Statement from the Accreditation Council for Continuing Medical Education (ACCME) to the Institute of Medicine Committee on Conflict of Interest in Medical Research, Education, and Practice

June 2008

TABLE OF CONTENTS

Governance 3

The ACCME System of Accredited Providers 5

The Role of Standards and Oversight in Continuing Medical Education 6

ENSURING THE TRUTHFULNESS AND FAIRNESS OF CONTINUING MEDICAL EDUCATION 6

Eligibility 6

Validity 6

Creation of Boundary Issues 7

PERSONAL FINANCIAL RELATIONSHIPS 8

COMMERCIAL SUPPORT OF CME 8

Amount of Commercial Support 9

Distribution of Commercial Support 9

The Possible Consequences of Personal Financial Relationships and Commercial Support in CME - Potential Undesirable Outcomes of Conflict of Interest in CME 10

MANAGEMENT OF BOUNDARY ISSUES 11

The ACCME Standards For Commercial Support: Standards to Ensure Independence in Cme[sm] 11

COMMERCIAL BIAS IN CME 11

Accme's Approach: Managing Conflict of Interest in CME Using Standards, Transparency and Oversight 12

STANDARDS 12

TRANSPARENCY 14

OVERSIGHT 15

Initial Accreditation 15

Re-Accreditation: A Two Step Process 15

MONITORING 16

Summary Regarding ACCME and Conflicts of Interest In Continuing Medical Education 17

ACCME'S APPROACH TO IDENTIFYING AND MANAGING CONFLICTS OF INTEREST IN CONTINUING MEDICAL EDUCATION

To meet the needs of the 21st century physician, CME will provide support for the physicians' professional development that is based on continuous improvement in the knowledge, strategies and performance-in-practice necessary to provide optimal patient care[1].

GOVERNANCE

Continuing medical education (CME) in this context is the population of educational resources developed by institutions and organizations accredited within the ACCME system that support the **continuing professional development** of physicians[2].

The Accreditation Council for Continuing Medical Education ("ACCME") is a not-for-profit corporation under the laws of the State of Illinois. In 1980 the ACCME was established as the successor to the Liaison Committee on Continuing Medical Education and the Committee on Accreditation of Continuing Medical Education of the American Medical Association.

The ACCME is organized exclusively for educational or scientific purposes within the meaning of Section 501(c) (3) of the Internal Revenue Code.

The purposes of the ACCME[3] are to identify, develop, and promote standards for continuing medical education (CME) utilized by physicians in their maintenance of competence and incorporation of new knowledge; to improve quality medical care for patients and their communities; to relate continuing medical education to medical care and the continuum of medical education; to apply these principles, policies, and standards in the accreditation of institutions and organizations offering continuing medical education through a voluntary system for accrediting CME Providers that is responsive to changes in

---

[1] ACCME Task Force on Competency and the Continuum, April 2004 available at http://accme.org/index.cfm/fa/news.detail/news_id/cfefdccd-10f5-44c3-8a9f-b4e1d0b809dc.cfm

[2] Regnier, et al JCEHP, 25,174, 2005

[3] ACCME Bylaws available at http://accme.org/index.cfm/fa/about.bylaws.cfm

medical education and the health care delivery system; and to deal with such other matters relating to continuing medical education as are appropriate.

The functions of the ACCME are to,

a. Serve as the body accrediting institutions and organizations offering continuing medical education;

b. Serve as the body recognizing institutions and organizations offering continuing medical education accreditation;

c. Develop criteria for evaluation of both educational programs and their activities by which ACCME and state accrediting bodies will accredit institutions and organizations and be responsible for assuring compliance with these standards;

d. Develop, or foster the development of, methods for measuring the effectiveness of continuing medical education and its accreditation, particularly in its relationship to supporting quality patient care and the continuum of medical education;

e. Recommend and initiate studies for improving the organization and processes of continuing medical education and its accreditation;

f. Review and assess developments in continuing medical education's support of quality health; and

g. Review periodically its role in continuing medical education to ensure it remains responsive to public and professional needs.

