July 11, 2008

The Honorable Herb Kohl
Chairman
Special Committee on Aging
United States Senate
Washington, DC 20510-64500

Dear Senator Kohl,

Please find attached the information you requested in your letter to the Accreditation Council for Continuing Medical Education (ACCME) of June 20th, 2008. In the information supplied we have directly addressed the four questions you presented to us.

The ACCME is grateful for the opportunity to supply this information to the Special Committee on Aging. Please let us know if we can be of further assistance.

Sincerely,

Murray Kopelow, MD, MS(Comm), FRCPC
Chief Executive

/MK
INFORMATION FROM THE ACCREDITATION COUNCIL FOR CONTINUING MEDICAL EDUCATION (ACCME) FOR THE SPECIAL COMMITTEE ON AGING OF THE UNITED STATES SENATE

Background about ACCME ........................................................................................................... 3

The Special Committee on Aging asked for
“A copy and written description of the accreditation process for CME courses.” ................................................................. 8

The Special Committee on Aging asked for
“Any criteria the ACCME uses as part of the accreditation process, regarding the scientific validity of course content.” .................................................................................................................. 14

The Special Committee on Aging asked for
“Any mechanisms the ACCME has in place to ensure that no undue influence by any industry is being exerted through courses.” ........................................................................................................... 16

The Special Committee on Aging asked ACCME
for “Any further plans the ACCME may have in place to develop such mechanisms [to ensure that no undue influence by any industry is being exerted through courses].” ........................................................................................................... 23
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 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 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;

GOVERNANCE

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.

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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.

**ACCREDITATION PROCESS**

ACCME accreditation is a mark of quality continuing medical education (“CME”) activities that are planned, implemented and evaluated by ACCME accredited providers in accordance with ACCME’s Essential Areas and Elements and Accreditation Policies (“Accreditation Requirements”). ACCME accreditation assures the medical community and the public that such activities provide physicians with information that can assist them in maintaining or improving their practice of medicine. These activities are free of commercial bias and based on valid content.

The ACCME is the organization that sets educational standards for CME activities, and monitors its accredited providers’ adherence to those standards. The ACCME accredits organizations, and does not accredit individual CME learning activities. Non-accredited organizations that partner with an ACCME accredited provider in the provision of quality CME can enter into joint sponsorship with an accredited organization.

**ACCREDITED CONTINUING MEDICAL EDUCATION FROM WITHIN THE ACCME SYSTEM**

It is important to note that the ACCME does not reward the continuing educational accomplishments of individual physicians. Rather, those accomplishments are rewarded by other organizations which, for example, require physicians to complete a certain amount and/or type of CME for membership or re-licensure. The requirements for granting credit are maintained by the other organizations themselves.
The ACCME uses the term **accredited CME** to encompass the educational programs and educational activities of providers accredited within its system. The ACCME holds (state and ACCME) accredited providers accountable for all activities presented under the ‘mark’ of the ACCME/SMS **accreditation statement**. Any requirements the ACCME promulgates are applicable to all continuing medical education activities presented by ACCME/SMS accredited providers. In turn, the ACCME stands accountable to the public, the physicians, the government, the ACCME member organizations and the organization of medicine in general for the manner in which this accredited CME is conducted and presented. The ACCME cannot be held accountable for all CME for which learners receive ‘credit’ or all CME that is ‘certified for credit’ – but only for CME presented under the umbrella of an ACCME (or state medical society) accreditation statement.

Examples of continuing medical education activities that are ‘certified’ or associated with ‘credit’ that are **not** accredited CME from within the ACCME system are,


3. CME activities identified and claimed for AMA PRA Category 2 by physicians (see page 18 at [http://www.ama-assn.org/ama1/pub/upload/mm/455/pra2006.pdf](http://www.ama-assn.org/ama1/pub/upload/mm/455/pra2006.pdf)).

4. CME Activities accredited by the European Accreditation Council for Continuing Medical Education and converted to AMA PRA Category 1 Credit™ by the American Medical Association (see [http://www.ama-assn.org/ama/pub/category/14348.html](http://www.ama-assn.org/ama/pub/category/14348.html)).

