Accreditation Council for Continuing Medical Education

Responses to Calls-for-Comment

Organizational Responses

October 2008

ACCME

AMERICAN ACADEMY OF FAMILY PHYSICIANS
STRONG MEDICINE FOR AMERICA

September 10, 2008

Murray Kopelow, MD
Chief Executive
Accreditation Council for Continuing Medical Education
515 N. State Street, Suite 1801
Chicago, Illinois 60654

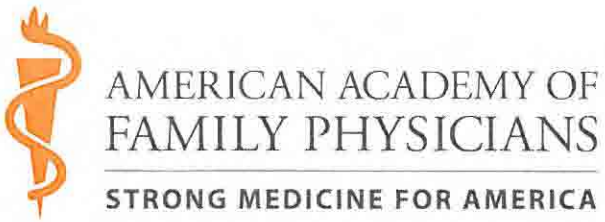
RE: ACCME Policy Announcements and Calls for Comment

Dear Dr. Kopelow:

The American Academy of Family Physicians (AAFP) is pleased to offer a response to the proposed policy changes to the Accreditation Council for Continuing Medical Education (ACCME) Standards for Commercial Support. In this response we will reflect three perspectives — that of family physicians across the U.S. who seek quality, unbiased continuing medical education (CME); that of a professional medical specialty society; and that of an ACCME-accredited provider of CME.

First, AAFP affirms that ACCME is now, and should remain, the leading national multi-specialty entity that develops and disseminates CME rules and regulations. A strong ACCME is in the best interest of both physicians and the patients they serve. We also assert that the AAFP carefully monitors our adherence to the ACCME's 2004 Standards for Commercial Support, as well as other pertinent laws, regulations, ethical codes, guidelines and considerations that inform our ability to ensure the identification, disclosure, and resolution of real or perceived conflicts of interest and/or bias, and are proud to have earned the designation of "Accreditation with Commendation" from the ACCME in 2001 and again in 2007. However, the AAFP disagrees with several premises or solutions set forth by ACCME in its June and August 2008 calls for comment on the following three matters:

11400 Tomahawk Creek Parkway • Leawood, KS 66211-2672 • 800.274.2237 • 913.906.6000 • Fax: 913.906.6075 • fp@aafp.org



I. The ACCME Will Ensure Current Processes of Attaining Commercial Support Will Not Undermine the Independence of Continuing Medical Education.

II. The ACCME Believes that Due Consideration be Given to the Elimination of Commercial Support of Continuing Medical Education Activities

III. ACCME Proposes Additional Features of Independence in Accredited Continuing Medical Education

I. The ACCME Will Ensure Current Processes of Attaining Commercial Support Will Not Undermine the Independence of Continuing Medical Education.

ACCME proposes that "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 ... deliver that content."

AAFP agrees with ACCME that independence of CME must be assured; but AAFP objects to further restrictions in communications between accredited providers and commercial interests regarding various practical topics for consideration that pertain to the financial support but not the educational content of CME. AAFP believes that the current ACCME guidelines for interactions between accredited providers and commercial interest are sufficiently effective in assuring independence, and that further restrictions on communication could jeopardize best practices in patient care by restricting or slowing the translation of medical research into education and practice.

As an ACCME-accredited provider and the country's first national CME accreditor, AAFP appreciates the fact that ACCME will update its criteria and expectations on a regular basis to support continuous improvement in the provision of CME. In fact, AAFP has adopted ACCME's criteria for AAFP-provided CME, and we require that CME providers seeking AAFP CME credit likewise comply with ACCME policies and standards for commercial support. We agree on the importance of rigorously applied safeguards to assure CME independence, such as the identification, disclosure, and resolution of real or potential conflicts of interest. We remain committed to ensuring that AAFP-provided CME and AAFP-accredited CME is objective and relevant; not influenced inappropriately by external support or other factors that would introduce bias in a manner that could jeopardize the appropriate translation of science into research, education, and practice. We regularly and rigorously verify that AAFP CME is designed and conducted in a manner that supports improvements in professional competence, practice performance, and ultimately, patient outcomes.

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AAFP disagrees, however, with ACCME's proposed additional restrictions in interactions between accredited providers of CME and industry; they are both unnecessary and operationally impractical. Professional medical specialty societies seeking funding must be allowed to communicate, directly when appropriate, with industry about matters of mutual interest which may at times include discussion of broad therapeutic topics for educational content, or scientific evidence for the incidence and burden of various diseases and conditions. Likewise, external supporters, whether commercial, private foundations, government agencies, or other entities, must be allowed to convey in broad terms what activities they are willing to fund. No evidence has been disseminated by ACCME or others to show that such broad conversations lead to '... guidance, either nuanced or direct ...' in a manner that inappropriately influences CME.

II. The ACCME Believes that Due Consideration be Given to the Elimination of Commercial Support of Continuing Medical Education Activities

ACCME proposes that "...if the following (four) conditions were all met, then the commercial support of individual activities would be in the public interest and could continue to be allowed."

1. When educational needs are identified and verified by organizations that do not receive commercial support and are free of financial relationships with industry ((e.g., U.S. government agencies), and
2. If the CME addresses a professional practice gap of a particular group of learners that is corroborated by bona fide performance measurements (e.g., National Quality Forum) of the learners' own practice; and
3. When the CME content is from a continuing education curriculum specified by a bona fide organization, or entity, (e.g., AMA, AHRQ, ABMS, FSBM); and
4. When the CME is verified as free of commercial bias.

AAFP views ACCME's proposal of such a list as problematic in principle, and as operationally impractical. In particular, we disagree with items 1 and 3 in ACCME's list of conditions for allowance of commercial support.

Regarding item 1, educational needs: The identification and verification of educational needs is core to the organizational mission of professional medical specialty societies. Specifically, a cornerstone of AAFP's mission is to educate our members — practicing family physicians, family medicine residents and medical students – this is one of the four strategic objectives of the organization. AAFP serves as its members' steward and advocate, and is thus uniquely positioned to best know and understand physician members' educational needs and learning or performance practice gaps. Thus AAFP strongly objects to ACCME's suggestion that such educational needs are better understood by U.S. government agencies. It is a false premise that U.S. government

agencies are free of financial relationships with industry, as indicated by the prevalence of lobbying that occurs regularly in our nation's capital.

Regarding item 2, measurable performance practice gaps: AAFP agrees with ACCME that CME should address learners' professional practice gaps as corroborated by bona fide performance measurements. We agree that the National Quality Forum is one, but not the only, organization from which such performance measurements may be set forth.

Regarding item 3, CME curriculum: AAFP does not question the valuable contributions that ABMS, AHRQ, and FSMB make in regards to the advancement and assurance of quality medical research, education and practice, but AAFP strongly disagrees with ACCME's designation of those organizations as the bona fide entities for specification of CME content or curriculum. Should such a list exist, it must explicitly acknowledge the unequivocal role and responsibility of professional medical specialty societies in determining or overseeing specialty-specific CME curriculum. As noted in ACCME's 2007 annual report (published August 28, 2008), Physician Membership Organizations currently provide over 23% of all of ACCME-accredited CME in the United States. Whatever approach is adopted to ensure that physicians are properly trained must include a major role for these medical specialty societies, including the identification and verification of educational needs, and the specification of educational curriculum.

Regarding item 4, freedom from commercial bias: AAFP agrees with the ACCME's commitment to verify CME is free from bias – whether due to commercial support or due to any other means by which bias may arise. However, AAFP has not found evidence in our own experience as an ACCME-accredited provider and as an accreditor, that commercially supported certified CME equates to content bias.

And according to a June 2008 report by Ronald Cervero and Jiang He, entitled *"The Relationship between Commercial Support and Bias in Continuing Medical Education Activities: A Review of the Literature"* – a report commissioned by ACCME, and is now posted on its website:

> *"There is no published study that addresses the relationship between commercial support and bias in accredited CME activities. Although it has been speculated that commercial support produces bias in CME activities, there is no evidence to support or refute this assertion."*

The profession has made significant strides in reducing the potential for bias in certified CME during the past decade — both via development of formal safeguards such as codes and official guidelines, and through practical implementation of mechanisms for identifying, disclosing, and resolving actual or perceived conflicts of interest. We do not

believe that additional restrictions are necessary, in fact we are concerned that they could ultimately cause more harm than good.

Indeed, AAFP strongly disagrees with ACCME's call for the elimination of commercial support; we are deeply concerned that such action could harm, rather than help, physicians and ultimately the health of this nation's citizens. We urge ACCME to acknowledge with us that patients deserve access to the best care possible, and that the ultimate purpose of CME is to equip physicians and other healthcare professionals with the knowledge, skills, and professional development experiences needed to provide quality patient care. To the extent that industry's products are based upon solid medical science and best clinical practices, physicians and physicians in training have the right and the responsibility to be trained in the appropriate use of such products in order to provide appropriate quality care for their patients; and to offer patients anything less would be socially and professionally irresponsible.

Additionally, AAFP is concerned that the elimination of commercial support for accredited CME would in effect require physicians to incur all costs associated with their continuing education. At the present time, when the cost of medical education across the continuum (UME, GME, CME) continues to rise, and when the relative fee levels for delivery of care continue to decline, such action cannot be condoned without a reasonable, feasible alternative. AAFP is particularly concerned that elimination of external support for accredited CME would place a particularly unreasonable financial burden on primary care physicians who often practice in solo practices, rural communities, underserved areas, and other types of practice settings that do not offer salaries or institutional mechanisms for tuition CME reimbursement.

III. ACCME Proposes Additional Features of Independence in Accredited Continuing Medical Education

ACCME poses two questions in its August 2008 call for comments:

1. Should those who write promotional materials be excluded from having any role in writing CME content?
2. Should those who teach in promotional activities be excluded from teaching in independent CME activities?

As an ACCME-accredited provider and as an AAFP CME accreditor, AAFP agrees with ACCME on the importance of assuring independence of those involved in writing CME content or in teaching CME activities. However, AAFP disagrees that individuals involved in independent promotional education should automatically be excluded from having any role in certified CME.

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Specifically, AAFP agrees with the position of the Council of Medical Specialty Societies on this matter, in which it asserts that: "Persons paid to create or present promotional materials on behalf of commercial interests (who therefore disclose a conflict of interest) need not be excluded from accredited continuing medical education on the same subject if their conflict of interest can be resolved" via peer review, evidence-based presentation, content modification, and/or on-site monitoring of the activity.

Thank you for this opportunity to comment.

Sincerely,

Douglas E. Henley, M.D.
Executive Vice President

DH:jh

AAMSE . . . Advancing Professionalism in Medical Society Management
AMERICAN ASSOCIATION OF MEDICAL SOCIETY EXECUTIVES
555 East Wells Street, Suite 1100, Milwaukee, WI 53202 ◈ 414-221-9275 ◈ FAX 414-276-3349
Web Site: www.aamse.org

September 12, 2008

Murray M. Kopelow, MD, MS, FRCPC
Chief Executive Officer
Accreditation Council for Continuing Medical Education
515 N. State Street, Suite 1801
Chicago, IL 60654

Dear Dr. Kopelow:

The American Association of Medical Society Executives (AAMSE) appreciates the opportunity to comment on ACCME's position that *"due consideration be given to the elimination of commercial support of continuing medical education activities. The proposal is that the commercial support of continuing medical education end."*

AAMSE is the professional organization of more than 900 medical society executives and staff specialists. Through its more than 380 member organizations, it advances the profession of medicine through education, communication of knowledge, leadership development and collaboration.

AAMSE fully supports the ACCME Standards for Commercial Support, including the 2004 updates. Taken as a whole, these standards, and the criteria for meeting them, ensure that CME educational content offered by accredited providers remains free from commercial bias. Moreover, if ACCME adopts stricter provider compliance procedures – as proposed – such procedures will build an even stronger firewall against the mere possibility of commercial bias. For these reasons, AAMSE does not support the proposal to end commercial support of CME.

Medical societies have invested great effort and resources in recent years to help develop and set standards for industry support, as well as to embrace and fully comply with new and stringent standards for continuing medical education set by ACCME. We believe strongly that providers and regulatory bodies have made substantial improvements in the regulation of CME in recent years. These standards have already been adopted by accredited CME providers and most, if not all, industry funders. Before drastic and wholesale changes are made in the current system, the positive and proactive progress that has been made must be given a chance for full implementation and evaluation.

As you are aware, AAMSE recently convened an Advisory Council on continuing professional development and medical education. Its recommendations to medical association and specialty society leadership will encourage formation of strategic alliances between the continuing medical education and quality improvement arenas; such alliances hold great promise for ensuring the highest quality education possible resulting in improved physician competence, performance and patient outcomes.

We agree that the relationship between industry and CME providers warrants careful, thoughtful and transparent scrutiny to assess whether processes and mechanisms are working, both to prevent industry influence and improve medical education quality. We believe, however, that eliminating industry funding of certified CME in its entirety will marginalize critical roles that industry, and many physicians working in industry, play in critical medical research alliances. The practical impact of such a funding ban would greatly diminish not only the availability or quantity of certified medical education, but its quality as well. The scenario will not serve the needs or interests of patients and physicians, both striving to increase quality of care.

Progress in all endeavors is ultimately based on building strong partnerships and alliances, and building trust. The CME community and medical societies are providing outstanding leadership in building those alliances and demanding a high standard of transparency and trust. They need time to fulfill their vision of the future of CME.

Sincerely,

Cal Chaney, JD, CAE
AAMSE President
Associate Executive Director, Policy,
And General Counsel
American College of Emergency Physicians

cc: AAMSE Board of Directors
AAMSE Advisory Council for the Medical Education
Leadership Forum

AMERICAN COLLEGE OF CHEST PHYSICIANS

The leading resource for the improvement in cardiopulmonary health and critical care worldwide

September 12, 2008

Murray Kopelow, MD, MS(Comm), FRCPC
ACCME Board of Directors
Accreditation Council for Continuing Medical Education
515 North State Street, Suite 1801
Chicago, IL 60654

Dear Dr. Kopelow and the ACCME Board of Directors:

Thank you for giving the American College of Chest Physicians (ACCP) the opportunity to share our opinion on the recent call for comments. As you know, 2008 has been and continues to be a year of reflection, discussion, and change. The ACCP firmly believes that the ACCME needs to facilitate annual strategic meetings with necessary stakeholders who can assess and provide suggestions on how best to move forward with a new quality and outcomes-based CME initiative throughout the United States. Our response to each of the questions posed to the CME community appears below and reflects this concept with responses that impact the future of ACCME policies.