THE ACCME SYSTEM OF ACCREDITED PROVIDERS

The ACCME system includes ~730 organizations that are directly accredited by ACCME and another 1684 organizations accredited within the ACCME's state-based system[4]. The state-based CME system is made up of 46 organizations that are "Recognized"[5] by the ACCME as accreditors of state-based CME Providers. Recognition is achieved through ACCME's formal review process[6]. The ACCME's Recognition decision-making is criterion referenced against a predetermined set of standards[7]. The Recognized entities, in turn, accredit approximately 1750 CME Providers.

The ACCME system is one national system with respect to accreditation standards. The Providers accredited within the state-based system must follow the same ACCME Standards for Commercial Support[SM] as well as the Essential Areas Elements and Policies[8]. The Recognized entities are accountable to the ACCME for their own performances as accreditors as well as for the performance of their Providers as judged by the Providers' compliance with the current ACCME accreditation requirements.

	National	Regional	Total
Providers	729	1,684	**2,413**
Activities	93,582	56,302	**149,884**
Available Hours	712,163	349,696	**1,061,859**
MD Participants	8,255,017	3,136,610	**11,391,627**
Non MD Partcipants	4,577,078	1,682,420	**6,259,498**

The **size** of the CME enterprise has grown over the years.

	Year	1998	1999	2000	2001	2002	2003	2004	2005	2006
Counts	ACCME accredited	632	666	682	685	686	697	716	716	729
	State accredited	No data	No data	No data	No data	No data	1,598	1,591	1,606	1,684
	Total # Providers						**2,295**	**2,307**	**2,322**	**2,413**
Activities	ACCME-accredited	48,094	47,147	49,582	50,873	56,146	66,788	71,564	79,820	93,582
	State accredited	No data	No data	No data	No data	No data	76,430	57,526	54,901	56,302
	Total # of Activities						**143,218**	**129,090**	**134,721**	**149,884**

[4] List of state accredited providers: http://www.accme.org/index.cfm/fa/home.popular/popular_id/66be063a-8081-40f2-9615-042a733485d8.cfm
[5] Recognized organizations: http://www.accme.org/index.cfm/fa/home.popular/popular_id/5da735fd-e943-4acd-9cc5-7a1d3a253917.cfm
[6] Recognition Process http://www.accme.org/index.cfm/fa/RecognitionProcess.home/RecognitionProcess.cfm
[7] Recognition requirements: http://www.accme.org/index.cfm/fa/RecognitionRequirements.home/RecognitionRequirements.cfm
[8] Accreditation Requirements: http://www.accme.org/index.cfm/fa/AccreditationRequirements.home/AccreditationRequirements.cfm

THE ROLE OF STANDARDS AND OVERSIGHT IN CONTINUING MEDICAL EDUCATION

The ACCME is committed to ensuring that physicians have access to quality continuing medical education. The ACCME is resolute in its efforts to ensure that CME is provided through a valid and credible accreditation system. The ACCME has long felt that it is mission critical that CME be about improving patient care, be independent of commercial interests and be content valid.
ACCME defines a 'commercial interest' as any entity that produces, markets, resells or distributes health care products or services used by or on patients.

ENSURING THE TRUTHFULNESS AND FAIRNESS OF CONTINUING MEDICAL EDUCATION

ELIGIBILITY

Providers are not eligible for ACCME accreditation or reaccreditation if they present activities that promote recommendations, treatment or manners of practicing medicine that are not within the definition of CME, or are known to have risks or dangers that outweigh the benefits or known to be ineffective in the treatment of patients. An organization whose program of CME is devoted to advocacy of unscientific modalities of diagnosis or therapy is not eligible to apply for ACCME accreditation.

VALIDITY

Accredited Providers are responsible for validating the clinical content of CME activities that they provide. Specifically, (1) All the recommendations involving clinical medicine in a CME activity must be based on evidence that is accepted within the profession of medicine as adequate justification for their indications and contraindications in the care of patients; and (2) All scientific research referred to, reported or used in CME in support or justification of a patient care recommendation must conform to the generally accepted standards of experimental design, data collection and analysis.[9]

[9] ACCME Content Validation Statements, 2002 http://accme.org/index.cfm/fa/Policy.policy/Policy_id/16f1c694-d03b-4241-bd1a-44b2d072dc5e.cfm

CME, as practice-based learning and improvement, has construct, concurrent and face validity[10,11]. The CME literature shows that CME is effective at meeting its educational objectives with enduring results[12,13].