5. CME activities associated with AMA PRA Category 1 Credit™ by the American Medical Association through its International Recognition Program (see [http://www.ama-assn.org/ama/pub/category/2641.html](http://www.ama-assn.org/ama/pub/category/2641.html)).
These activities are not reviewed by the ACCME for compliance with the ACCME educational accreditation requirements and are not reviewed by the ACCME for compliance with the ACCME Standards for Commercial SupportSM.

ELIGIBILITY FOR ACCME ACCREDITATION

Only certain organizations are eligible to receive ACCME accreditation. The following criteria must be met before an organization will be considered for ACCME accreditation.

The organization must,

- Be located in the United States and its Territories.

- Be developing and/or presenting a program of CME for physicians on a regular and recurring basis.

- Not be a commercial interest. (A commercial interest is any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients.)

- Not be developing and/or presenting a program of CME that is, in the judgment of the ACCME, devoted to advocacy on unscientific modalities of diagnosis or therapy.

- Present activities that have “valid” content. Specifically, the organization must be presenting activities that promote recommendations, treatment or manners of practicing medicine that are within the definition of CME. The ACCME definition of CME reads,

  “Continuing medical education consists of educational activities which serve to maintain, develop, or increase the knowledge, skills, and professional performance and relationships that a physician uses to provide services for patients, the public, or the profession. The content of CME is that body of knowledge and skills generally recognized and accepted by the profession as within the basic medical sciences, the discipline of clinical medicine, and the provision of health care to the public.”
Providers are not eligible for accreditation if they present activities that promote treatments that are known to have risks or dangers that outweigh the benefits or are known to be ineffective in the treatment of patients.

The ACCME accredits the following institutional or organizational types, if they choose to seek accreditation and are deemed eligible:

- Government or military
- Hospital / Health Care delivery systems
- Insurance Companies and Managed Care Companies
- Non-profit organizations including physician membership organizations
- Publishing and education companies
- Schools of Medicine
The ACCME is the organization that sets educational standards for CME activities, and monitors its accredited providers’ adherence to those standards. The ACCME accredits organizations, and does not accredit individual CME learning activities.

THE PRE-APPLICATION PROCESS

The first step in becoming accredited is completion of a “Pre-application for ACCME Accreditation” (“Pre-application”). The purpose of the Pre-application is to provide an opportunity to demonstrate eligibility for ACCME accreditation, as well as to demonstrate that an organization has mechanisms in place to fulfill ACCME’s Essential Areas and Elements and Accreditation Policies (“Accreditation Requirements”) in their CME activities.

Once an organization has completed and submitted to the ACCME the Pre-application and fee, the ACCME will notify the organization whether it is eligible to continue with the initial accreditation process.

THE SELF STUDY PROCESS

If the organization is deemed eligible to continue with the initial accreditation process, the Provider will complete and submit an Initial Self Study Report for ACCME accreditation. Once all required information and payment has been received, the ACCME will schedule the survey. First-time applicants must fulfill two requirements with respect to their survey: they must have a survey at their administrative offices and have a CME activity reviewed. There is no prescribed order for the two requirements, but the first survey must take place prior to Provisional Accreditation, and both requirements must be completed prior to Accreditation.

The interview provides an opportunity for the organization to meet with two ACCME volunteer surveyors to discuss the objectives of the CME program, and the Provider’s approach to compliance with ACCME Requirements. Following the interview, the surveyors document the results of their conversations with the organization and send
the findings to the ACCME. Three times per year, the ACCME makes accreditation decisions. The decision making process includes review by two ACCME committees - first, the Accreditation Review Committee, and second, the Decision Committee. All accreditation decisions are ratified by the full Board of Directors of the ACCME. This multi-tiered system of review provides the checks and balances necessary to ensure fair and accurate decisions. The fairness and accuracy of ACCME decisions is also enhanced by the ACCME's use of a criterion-referenced decision-making system.

The decision making process assesses providers' level of compliance with the Accreditation Requirements based on information furnished by the provider, via the Self Study Report or Progress Report, as well as information collected, if applicable, by ACCME accreditation surveyors. Compliance options for each individual Requirement include:

- Compliance (the provider meets the criteria for Compliance)
- Non-Compliance (the provider does not meet the criteria for Compliance)

Based on the accumulated compliance findings for each individual Accreditation Requirement, the ACCME makes initial and reaccreditation decisions regarding the provider's accreditation status. This decision could be one of five options:

1. Provisional Accreditation,
2. Accreditation,
3. Accreditation with Commendation,
4. Probation, or
5. Non-Accreditation.