1. **Accredited providers must not receive communications from commercial interests announcing or prescribing any specific content that would be preferred, or sought-after, topic for commercially supported CME (*eg,* therapeutic area, product-line, pathophysiology) 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 Support.**

   We agree that specific content that reflects a specific treatment or product can be perceived as potentially influencing medical education content. However, we do not agree with completely eliminating all communication with industry about health issues that health-care providers experience daily. Company representatives hear these stories, some of which they cannot address immediately but we, as CME providers, can. If there is no communication between industry and CME providers, we lose access to potentially important information. This proposal as written should be reconsidered with a view toward permitting communication with industry and CME providers while protecting from undue influence related to a specific product line.

3300 Dundee Road • Northbrook, Illinois 60062-2348 • USA
(847) 498-1400 *voice* • (847) 498-5460 *fax* • accp@chestnet.org *e-mail*
www.chestnet.org

2. **Receiving communications for 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.'**

We agree completely with this proposal. Having over 16,000 professional members who are content experts in the fields of pulmonary, critical care, and sleep medicine, the ACCP as a CME provider has access to the best teachers on a variety of content used in our certified/accredited CME activities that are also of interest to potential commercial supporters. Using these content experts accredited providers should not ask commercial supporters to define their internal criteria, especially for the approval of financial support, so that the request can be formulated and worded in such a manner to ensure approval of financial support by the potential supporter.

3. **The proposal is that the commercial support of continuing medical education end.**

We disagree with a blanket ban on all commercial support of CME. In 2006, 61% of CME revenue was derived from commercial sources, including the pharmaceutical and medical device industries. We recognize that the problem is not the amount of revenue that is generated, but rather that 20% of ACCME-accredited organizations are in noncompliance with one or more elements of the Standards for Commercial Support. We also recognize that the ACCME reviews are done retrospectively, and that it may take months or years for a CME provider to change a program to put it in compliance. These issues must be addressed, but a complete ban on commercial support should be implemented only when there is some empirical evidence that commercial support introduces bias or influences the content of certified/accredited medical education positively or negatively; obtaining that evidence would require some further study. ACCME recently agreed to this in its own response to the Macy Foundation report. Given that statement, we propose that ACCME act by facilitating a meeting of stakeholders from the CME provider community to discuss how commercial support is identified, used and managed in CME, as well as to develop and implement ways to assure compliance with ACCME's current Standards for Commercial Support. No such task force has been convened, other than the Consortium for Academic Continuing Medical Education (CACME) attempt to address these issues with a risk stratification tool that estimates the potential for commercial influence. Collecting this type of evidence would facilitate buy-in from CME providers without resorting to the elimination of all commercial support, and the resulting impact on certified and accredited CME. Prohibiting industry support for CME would probably lead to a reduction of accredited CME hours and a proportional increase in industry-sponsored promotional activities. We believe that industry will spend its dollars to reach physicians with or without CME funding, and that it is in the best interests of professional learners and patients that industry funds be channeled toward CME that is in compliance with ACCME criteria.

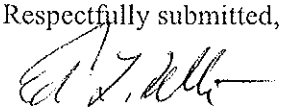
4. Persons paid to create, or present, promotional materials on behalf of commercial interests cannot control the content of accredited continuing medical education on that same content.

We disagree with a proposed policy that potentially eliminates content medical experts from participating in both promotional programs and accredited continuing medical education. Many times, the medical community seeks these key knowledge leaders' expertise. If this policy is implemented, physician learners will probably attend promotional activities to hear information from experts who no longer participate in CME programs. In our opinion, this policy would not solve the issues of potential bias by physician experts who present both in promotional and accredited medical education.

In conclusion, we emphasize the need to address the issues collaboratively as health care professionals and educators to ensure that educational programming is evidence-based, free of commercial influence and with effective and measurable outcomes. Imposing additional regulations in the absence of such study and development of reasonable guidelines will probably hurt the prospects of high-quality CME, especially now when providers are working to adapt to the updated criteria being implemented this year.

Thank you for your consideration. We would be happy to answer any additional questions that might develop from our responses, and look forward to future discussions on these important issues.

Respectfully submitted,



Ed Dellert, RN, MBA
Vice President, Educational Resources
American College of Chest Physicians

cc: Alvin V. Thomas, Jr., MD, FCCP, *ACCP President*
COL Lisa K. Moores, MC, USA, FCCP, *Chair, Education Committee*
Mark J. Rosen, MD, FCCP, *Vice-Chair, Education Committee*
Alvin Lever, MA, FCCP(Hon), *Executive Vice President & CEO*

ALLIANCE for CME
The International Association of CME Professionals

Southcrest Building, Suite 105
1025 Montgomery Highway
Birmingham, Alabama 35216-2856
Phone: 205/824-1355
Fax: 205/824-1357
Email: acme@acme-assn.org
Website: www.acme-assn.org

Mission
The Alliance for CME is a membership organization that provides professional development opportunities for CME professionals, advocates for CME and the profession, and strives to improve health care outcomes.

September 12, 2008

Murray Kopelow, MD
Chief Executive
Accreditation Council for CME
515 North State Street, Suite 1801
Chicago, IL 60610

Dr. Kopelow:

The Alliance for Continuing Medical Education (Alliance) is an international membership organization of more than 2,600 professionals devoted to designing and implementing continuing medical education (CME) activities for physicians. The Alliance provides professional development opportunities for CME professionals, advocates for CME and the profession, and strives to improve patient health care outcomes. The Alliance appreciates the opportunity to provide comment on issues identified in the ACCME's June and August Call for Comments issued to Accredited CME Providers.

I. The ACCME will ensure current processes of attaining commercial support will not undermine the independence of continuing medical education.

The ACCME has asked for comment on the issue of whether providers should receive "communications from commercial interests announcing or prescribing any specific content that would be preferred, or sought after, topic for commercially supported CME…" Such communication "would be considered 'direct guidance on the content of the activity'" which would place the Accredited CME Provider in non-compliance with the Standards for Commercial Support.

The Alliance supports the concept that specific content should not be communicated from commercial supporters to Accredited CME Providers. We draw a distinct line between the concept of "specific content" and "topic." In order to ensure independence of certified continuing medical education, we agree that industry should not "prescribe any specific content" for an educational activity. We recognize that this may be seen as controlling content – although we wish to note that Accredited CME Providers have the choice of whether or not to apply for the commercial support. Should they chose to apply for this commercial support, they would need to provide their own needs assessment data supporting the activity they are planning. This said, we recognize that there can easily be a blurring of the lines between acceptable and unacceptable industry input. The monitoring of this would be onerous for the ACCME.

The Alliance does not support the concept that commercial supporters should be restricted from being allowed to communicate topics for which they are willing to provide support. Again, an Accredited CME Provider is under no obligation to seek financial or in-kind support from the commercial supporter who makes this information available. Instead, Accredited CME Providers may use this information to direct their requests for commercial support. It is unrealistic to expect individual companies to fund education outside the scope of their corporate mission. Topic parameters provided by commercial supporters will ease the work of frequently stretched CME offices. This is consistent with the fact that not-for-profit foundations post their mission and objectives to guide grant requests.

ACCME also seeks comment on whether Accredited CME Providers should receive "communications from commercial interests regarding a commercial interest's internal criteria for providing commercial support." ACCME states that this type of communication "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 Alliance is concerned with these statements.

We ask ACCME to clarify the definition of "internal criteria." If, by "internal criteria" ACCME means that the commercial interests cannot provide an application form that includes information used by the commercial supporter to evaluate the request for funding, we would not support this statement. Accredited CME Providers seek support from a wide range of commercial supporters. As long as Accredited CME Providers hold true to the concept of not accepting input into the educational activity from industry, the fact that industry, in its review, knows the planned content of a proposed activity does not represent either nuanced or direct guidance. Industry can decide not to support the activity and the Accredited CME Provider is free to seek support from other companies. The only problem that could occur is if the Accredited CME Provider changed its activity based on feedback from industry in response to a completed application. In such a case, we would agree that the Accredited CME Provider would be out of compliance with the Standards for Commercial support.

If by "internal criteria" ACCME means that industry cannot make clear which specific treatment modalities/interventions must be addressed, or specific content presented in order for support to be offered, we concur with ACCME. This type of information could be perceived as crossing the bounds by influencing the content of the program. While it could be argued that Accredited CME Providers need not apply for the support if this information did not conform with their own plans, this would be considerably difficult to monitor.

II. The ACCME believes that due consideration be given to the elimination of commercial support of continuing medical education activities.

The Alliance does not support the ACCME proposal to eliminate commercial support of certified continuing medical education. There is currently no evidence available to suggest that commercial support increases or decreases bias in educational programming or negatively impacts physician decision making after attending a certified CME activity. This statement is corroborated by ACCME's own "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."

ACCME has been a leader in addressing the issue of conflicts of interest and commercial support. In 2004, the ACCME released the revised Standards for Commercial Support; in 2006, the ACCME released the updated criteria for accreditation; and in 2007, the ACCME clarified what it defines as a commercial supporter. These initiatives have clarified the appropriate management of commercial support and conflicts of interest. Accredited CME Providers have been actively improving their practices to conform to these updated Standards and Criteria.

Relationships with commercial interests are also guided by the Department of Health and Human Services - Office of the Inspector General (OIG), Food and Drug Administration (FDA), American Medical Association (AMA), PhRMA, and AdvaMed to help ensure independence, transparency and the integrity of commercial medical educational activities. The ACCME recommendation to eliminate commercial support completely would potentially negate the impact of all the CME components of regulations and codes that have been strengthened and enforced over the past four years.

It is the opinion of the Alliance that the ACCME should take into account the valued added benefits to broaden and improve the quality and reach of certified educational programming when sufficiently funded, regardless of funding source. Funding from commercial interests has supported accredited provider's efforts to develop educational activities designed to utilize the most effective methods of instruction based upon the specific needs of the target audience. The CME provider, therefore, is better positioned to deploy the full

range of educational tools, techniques and resources to provide the best possible continuing medical education for physicians.

In addition to the above, it is important to note that advancements in medicine, both therapeutic and technologic, are not stagnant. Providers of continuing medical education rely on the financial support of industry so that they can offer ongoing education on the advancements of medical technologies and their application in the practice of medicine. Without access to viable commercial funding by providers of certified continuing medical education, industry will need to fill the educational void, thus increasing industry influence over content; a situation that would be in direct contrast to the intended goal to decrease industry influence.

To date, there is no existing evidence that supports the far-reaching premise that the elimination of commercial support for educational activities would eliminate bias in CME. Rather, the Alliance supports the ACCME's "status quo" option, whereby all commercial relationships must be disclosed and managed appropriately. It is the responsibility of Accredited CME Providers to ensure that certified educational activities are free from commercial bias and are based on the highest available level of evidence.

The Alliance shares the belief that certified continuing medical education should be independent and free of commercial bias. The Alliance has adopted its own Conflict of Interest Principles that aim to ensure transparency, thereby creating a stronger barrier between commercial interests and the content of certified continuing medical education. These principles are:

1. **The content of CME activities must be based on evidence that is accepted by the medical profession. This evidence may be drawn from research, performance guidelines, epidemiological data, and current practice.**

2. **All financial relationships between commercial entities and providers of certified continuing medical education must be disclosed to both the planners and the participants. The CME provider must ensure that the planning and implementation of CME activities are accomplished with no influence from commercial entities. CME providers must disclose the process by which they manage conflicts of interests with commercial entities as well as individuals and organizations.**

3. **All financial relationships between commercial entities and individuals responsible for planning, implementing and presenting educational activities must be disclosed both to the accredited CME provider and to the participants of the educational activities, and managed appropriately.**

The ACCME has also asked for comment with regard to a possible new paradigm for commercial support. After reviewing the proposed new paradigm, we believe the model offered is unnecessarily burdensome and will, by default, preclude most providers from qualifying for commercial support.

Rather than create a new paradigm for commercial support, the Alliance recommends that the ACCME invest resources to enhance the surveillance and enforcement of existing Essentials, Elements, Standards and Policies. We steadfastly support the need for robust, scientifically sound research investigating the impact of commercial support on educational programming and bias, and consequently on physician behavior and patient care.

III. "Persons paid to create, or present, promotional materials on behalf of commercial interests cannot control the content of accredited continuing medical education on the same content."

The Alliance considers this a very important statement that should be openly debated. We have serious concerns with this proposed policy. Industry upholds contracts with subject matter experts to present information about their products and services. These presentations may include education on the clinical benefits and safety considerations for a marketed pharmaceutical product or device. Many times, the researchers who have conducted the clinical trials which investigated the safe and effective uses of the product are then called upon to discuss their findings in a promotional setting. This is all acceptable under the regulations set forth primarily by the Food and Drug Administration.

The Alliance is concerned that the ACCME appears to be suggesting that those contributing to the development and presentation of certified continuing medical education are not capable of fulfilling more than one role without becoming ethically and professionally compromised. The Alliance believes that when accredited providers comply with the ACCME's Essentials, Elements, Policies, and Standards there are sufficient safeguards to ensure that certified continuing medical education activities are developed in a fair and balanced manner, upholding the standard of providing the best available evidence in a manner that will positively impact patient care. Should the

ACCME adopt this policy, it is reasonable to believe that many excellent contributors to the advancement of clinical research and medicine would be barred from speaking as experts on the very content for which they were sought after by industry and Accredited CME Providers. Further, the Alliance is concerned by the lack of documented evidence which demonstrates a problem exists and that the ACCME's Essentials, Elements, Policies and Standards are not ensuring the highest quality of certified continuing medical education without bias being properly managed. The Alliance strongly believes that policy development should be driven by sound, evidence-based data and that change to the accreditation system should not be made in the absence of relative supporting data.

The Alliance acknowledges the ACCME's intent to improve the quality and independence of continuing medical education as the impetus for the clarifications on interactions between Accredited CME Providers and commercial supporters and the proposal to eliminate commercial support. On behalf of our membership, the Alliance offers its assistance in supporting Accredited CME Providers in meeting the ACCME's Essentials, Elements, Standards and Policies. Lastly, the Alliance supports the concept of more diligent surveillance and further study.