The content validity of accredited CME is critical to ACCME as the current educational focus of ACCME's accreditation requirements is one of heath care improvement [14,15]. ACCME's *Updated Criteria* focus on rewarding Providers for changing and improving their learners' professional practice. Since September 2006 accredited CME has been synonymous with practice–based learning and improvement as educational needs must be derived from professional practice gaps (ACCME Criterion 2), activities must be designed to change competence, performance or patient outcomes (ACCME Criterion 3), content of CME must match the scope of the learner's practice (ACCME Criterion 4) and measurements of change in competence, performance or patient outcomes must be made (ACCME Criterion C11.)

CREATION OF BOUNDARY ISSUES

1. Teachers and authors who have personal financial relationships with industry can teach and write in CME.
2. CME Providers can receive financial, or in-kind, contributions given by a commercial interest which is used to pay all or part of the costs of a CME activity (commercial support)[16].

Both these facts and circumstances create conflict of interest in CME[17].

[10] ACGME General Competencies www.acgme.org

[11] ABMS Maintenance of Certification www.ABMS.org

[12] Robertson, K., et al, JCEHP 23, 146, 2003

[13] *EFFECTIVENESS OF CONTINUING MEDICAL EDUCATION,* Structured Abstract. February 2007. Agency for Healthcare Research and Quality, Rockville, MD. http://www.ahrq.gov/clinic/tp/cmettp.htm

[14] ACCME's Updated Accreditation Criteria http://accme.org/index.cfm/fa/news.detail/news_id/a0b69346-7d90-42ab-a5cc-c84b2adaa0a5.cfm

[15] ACCME "Bridge to Quality" available at http://accme.org/index.cfm/fa/news.detail/News/.cfm/news_id/79e6296e-5037-4908-ae85-dbe22c4d73c9.cfm

[16] http://accme.org/index.cfm/fa/Policy.policy/Policy_id/9456ae6f-61b5-4e80-a330-7d85d5e68421.cfm

[17] Conflict of Interest in CME http://www.accme.org/dir_docs/doc_upload/dc0e76c4-16bd-4b78-819b-912ff57ca936_uploaddocument.pdf

PERSONAL FINANCIAL RELATIONSHIPS

"Q: When do relationships create 'conflicts of interest' in CME? (extracted from www.accme.org)

ACCME: The ACCME considers financial relationships to create actual conflicts of interest in CME when individuals have both,

- A current financial relationship with a commercial interest **and**
- The opportunity to affect the content of CME about the products or services of that commercial interest.

The relationship creates an incentive to insert bias into the CME activity in favor of the product or service."

COMMERCIAL SUPPORT OF CME

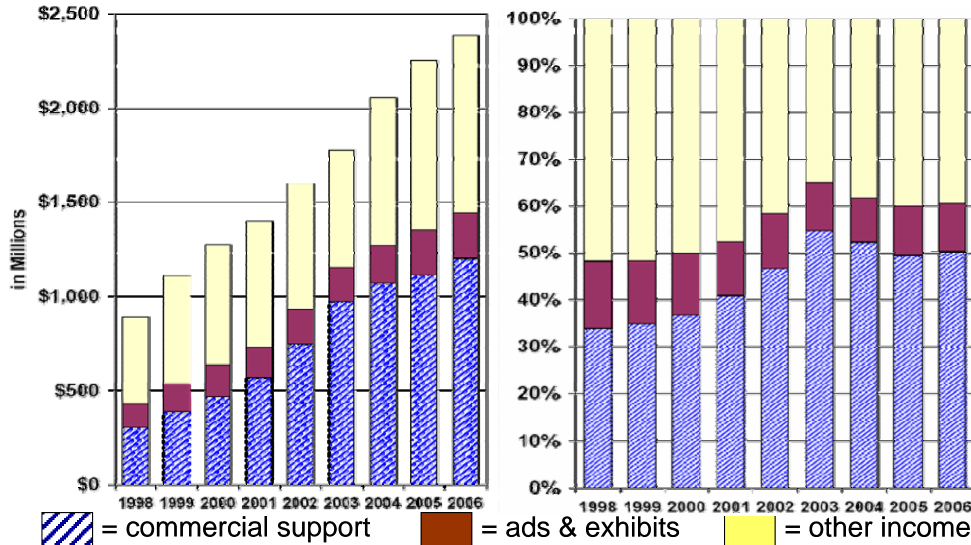
The ACCME has long recognized that the presence of commercial support in CME creates conflicts of interest for the organization receiving the commercials support. In 2006 the CME enterprise reported total expenses of approximately $1.9 Billion with a total income of approximately $2.5 Billion.