Providers that receive Non-Compliance in any one of the ACCME's Essential Areas and Elements, including the Standards for Commercial Support and Accreditation Policies ("Accreditation Requirements") during their reviews for initial or reaccreditation, will be required to submit an ACCME Progress Report. Historically, approximately 35% of providers have been required to submit Progress Reports. The ACCME will notify providers whether they are required to submit a Progress Report via their Decision Report. In the past the usual due date for a Progress Report was one year from the date of the original finding. The ACCME is modifying its process to move up the original
submission to a few weeks after the finding with verification supplied as soon as the new practices have been put into place.

The ACCME Progress Report furnishes the provider with the opportunity to describe and demonstrate improvements that they have made to bring the issue(s) in question into Compliance. The requirement to improve is an integral part of the ACCME’s accreditation system. Progress Reports serve as important opportunities for providers to demonstrate that they have mechanisms in place to make improvements to their CME program.

**ACCME’S EXPECTATIONS OF PROVIDERS**

The ACCME continues to emphasize that CME must be a strategic asset to all stakeholders who seek to improve healthcare in the U.S. Since 2006, the ACCME has maintained a focus on supporting a well-organized transition to a criterion-based system for the accreditation of CME providers that matches the gaps in physician competence, performance, and patient outcomes (ie, professional practice gaps) with practice-based learning and change. The 2006 ACCME Updated Criteria for Accredited Providers are the essence of the ACCME’s emphasis on “CME as a Bridge to Quality.” While putting new resources into the management of issues to ensure the independence of CME from commercial influence, the ACCME is steadfast in its delivery of a valid accreditation system based upon the Updated Criteria.

These criteria more closely align CME planning with the professional improvement concerns of practicing physicians and empower Accredited Providers to seek novel strategies and methods to overcome barriers to physician change and improvement through engagement with the wider healthcare community.

Accredited Providers are required to understand their physician learners – to articulate how the skills, performance, and outcomes of care may be improved. This understanding provides the basis for CME professionals to design interventions that effectively address these issues to close the gaps.
Every CME activity is to be planned in the context of a recognized ‘competency’ (desirable physician attribute) and must match the learner’s scope of practice. The educational methods must be appropriate for the change desired.

In the ACCME Criteria for Accreditation with Commendation, accredited providers are asked to integrate their program of CME into the process for improving professional practice and use non-educational strategies (eg, reminders, patient education, feedback systems) to enhance change. The ACCME rewards accredited providers that identify factors outside their control that impact patient outcomes and implement educational strategies to overcome barriers to physician change. In keeping with ACCME’s own strategic imperatives, the ACCME asks Accredited Providers to build bridges with other stakeholders through collaboration and cooperation, to participate within a framework for quality improvement—and to ensure they are positioned to influence the scope and content of CME.

ACCREDITATION REQUIREMENTS

ACCME requires that,

1. Providers focus their CME programs through a clearly articulated educational mission of change and improvement.

   **Criterion 1.** The provider has a CME mission statement that includes all of the basic components (CME purpose, content areas, target audience, type of activities, expected results) with expected results articulated in terms of changes in competence, performance, or patient outcomes that will be the result of the program.

2. Providers’ programs of CME are practice-based, change-focused, aligned with the learners’ professional practice, use the appropriate educational format, and are linked to desirable physician attributes.

   **Criterion 2.** The provider incorporates into CME activities the educational needs (knowledge, competence, or performance) that underlie the professional practice gaps of their own learners.
Criterion 3. The provider generates activities/educational interventions that are designed to change competence, performance, or patient outcomes as described in its mission statement.

Criterion 4. The provider generates activities/educational interventions around content that matches the learners' current or potential scope of professional activities.

Criterion 5. The provider chooses educational formats for activities/interventions that are appropriate for the setting, objectives and desired results of the activity.

Criterion 6. The provider develops activities/educational interventions in the context of desirable physician attributes (eg, IOM competencies, ACGME Competencies).

3. Providers' programs appropriately manage the boundary issues created by personal and organizational financial relationships with ACCME-defined commercial interests through compliance with the ACCME Standards for Commercial SupportSM.