Sincerely,

SueAnn Capizzi, MBA
President

ASSOCIATION FOR HOSPITAL MEDICAL EDUCATION
109 Brush Creek Road • Irwin, PA 15642 • 724.864.7321 • www.ahme.org • info@ahme.org

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ACCME

August 1, 2008

Murray Kopelow, MD, MS (Comm), FRCPC
Chief Executive and Secretary
Accreditation Council for Continuing Medical Education
515 North State Street, Suite 1801
Chicago, Illinois 60654

To whom it may concern:

On behalf of the Association for Hospital Medical Education (AHME), we would like to thank the Accreditation Council for Continuing Medical Education (ACCME) for the opportunity to respond to your "Call for Comments" of June 11, 2008.

In response to these proposals, AHME sent an electronic survey to our membership and received 67 responses. While this is not a large proportion of our membership, we believe the information accurately represents the views of the larger group of AHME members who are involved in providing CME. The unedited responses to this survey, including both tabulated data as well as the appended commentary are attached for your review. In addition, a few comments regarding the views of the respondents to our survey are included.

The majority of the respondents strongly or mildly disagree with the "complete elimination of commercial support for CME". Most AHME respondents felt that this would have an adverse impact on medical education in their hospitals unless or until alternative funding mechanisms could be developed. On the other hand, it is interesting that 21 (31%) of those responding to the survey strongly or mildly agreed with eliminating commercial support. The variety of responses to this question and a number of other questions reveal that initiatives in this area are likely to generate considerable controversy.

Over sixty percent of the respondents said that we should maintain the "status quo". This is consistent with the number who responded that they disagreed with eliminating commercial support. The text responses most frequently indicated that as long as providers abide by the ACCME Standards for Commercial Support and continue to monitor for commercial bias in our programs, we should continue to accept this funding mechanism for CME. We regard this response as a vote of confidence for the progress ACCME has already made in this important area. We also believe it may reflect the anticipated impact of the increased monitoring and enforcement of compliance with the existing standards related to commercial support.

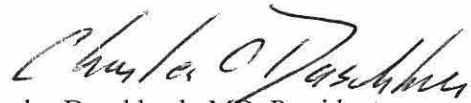
The AHME members responding to the survey strongly agreed with the concept that CME providers should not receive guidance from industry and that we should not respond to "Requests for Applications" from pharmaceutical companies. The responses indicated that the CME provider must choose the topics for CME independent of the pharmaceutical company suggestions.

The AHME response to the proposal for a "new paradigm" for funding of CME was almost equally divided between support and disagreement. One concern with this plan is that industry would have little motivation to contribute to such a fund, thus raising questions about the viability of this proposal. Another concern was that it would add a level of bureaucracy and paperwork to the process. Finally, a number of respondents expressed the concern that this proposal would disproportionately disadvantage smaller institutions where, in many cases, there is a greater need for continuing medical education activities.

We hope the ACCME finds this information helpful, and that some of the creative ideas submitted by individual respondents to the survey will be helpful as these discussions continue. In closing, we thank you again for the opportunity to provide this input and we look forward to continuing to work with the ACCME to improve medical education in our hospitals and other institutions.

Sincerely,

David Pieper, PhD, Chair
Council on Continuing Medical Education



Charles Daschbach, MD, President
Association for Hospital Medical Education

AHME Response to ACCME

1. All commercial support for CME activities should be eliminated entirely.

	Response Percent	Response Count
Strongly agree	10.6%	7
Mildly agree	19.7%	13
No opinion	6.1%	4
Mildly disagree	25.8%	17
Strongly disagree	**37.9%**	25
	Comment:	23
	answered question	**66**
	skipped question	**0**

2. The "status quo" should be maintained, in that CME providers should continue to be able to accept grant awards from commercial interests in support of CME activities and in accordance with the ACCME Standards for Commercial Support.

	Response Percent	Response Count
Strongly agree	27.3%	18
Mildly agree	**34.8%**	23
No opinion	6.1%	4
Mildly disagree	19.7%	13
Strongly disagree	12.1%	8
	Comment:	8
	answered question	**66**
	skipped question	**0**

3. 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 (this would also eliminate pharmaceutical company "Requests for Application").

	Response Percent	Response Count
Strongly agree	**57.6%**	38
Mildly agree	24.2%	16
No opinion	6.1%	4
Mildly disagree	6.1%	4
Strongly disagree	6.1%	4
Comment:		7
answered question		**66**
skipped question		**0**

4. The ACCME should work to design and propose a "new paradigm" for funding of CME activities whereby, industry-donated funds are deposited into a national pool and distributed to accredited CME providers based on strict, defined criteria. (Individual activity funding would depend upon a verified educational need, documented knowledge gap, and verified as free of commercial bias.)

	Response Percent	Response Count
Strongly agree	19.7%	13
Mildly agree	**25.8%**	17
No opinion	7.6%	5
Mildly disagree	21.2%	14
Strongly disagree	**25.8%**	17
Comment:		21
answered question		**66**
skipped question		**0**

AHME Response to ACCME Comments:

All commercial support for CME activities should be eliminated entirely.

1. CME is important enough that alternate funding should be assured before severing external support.
2. The effort required for the resultant grant award is almost not worth it.
3. This would place a great burden on small, not-for-profit teaching institutions.
4. Education is costly. Physicians need continuing medical education that is the most current, evidence-based information. Specific education is best provided by those who require reimbursement that most CME programs do not have funding for. Elimination of grants will eliminate those opportunities for many.
5. If the commercial support is given to the institution to help support the overall CME program, without any strings, etc. Higher quality programs might result.
6. This would have a drastic impact on CME. Most CME offices do not have the budget to support all their programs.
7. I actually think it should be eliminated. But let's be realistic. In many institutions and for many local, national and international medical organizations, CME and meetings in general would be impossible without major industrial support. On the other hand, is there evidence that the big annual meetings of the major medical societies (usually heavily funded by industry) actually do any good for anyone?
8. I think that the key is regulation and oversight, not elimination. For example, if an arrangement between a teaching hospital or medical school and industry, if properly supervised, can be a positive in medical education without the presence or appearance of impropriety.
9. We should be looking to those companies who provide us commercial support as partners in CME, education is a two-way street. As a CME provider, we have standards to follow, let us do our job.
10. If all providers would adhere to the ACCME SCS, there would be no issues.
11. This would shift the cost of most local CME to the hospitals and the medical staffs who already are seeing reimbursements fall
12. Compliance with Standards for Commercial Support justifies occasional use.
13. This would essentially end CME at some smaller hospitals which rely upon exhibitor fees
14. Need a way to support CME but to clearly keep bias away!
15. Eliminating funding for CME activities will cripple CME programs, particularly in community hospitals.
16. There should be a "superfund" to which all commercial entities pay in. Educational groups can apply for funding from it.
17. First we must develop other sources of funding: registration, dues, hospital support, other.
18. UPMC has set the model for CME Ethics
19. We need realistic options before our primary funding source is arbitrarily eliminated. The ACCME interpretation and presentation of its national survey data is vastly understated. If you look carefully at the data, more than 55% (400+ providers) receive at least $100,000 up to $1M in external funding. The ACCME needs to make public the mean support for all providers in this cohort to truly understand the level of dependency these providers have on external funding. CME programs at most hospitals around the country would be greatly reduced and registration fees for participants will cost hundreds of dollars more if these conferences are to be self-supporting programs.
20. The right position from an ethics standpoint and public good, but difficult to implement without identifying alternative funding. Tuition from individuals (highest paid profession in the world cannot pay for its own continuing education?) or home institution support are the most workable long range alternatives. Pharmaceutical advertising must also be addressed if this position is to be effective - CME should not "go it alone" in achieving a public good. Start by getting the FDA and the FCC to eliminate TV ads for pharmaceuticals, or at least the ones for "ED", for crying out loud.

21. I think this is an idyllic response. There is an expense to CME and industry can support it under proper parameters
22. The term commercial support is too broad. Can we accept advertising from non-medical companies, such as care dealerships or restaurants? The real issue is the pharmaceutical and device manufacturers, whose products must be ordered by physicians.
23. As long as we adhere to very rigid guidelines on how support can be accepted and avoid speaker's bureaus, establish reasonable honoraria standards, etc.

The "status quo" should be maintained, in that CME providers should continue to be able to accept grant awards from commercial interests in support of CME activities and in accordance with the ACCME Standards for Commercial Support.

1. As long as CME programs comply with Standards of Commercial Support and are driven by physician planners, this should continue to be an excellent source of education.
2. You would have to define the "status quo"... how one institution engages commercial support may be different from another CME provider.
3. Some providers must be reviewed and advised.
4. Itv is functioning in a responsible way ,currently
5. I believe there must be a step-down plan or we would potentially destroy our CME activities.
6. Maintain until have other sources.
7. The Standards for Commercial Support are working very well, except in a few highly publicized incidents. However, CME providers should continue to push industry toward other mechanisms for distributing educational grants---eg. 1) use of block grants for multiple programs; 2) hiring of third party administrators to receive, review and award grant applications; or 3) establishment of a national CME fund, administered by local intermediaries (the Medicare model).
8. See answer #1 above. ACCME Standards for Commercial Support are largely a paper chase. Enforcement by the ACCME is mostly bluster, lots of talk, little real action. As long as the ACCME continues to accredit drug companies and their marketing partners (aka "education" companies) as CME providers, the SCS will continue to be a bad joke.

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 (this would also eliminate pharmaceutical company "Requests for Application").

1. Control of content must be approved by the planners - not the pharmaceutical company.
2. As a CME provider, we are supposed to oversee or control the content of the message/information being delivered to our audience anyway...
3. The selection of content and speakers must be made by providers completely independent of commercial interest.
4. Should stop being for sale.
5. The RFP process endorsed by Pfizer and others has far greater potential to influence content than not. It should not be allowed.
6. See answer #1 above. Also, is this different than #2? How about eliminating speakers bureaus and consulting fees?
7. Sometimes industry makes really good suggestions on speakers that are not biased.

The ACCME should work to design and propose a "new paradigm" for funding of CME activities whereby, industry-donated funds are deposited into a national pool and distributed to accredited CME providers based on strict, defined criteria. (Individual activity funding would depend upon a verified educational need, documented knowledge gap, and verified as free of commercial bias.)

1. This would potentially leave smaller institutions with smaller programs at the back of the list of consideration and may leave them out completely when it comes to being competitive for grant awards.
2. We shouldn't be forced into such direct competition with our peers for "pool" allocations.
3. Possibly agree - As long as the new paradigm does not eliminate allowance of individual programs planning of activities to include current status quo, which is "working" very well for us. We do follow the Guidelines for Commercial Support.
4. What is the motivation for industry to donate to such a fund? Might as well eliminate all funding because that would be the result.
5. Why would industry do this?
6. This would be ignoring the potent and well-staffed efforts of a number of academic institutions to police themselves according to ACCME guidelines. These guidelines should be strictly enforced, but bypassing strong local committees and resources in favor of an ill-defined national pool seems quite counter-productive.
7. Do we really need this level of CME bureaucracy??? The large CME departments and university-based structures would certainly benefit from the pooling of funds given their grant-writing resources, etc. A smaller institution would be at a disadvantage given their limited resources...
8. A system like this could be unfair to smaller providers who lack the manpower to apply competitively with large CME departments.
9. The CME accrediting bodies on a local basis should continue to be the watchdog for commercial conflicts of interest. The ACCME should continue their efforts to refine and improve the requirements for unbiased CME.
10. Much of the new paradigm appears to be a credible advance. The accredited provider must determine the gap/need of its learners in the design of activities. The principle of free enterprise should be preserved. Acknowledgment of ethical commercial support for medical education is an incentive for industry to continue to develop new products for the improvement of health care.
11. The "big Dogs " would do well . the little guys would be trampled & shut out
12. I'm afraid that more high-powered CME providers (with larger staff and greater resources) would edge out the smaller institutions who may have one individual completing grant requests for multiple programs.
13. ACCME should recognize the integrity of accredited CME providers. This level of regulation is unacceptable, it particularly rankles that ACCME institutes regulations with no clear concrete examples for implementation.
14. I agree with the concept. I do not think the ACCME should be involved in the implementation.
15. Does this add another layer of bureaucracy? How do we keep it from getting out of hand? Who controls?
16. ACCME and AHME should follow Pfizer's lead and stop accrediting third party speakers comm. companies. They should also take a vote in total membership proposing that pharm companies should eliminate promotional talks entirely. This already has great support by most pharm reps in the country. I think it'd be a positive step toward enhancing the senate's financial comm on CME programs.
17. The ACCME should seek alternative funding methods. However, the proposed "new paradigm" with the proposed ACCME criteria as stated are so stringent that they would "de facto" eliminate most institutions from qualifying for funding. They are borderline absurd and completely irrational. We need rational solutions, not a standard that sets the bar so high, no provider could succeed. Any new

paradigm may require legislation. The ACCME and parent organizations should advocate rationale alternatives for change.

18. I strongly agree with the need for a new approach. However, unless we are talking about a federal tax on pharmaceuticals, a national funding pool as described is not practical. It is preferable to eliminate pharmaceutical funding in any form, providing a real alternative for funding is available.
19. The good side is this would put everything in a very tight regulatory box. The bad side is this would put every thing in a very tight regulatory box and stifle funding for really creative projects.
20. Overhead costs of administration? Equitable distribution? Does this mean nationally mandated CME topics based on maintaining MOC?
21. Once again, this is ideal but may be a bit "pie in the sky"

September 12, 2008

Murray Kopelow, MD, MS (Comm), FRCPC
Chief Executive
Accreditation Council for Continuing Medical Education
515 North State Street, Suite 1801
Chicago, IL 60654

Dear Dr. Kopelow:

The Accreditation Council for Continuing Medical Education (ACCME) recently sent out three Calls for Comment to the CME community in the U.S. The American Medical Association's (AMA) Council on Medical Education (Council) appreciates the opportunity to submit comments on all three of them.

Call for Comment 1: The ACCME will ensure current processes of attaining commercial support will not undermine the independence of continuing medical education.

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

Council on Medical Education's comments:

The Council is committed to ensuring that all CME activities that are certified for *AMA PRA Category 1 Credit*™ are planned and implemented independent of commercial interests at all stages. The Council does not believe that commercial entities should have any influence over the content of certified CME activities, as stated in our relevant Council on Ethical and Judicial Affairs opinions. However, it is unclear what value the proposed policies add to the current process.

