



## Preamble to the ACCME Standards for Commercial Support<sup>SM</sup>

### *Standards to Ensure Independence in CME Activities<sup>SM</sup>*

**Purpose of CME.** The purpose of Continuing Medical Education (CME) is to facilitate life-long learning among physicians so that their practices may reflect the best medical care for their patients. The goal of CME is to help physicians enhance their performance in practice. All involved in the CME enterprise – educators, meeting planners, faculty, authors, speakers, accredited providers, supporters, and the physician learners themselves – are responsible for fulfilling this purpose and this goal.

**Commercial bias.** When ACCME-defined commercial interests<sup>1</sup> contribute funds and services for the development of CME activities, it is considered commercial support. Commercial support has significantly enhanced the ability of the CME enterprise to fulfill its purpose. However, commercial support has the potential to introduce commercial bias that threatens the integrity of the CME enterprise. When individual's have financial relationships with commercial interests and are in a position to control the content of CME, there is also the potential for commercial bias. The Accreditation Council for Continuing Medical Education (ACCME) believes that CME must be free of the control of commercial interests. The ACCME believes that this independence from commercial interests will help ensure that CME is free of commercial bias.

**Federal regulation.** Elements of the federal government have, over the years, indicated the value and importance of this independence. In 1997, the United States Food and Drug Administration wrote:

*"The FDA has not regulated and does not intend to regulate, under the labeling and advertising provisions of the Federal Food, Drug, and Cosmetic Act, Industry Supported Scientific and Educational Activities that are independent of the influence of the supporting company. Companies and providers who wish to insure that their activities will not be subject to regulation should design and carry out their activities free from the supporting companies' influence and bias . . . ."*<sup>2</sup>

In 2003, the Office of Inspector General of the U.S. Department of Health and Human Services wrote:

*"Absent unusual circumstances, grants or support for educational activities sponsored and organized by medical professional organizations raise little risk of fraud or abuse, provided that the grant or support is not restricted or conditioned with respect to content or faculty . . . Codes of conduct promulgated by the CME industry may provide a useful starting point for manufacturers when reviewing their CME arrangements."*<sup>3</sup>

In 2010, the Deputy Director of the National Institutes of Health wrote,

*"We applaud the Accreditation Council for Continuing Medical Education's efforts to provide additional guidance for ensuring research independence and a free flow of scientific exchange, while safeguarding*

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<sup>1</sup> ACCME Definition: A commercial interest is any entity producing, marketing, re-selling, or distributing health care goods or services, consumed by, or used on, patients. The ACCME does not consider providers of clinical service directly to patients to be commercial interests. (from [www.accme.org](http://www.accme.org))

<sup>2</sup> Federal Register, Vol. 62, Number 232, December 3, 1997

<sup>3</sup> Federal Register, Vol. 68, No. 86, Monday, May 5, 2003

*accredited CME from commercial influence. Your vigilance in this important matter contributes to the best practices of unbiased information-sharing and will benefit, ultimately, the health of the American public.”*

**Updating process.** ACCME considers itself responsible for assuring that its SCS are adequate to promote independence from commercial interests and to separate promotion from education. In 1987, the ACCME first adopted “Guidelines for Commercial Support,” which were updated and expanded into the 1992 “Standards for Commercial Support.” In 2001, the ACCME initiated a review of its SCS as part of its strategic plan. The SCS review process was an open one that included a special ACCME task force to revise the SCS seeking, receiving and reviewing comments delivered in writing and through testimony from providers and commercial supporters. Several drafts of updated SCS were distributed within the CME enterprise and the ACCME prior to their adoption in 2004. They were unanimously approved by the seven ACCME member organizations.

**Updated standards.** The 2004 ACCME Standards for Commercial Support describe practices that the ACCME considers appropriate for accredited providers to ensure that their CME activities are independent, free of commercial bias and beyond the control of persons or organizations with an economic interest in influencing the content of CME. The 2004 SCS describe six Standards: (1) independence, (2) resolution of personal conflicts of interest, (3) appropriate use of commercial support, (4) appropriate management of associated commercial promotion, (5) content and format without commercial bias, and (6) disclosures relevant to potential commercial bias.

These Standards underscore continued voluntary self-regulation by the CME community, ensuring that physicians have opportunities to engage in commercially unbiased life-long learning facilitated by accredited providers.