ACCME Standards for Commercial Support of CME
- Hypothetical Questions and Interpretive Answers on the AOA CME Quality Requirements with a Focus on the Uniform Guidelines for Commercial Support for Accrediting Agencies
- Council on Ethical Judicial Affairs of the AMA, Opinion 8.061, Gifts to Physicians from Industry and Opinion 9.011, Continuing Medical Education

For more information about these documents, contact the following organizations:

- AMA, Division of CME, phone 312-464-4671
- ACCME, phone 312-464-2500
- FDA, Division of Drug Marketing, Advertising, and Communications, phone 301-827-2828
- AOA, Division of CME, phone 312-280-5800

CME DO'S AND DON'TS

The following chart summarizes some general guidelines about what representatives of pharmaceutical companies may and may not do when they are involved in CME activities.

Representatives May	Rationale
Provide <i>written</i> input, when requested by the accredited provider, for faculty names, site suggestions, and local market information	Heightens the logistical appeal and drawing power for audience generation by using the special knowledge that marketing representatives have about local conditions
Assist in the audience generation of physicians if requested by the accredited provider	Helps reach those most interested in or in need of the activity
Attend as an <u>observer</u> (if permitted by the accredited provider)	Strengthens the representative's understanding of therapeutic area; lets companies hear clinical concerns of physicians in a nonmarketing context
Provide postmeeting input to the accredited provider for future activities	Helps identify information that can be used in assessing current programs and planning new activities

Representatives May Not	Rationale*
Contact faculty directly about speaking commitments, logistical details, or lecture content	Program content and logistics can only be arranged by the accredited provider; representative must be careful not to create a perception of influencing the faculty
Conduct selling or distribute sales or product literature at a CME conference	This is a direct violation of CME goals (which are educational, not promotional), the Standards for Commercial Support, and the FDA Draft Policy Statement
Participate in question-and-answer session or group discussion	CME activities are for the express purpose of physician education, not indirect promotion, which may arise from grantor representative participation
Escort speakers to and from an activity, entertain them before or after the meeting, or provide gifts	This could instill a sense of obligation on the part of the speaker toward the grantor company, rather than the accredited sponsor of the activity. It <u>creates an appearance of undue influence</u> .

*** The fundamental rationale behind all these restrictions is that the FDA is extremely wary about the potential (or even the appearance of such potential) for a pharmaceutical company to attempt to control or influence the content of a CME program. As mentioned previously, violations of CME rules have serious consequences for the funding companies and the sponsor-providers of CME programs.**

CME FAQ

Answers to the most frequently asked questions about CME

CME CONTENT

Q: Can product brand names be part of the title of a CME activity if there are no competing products on the market?

A: No. The goal of CME is nonpromotional education; using product names is a clear signal of promotional intent. Generic names are to be used in lecture discussions except in those cases where the name is not generally recognized—and in that case, brand-name and generic references must be stated.

Q: Pharmaceutical company representatives cannot talk with physicians about the product or therapy under discussion during the CME lecture, but can the representatives mention other products not related to the CME activity?

A: No. Any type of detailing immediately before, during, or after a CME lecture is strictly forbidden. Sales activity undermines the perception and value of the CME learning experience in the physician's mind.

CME LOGISTICS

Q: Are restaurants appropriate settings for certified CME activities?

A: That depends—if a local facility has appropriate decor and space (ie, a private room) that would be conducive to the conduct of an educational meeting, it might be acceptable. These activities are best conducted at local hotels or conference centers that are specifically equipped for the conduct of professional meetings. Site selection takes into account a number of factors, including space; audiovisual equipment; food and beverage resources; and common sense—naturally, a local bar/lounge would not be an appropriate setting for CME! In any case, it is the accredited provider who is responsible for the final selection.

Q: May alcohol be served before, during, or after a CME event?

A: This is a question that concerns appearance and propriety. In general, it is preferable not to serve alcohol at any speaker program, particularly a certified CME activity. It tends to send the wrong

signal—that the goal of the event is more social/recreational than educational.

Q: If a CME program is held at a local hotel or restaurant, can the pharmaceutical company representative offer to help with arrangements or pay part of the bill?

A: No. All CME logistical arrangements and disbursement of funds must be handled by the accredited provider. However, input from grantor representatives is welcome, provided such input is given in writing and in compliance with CME guidelines.

Q: May a physician's spouse be invited to attend a CME dinner meeting?

A: No. The concern here is twofold. First, this is a CME event where an extraneous guest might create the perception that the activity is more social than educational. Second, the ACCME Standards for Commercial Support require that grant funds be used only in support of the educational activity and the registrants for that activity. Inviting a spouse violates the purpose and the funding intent of the Standards.

Q: When activities take place on multiple days, may a physician bring his or her spouse?

A: In situations such as this, the accredited provider often will have an optional guest fee, which is paid by the registrant, to fund that portion of the activities in which guests will participate.

PHYSICIAN-REPRESENTATIVE CONTACTS

Q: Is it acceptable for the pharmaceutical company providing a CME grant to provide dinner cruises, theater or sports tickets, or other social amenities to the lecture participants before or after a CME lecture?

A: The American Medical Association's (AMA's) Guidelines on Gifts to Physicians from Industry stipulate that social events planned in conjunction with a CME activity should be modest so that the CME activity is not overshadowed. The events should also be conducive to the discussion and exchange of ideas, which clearly precludes sport-