Criterion 7. The provider develops activities/educational interventions independent of commercial interests (SCS 1, 2 and 6).

Criterion 8. The provider appropriately manages commercial support (if applicable, SCS 3 of the ACCME Standards for Commercial SupportSM).

Criterion 9. The provider maintains a separation of promotion from education (SCS 4).

Criterion 10. The provider actively promotes improvements in health care and NOT proprietary interests of a commercial interest (SCS 5).
4. Providers’ programs of CME measure their successes at meeting their missions and respond appropriately to what the data says – with changes and improvements.

**Criterion 11.** The provider analyzes changes in learners (competence, performance, or patient outcomes) achieved as a result of the overall program’s activities/educational interventions.

**Criterion 12.** The provider gathers data or information and conducts a program-based analysis on the degree to which the CME mission of the provider has been met through the conduct of CME activities/educational interventions.

**Criterion 13.** The provider identifies, plans and implements the needed or desired changes in the overall program (eg, planners, teachers, infrastructure, methods, resources, facilities, interventions) that are required to improve on ability to meet the CME mission.

**Criterion 14.** The provider demonstrates that identified program changes or improvements, that are required to improve on the provider’s ability to meet the CME mission, are underway or completed.

**Criterion 15.** The provider demonstrates that the impacts of program improvements, that are required to improve on the provider’s ability to meet the CME mission, are measured.

5. Providers’ programs of CME operate in the context of the healthcare environment in which they are situated by being an asset to those attempting to improve professional practice, working to overcome barriers to change and collaborating with others.

**Criterion 16.** The provider operates in a manner that integrates CME into the process for improving professional practice.
Criterion 17. The provider utilizes non-education strategies to enhance change as an adjunct to its activities/educational interventions (eg, reminders, patient feedback).

Criterion 18. The provider identifies factors outside the provider’s control that impact on patient outcomes.

Criterion 19. The provider implements educational strategies to remove, overcome or address barriers to physician change.

Criterion 20. The provider builds bridges with other stakeholders through collaboration and cooperation.

Criterion 21. The provider participates within an institutional or system framework for quality improvement.

Criterion 22. The provider is positioned to influence the scope and content of activities/educational interventions.

Also see Essential Areas and Elements, including the Standards for Commercial Support (PDF) and ACCME Accreditation Policies - All (PDF) on www.accme.org.

THE SPECIAL COMMITTEE ON AGING ASKED FOR “ANY CRITERIA THE ACCME USES AS PART OF THE ACCREDITATION PROCESS, REGARDING THE SCIENTIFIC VALIDITY OF COURSE CONTENT.”

The ACCME adopted policy in 2002 to ensure that Providers present activities that have valid content. Specifically, the organization must be presenting activities that promote recommendations, treatment or manners of practicing medicine that are within the definition of CME. The ACCME definition of CME reads,

“Continuing medical education consists of educational activities which serve to maintain, develop, or increase the knowledge, skills, and professional performance and relationships that a physician uses to
provide services for patients, the public, or the profession. The content of CME is that body of knowledge and skills generally recognized and accepted by the profession as within the basic medical sciences, the discipline of clinical medicine, and the provision of health care to the public.”

Providers are not eligible for accreditation if they present activities that promote treatments that are known to have risks or dangers that outweigh the benefits or are 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.

Accredited providers are responsible for validating the clinical content of CME activities that they provide. Specifically,

- 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.

- 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.

The ACCME has established a decision-making algorithm to judge the Providers’ success at establishing the content validity of CME. Any stage of the accreditation process (Surveyors, Accreditation Review Committee or the ACCME’s Board of Directors or Decision Committee) can trigger this secondary review.

The content validity of accredited CME is critical to ACCME as the current educational focus of ACCME’s accreditation requirements is one of healthcare improvement. The ACCME’s Updated Criteria focus on rewarding Providers for changing and improving their learners’ professional practice. Since September 2006, it has been an ACCME requirement that 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.)

THE SPECIAL COMMITTEE ON AGING ASKED IF “ANY MECHANISMS THE ACCME HAS IN PLACE TO ENSURE THAT NO UNDUE INFLUENCE BY ANY INDUSTRY IS BEING EXERTED THROUGH COURSES.”

Teachers and authors who have personal financial relationships with industry can teach and write in CME. 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). Both these facts and circumstances create conflict of interest in CME.