The Council is unsure what ACCME means by "internal criteria." The grant application process for accredited CME providers to solicit funds from commercial entities should be a transparent one. The fact that a commercial interest lets providers, or the public in general, know what general areas it is willing to support and the process it uses in awarding grants does not necessarily interject commercial bias. In a time of fewer resources for accredited CME providers it is important they don't spend time applying for grants for which they would not qualify. Accredited CME providers have no control over how commercial entities disseminate their policies and procedures in legitimate ways for legitimate purposes. It also appears that these policies as currently written would be difficult to assess and monitor.

American Medical Association 515 N. State St. Chicago IL 60654
(312) 464-5000 www.ama-assn.org

Call for Comment 2: The ACCME believes that due consideration be given to the elimination of commercial support of continuing medical education activities.

Three possible scenarios:

1. The status quo with commercial support of CME an acceptable funding mechanism

Council on Medical Education's comments:

The AMA's House of Delegates supports the ACCME's 2004 Updated Standards for Commercial Support (SCS) and the AMA Code of Medical Ethics, Opinion E-8.061 "Gifts to Physicians from Industry" and Opinion E-9.011 "Continuing Medical Education." There are no data to demonstrate that an accredited CME provider's correct implementation of the ACCME SCS and the AMA ethical opinions does not eliminate commercial bias. Until there is evidence to show that this is the case, we should not be in a hurry to change the system once again.

2. The complete elimination of commercial support

Council on Medical Education's comments:

While the elimination of all commercial support is an option and needs to be discussed by all of the stakeholders in CME, the Senate Finance Committee has stated that commercial support of CME is not an issue as long is it is transparent and there are safeguards in place to ensure that there is no commercial bias. The Council is concerned that if commercial support is withdrawn from certified CME activities, commercial entities will invest a larger portion of their funds into Direct to Consumer advertising and promotional activities. Is this really where we want physicians to get information about new products or research? Further, the elimination of commercial support from certified CME activities would not guarantee the elimination of commercial bias from these activities.

3. Proposed new paradigm

   If the following conditions were **all** met, then the commercial support of individual activities would be in the public interest and could continue to be allowed:

   1. When educational needs are identified and verified by organizations that do not receive commercial support and are free of financial relationships with industry (eg, US government agencies) **and**
   2. If the CME addresses a professional practice gap of a particular group of learners that is corroborated by *bona fide* performance measurements (eg, National Quality Forum) of the learners' own practice; **and**
   3. When the CME content is from a continuing education curriculum specified by a bona fide organization or entity, (eg, AMA, AHRQ, ABMS, FSMB), **and**
   4. When the CME is verified as free of commercial bias.

Council on Medical Education's comments:

The Council would like to begin by stating that if an organization is able to verify that the certified CME activity is free of commercial bias (condition 4), which is the goal, there may be other processes, other than the one stated above, that CME providers can use to ensure this, and conditions 1-3 above would appear to be unnecessary.

Accredited providers are in the best position to identify the performance gaps of their target audience and of individual physicians. National, regional and state data are valid sources for needs assessment, but may not be sufficient to identify the particular gaps specific to a specific provider's physician audiences. Many of the learning formats approved for *AMA PRA Category 1 Credit*™ are geared toward individual physicians, with educational needs identified individually by the accredited provider and the physician.

While performance measures are valuable and should be used whenever possible, performance measures do not exist for every clinical condition. There are no current performance measures, for example, for some subspecialties or practice areas; this puts physicians in these groups at a disadvantage. Also, since medicine is ever-changing, there is often new information that needs to be disseminated to physicians before performance measures have been developed.

While the Council agrees that the concept of a continuing education curriculum is a good idea, there is not currently a continuing education curriculum for all specialties. In order to be truly useful, these curricula would need to be revised on a continual basis as new information and research becomes available. They would also need to be adaptable to the individual physician's specialty.

Call for comment 3: The ACCME proposes the following policy:

> Persons paid to create, or present, promotional materials on behalf of commercial interests cannot control the content of accredited continuing medical education on the same content.

Council on Medical Education's comments:

The Council believes that it is important to ensure a clear separation between promotional activities and certified CME activities. However, we would like some clarification on ACCME's proposed policy. Is it intended to be restricted to financial relationships within the past 12 months (as with the SCS 2.1) or is it time unlimited?

SCS 2: Resolution of Personal Conflicts of Interest requires that accredited CME providers identify and resolve all relevant financial relationships prior to the educational activity being presented to participants. Providers are also required to determine that the content of presentations promote improvements or quality in healthcare and not a specific proprietary business interest of a commercial interest (SCS 5.1).

Physicians also have ethical responsibilities when presenting at certified CME activities. CEJA Opinion E-9.011 states that faculty should ensure that "the content of their presentation is not modified or influenced by representatives of industry of other financial contributors, and they do not employ materials whose content is shaped by industry."

ACCME's interpretation of how accredited CME providers are implementing the Updated Standards for Commercial Support is still evolving. In the absence of data that the system is not working, it is only a perceived need to change it at this time, not an evidence-based need.

When physicians are involved with promotional activities, they have legal and ethical responsibilities to ensure that participants are aware of that activity's promotional nature. CEJA Opinion E-9.011 states that, "When invited to present at non-CME activities that are primarily promotional, faculty should avoid participation unless the activity is clearly identified as promotional in its program announcements and other advertising." This is also reinforced for speakers in the new version of the Code on Interactions with

Healthcare Professionals that was recently released by the Pharmaceutical Research and Manufacturers of American (PhRMA).

The AMA, as the owner of the AMA PRA credit system, has a vested interest in ensuring that all activities that are designated for *AMA PRA Category 1 Credit*™ are beyond reproach. The AMA has granted the privilege to award *AMA PRA Category 1 Credit*™ to organizations accredited through the ACCME system with the expectation that they will take all the steps necessary to ensure the integrity of certified CME activities. The Council appreciates the effort that the ACCME takes to ensure that accredited providers meet the standards that have been established. We offer our expertise and service to assist in this endeavor.

Sincerely,

Alejandro Aparicio, MD, FACP
Director
Division of Continuing Physician Professional Development
Staff Liaison to the ACCME
American Medical Association

Anna S. Richo
Senior Vice President &
Chief Compliance Officer

AMGEN

Amgen Inc.
One Amgen Center Drive, M/S 38-4-C
Thousand Oaks, CA 91320-1799
(805) 447-7830 - Direct
(805) (805) 499-9371- Fax
aricho@amgen.com

September 12, 2008

Sent via Facsimile
Mr. Murray Kopelow, MD, MS, FRCPC
Chief Executive
Accreditation Council for Continuing Medical Education
515 North State Street, Suite 1801
Chicago, IL 60654

Dear Dr. Kopelow,

Thank you for the opportunity to comment on recent proposals for updating the ACCME Standards for Commercial Support. As a company dedicated to pioneering science, Amgen is committed to supporting quality continuing medical education (CME) that advances medicine and improves patient care. The public relies on physicians for the one thing that matters most—their health and well being. It is generally agreed that CME is an essential element of continuous physician learning and improvement and contributes significantly to patient care and well-being.

ACCME has opened three topics for comment;

I. Limiting Interactions between Accredited Providers and Commercial Interests over Commercial Support
II. Considerations to Eliminate Commercial Support of Continuing Medical Education Activities
III. Proposed Additional Feature of Independence in Accredited Continuing Medical Education

First and foremost, Amgen supports the comments presented to ACCME by the Pharmaceutical Research and Manufacturers of America (PhRMA). We want to reinforce that there are sound reasons for CME providers to have appropriate, controlled interactions with the pharmaceutical industry, and we agree with PhRMA that the new Code on Interactions with Healthcare Professionals and ACCME's revised Standards for Commercial Support should be implemented, monitored and enforced before additional substantive changes are made to the ACCME Standards.

On the issue of Independence in Accredited Continuing Medical Education, Amgen strongly supports independence of content, as reflected in our U.S. Standard for Independent Medical Education and in our contractual agreements with educational providers. Further, Amgen requires educational providers to certify that they do not also provide marketing services to Amgen, unless an appropriate firewall is in place to assure that personnel and files associated with those marketing services are kept separate from personnel and files associated with CME proposals. We support ACCME's goal of maintaining freedom from bias and we believe that the provisions within the OIG Guidance and the new PhRMA Code will achieve this goal, without the need for a sweeping prohibition of commercial funding or limiting individual healthcare professionals from participating in both FDA regulated promotional speaker programs and accredited CME programs.

Mr. Murray Kopelow, MD, MS, FRCPC
Chief Executive
Accreditation Council for Continuing
Medical Education
September 12, 2008

In today's highly scrutinized and dynamic environment, diligence is required by all parties involved in the continuing medical education process. Amgen takes seriously its commitment to healthcare compliance related laws and standards and has a dedicated Medical Education department staffed with compliance professionals, fully separate from any commercial function. Amgen has demonstrated industry leadership by publicly disclosing Healthcare Donations and Medical Education Grants, beginning with 1st Quarter 2008 and consistently supports efforts to increase transparency through our Clearly Amgen initiative, launched in 2007.

Amgen supports the ACCME's mission of identification, development, and promotion of standards for quality continuing medical education and encourages the enforcement of these standards by your organization as appropriate. We are confident that by working together with providers and industry, ACCME Standards for Commercial Support will continue to improve CME and ensure that healthcare professionals continue to receive quality education. Amgen is dedicated to partnering with ACCME to ensure that standards and guidelines continue to evolve with the needs of healthcare. If I or my staff can be of further assistance please do not hesitate to contact me directly.

Sincerely,

Anna S. Richo

ASR:nml

October 7, 2008

Murray Kopelow MD, MS(Comm), FRCPC
Chief Executive and Secretary
Accreditation Council for Continuing Medical Education (ACCME)
515 North State Street, Suite 1801
Chicago, Illinois 60654

Dear Dr. Kopelow:

Thank you for speaking with us on September 11 and extending the deadline to allow the American Medical Writers Association (AMWA) to comment on ACCME's proposal for additional features of independence in accredited continuing medical education (CME). AMWA represents 5,600 medical communicators (writers and editors) in North America and around the world, and the ACCME proposal may have implications for many of them.

In this response letter, we have focused on the single ACCME policy proposal that specifically affects medical communicators:

> *Persons paid to create, or present, promotional materials on behalf of commercial interests cannot control the content of accredited continuing medical education on that same content.*

We do not intend our remarks to address issues related to scientific or medical experts who create or present continuing education. They should be considered under a separate policy. Our concern is for medical communicators who work with subject matter experts in the development of promotional or CME materials.

Although we agree in principle with the premise that medical education needs to be independent of commercial bias and that writers should not introduce bias, we found that ambiguities in the proposed ACCME policy statement led us to different opinions about the policy based on our varied interpretations of it. Some clarification will help providers to implement the final policy in the real-world setting.

The intent of the proposed ACCME policy appears to be that those who control the content of promotional materials should not be able to control the content of CME on the same material. Promotional materials are inherently supportive of a specific product or service. A medical communicator who controls promotional content could have the opportunity to introduce bias into similar CME content, and should therefore be excluded from controlling similar CME content.

However, medical communicators rarely have full control of content they develop as freelance writers or editors doing work for hire or as employees of a CME provider. Medical communicators who assist authors may think they are exempt from the proposed ACCME policy because the named authors or clients have final responsibility for the content of most types of medical writing. Therefore, we request clarification: Under the proposed ACCME policy, would

medical communicators who contribute substantially to—but do not have full control over—their work product be excluded from controlling the content of CME activities?

If so, the underlined text below might clarify this point:

> *Persons paid to create, or present, promotional materials on behalf of commercial interests cannot control the content of or make substantial contributions to accredited continuing medical education on that same content.*

On the other hand, if control is to be interpreted strictly, then many writers would be exempt from the proposed policy, which may be what the ACCME intends.

We also request clarification of "promotional materials." It is our understanding that "promotional materials" refers to materials originally intended for marketing/advertising purposes. If the ACCME agrees with that definition, medical communicators who perform the following non-commercial services on behalf of commercial interests would not be prohibited from controlling the content of CME activities on the same content.

- Helping prepare documents for submission to regulatory bodies (eg, FDA)
- Helping authors prepare manuscripts (including review articles) for medical journals
- Helping authors prepare abstracts, slides, or poster presentations for medical congresses

If the ACCME agrees, we suggest clarifying the proposed policy as follows:

> *Persons paid to create, or present, promotional materials on behalf of commercial interests cannot control the content of or make substantial contributions to accredited continuing medical education on that same content. Documents for submission to regulatory bodies, manuscripts (including review articles) for medical journals, and presentations for medical congresses are not considered promotional materials.*

Finally, we would like to request clarification surrounding the intent of the medical communicator. A medical communicator may help prepare a document for nonpromotional purposes, which is subsequently repurposed, in whole or in part, for promotional use, by parties outside the control of the writer. Would a medical communicator whose nonpromotional work product is repurposed for commercial use be excluded from controlling the content of CME activities?

If not, we suggest inserting the underlined clarification below:

> *Persons paid to create, or present, promotional materials on behalf of commercial interests cannot control the content of or make substantial contributions to accredited continuing medical education on that same content. Documents for submission to regulatory bodies, manuscripts (including review articles) for medical journals, and presentations for medical congresses are not considered promotional materials. Persons whose noncommercial work product*

is subsequently repurposed for commercial use outside of their control are exempt.

In general, we urge the ACCME to consider the implications of its proposal carefully, because such a sweeping prohibition has the potential to unfairly restrict qualified writers and editors from being employed in CME. The comprehensiveness of the policy should be commensurate with the risk it seeks to mitigate.

Again, we thank you for granting us an extension to submit our response for your consideration. We did not have time to obtain endorsement of this response by AMWA's Board of Directors, which is the voting body. Therefore, please consider this the response of the undersigned only, reflecting our individual perspectives as experienced medical communicators. We appreciate the opportunity to continue to work with you on issues related to medical communicators in CME.

Sincerely,

Sue Hudson
President, AMWA
Principal, Medical Writing Associates

Jim Cozzarin, ELS
Past President, AMWA

Cindy W. Hamilton, PharmD, ELS
President Elect, AMWA
Principal, Hamilton House

September 10, 2008

Murray Kopelow, MD, FRCPC
Executive Director
Accreditation Council for Continuing Medical Education
515 North State Street, #1801
Chicago, IL 60654

Dear Dr. Kopelow:

The American Society of Anesthesiologists wishes to respond to the June, 2008 American Council for Continuing Medical Education (ACCME) request for comment on the proposal "that the commercial support of continuing medical education end."