	National Providers	Regional Providers	Total
n	729	1772	2500
Total Expenses	$1,820,708,534	$136,454,743	**$1,957,163,277**
Total Income	$2,384,581,430	$134,499,284	**$2,519,080,714**
Amount of Total Income that is Commercial support	$1,199,405,519	$ 39,415,446	**$1,238,820,965**

The state system of regional Providers constitutes approximately 70% of accredited Providers, 40% of CME by activity count (30% by hours, 25% by physician registrants) and receives about 3% of the total commercial support available.

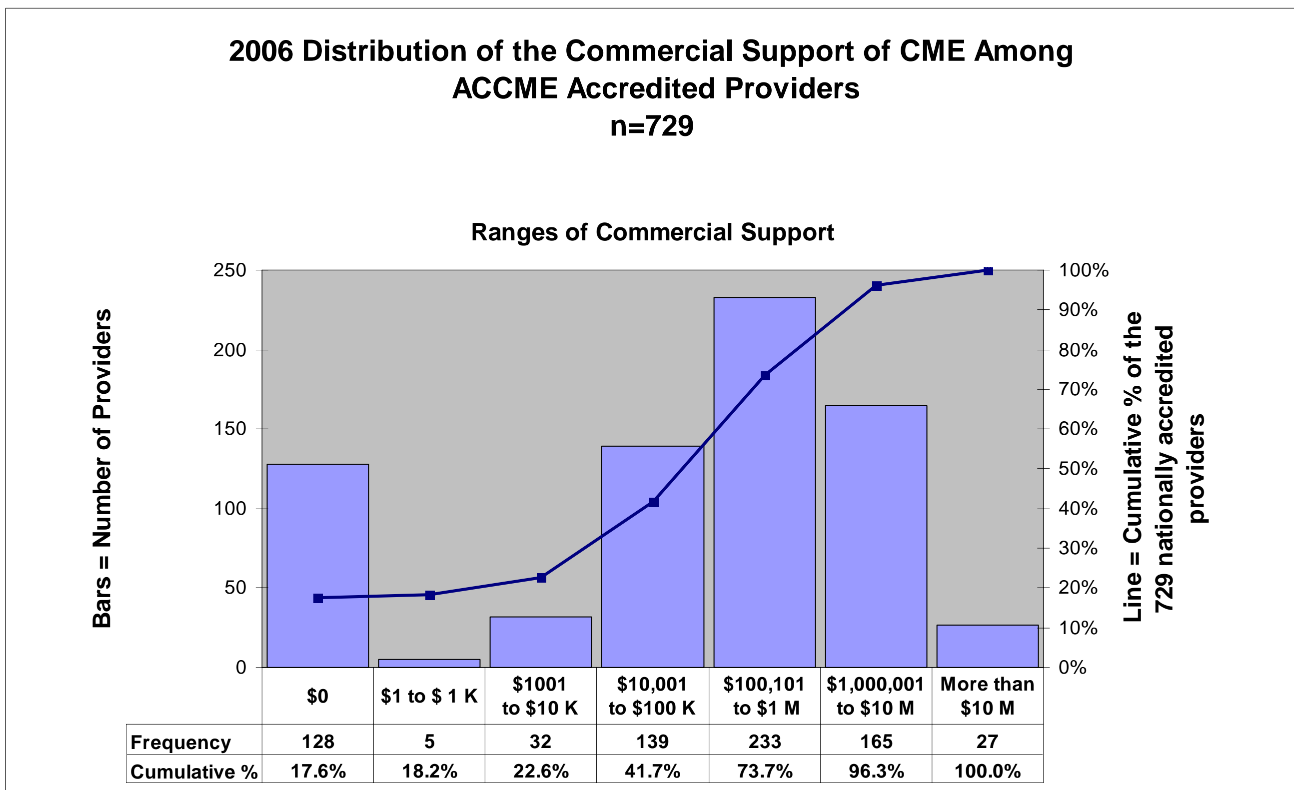
AMOUNT OF COMMERCIAL SUPPORT

The amount of commercial support has grown over the years (data for ACCME accredited Providers only).