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.

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

In 2006, the commercial support of continuing medical education was not distributed uniformly across 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 $1 million or less of commercial
support.

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 (ie, 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
the presence of 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.

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 have evolved today to the ACCME Standards for
Commercial Support: Standards to Ensure the Independence of Continuing Medical
EducationSM.

An undesirable outcome of undue influence by commercial interests in CME would be
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. The 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 SupportSM 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 SupportSM. Articles on the use of CME by industry in marketing strategies are all based on data and observations made about CME that preceded the implementation of the 2004 ACCME Standards for Commercial SupportSM.

There are many opinion pieces in the lay and medical literature that express the belief, or imply, that CME must be commercially biased by virtue of the presence of commercial support. The belief is maintained in the absence of empiric evidence developed since the May 2005 implementation of the 2004 ACCME Standards for Commercial SupportSM.

**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, clarifying and additional polices and supplementary information proved through “frequently asked questions.” 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. The ACCME is explicit. Providers cannot receive guidance, either nuanced or direct, on the content of the activity or on who should deliver that content.
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 SupportSM 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. The 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 SupportSM 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 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.

The ACCME manages for bias through Standard 5 of the ACCME Standards for Commercial SupportSM.

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 SupportSM 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;
- 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: At initial accreditation no Provider can become accredited if it is found in non-compliance with any accreditation element. Reaccreditation is a two step process. In Step 1, at a reaccreditation 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 SupportSM. In Step 2, in the presence of Non Compliance findings ACCME intervenes with a demand for verification of change and
Compliance. All Providers with a 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 and to intervene to drive change and improvement on the part of the Providers. The ACCME recently provided the new information to the CME community about this process. The ACCME believes that Accredited Providers found in Non Compliance with accreditation requirements can implement improvements faster then in the past. It has always been the case that every Provider found in Non Compliance with any accreditation requirement is required to bring their programs into full Compliance. In the past, the ACCME gave Providers months to make the changes and over a year to provide verification of compliance. The ACCME will now be asking providers to describe changes in policy or procedure within **weeks** of determining Non Compliance findings, followed by verification of changes in performance within **months** of the Non Compliance findings. This new process will require Providers to establish an improvement plan (which will be submitted to ACCME soon after receipt of the accreditation decision) followed by the submission of verification of improvements within a year. This two-step improvement process is intended as a mechanism for assisting and encouraging providers to identify solutions to their issues and rapidly remediate them. The process is designed to help Providers as well as to ensure that learners are receiving the highest quality CME. The ACCME will work with Providers to ensure that reasonable timeframes are imposed.

The ACCME’s accreditation system is a careful and deliberate process in which serious and systemic issues that place providers and their learners at risk can be identified. The ACCME has learned over the years that an accreditation status of Probation sends a clear message that significant changes need to be made. The ACCME has also observed that the vast majority of providers make the necessary
changes, leading to sustained Compliance, and in a number of instances Accreditation with Commendation.

In order to make full use of this effective strategy, the ACCME is now putting more Accredited Providers on Probation - especially those found in Non Compliance with elements of the ACCME Standards for Commercial SupportSM. The current rate of Probation has increased to about 10% of Providers seeking Reaccreditation from about 1% in the past.

**MONITORING:** The ACCME has always maintained 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.

**THE SPECIAL COMMITTEE ON AGING ASKED ACCME FOR “ANY FURTHER PLANS THE ACCME MAY HAVE IN PLACE TO DEVELOP SUCH MECHANISMS [TO ENSURE THAT NO UNDUE INFLUENCE BY ANY INDUSTRY IS BEING EXERTED THROUGH COURSES].”**

The ACCME is working on developing new capabilities for maintaining a CME activity database that will provide a new source of information for ACCME’s newly emphasized oversight processes. The ACCME’s maintenance of an accurate and complete database of CME activities and participants is critical to the ACCME’s ability to provide additional, direct oversight of activities in real-time. All Accredited Providers will be required to transmit to the ACCME an enhanced data set of information descriptive of each of CME activity. Transmission of data to the ACCME will be through a web-based portal or direct transmission of appropriately formatted spreadsheets. Maintenance of accreditation will depend on the ACCME’s receipt of complete information in a timely fashion. The ACCME will expand the database of activity information to include data derived directly from ACCME ‘monitors’ present at activities. This will include information from learners and from other special ACCME observers. It may also be
expanded to include lists of participants. Subsequently, the ACCME database can be expanded to include self-assessment data that is reported to ACCME by Accredited Providers about their programs of CME. The ACCME will be requiring that Accredited Providers measure for commercial bias and content validity, and report their results in real-time through a web portal. A Provider’s analysis of these data and its response to the findings will contribute to its compliance with Criteria 12 and 13. There will be transparency and disclosure of compliance information. What the ACCME knows about provider compliance will be published publicly on www.accme.org.

