

## MEMO

**Sent via ACPE CE Provider Listserve on February 8, 2005**

Over the past three years, a tremendous amount of attention has been placed on the role of the pharmaceutical and biomedical device industry in continuing education. The following guidance documents have been released:

- a. PhRMA (Pharmaceutical Research and Manufacturers of America) Code of Interactions with Healthcare Professionals (2002)
- b. AdvaMed (Advanced Medical Technology Association) Code of Ethics on Interactions with Healthcare Professionals (2004)
- c. Updated ACCME (Accreditation Council for Continuing Medical Education) Standards for Commercial Support (2004)
- d. Office of the Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers (2003)

The guidance from the Office of Inspector General of the United States (OIG) includes a Compliance Program Guidance for Pharmaceutical Manufacturers which includes recommended restrictions in regard to continuing education (CE) programs sponsored by manufacturers. A manufacturer that maintains any influence over the subject matter of such programs or the presenters, or provides funding for attendees or other incentives with respect to the attendance of the CE program potentially could be subjected to liability under various federal statutory provisions. While these guidelines provide a safe harbor for manufacturers, strict compliance essentially relegates manufacturers solely to providing unencumbered educational grants to CE providers.

The ACPE Criteria for Quality require the provider to control the content speakers or authors of a CE program. The OIG Guidelines provide that the manufacturer, with regard to continuing education, should have no control over the content or speakers/authors of CE programs. It follows that a manufacturer cannot meet both the ACPE criteria and the OIG Guidelines.

In the past, ACPE has accredited certain pharmaceutical and biomedical device manufacturers as continuing education providers which, on paper, have met the *ACPE Criteria for Quality and Interpretive Guidelines*. However, ACPE, in carrying out its responsibilities to the boards, the profession and the public, must now accredit only those providers who are in compliance with ACPE criteria and the OIG guidelines. After consultation with legal counsel, the ACPE Board of Directors approved the following at the January 2005 meeting:

1. Commencing February 1, 2005, ACPE will not accept applications from pharmaceutical and biomedical device manufacturers seeking accreditation as providers of continuing education.
2. Effective July 1, 2005, ACPE will not recognize pharmaceutical and biomedical device manufacturers as accredited providers. (This timeframe was chosen to allow the organizations to complete any continuing education programs presently planned and permit ACPE to give adequate notice to these providers of its new policies in respect to the accreditation of manufacturers as CE providers). Organizations with a commercial interest and any proprietary entity producing health care goods or services, with the exception of nonprofit or government organizations, and non-health care related companies, will not be eligible for ACPE accreditation status. Furthermore, any organization with a commercial interest will not be able to engage in the co-sponsorship of relationship with an ACPE accredited provider.

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As a result, any statement of credit issued by a pharmaceutical or medical device manufacturer after June 30, 2005 will not be valid evidence of completion of ACPE accredited continuing education. Manufacturers and ACPE will both be making efforts to communicate this action to all stakeholders, including pharmacists seeking accredited continuing education. Manufacturers still retain the ability to provide educational grants to accredited providers within the confines of the OIG Guidelines.

ACPE has contacted all the accredited providers, which it knows to be pharmaceutical or medical device manufacturers and informed them directly of the Board's decision. Pharmaceutical or medical device manufacturers, who have not been contacted by ACPE, need to contact ACPE as soon as possible to ensure compliance with the Board's action.

If you have any questions regarding the above, please contact the ACPE office.

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ACPE was founded in 1932 as the American Council on Pharmaceutical Education

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