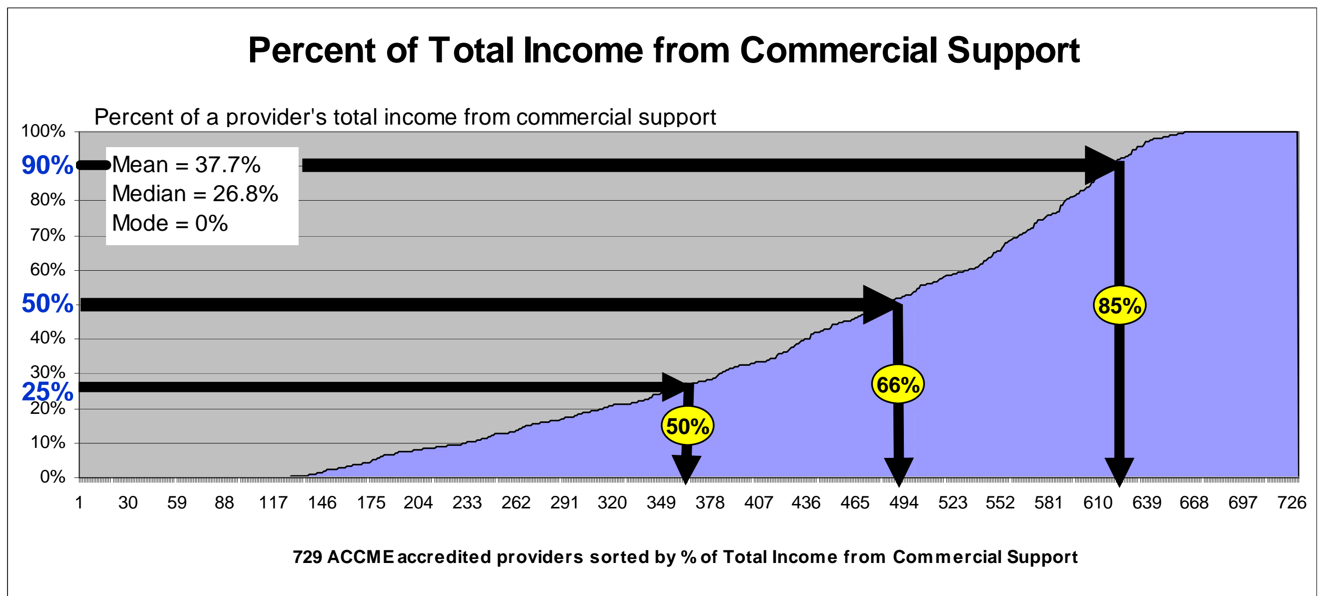
DISTRIBUTION OF COMMERCIAL SUPPORT

In 2006 the commercial support of continuing medical education was not distributed uniformly across



	$0	$1 to $ 1 K	$1001 to $10 K	$10,001 to $100 K	$100,101 to $1 M	$1,000,001 to $10 M	More than $10 M
Frequency	128	5	32	139	233	165	27
Cumulative %	17.6%	18.2%	22.6%	41.7%	73.7%	96.3%	100.0%

the CME enterprise. One hundred and twenty eight Providers (~18%) received no commercial support. One hundred and seventy six Providers (~24%) received between $1 and $100,000. Two hundred and thirty three Providers (~33%) received between $100,000 and $1,000,000. One hundred and ninety-two Providers (~26%) received more then $1,000,000 of commercial support. Approximately 42% of Providers received less then $100,000 and 74% receive a $1 million or less of commercial support. There is variation between Providers with respect to what percentage of their total income is derived



from commercial support. The average percentage is less then 38%. Half of the Providers receive less than 27% of their income from commercial support. Sixty-six percent of Providers receive less than or equal to 50%. Fifteen percent of Providers receive 90% or more of their income from commercial support.