**MONITORING:** In 2008, 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.

We recently informed our Providers that the ACCME has adopted an enhanced focus on monitoring and surveillance of the CME system. Two new ACCME committees have been established to assist in this important task. Both groups have met and begun their work to assist and advise the ACCME with the implementation of new initiatives in 2008.

We have begun closer scrutiny of selected providers. The ACCME has put into place a mechanism for screening segments of the CME enterprise for Non Compliance with the spirit or word of the ACCME’s requirements. Currently, this is being done through the ACCME Complaints and Inquiries process. Accredited Providers that receive a large percentage of the systems’ commercial support, or present CME whose content may need further validation or CME providers that offer only jointly sponsored activities with non accredited organizations will be the subject of enhanced scrutiny by the ACCME. Approximately 100 accredited providers who are high commercial-support recipients have been asked to provide additional information about their compliance practices under this new approach. The ACCME is seeking verification that the content and process of the Accredited Providers’ interactions with commercial supporters from inception to CME presentation is being conducted independent of the influence of
commercial interests—as is required by the ACCME Standards for Commercial SupportSM. Blinded results of inquiries will be made available on www.accme.org.

SYSTEM WIDE CHANGES: The ACCME Board of Directors is committed to improving the organization’s ability to ensure that CME is independent of commercial interests and free of commercial bias in all CME topic selection, planning decision, and presentation content. The ACCME’s position has been that in CME the concepts of independence from industry and collaboration with industry in the development of content are mutually exclusive. Although commercial interests may provide commercial support for educational activities as defined by the ACCME Standards for Commercial SupportSM, in the U.S. in the context of independence, there is no role for ACCME-defined commercial interests in the development or evaluation of accredited CME activities in this context, the ACCME Board of Directors adopted the following,

“CME providers can receive commercial support from industry. CME providers cannot receive guidance, either nuanced or direct, on the content of the activity or on who should deliver that content.”

In addition, the ACCME is taking steps to ensure that any current processes for attaining commercial support will not undermine the independence of continuing medical education. The ACCME intends to limit the interactions between accredited providers and commercial Interests over commercial support.

It is ACCME’s position that the manner of interaction between potential commercial supporters, or their agents, and some Accredited Providers may need to be altered. The ACCME takes the position that the following is the manner of interaction required in order for an Accredited Provider to maintain its compliance with SCS 1: Independence of the ACCME Standards for Commercial SupportSM – and has distributed this position as a ‘call-for-comment’ to the CME enterprise.

1 Accredited providers must not receive communications from commercial interests announcing or prescribing any specific content that would be a preferred, or sought-after, topic for commercially supported CME (eg,
therapeutic area, product-line, patho-physiology) - as such communication would be considered ‘direct guidance on the content of the activity’ and would result in Non Compliance with Standard 1 of the ACCME Standards for Commercial SupportSM.

2 Receiving communications from commercial interests regarding a commercial interest’s internal criteria for providing commercial support would also be considered the receipt of ‘guidance, either nuanced or direct, on the content of the activity or on who should deliver that content.’

The ACCME also believes that due consideration be given to the elimination of commercial support of continuing medical education activities. In January 2007, the ACCME initiated a nation-wide discussion by announcing that it would be considering taking action regarding the funding structure of continuing medical education. In March 2008, the ACCME again expressed the belief that due consideration be given to the elimination of commercial support of continuing medical education. Many stakeholders inside and outside the CME enterprise have expressed their views on this subject. The ACCME recognizes that although CME exists in a data-driven, evidence-based world, many are motivated by firmly held personal beliefs about propriety and professionalism. The ACCME values both perspectives and now seeks input on this matter.