ASA believes that it is unnecessary to totally ban commercial support of accredited CME by the medical supply and pharmaceutical industry when changes that have been made and continue to be refined in the oversight process can eliminate undue industry influence on continuing education. ACCME through its Standards for Commercial Support (2004), plus due diligence by CME providers themselves contribute to the ongoing clarification of the role of commercial entities in the context of continuing medical education.

ACCME's updated accreditation criteria (2006) and definitions of commercial entities (2007) are additional contributions to assuring physicians and the public that vigilance in maintaining the standard of commercially unbiased CME is on-going. Two additional ACCME proposals limiting the role of individuals paid to create or present promotional material in controlling CME content and limiting the communication from sponsors to accredited providers regarding CME content are supported by the ASA. These will further the standard of commercially unbiased CME. Compliance with ACCME's Essential Elements and Standards for Commercial Support is essential to maintain accreditation status for CME providers.

While the intention of ACCME to support the rigorous scrutiny of funding sources is noble, without sufficient study little is known of the consequences of eliminating commercial support. Consideration has not been given to the impact on physician continuing education by eliminating commercial support. Currently, no alternative funding exists for much physician continuing education. Similarly, in the absence of studies linking commercial bias in education to negative impacts on patient care leaves the decision to eliminate commercial support with no sustaining scientific grounding.

While the ACCME proposal for a new paradigm for ACCME accreditation is laudable, it is not realistic or obtainable in the near future. As examples:

- *Condition 1*) "when educational needs are identified and verified by organizations that do not receive commercial support and are free of financial relationships with industry (e.g. US Government agencies)". Most continuing education needs

520 N. Northwest Highway
Park Ridge, IL 60068
847-825-5586
www.asahq.org

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assessment and CME activities occur through professional societies, most of which receive commercial support. No government agencies are currently surveying or identifying educational needs, nor are they likely to in the near future.

- *Condition 2*) "if the CME addresses a professional practice gap…..that is corroborated by *bona fide* performance measurements of the learner's own practice". Such performance measurements do not now exist for most practices and are unlikely to be available for several more years.

- *Condition 3*) "when the CME content is from a continuing education curriculum specified by a bona fide organization, or entity". These organizations do not currently have defined continuing education curricula applicable to all specialties.

ASA supports continued efforts to structure policies and procedures for identifying and managing potential conflicts of interest by physicians and industry. However, it is the view of this organization that the elimination of commercial support without data to support its removal and a systematic consideration of funding alternatives make such a decision ill advised.

Sincerely,

Charles W. Otto, MD.

Charles W. Otto, MD, FCCM
Vice President for Scientific Affairs

520 N. Northwest Highway
Park Ridge, IL 60068
847-825-5586
www.asahq.org

AMERICAN SOCIETY OF HEMATOLOGY

1900 M Street, NW, Suite 200, Washington, DC 20036 **phone** 202-776-0544 **fax** 202-776-0545 **e-mail** ASH@hematology.org

Conquering Blood Diseases – From Research to Patient Care

September 12, 2008

Murray Kopelow, MD, MS, FRCPC
Chief Executive
Accreditation Council for Continuing Medical Education
515 N. State Street, Suite 1801
Chicago, IL 60654

Dear Dr. Kopelow:

On behalf of the officers and members of the American Society of Hematology (ASH), I am responding to the ACCME's June 2008 request for comment on the proposal "that the commercial support of continuing medical education end."

The ASH Conflict of Interest Policy (attached in testimony version) extends to all aspects of the Society – from committee meetings to live meeting organization and speakers, its journal and other publications, and the development of clinical guidelines. ASH has consistently recognized both the importance of collaboration between scientists and industry as well as the conflicts of interest these arrangements may present. To that end, the Society has created and maintains clear policies designed to protect the integrity of its core mission from inappropriate influence by commercial supporters.

Just as ASH promises its annual meeting attendees a program based on solid scientific research, it urges ACCME not promulgate rules that would end commercial support of CME unless substantial evidence emerges that confirms the opinions and assertions that the elimination of commercial support as a funding source of CME will truly end bias.

ASH remains committed to balanced and scientifically rigorous CME content, free from both commercial and non-commercial bias.

Thank you for your consideration of ASH's comments on this issue.

Sincerely,

Kenneth Kaushansky, MD
President

ORAL TESTIMONY

Presented by Dr. Kenneth Kaushansky

President, American Society of Hematology

to the

Institute of Medicine

concerning

Conflicts of Interest

May 22, 2008

Good Morning. My name is Kenneth Kaushansky, and I currently serve as Chair of the Department of Medicine at the University of California, San Diego. I am pleased to be a member of the Institute of Medicine and to testify before the IOM today. I am here as President of the American Society of Hematology. ASH has provided written testimony concerning our organization's conflict of interest policies and I will briefly highlight and comment on that testimony now.

Research and development sponsored by the biomedical industry plays an important role in biomedical research. We know that academic – industrial relationships have led to the development of many useful and life saving products. In hematology for example, Dr. Brian Druker's understanding of chronic myeloid leukemia led him to look for a way to interrupt signaling at the molecular level. From his position at the Oregon Health Sciences University, Dr. Druker worked with scientists from a company now known as Novartis, to bring forward the concept of kinase inhibition for leukemia. Together, they designed clinical trials to inhibit the signals from a mutant kinase; the result was the first effective targeted therapy for chronic myelogenous leukemia. Much of Brian's work over the past decade was presented at the American Society of Hematology's annual meeting, and appeared in our journal, *Blood*. Today, the drug that emerged from that trial is frontline therapy for patients with CML, producing a survival rate of up to 95% over 5 years. This is the kind of partnership that Congress envisioned with the passage of the Bayh-Dole Act in 1980.

The United States relies on public-private partnerships for the development of drugs and medical devices. As the leading organization representing hematologists worldwide, ASH has developed policies that preserve the scientific integrity of the discipline while interacting with industry.

For many years, ASH has recognized that interactions with industry carry the potential for conflicts of interest. For example, many drug and biotech companies have participated in the Corporate Symposia that precede the ASH annual meeting. In many cases, companies provide unrestricted educational grants to support the Society's educational and scientific missions. And many ASH members, speakers, authors, -- and their institutions -- are involved in pharmaceutical-sponsored clinical trials or have other relationships with industry.

ASH's policies concerning conflict of interest have evolved over time. While we recognize the value that industry-sponsored scientists have to offer, we use disclosure and peer-review to identify their conflicts and manage them. Let me illustrate a few of our management practices.

We have found that by working with corporations interested in hematology and discussing our concerns with them, we can find solutions that work for us and for industry. Consequently, ASH does not schedule programs on the day that precedes our annual meeting; this creates a convenient time for industry-sponsored symposia. In return, we have industry's agreement not to schedule

events in competition with the 4 day ASH meeting. If any corporation violates this rule, ASH will ban that company from participating in the ASH exhibit hall and subsequent corporate symposia.

While ASH accepts corporate support to offset the costs of our CME-accredited meetings, the Society restricts product promotion to an exhibit hall which is physically separate from the educational program.

ASH has long insisted that the corporate symposia be CME accredited, and follow a number of rules to prevent bias. This year, a new rule prohibits individuals invited to speak at the ASH meeting from also speaking at a corporate symposium.

ASH's policies concerning disclosure have also evolved over time. The Society now requires every committee chair to appoint a conflict of interest compliance officer. The COI officer is a member of the committee who is responsible for reviewing all committee disclosure forms and who remains attuned to and deals with conflicts in each ASH committee meeting. This brings focus to the need for all committee members to behave "as if they were in an NIH study section" as they consider agenda items. It has become routine for committee members to announce a possible conflict, ask whether they have any information that others may desire, and then leave the room (or the call) until the matter is decided. The

tone is set by the executive committee, the ASH board, and is evident throughout our organization.

Sometimes modeling isn't sufficient to make compliance the norm. For example, when the Society required meeting speakers to begin presentations with disclosure slides, we quickly learned that we needed to set up systems so that speakers don't have the chance to speed by these slides in an effort to get to the substance of their presentations. The audiovisual personnel at the ASH meetings now control the slides that list conflicts of interest; speakers cannot advance their disclosure slide until AV personnel determine that the audience has had sufficient time to review it.

Sometimes the target audience requires special treatment. The ASH Clinical Research Training Institute aims to help fellows and junior faculty who wish to obtain the skills needed to design and conduct studies involving human subjects. No corporate contributions have been sought or obtained for its funding. From time to time, because of their knowledge of the drug development process, speakers who work for a pharmaceutical company are included as faculty at the CRTI. These individuals are chosen for their knowledge of the subject matter and they do not, of course, make promotional presentations of any kind.

ASH agrees with the AAMC that conflicts of interest extend to all phases of biomedical research, including pre-clinical research. At the CRTI, faculty discuss

how, in pre-clinical research, financial conflicts can lead to bias. This includes clinical or translational research that may become a component of an IND submission or lead to research involving human subjects. We also are firmly committed to declaration of conflicts of interest in basic research. For example, we require declarations of conflict during the presentation of studies focusing on yeast genetics, Zebrafish morpholinos and proteomic analysis of a hematopoietic stem cell.

ASH is also willing to adopt new approaches to assure that conflicts don't lead to bias. The Society has just taken the step of changing our policies to prohibit individuals with recent relevant financial conflicts from serving as a member of a clinical guideline writing committee.

In closing, I'd like to ask an important question:

When designing an experiment, a clinical trial or on planning a new program, IT IS always useful to ask: "What is the question or problem we are trying to solve?"

As an officer of ASH, I want to be sure that there is no bias in presentations made at our meetings or programs; physicians must be able to rely absolutely on the quality of ASH educational products.

As past editor of our Journal, I used the peer review system to evaluate manuscripts and screen for bias. In 2002, one of my editorials established the requirement that all primary data submitted to Blood be personally evaluated by the lead author of multi-centered clinical trials, one of the first journals to require this. In 2007, *Blood* was among the first biomedical journal to add a process that screens all submitted images to detect manipulation.

As chair of medicine at a research-intense medical school, I know it is my responsibility to review faculty conflicts of interest; no one wants physicians to compromise patient care or research design because of financial incentives.

Much of the justification for the intense present focus on conflicts of interest, however, seems to be based on potential conflicts or the appearance of conflicts – not whether there is actual bias. One might ask whether this perception is the problem we are trying to solve? I hope our testimony conveys the Society's view that bias is the problem to be resolved.

But perhaps we should delve further and ask if the underlying public health concern is the cost of drugs and devices, their appropriate use, and their availability? If it is the latter, then we must remember the importance of health system reform, including finding a way to cover the uninsured, as central to its resolution.

Thank you. I'd be pleased to respond to any questions you have.

AstraZeneca

September 11, 2008

Murray Kopelow, MD, MS(Comm), FRCPC
Chief Executive
Accreditation Council for Continuing Medical Education
515 North State Street
Suite 1801
Chicago, IL 60654

RE: ACCME Calls for Comments related to Independence and Commercial Support

Dear Dr. Kopelow:

AstraZeneca Pharmaceuticals, LP appreciates the opportunity to comment on the recent calls for comments by the ACCME related to commercial support.

Let me begin by explaining who we are. AstraZeneca is a leading global pharmaceutical company who is strongly committed to enhancing the health and well being of people everywhere. One dimension of our commitment is supporting independent medical education because we believe that it can enhance patient care by providing health care professionals with the most current information on disease states, treatment options and effective doctor-patient interactions. In early 2005, AstraZeneca set up a separate grant-making department, known as the AstraZeneca Medical Education Grants Office. Using objective criteria and a rigorous review and decision process, the Medical Education Grants Office is responsible for ensuring that AstraZeneca funds bona fide independent educational activities. Our processes are based on policies at AstraZeneca that are consistent with the FDA Guidance on Industry-Supported Scientific and Educational Activities, the PhRMA Code on Interactions with Healthcare Professionals, the OIG Compliance Program Guidance and the ACCME Standards for Commercial Support. Our decisions to provide support are also based on available budgets and the quality of the grant application submitted by educational providers. These applications propose activities that address identified educational needs of health care professionals in their efforts to enhance patient care.

We believe that a number of changes announced recently by PhRMA and the ACCME will address some of the continuing concerns related to industry's CME contributions. The recently revised PhRMA Code on Interactions with Healthcare Professionals that will take effect on January 2009 includes a number of new provisions that reflect guidance provided by the OIG and ACCME since the first PhRMA Code was released in 2002. The revised PhRMA Code reinforces the principles of independence in medical education activities conducted by educational providers. PhRMA has strengthened the section on Adherence to the Code with the inclusion of companies publicly stating their commitment to abide by the Revised PhRMA Code and to self-certify annually that they have policies and procedures in place to foster compliance with the encouragement to have an external verification of this.

AstraZeneca LP
1800 Concord Pike PO Box 15437 Wilmington DE 19850-5437

Tel 302 886 3000
www.astrazeneca-us.com

You also recently announced plans to enhance the ACCME's focus on monitoring and surveillance of the CME system. These steps to strengthen the ACCME's oversight are encouraging. We also find encouraging your intent to be transparent and disclose compliance information on your website. The information you obtain about a provider's compliance will be valuable to industry in evaluating applications. Currently, it is difficult to obtain information about providers who are non-compliant, except through our own, necessarily limited monitoring efforts. As a commercial supporter, AstraZeneca wants to make informed decisions when awarding grants so that grants are given to ACCME-compliant educational providers.

We also applaud the recent changes made by the ACCME to the Essentials and Elements and Accreditation policies. These changes will continue to raise the bar in CME by focusing on the important connection between the educational provider developing and evaluating quality educational programs and the adoption by health care professionals of best practices based on best evidence and available data. These criteria are only now being implemented and used as a measure for accreditation by the ACCME.

Time is needed to fully implement all of these recent changes on top of the changes since 2003 and to assess their impact before considering further changes relating to commercial support.

In response to ACCME's specific Calls for Comments:

1) **Ensuring that the Current Processes of Attaining Commercial Support Will Not Undermine the Independence of Continuing Medical Education – *Limiting the Interactions between Accredited Providers and Commercial Interests over Commercial Support***

AstraZeneca receives over 4000 grant applications per year from a wide range of educational providers. We seek to provide an efficient and effective grant review process that enables organizations to request commercial support for quality independent education that addresses the unmet educational needs of health care professionals and also aligns with areas of interest within AstraZeneca. It is the responsibility of the educational provider to conduct needs assessments and to design educational activities that address those identified gaps by providing valuable information designed to assist health care professionals in their efforts to enhance patient care. We see our role as deciding whether or not we will be a commercial supporter of a particular educational activity after careful review of the grant application received.