THE POSSIBLE CONSEQUENCES OF PERSONAL FINANCIAL RELATIONSHIPS AND COMMERCIAL SUPPORT IN CME - POTENTIAL UNDESIRABLE OUTCOMES OF CONFLICT OF INTEREST IN CME

It is possible that through their implicit or explicit control of, or influence on, CME content that commercial interests could create commercial bias in CME (i.e., favoritism) that will result in a learner's inclination towards, or actual, use of a product or service that is more than is necessary. This would be a two step process. First, there would be commercial bias. Secondly, there would be an undesirable

change in the learners. Bias could be inserted by people that develop and present CME because of the incentives created by their financial relationships with commercial interests.

MANAGEMENT OF BOUNDARY ISSUES

THE ACCME STANDARDS FOR COMMERCIAL SUPPORT: STANDARDS TO ENSURE INDEPENDENCE IN CME[SM]

In 1987 the ACCME drafted "Guidelines for the Management of Commercial Support of Continuing Medical Education". These became finalized as the 1992 Standards for Commercial Support and which survive today as the 2004 *Standards for Commercial Support: Standards to Ensure the Independence of Continuing Medical Education*[SM].

COMMERCIAL BIAS IN CME

At least two forms of commercial bias could exist.

Commercial content bias would be where the content or format of a CME activity, or its related materials, is designed so as to promote a specific proprietary business interest of a commercial interest. Commercial topic bias is where the prevalence of topics is caused to be skewed towards those topics that will be commercially supported.

The ACCME does not have data from its own direct measurements or from measurements made by Providers on the prevalence or incidence of commercial bias in today's CME. No data demonstrating commercial content bias is found in the medical education or regulatory literature. ACCME has commissioned an independent review of the literature looking for the evidence base to support the conjecture that accredited commercially supported CME is commercially biased. Although it has been speculated that commercial support produces bias in CME programs, no published studies have examined this question. Therefore, there is no evidence to support or refute this assertion.

In addition, the impact of the 2004 ACCME Standards for Commercial Support[SM] on commercial bias has not yet been measured. No studies have been reported using data derived from CME planned and presented under the supervision of the 2004 ACCME Standards for Commercial Support[SM]. Articles on the use of CME by industry in marketing strategies are all based on data and observations made about

CME that preceded the May 2005 implementation of the 2004 ACCME Standards for Commercial Support[SM].

There are many opinion pieces in the lay and medical literature[18,19,20,21,22,23,24] that express the belief, or imply, that CME must, be commercially biased by virtue of the presence of commercial support. They express a firmly held, implied or explicit, belief that the commercial support of CME results in the commercial bias of CME. The belief is maintained in the absence of empiric evidence developed since the May 2005 implementation of the 2004 ACCME Standards for Commercial Support[SM].

ACCME'S APPROACH: MANAGING CONFLICT OF INTEREST IN CME USING STANDARDS, TRANSPARENCY AND OVERSIGHT

STANDARDS

Since 1987 the ACCME has been the custodian of a set of Guidelines, or Standards, managing the boundary issues associated with the presence of commercial support in continuing medical education. The ACCME's acceptance of a responsibility in this area antedates by decades the appearance of such Standards in other areas of medical education, research or professional practice.

As already mentioned, the accredited CME system is guided by ACCME's accreditation requirements[25], clarifying and additional polices[26] and supplementary information proved through "frequently asked questions"[27]. Taken together these three components constitute the regulatory standards that ACCME imposes on CME Providers accredited within the ACCME system.

The ACCME manages and restricts the interactions between commercial supporters and CME Providers. ACCME is explicit. Providers cannot receive guidance, either nuanced or direct, on the

[18] Brennan, Troyen A. at al, Health Industry Practices That Create Conflicts of Interest A Policy Proposal for Academic Medical Centers JAMA, 2006;295: 429-433.

[19] Hager M, Russell S, Fletcher SW, editors. Continuing Education in the Health Professions: Improving Healthcare Through Lifelong Learning, Proceedings of a Conference Sponsored by the Josiah Macy, Jr. Foundation; 2007 Nov 28 - Dec 1; Bermuda. New York: Josiah Macy, Jr. Foundation; 2008. Accessible at www.josiahmacyfoundation.org

[20] Steinbrook, R., Financial Support of Continuing Medical Education JAMA 2008; 299:1060-1062

[21] Blumenthal, D., Doctors and Drug Companies NEJM 351;18 October 28, 2004

[22] Relman AS. Separating continuing medical education from pharmaceutical marketing. JAMA 2001;285:2009-12

[23] Hensley, S., When Doctors Go to Class, Industry Often Foots the Bill, Wall Street Journal, 6 Dec 2002

[24] Committee Staff Report to the Chairman and Ranking Member: Use Of Educational Grants By Pharmaceutical Manufacturers, Authors Staff of the Committee on Finance United States, April 2007, accessible at http://www.finance.senate.gov/press/Bpress/2007press/prb042507a.pdf

[25] ACCME Accreditation Requirements: http://accme.org/dir_docs/doc_upload/f4ee5075-9574-4231-8876-5e21723c0c82_uploaddocument.pdf

[26] ACCME Policies: http://accme.org/index.cfm/fa/Policy.home/Policy.cfm

[27] ACCME Q and A: http://accme.org/index.cfm/fa/faq.home/Faq.cfm

content of the activity or on who should deliver that content[28]. Commercial supporters cannot influence the content of CME nor suggest speakers for CME activities.

Organizational conflicts of interest for ACCME-defined commercial interest are irreconcilable and managed by recusal – with no exceptions.

Standards 1.1 and 1.2 of the ACCME Standards for Commercial Support[SM] demand that commercial interests not control the content of CME.

> **SCS 1.1** A CME provider must ensure that the following decisions were made free of the control of a commercial interest. (The ACCME defines a "commercial interest" as any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients)
>
> (a) Identification of CME needs;
> (b) Determination of educational objectives;
> (c) Selection and presentation of content;
> (d) Selection of all persons and organizations that will be in a position to control the content of the CME;
> (e) Selection of educational methods;
> (f) Evaluation of the activity.
>
> **SCS 1.2** A commercial interest cannot take the role of non-accredited partner in a joint sponsorship relationship.

Personal conflicts of interest are reconcilable. ACCME requires Providers to manage the personal conflicts of interest of teachers, authors and planners of CME. In CME personal conflicts of interest are managed by taking action to resolve the conflict of interest and disclosing the conflict to the learners (ACCME Standards for Commercial Support[SM] elements SCS 2.2, 2.2 and 2.3).

> **SCS 2.1** The Provider must be able to show that everyone who is in a position to control the content of an education activity has disclosed all relevant financial relationships with any commercial interest to the

[28] ACCME August 2007 Announcements available at http://accme.org/index.cfm/fa/news.detail/news_id/3605f21a-302a-40d1-ab4d-3ceb88087b1a.cfm

Provider. The ACCME defines "'relevant' financial relationships" as financial relationships in any amount occurring within the past 12 months that create a conflict of interest.

SCS 2.2 An individual who refuses to disclose relevant financial relationships will be disqualified from being a planning committee member, a teacher, or an author of CME, and cannot have control of, or responsibility for, the development, management, presentation or evaluation of the CME activity.

SCS 2.3 The Provider must have implemented a mechanism to identify and resolve all conflicts of interest prior to the education activity being delivered to learners.

The ACCME has provided the opportunity to Providers to seek their own and best mechanisms for managing conflict of interest.[29]

The ACCME manages for bias through Standard 5[30] of the ACCME Standards for Commercial Support℠.

STANDARD 5. Content and Format without Commercial Bias

SCS 5.1: The content or format of a CME activity or its related materials must promote improvements or quality in healthcare and not a specific proprietary business interest of a commercial interest.

SCS 5.2 Presentations must give a balanced view of therapeutic options. Use of generic names will contribute to this impartiality. If the CME educational material or content includes trade names, where available trade names from several companies should be used, not just trade names from a single company.