Our position is that Industry should be able to provide information on their grant application process as many do on their websites currently or through formal calls for grant applications. The desire is to be as transparent as possible about the grant process. At AstraZeneca, we provide grants to support medical education that address the unmet education needs of health care professionals but they must also align with

educational areas of interest within AstraZeneca. Completing applications for grants is time consuming and so educational providers need to know if their planned educational activities will be considered by a commercial interest when seeking commercial supporters. Information provided by the commercial interest, including therapeutic areas of interest or budget availability, can assist the educational provider in determining whether or not they want to submit a grant application to a commercial interest.

Our position is that posting information on our website or requests for educational grant applications with general requirements identified is a similar approach taken by other grant making entities such as the National Institutes of Health (NIH) and should not be considered "inappropriate guidance" by the ACCME with the understanding that accredited providers have the responsibility to conduct needs assessments and to have full control of their developed educational activities.

We request that ACCME clarify their intent with the statement on "internal criteria". It should be appropriate for companies to identify areas of educational interest and broad categories of information needed by the commercial interest to evaluate grant applications such as needs assessment, learning objectives, audience and budget details. Requesting certain information may be necessary in order to assure compliance with applicable law and guidances from the OIG and FDA as well as compliance to the ACCME Standards for Commercial Support and the PhRMA Code. Communicating on logistical matters is also necessary at times. It should also be appropriate to communicate with the grant requester on general reasons for denial. These types of communications bolster transparency in our processes and should not be misinterpreted as direct guidance from the commercial interest or controlling content and creating commercial bias.

2) Proposal on the Elimination of Commercial Support of Continuing Medical Education Activities.

We believe that the many changes in policies and guidances that have occurred since 2004 are strengthening the framework to ensure Independence of CME from commercial bias. However, the impact of these changes "on commercial bias has not yet been measured" and "no studies have been reported using data derived from CME planned and presented under the supervision" of the ACCME Standards as was noted in the ACCME July 11, 2008 response to the Senate Committee on Aging. Suspicions of commercial bias from industry support of CME are based on data and observations from before 2004 and pre-implementation of the revised 2004 ACCME SCS and the 2003 OIG Compliance Program Guidance. Just this past July, the revised PhRMA Code was released that now more closely reflects the changes to the ACCME Standards for Commercial Support that were effective May 2005 and the more recent changes to ACCME policies effective January 2008.

Time is needed to fully implement all of these recent changes on top of those since 2003 and to assess their impact before considering further changes relating to

commercial support. Decisions should reflect the current paradigm and be evidence-based and data-driven. The current paradigm is the New Paradigm since there have been too many recent changes to call it status quo.

As one of the world's leading pharmaceutical companies, AstraZeneca has a proud history of developing effective, innovative medicines that have impacted medical practice. We strive to develop future treatments for fighting serious and chronic diseases and by doing so to have a positive impact on patient lives. We are committed to awareness, education and support. AstraZeneca's giving encompasses community support, charitable contributions to non-profit organizations, disaster relief, patient assistance programs, product donations, research and yes, independent medical education. Our commitment to supporting independent medical education is because we believe in the importance of having well educated health care professionals who are up to date on information concerning patient care.

As we have stated previously, much has been done to strengthen the framework for ensuring independence from commercial bias and more is planned with ACCME's enhanced monitoring and oversight of the accredited providers. We encourage you to allow time for full implementation and assessment before any further changes are considered. We are concerned that the elimination of commercial funding of CME may needlessly hurt patient care by impacting the availability of quality educational activities that health care professionals need to stay current on medical information to assist them in caring for patients and to meet requirements for maintenance of certification and maintenance of licensure.

The new paradigm proposed is concerning on several levels. The idea of meeting all four conditions may not be achievable, may set an unattainable threshold and is not in the best interest of patient care.

> *Condition 1 requires needs to be identified and verified by organizations (eg US Government agencies) that do not receive commercial support and free of financial relationships with industry*. There is concern that significant needs and practice gaps will not be identified since these types of organizations are currently not tasked with this objective and may not be able to do so in a timely manner. Some diseases may never receive the attention of organizations and government agencies since they impact small numbers of patients. However, there may be educational needs on these diseases for health care professionals.
>
> *Condition 2 requires CME must address a professional practice gap of a particular group of learners that is corroborated by bona fide performance measurements (eg National Quality Forum) of the learners' own practice.* Usually these have been based on established standards of care and do not cover recent innovations and treatment that could impact patient care. Utilization of performance measures can take years to implement and assess. Health care professionals need education to reinforce accepted standards of care but they also need education on new approaches to patient care and therapies.

Condition 3 requires CME content from a continuing education curriculum specified by a bona fide organization (eg, AMA, AHRQ, ABMS, FSMB). The entities such as the medical boards listed have identified competencies but do not usually create educational curricula. Additional concern includes national curricula not taking into account local or regional needs of health care professionals and diseases that may only affect small numbers of patients. The time required for establishing such a curriculum may not afford the capability of including relevant or new information such as recent safety and efficacy data or procedural discoveries to health care professionals in a timely manner.

Condition 4 requires CME to be verified as free from commercial bias. Our understanding is that accredited providers certify that their activities conducted during a specific time frame are free of commercial bias during the accreditation and re-accreditation process. Is the ACCME proposing to conduct pre-activity verification? If yes, then we would question the need to meet all three previous conditions above in addition to this verification in order to seek commercial support. Accountability to conduct needs assessments and to develop the educational content free from commercial bias rests on the shoulders of the accredited providers. The proposed enhanced monitoring and oversight by the ACCME should focus on compliance with the ACCME Standards for Commercial Support as one of their components and provide the documentation needed to ensure independence from commercial bias. If the goal is to ensure independence from commercial bias and there is transparency and disclosure of compliance information, then the need to meet all four conditions seems to add a level of complexity that may be unnecessary and may potentially limit quality educational opportunities for health care professionals and ultimately impact negatively patient care.

3) **In order to further define the independence of accredited continuing medical education, the ACCME proposes the following policy: *Persons paid to create, or to present, promotional materials on behalf of commercial interests cannot control the content of accredited continuing medical education on that same content.***

Accredited CME educational activities and industry-supported, FDA-regulated promotional programs are both important educational activities because they provide information needed by health care professionals.

Accredited CME is one mechanism for health care professionals to obtain evidence-based, data driven medical information that will enhance their knowledge and skills to improve patient care. The 2004 revised ACCME Standards for Commercial Support went beyond just disclosure of relevant financial relationships between faculty and industry to require management and resolution of such conflicts for all individuals who are in a position to control the content including planning committee members, teachers and authors.

Industry-supported, FDA-regulated programs provide a venue for sharing product-specific information. These types of educational programs are on-label and must be fair-balanced with safety and efficacy data provided as defined by the FDA. Experts involved in company speakers' bureaus are trained, must use company-approved presentation materials and have service contract agreements with the company.

Speakers and medical writers need to understand the distinction between the two and if they choose to participate in both, then they need to know how to conduct themselves in both forums.

We urge ACCME to reconsider this change in policy. An alternative focus is to ensure adherence to the ACCME standards of Commercial Support by accredited providers. This should be a priority for the ACCME as you develop the enhanced monitoring and oversight of the CME system. In particular, adherence to these guidelines on resolving conflicts of interest will be important.

AstraZeneca appreciates your consideration of our comments.

Sincerely,

Pamela L. Mason
Director, Medical Education Grants Office
AstraZeneca PLP

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INDUSTRY ORGANIZATION

September 12, 2008

Murray Kopelow, MD, MSC, FRCPC
Chief Executive
Accreditation Council for Continuing Medical Education (ACCME)
515 N. State Street, Suite 1801
Chicago, IL 60654

Re: **Request for Comments regarding Independence of and Commercial Support for Continuing Medical Education (CME)**

Dear Dr. Kopelow:

The Biotechnology Industry Organization (BIO) appreciates the opportunity to comment on the commercial support issues raised by the ACCME in your June 11 and August 6, 2008 calls for comments.

BIO represents more than 1,200 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology technologies, thereby expanding the boundaries of science to benefit humanity by providing better healthcare, enhanced agriculture, and a cleaner and safer environment.

As an organization whose biopharmaceutical company members are committed to supporting quality CME, BIO appreciates ACCME's role in developing standards for conducting CME programs to benefit physicians, other health care providers, and their patients. We encourage the continuing dialogue on what factors and characteristics create CME that is unbiased, independent and contributes to advancing medical care.

Specifically, BIO submits these comments to fulfill the ACCME's request for comments by: (1) discussing why the current processes of attaining commercial support will not undermine the independence of CME; (2) addressing the proposal to consider the elimination of commercial support of continuing medical education activities; and (3) providing practical feedback on how to define "commercial interest" to assure that CME content provided by particular individuals does not compromise independence. These issues are addressed below.

1201 Maryland Avenue, SW • Suite 900 • Washington, DC 20024-2149 • 202.962.9200 • Fax 202.488.6301 • www.bio.org

I. Ensuring That the Current Processes of Attaining Commercial Support Will Not Undermine the Independence of Continuing Medical Education

ACCME's Standards for Commercial Support (SCS), Standard # 1, Independence, states that a CME provider must ensure that decisions regarding the identification of CME needs, determination of educational objectives, selection and presentation of content, selection of persons/organizations in control of content, selection of educational methods, and evaluation of the activity are *"free of the control of a commercial interest."* In the context of this standard, ACCME seeks comment on the interpretation that:

- Accredited providers may not receive communications from commercial entities announcing or prescribing any specific content that would be a topic for CME; and
- Accredited providers may not receive communications from commercial interests regarding internal criteria for providing commercial support.

BIO has concerns regarding the potential impact of such an interpretation on the ability of both providers and prospective commercial supporters to efficiently communicate areas of potential support. Without such identification, prospective providers stand to "shoot in the dark", resulting in wasted resources that properly should focus on real educational needs. BIO seeks clarity from the ACCME regarding exactly what interactions between CME providers and commercial interests would be permissible. *Is ACCME seeking to disallow all transparent communications from a commercial interest to multiple CME providers regarding general areas of interest, or only one-on-one communications regarding potential topics, or both? If such communications are permissible, is ACCME seeking to limit the format or content of such communications, or both?*

For example, a commercial entity may wish to post proposed general topics of interest on its website for potential providers to access as they wish, and to enable interested providers to respond. Such proposed topics may be very broad in nature, *e.g.* "Company X would be interested in supporting CME on depression" or may communicate interest in supporting CME in a subset of a broad therapeutic area, *e.g.*, "Company Y is interested in providing support for CME addressing treatment options for patients with advanced breast cancer." This is similar to the posting of calls for grant applications from various entities, and, as is the case here, it is not a matter of introducing bias, but rather of creating an efficient and effective system. *Is it ACCME's intent to disallow a CME provider from accessing a general communication by a commercial entity stating that it is interested in supporting CME in a general topic area? Is it ACCME's intent to disallow a communication such as this in a website posting, or in a general letter to a group of CME providers, or both?*

Additionally, a potential CME provider may wish to obtain information regarding a commercial entity's interest in or application requirements for providing commercial support. *Is it ACCME's intent to prohibit a CME provider from seeking to obtain such information by requesting it from one or more potential commercial supporters?*

In another example, a commercial entity may wish to conduct a vetting process of CME providers to determine what their compliance records and capabilities are, and to ensure high educational value, in the interest of supporting CME that is independent and fully compliant. The commercial entity may subsequently wish to send a call for grant applications or a request for proposal (RFP) to a subgroup of these CME providers, who meet its predefined criteria, identifying a general topic area of interest which they would be interested in supporting. In follow-up, a commercial entity may then wish to communicate a grant evaluation decision to an applicant, including information about the reasons for a denial, such as budgetary reasons or failure to provide an adequate needs-assessment. A commercial entity may also wish to post information regarding approved CME grants, in an effort to be more transparent. *Would communications to identify compliant/capable CME providers be permissible? Would distribution of an RFP be permissible? Would communications regarding a grant decision, or to identify grant recipients, be acceptable to the ACCME?* BIO is concerned that that without guidance from potential commercial supporters regarding information to be submitted by a CME provider seeking a grant, the process of submitting and evaluating the grants would be less efficient, and educational provider requests could potentially be denied because of failure to provide adequate information, even where the request did not lack merit.

If it is ACCME's interpretation/intent to disallow these exchanges, BIO is concerned that such limitations on information dissemination would adversely impact realization of the value and purpose of CME programming. Such prohibitions would effectively banish an efficient method of matching accredited CME providers with potential CME supporters, and matching independently-identified educational needs with appropriate and compliant sources of funding. This would likely result in the inefficient use of resources by providers and commercial interests, as well as missed opportunities to positively impact patient care.

BIO believes that general communications announcing interest in a general topic/area, without any suggestion of specific content, presenters, or products are appropriate and acceptable. Such communications do not interfere with the independence of CME, as the mere suggestion of a general topic or criteria for support or application need not influence the outcome and educational value of a program or activity. There are numerous other controls in place to assure that CME activities remain independent, objective and educational. For example, SCS Standard #5, "Content and Format without Commercial Bias", requires that CME programs promote improvements or quality in healthcare by providing education on a full range of treatment options, rather than focusing on a particular medicine. Also, pursuant to SCS Standard#1, "Independence", it is the responsibility of CME providers to identify CME needs and education objectives, and select the content for a CME program, without control of a commercial interest. *What concerns does the ACCME have regarding general communications from potential commercial supporters to CME providers?* BIO believes that a limitation on general communications intended to identify potential sponsors would serve only as an impediment while adding no real benefit to the quality or independence of CME.

We further note that the newly issued PhRMA Code on Interactions with Healthcare Professionals

(http://www.phrma.org/code_on_interactions_with_healthcare_professionals/) states that "a company may communicate to multiple CME providers or the public a general topic for a CME program that might be of interest to physicians." (See PhRMA code, Q. 21) BIO agrees that such communications are appropriate and useful, and can contribute to the development of CME that can meet the needs of the medical community and benefit patients.

Finally, BIO also seeks clarification on whether ACCME's interpretation of SCS #1 would impact logistical discussions between commercial supporters and CME providers. Logistical discussions may include communications about potential types of educational design (e.g., live activity versus web-based activity), timing of educational initiatives, budget for educational initiatives, geographical location, status updates regarding a grant budget, and other matters unrelated to the content of or audience or faculty for the activity. *Given that such discussions do not involve the content of a CME program, or the selection of faculty/presenters, does ACCME agree that such logistical communications are acceptable and do not interfere with the independence of a CME activity?*

II. Consideration of the Proposal To Eliminate Commercial Support of Continuing Medical Education Activities

ACCME seeks comment on whether commercial support of CME activities should continue or should be eliminated, and requests that stakeholders, including the medical community, education community, and the public weigh in on and debate the subject. ACCME further seeks comment on whether a new paradigm should be created as an alternative to the current structure of commercial support for CME.

If such changes to the current model of CME are being considered, a broad gathering of input and information and full debate is warranted. This is a very complex and significant issue for stakeholders, including BIO members. Creating a new paradigm would have a major impact on how CME is conducted and how opportunities for medical education are created. In turn, BIO is concerned that if health care providers have less access to quality CME, this could have a negative impact on patient outcomes. Without any evidence that commercial support for CME results in programming that is inherently biased, a change in the current ACCME standards may be unwarranted. In fact, a report commissioned by the ACCME concludes that there is no empirical scientific evidence that industry support of CME results in bias[1]:

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[1] Ronald M. Cervero PhD and Jiang He, MPA, "The Relationship Between Commercial Support and Bias in Continuing Medical Education Activities: A review of the Literature" (June 2008) http://www.accme.org/dir_docs/doc_upload/aae6ecc3-ae64-40c0-99c6-4c4c0c3b23ec_uploaddocument.pdf

> "With the widespread concern about the impact of industry support on medical research, practice, and education, the question of whether this support produces bias in accredited CME activities is critically important. The ACCME Standards for Commercial Support are designed to assure that CME activities are not biased toward the commercial interest supporting the activity. However, to date, there is no empirical evidence to support or refute the hypothesis that CME activities are biased."[2]

Further, as noted previously, there are numerous other controls in place to assure that CME activities remain independent, objective and educational. In addition to the PhRMA Code, FDA's 1997 "Guidance for Industry: Industry Supported Scientific and Educational Activities" addresses company funding, disclosure of relationships, and other aspects of CME programs to ensure that commercially supported CME is not considered promotional.

Given the significance of such a major potential policy change, BIO recommends that ACCME should proceed deliberatively. It would be premature to reach a conclusion regarding support for CME without further assessment of the need for a change, evidence that there is, indeed a concern to be addressed, and what the impact of specific changes is likely to be.

In assessing commercial support for CME, there are a number of questions to be considered, including:

- whether commercial support for CME compromises the independence and scientific quality of CME programs;
- whether the existence of commercially supported CME has a detrimental impact on medical education and patient care;
- whether the process of CME sponsorship will be consistent for all types of CME providers, including for profit-providers, university and hospital providers, and professional medical societies;
- whether existing controls and standards, such as disclosure of commercial support and financial relationships, are sufficient to achieve the goals of independence, non-bias, and educational quality; and
- whether elimination of commercial support would impact the quality and availability of CME activities.

BIO recommends that these and other data points should be studied and assessed before any major change is proposed or implemented. A paradigm shift such as this should not be undertaken without evidence of potential benefits to medical education and public health.

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[2] Id at p. 8.

Given that there have been a number of recent developments in this area, including issuance of the revised PhRMA Code, and that governmental and commercial entities are currently assessing and re-assessing these issues, ACCME should also take these other efforts into consideration prior to reaching any conclusions.

If, following such an assessment, ACCME determines that an alternative paradigm would be beneficial, it would then be appropriate to launch a pilot project, to test the impact of any new program prior to it adopting it more broadly.

III. How to Define "Commercial Interest" To Assure That CME Content Provided by Particular Individuals Does Not Compromise Independence

ACCME's Standards for Commercial Support, Standard #1, Independence, states that a CME provider must ensure that decisions regarding selection of CME presentation and content, and the persons in a position to control the content must be free of the control of a commercial interest. In this context, the ACCME seeks comment on whether individuals who are not employees of a commercial interest, but who are involved in the promotion of that company's products and services, should be excluded from controlling CME content. For example, the ACCME asks whether physicians who are paid by commercial entities to deliver promotional content to other physicians may also teach in independent CME activities. ACCME seeks comment on the following policy:

- Persons paid to create, or present, promotional materials on behalf of commercial interests cannot control the content of accredited continuing medical education on the same content.

The ACCME expands on this proposal, stating that not every financial relationship between an individual and industry would implicate this policy.—*e.g.,* persons conducting research funded by industry, or reporting on the results of industry-funded research, would not be affected unless they also participate in promotional activities on the same content.

BIO appreciates the ACCME's efforts to define the appropriate methods of assuring that education is separate from promotional activities, and that CME programs are conducted independently. However, BIO is concerned that a policy excluding certain persons from CME participation may only address a perception of bias, and would not serve the primary goal of providing high quality independent CME.

Physicians involved in research and clinical trials on innovative therapies are generally the most knowledgeable about important advances in science and treatments, by virtue of both their background in a therapeutic area and participation in the research. Biopharmaceutical companies engage these experts to participate in research because of their specific expertise, and, following that research may also determine that these experts are the most informed and proficient to conduct training or educational sessions on the therapy for their colleagues, as consultants to a company. And again, when a CME provider is seeking experts to present at a CME program, these same physician experts may be the

most qualified, particularly in a niche therapeutic area, where the number of experts or specialists may be very limited.

BIO believes that such experts should not be prohibited from presenting CME content, solely because of a consulting relationship with a commercial interest in that content area. Exclusion of such experts could deprive CME program attendees of hearing from and learning from the best and the brightest in particular therapeutic areas. As stated previously, the existing ACCME Standards, including the requirements for disclosure of all relevant financial relationships with any commercial interest, and the provision of a balanced view of therapeutic options, are sufficient to produce CME programs that are independent and unbiased. The ACCME's proposal appears to assume that physicians with recognized expertise in an area would not be capable of presenting unbiased scientific/medical information, an assumption that we do not accept. Further, physicians who would attend such CME programs are sufficiently educated and sophisticated to assess the nature of the information presented and the relevant disclosures.

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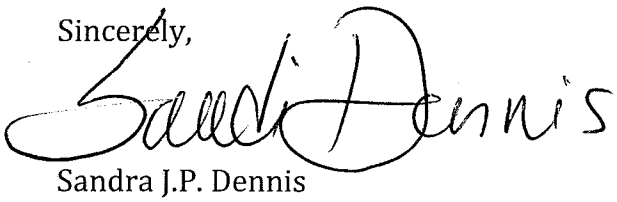
BIO appreciates your consideration of these comments and looks forward to ACCME's clarifications on the issues we have raised. If you have any questions, please contact me at 202-962-6673.

Sincerely,



Sandra J.P. Dennis
Deputy General Counsel for Healthcare

September 12, 2008

E-Mail and Electronic Submission

Murray Kopelow, MD
Chief Executive
Accreditation Council for Continuing Medical Education
515 N. State Street, Suite 1801
Chicago, Illinois 60654

RE: ACCME Policy Announcements and Calls for Comment

Dear Dr. Kopelow:

The Education Committee of the Coalition for Healthcare Communication (Coalition) appreciates this opportunity to respond to the recent policy announcements and calls for comments by the ACCME related to critical matters of public concern regarding the process, procedures and rules of accreditation at ACCME.

This response consists of two sections, the first addresses the public policy, process and procedural issues surrounding these matters, the second addresses each of the three major policy question areas placed for public comment. Stated simply, these three questions are:

1. Should commercial support of certified CME end ?

2. Should all professional writers and faculty that have been employed by commercial interests for marketing or promotional projects be systematically excluded from related certified CME activities?

3. Should certain announcements by grantors be banned, specifically "internal criteria" for grant approval and "topics" of interest?

I. Public Policy, Process and Procedural Issues

The Coalition for Healthcare Communication (Coalition) and its education members have long noted the public policy and public health importance of the ACCME. Members that are Accredited Providers (providers) and joint sponsors of certified CME believe that the public, the medical profession and patients are best served by a strong ACCME that is respected by the medical community, the press, policy makers, law enforcement officers and the public. We are dedicated to support and strengthen ACCME so long as it maintains its current leadership position in medical education.

The ACCME is the leading accrediting body for the certified CME activities that enable physicians to maintain their official licenses to practice medicine. The vast majority of physicians cannot practice medicine in the United States without obtaining certified CME credits (AMA PRA category 1 credits). These credits are required for re-licensure by 45 states. Forty-three states accept the AMA PRA certificate as equivalent for license re-registration. Sixty-two boards require some form of participation in certified CME activities as a part of the requirement to maintain board certification. In addition, virtually all hospitals require physicians to demonstrate participation in formal CME activities in order to maintain privileges. Federal government agencies, including the Food and Drug Administration (FDA), recognize that compliance with the voluntary standards of accrediting agencies such as the ACCME help insure that provider activities are independent as required when funded by the regulated industry. As such, the process, procedures and substance of the ACCME system of accreditation are inextricably tied to the official, governmental process of professional certification.

The ACCME directly designates “Accredited Providers,” the entities authorized to offer certified CME programs at the national level. In addition, ACCME, through its program of Recognition, designates state and territorial medical societies to, in turn, accredit providers of CME in their local areas, so long as these agencies follow standards at least as strict as those promulgated by ACCME for national Accredited Providers. As such, ACCME essentially is the licensing agent for Accredited Providers on behalf of the state agencies that oversee the licensure of physicians.

Furthermore, over the past decade, the oversight of certified CME in the United States has become a matter of very intense public concern and a topic of considerable public comment, oversight and public policy discussion. As ACCME, its Board and Affiliated Organizations fully recognize, the ACCME accrediting process is considered an integral component of the United States system for post graduate education of clinical doctors, and thus the delivery of health care to America's patients. The ACCME program is recognized and relied upon by major federal and state agencies, including the Food and Drug Administration, the Department of Health and Human Services, the United States Congress, and state licensing boards and law enforcement agencies. Just a few weeks ago, for example, the Massachusetts legislature took official notice of ACCME in its passage of a major healthcare reform package.

ACCME is not a private organization. Its decisions are fully intertwined with the public interest and the delivery of health care in America for at least three reasons.

1. Many of the nation's doctors are dependent on AMA PRA category 1 credit for re-licensure, continuation of Board certification, and maintaining privileges at hospitals.

2. Accredited Providers are totally dependent on ACCME accreditation to continue in their business activities.

3. Federal and state regulatory agencies recognize and rely on ACCME policy and procedures in their own policy and enforcement decisions.

Because of ACCME's authoritative status, the public has a right to fully expect that it follow the usual, well understood and recognized legal and procedural rules of fairness and fundamental due process in its rule making and enforcement procedures. Indeed, ACCME may have rightly recognized these obligations by adopting the standard of review for its reconsiderations and appeals. That standard enables reviews on the grounds that the ACCME decision was: "(1) arbitrary, capricious, or otherwise not in accordance with the accreditation standards and procedures of the ACCME, or (2) not supported by substantial evidence."[1]

[1] *See* ACCME Decision Making policy documents related to the Accreditation Process and the Recognition Process under "Reconsiderations and Appeals." These are standards employed by government agencies.

There is solid legal authority requiring due process from otherwise private institutions when "the government has become so entangled in the actions of a private party, it may warrant the requirement that such private conduct conform to the constitutional standards of behavior."[2] In this case, in addition to the regulatory functions performed by ACCME noted above: (1) ACCME standards for commercial support and independence are recognized by FDA in the agency's review of promotional claims made during CME activities;[3] ; (2) FDA maintains a formal written procedure for ACCME accreditation of the educational and training activities conducted by its Center for Drug Evaluation and Research;[4] (3) state medical licensing boards recognize ACCME decisions in meeting annual educational requirements to retain medical licenses; and (4) two officials of the federal government serve of the 18-member board of the ACCME.[5]

Even in the unlikely event that a court would decide that the ACCME is a private organization to which the substantive due process provisions of the U.S. and state constitutions do not directly apply, the Coalition believes that ACCME should follow the basic fairness and due process principles of openness, transparency, and reasoned decision making expected of public institutions. As noted above, those principles are also intertwined in the arbitrary and capricious review standard adopted by the ACCME with

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Protection from arbitrary action is the essence of substantive due process under the protection of the Fifth and Fourteenth Amendment of the U.S. Constitution, *Slochower v. Bd. Of Higher Ed of City of New York*, 350 U.S. 551 (1956). Reh'g denied 351 U.S. 944 (1956).

[2] *Holodnak v. Avco Corp.*, 514 F.2d 285, 288 (2d. Cir. 1975), *cert. den.* 423 U.S. 892 (1975) 1st amendment constitutional challenge to dismissal of employee by private defense contractor and union for publishing an article critical to the employer. The U.S. Court of Appeals for the Second Circuit held that "[w]here nearly all land, buildings, machinery and equipment at the employer's plant were owned by the federal government, most of the work done at the plant was defense related, the Department of Defense maintained a large force at the plant to oversee operations, links between the employer and the federal government were such as to make the employer's action in discharging the employee 'state action' in the purview of the Fourteenth Amendment" (substantive due process).

[3] Industry Sponsored Commercial Support Guidance, 62 *FR* 64095-96 (Dec. 3, 1997); www.fda.gov/cder/guidance/isse.pdf.

[4] MaPP 4550.5; www.fda.gov/cder/mapp/4550.5R.pdf.

[5] ACCME By-Laws, Sec. 6.

respect to review, reconsideration and appeal of its decision making process.[6]

These standards serve ACCME well for at least three reasons:

1. For ACCME to continue to be considered by government policy makers and the medical community as the leading institution for education self regulation, *it must be and be seen to be a strong regulator with substance and integrity.* No organization that ignores fundamental fairness and due process principles can maintain that status.

2. As a practical matter ACCME must recognize that if it does not voluntarily adopt these principles, and follow its own stated review process, it will be forced to do so through private or public litigation.[7]

3. An open and fair vetting of the important and difficult issues raised in this proceeding will provide the ACCME with the additional information and balanced perspective necessary to formulate enlightened and lasting policy.