TRANSPARENCY

Since 1992, through the ACCME Standards for Commercial Support℠ ACCME has required **disclosure to the learners** of relevant financial relationships of teachers, authors and CME planners as well as the disclosure of any commercial support of CME. The exact requirements are,

STANDARD 6.Disclosures Relevant to Potential Commercial Bias

Relevant financial relationships of those with control over CME content

6.1 An individual must disclose to learners any relevant financial relationship(s), to include the following information:

- The name of the individual;

[29] See http://accme.org/index.cfm/fa/news.detail/news_id/eca8be88-0994-4513-b061-5a9df9413b15.cfm

[30] ACCME Standards for Commercial Support℠ available at http://www.accme.org/dir_docs/doc_upload/68b2902a-fb73-44d1-8725-80a1504e520c_uploaddocument.pdf

- The name of the commercial interest(s);
- The nature of the relationship the person has with each commercial interest.

6.2 For an individual with no relevant financial relationship(s) the learners must be informed that no relevant financial relationship(s) exist.

Commercial support for the CME activity.

6.3 The source of all support from commercial interests must be disclosed to learners. When commercial support is 'in-kind' the nature of the support must be disclosed to learners.

6.4 'Disclosure' must never include the use of a trade name or a product-group message.

Timing of disclosure

6.5 A Provider must disclose the above information to learners prior to the beginning of the educational activity.

OVERSIGHT

INITIAL ACCREDITATION

No Provider can become accredited if it is found in non-compliance with any accreditation element.

RE-ACCREDITATION: A TWO STEP PROCESS

Step 1: Re-Accreditation Review

The ACCME evaluates approximately 25% of its Providers for compliance with all these requirements on an annual basis. So far a total of 324 ACCME accredited Providers have had accreditation decisions made under the 2004 ACCME Standards for Commercial Support^{SM}.

Step 2: ACCME Intervention and Verification of Change

All Providers with an initial finding of **Non–Compliance** are immediately required to initiate a change and improvement process in order to maintain accreditation. Verification of this change to compliance is presented to ACCME within one year of the initial ACCME finding, in the form of an **ACCME Accreditation Progress Report**. The accreditation status of Providers with persistent non compliance findings is changed to PROBATION (time limited) by ACCME as a step towards changing the Provider's status to Non Accreditation.

The two-step ACCME accreditation process is sensitive and able to identify non compliance[31] and to intervene to drive change and improvement on the part of the Providers.

MONITORING

ACCME has always had a "Complaints and Inquiries" process that investigates and takes action regarding non compliance with ACCME requirements during a Provider's term of accreditation. Up until 2007 the process was mainly reactive to complaints from Providers, learners and the public. In 2007 the process was changed so that the ACCME itself could more easily initiate complaints or inquiries. In 2008 ACCME has established two new internal monitoring committees to advise and administer a new investigatory process. The ACCME has begun a process for looking into the practices of the approximately one hundred ACCME Providers that receive most of the commercial support.

An additional system is being developed to directly monitor educational activities so as to establish the prevalence of commercial bias and to determine if there is any subsequent over use or inappropriate use of commercial products as a result of continuing medical education.

[31] See http://www.accme.org/dir_docs/doc_upload/c91205e9-7c95-415c-89b3-0a9ff88de363_uploaddocument.pdf

SUMMARY REGARDING ACCME AND CONFLICTS OF INTEREST IN CONTINUING MEDICAL EDUCATION

The **Accreditation Council for Continuing Medical Education**,

1. Is committed to ensuring that physicians have access to quality continuing medical education.
2. Is resolute in its efforts to ensure that CME is provided through a valid and credible accreditation system.
3. Has long felt that it is mission critical that CME be about improving patient care, be independent of commercial interests and be content valid.
4. Believes that conflict of interest exists in continuing medical education.
5. Sets standards for the management of the two predominant causes of conflict of interest in CME (conflicts of interest in CME that originate from individual and organizational relationships between those in CME and those that produce, market, re-sell or distribute health care products or services that re used by or on patients).
6. Certifies that Providers meet these standards through its accreditation processes.
7. Is expanding its monitoring and surveillance capabilities to ensure a high prevalence of compliance with its requirements.
8. Is taking action to ensure that in depth quality monitoring by ACCME is performed to establish the extent to which the ACCME's standards are effective in preventing bias.