The Coalition raises the litigation possibility not because it has an intention to file a legal action. Instead, it raises it because the Coalition believes litigation is a logical reaction to ACCME's current procedural decisions and it hopes that ACCME will adjust its processes at least in part to avoid

[6] "Reasoned decisionmaking" is required to not be deemed arbitrary or capricious, *See Puerto Rico Education Assistance Corporation v. Riley* 10 F.3d 847, 853 (D.C.Cir. 1993)("one of the fundamental principles of administrative law is that an agency's decision must be supported by reasoned decisionmaking.");*Olenhouse v. Commodity Credit Corp.*, 42 F.3d 1560 (C.A.10, Kan., 1994)("The duty of the court reviewing agency action under the 'arbitrary and capricious' standard is to ascertain whether the agency examined the relevant data and articulated a rational connection between facts found and the decision made."); *Wisconsin Valley Improvement Company v. FERC*, 236 F.3d 738, 748 (D.C.Cir. 2001)("[A]n agency acts arbitrarily and capriciously when it abruptly departs from a position it previously held without satisfactorily explaining its reason for doing so."); *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mutual Auto Ins. Co.*, 103 S.Ct. 2856 (1983)("An agency changing its course by rescinding a rule is obligated to supply a reasoned analysis for the change beyond that which may be required when an agency does not act in the first instance.").

[7] The federal courts have recognized the standing of CME providers to initiate judicial review of ACCME decisions; *see* for example *Medical CME Associates v. ACCME*, 1990 WL 160075 (N.D. Ill 1990) (accepting a case for review but ultimately dismissing a complaint by a CME provider because the elements of an anti-trust case were not properly pled or proven).

litigation. We strongly urge ACCME to quickly go well out of its way to ensure that its policy making processes be as fair, open, reasoned and transparent as possible. Quick action need not be expensive or unduly delay these proceedings. Due process standards are well understood, and easily followed.

In the context of the rule making and enforcement actions at issue here, fundamental fairness and due process essentially require: full notice; the opportunity for all input to be heard; a public rulemaking record; and a decision-making process that is explained, reasoned and fact based. This generally means that rule changes be published for comment, giving the reasons and goals of the proposal, as well as an explanation of the underlying facts and assumptions. Interested parties are then allowed to comment for the record, including provisions for both data and arguments, and full access and the opportunity to comment upon the comments of other parties are also given. After this, the rulemaking body is expected to propose a specific rule, giving a full explanation of its reasoning based on the record of the proceedings including why certain comments prevailed and others did not.

Due process does not mean, as suggested in a recent letter to NAAMECC, that ACCME "consider the comment process to be a poll or vote." Rule making is not a voting procedure, but instead an open, contemplative process where the purpose, policy and procedures are fully vetted, and the decisions of the rule making body are based on transparent reasoning and record evidence.

In the context of adverse actions, due process allows a party subject to an adverse action to be given a full explanation of the reasons for the adverse action and an opportunity to appeal to an impartial and knowledgeable decision-maker. We recognize that ACCME has a published set of procedural rules for adverse actions, and applaud this. At ACCME adverse actions arise most often in the context of the re-accreditation of providers. The procedural processes given providers in such instances are substantive rights that cannot be arbitrarily modified in a specific enforcement action – which ACCME has appeared to have done with a number of providers that have received adverse decisions. Any changes in the criteria for ruling must be subject to rule making requirements similar to those described above.

Therefore, we recommend that ACCME, as quickly as possible, publicly announce that it intends to adopt the following four measures. The first three involve rule making procedures, and the fourth enforcement actions.

We recommend that ACCME:

1. **Open the Record on the Three Previously Announced Subject Areas.**

This would enable all interested parties to review the comments of all other parties, and review the entire record relied upon by ACCME. Given the current requirement that comments be submitted electronically, the posting of comments at a publicly available website should involve little additional time or cost. Indeed, if ACCME does not wish to bear any of the costs associated with the public posting of all comments, the Coalition agrees to organize an effort to enable this at no cost to ACCME. Meanwhile, the Coalition has created a page on its website where it will be posting all comments sent to it.

2. Establish a Reply Comment Period.

This would enable all participants to comment on recommendations and data submitted by others. The deadline for reply comments should be no shorter than 30 days from the date of the filing of the initial round of comments.

3. Commit to the Publication of a Further Notice.

This would enable ACCME to publish specific proposed rules on each of the three topic areas after an initial two rounds of comments. This further notice should include a clear explanation of the purpose of the rule, the problem (s) the proposed rule seeks to avoid, and the procedure(s) for implementation. This notice should clearly articulate the facts in the record of the proceeding that are the basis for the rule, and review the substantive recommendations in the record, and a reasoned explanation why or why not major recommendations did or did not prevail. Interested parties should then be given a reasonable period to comment on these proposed rules before implementation.

4. **Follow Due Process in Adverse Decisions Against Providers**.

ACCME must carefully review its adverse decision process rules, including strict adherence to its own rules, including recent probation decisions. For example, we note that on June 11th the ACCME announced, without seeking comment, that is "now putting more Accredited Providers on Probation—especially those found in Non Compliance with elements of the ACCME Standards for Commercial Support. The current rate of Probation has increased to about 10% of Providers seeking Re-accreditation from about 1% in the past." While perhaps justified, the action appears to be in direct opposition to ACCME published policies regarding the process of placing an accredited provider on probation.

The Coalition strongly recommends that the ACCME not change its enforcement procedures in a manner that substantively denies due process and appeal rights to providers without actual notice of such changes to the entire community, including following the general rule making procedures we recommend for the three topic areas addressed above.[8]

II. ACCME Questions for Comment

1. Should commercial support of certified CME end ?

Background:

The ACCME has called for comment regarding the elimination of commercial funding of CME. In its Call for Comment ACCME notes that in January of 2007 it initiated a discussion announcing that "it would be considering taking action regarding the funding structure of continuing medical education." It further stated that "although CME exists in a data-driven, evidence-based world, many are motivated by firmly held beliefs about propriety and professionalism. The ACCME values both perspectives and now seeks input on this matter."

ACCME acknowledged the need for identifying alternatives to the current funding scenario proposing three potential approaches: 1) no change to the

[8] Although we are not privy to any individual case, we have been told informally that this change in policy has also been accompanied by a substantive procedural change that severely limits the ability of parties to review the facts leading to probation decisions and limits their ability to appeal those decisions.

current acceptable funding mechanism 2) elimination of commercial funding 3) or a new paradigm. For this new paradigm, ACCME proposed the following conditions should be met:

1. Programs for educational needs identified by organizations free from financial relationships with industry,

2. Programs addressing the learner's practice gaps corroborated by bona fide performance measures (i.e., National Quality Forum),

3. CME content from a continuing education curriculum specified by a bona fide organization (i.e., AMA, AHRQ, ABMS, FSMB),

4. CME is verified as free of commercial bias.

ACCME also suggested that these conditions could provide the basis for distribution of pooled industry funding.

Coalition Position:

The Coalition disagrees with calls by individuals and groups to eliminate commercial support. Underlying this debate is the assumption by critics that commercial funding introduces bias; there is also the implicit assumption that physicians are incapable of detecting and managing bias should it occur. Bias is a term used to describe a tendency or preference towards a particular perspective, ideology or result, especially when the tendency interferes with the ability to be impartial, unprejudiced, or objective. Bias is ubiquitous and influences clinical trial designs, formulary decisions, the content of peer-reviewed journals, editorial commentary, the FDA approval process, news coverage, and election-year political activities.

Physicians encounter and manage bias every day when listening to patients, reviewing medical literature, speaking with payers, experiencing drug detailing, selecting practice guidelines, and when participating in CME activities. As discussed below, the ACCME and education providers have made tremendous strides in helping to create this now endangered, relative safe-haven for physicians. Unfortunately, the same <u>cannot</u> readily be said for the myriad other largely unaudited sources of information encountered and managed by physicians each day.

The Coalition believes that most CME activities are free of commercial bias and that physicians are well-equipped to manage bias if it occurs. We are seriously concerned that the ACCME has added its moral force to this debate by raising this question, and has done so without offering any evidence of bias from commercial support. As noted above, a fundamental principle of due process is reasoned decision making based on record evidence.

ACCME has included in this record **no objective evidence** that commercial support of CME introduces bias. ACCME's own recently commissioned report, The Relationship between Commercial Support and Bias In Continuing Education Activities: A Review of the Literature, failed to find "any objective evidence or studies documenting that commercially supported CME activities are biased." That report recommends that further "rigorous scientific studies" be conducted before conclusions are drawn. It also recommended answering the question: does commercially-sponsored CME lead to better patient care? The Coalition supports this position and strongly urges ACCME to avoid making any changes in its position on commercial funding until objective scientific data can be compiled that can provide guidance on how best to proceed.

The Coalition is greatly concerned that ACCME appears to be bowing to outside academic and political pressure from the critics of commercial support without demanding that those critics put evidence in the record as it calls for radical reform of the CME enterprise. ACCME demands evidence-based medicine and data-driven decision making by Accredited Providers and other CME professionals, yet here seems to be lending credence to critics who it recognizes "are motivated by firmly held personal beliefs about propriety and professionalism."

Moreover, ACCME's recent annual report confirms that commercial funding supports about half of CME in the United States today. Meanwhile, no one to date has offered a credible substitute funding source. Dr. Kopelow in a recent conference call with members of NAAMECC indicated that based on his review the $1.2 billion dollars in commercial support only accounts for 15% - 30% of the yearly total of actual hours of instruction. While this may be true and consistent with current recertification standards, the CME community now considers measures of improved patient care much more relevant and important than counts of hours of instruction. Commercial funding accounts for a far greater portion of innovative CME activity that is focused on improvement in patient care. In particular,

commercial support often funds new designs for educational programs to address practice gaps and has been a driver in creating non-traditional learning venues such as e-learning and other Internet–based activities.

The Coalition firmly believes that proposals to end half the funding of certified CME without offering plausible substitutes for that funding have no place in a serious public policy discussion on how to improve patient care. While some believe that government programs can replace commercial support, this is not realistic. Consider, for example, the current debate in Congress around adequate funding for FDA, clearly a critical priority. While most agree that the FDA has a current budget shortfall of at least a billion dollars a year, in 2008 Congress could only find one fourth of that for fiscal year 2009 and has not developed a consensus plan for fully funding this shortfall in subsequent years. If adequate funds cannot be found for a billion dollar shortfall at FDA, it is clearly unrealistic to expect that a similar amount could be found to substitute for commercial support for CME.

Even if adequate government funding were available, it may not be optimal. Government funded CME often introduces a dangerous bias in favor of adoption of the immediately-least-expensive therapeutic or diagnostic practice. This bias is not always consistent with either the long term best interest of patients or even the government. Similarly, it is unrealistic to expect physicians, facing increasing financial pressure on their income from reduced Medicare fees and lower managed care reimbursement, to pay for their own CME. With 663,900 physicians in practice in the United States, the absence of commercial support would create a shortfall of $1,807 per year for each physician.

Today it is clear to objective observers that clinicians participate in commercially funded activities to learn about new and better ways to diagnose and manage disease, and then return to their practices better prepared to treat their patients. While these activities are supported by industry, patients are the primary beneficiaries. At the same time, commercial supporters and providers have been leaders in studies and research on the value of CME to patient care in America.

The Coalition does appreciate the need for ACCME to respond to the criticism and continuing pressure to curtail commercial funding. However, it is important to emphasize that much of this criticism is based on past unacceptable practices and incidents that have now been addressed by industry, provider and ACCME reforms. The CME community has taken

significant steps over the past decade to insure both independence and quality for CME. These steps not only help insure independence from commercial influence, they also have elevated both the scientific standards for content and improved measurement of physician change and patient outcomes.

Since the 1997 U.S. Food and Drug Administration guidance document calling for clear separation between promotion and education in the US, the CME community has made consistent improvements. Pharmaceutical manufacturers have done their part as well: hiring compliance officers and instituting strict compliance policies; creating education groups and grant review committees that are independent of sales and marketing; removing all CME activity from their sales organizations; and other practices to insure the independence of the CME programs they fund. While it may be impossible to eliminate all bias, these reforms insure that any reasonable chance of introducing bias will be minimized.

While the Coalition applauds ACCME's effort to present a new paradigm for the commercial funding of CME, it sees several issues with the recommendations. For example, point number three recommends CME content from curriculum specified by "bona fide organizations." Unfortunately, this approach will inhibit the delivery of cutting edge education addressing the latest developments in medicine. In many instances, innovative education leads rather than follows these organizations in the development of new curricula and clinical guidelines. This is even more pronounced for government guidelines, which often are subject to several additional layers of review and regulatory process before adoption.

Limiting CME programs to practice gaps "corroborated by bona fide performance measurements (e.g., National Quality Forum)" could well negate the value of the ACCME recognized advances in the current "needs assessment" processes. To only subject commercially funded CME to this criterion would, superficially, seem like a reasonable approach, but in practice would only delay and inhibit the transfer of knowledge about new treatments and breakthroughs.

The CME community recognizes that conflict of interest is a legitimate concern for all in medical education. However, the elimination of commercial funding -- to address the issue of bias -- in the absence of collaborating evidence supporting such a move, is counterproductive. In fact, such a decision would cause a massive reduction in the amount of

available CME, hinder the dissemination of new cutting-edge medical information, undo the positive recent advancements in CME, and ultimately stifle improvements in patient care.

We respectfully submit that the current Standards of Commercial Support offer strong protection and independence of CME content from any bias and that to eliminate or further regulate commercial funding is unnecessary and unwarranted.

2. Should professional writers and faculty that have been employed by commercial interests be systematically excluded from related certified CME activities?

Background:

In its August 2008 publication titled "ACCME Proposes Additional Features of Independence in Accredited Continuing Medical Education," ACCME proposed, for comment, the following policy:

Persons paid to create, or present, promotional materials on behalf of commercial interests cannot control the content of accredited continuing medical education on that same content.

In accompanying commentary ACCME elaborated, suggesting that the intent was to systematically exclude persons who have been employed by commercial supporters : " In accredited CME some conflicts of interest are irreconcilable. The only way they can be resolved is by avoiding the circumstances that create the conflict. This is the basis of the SCS 1 (and) would be the case under this policy. Physicians paid by a commercial interest to do promotion presentations on a product could not teach in accredited continuing medical education on the same product. Anyone creating content for promotional activities would be excluded from creating content on the same product …" ACCME also noted that not every financial relationship would require exclusion, including conducting and reporting the results of industry research unless such persons also participated in promotional programs.

Coalition Position:

The Coalition strongly supports strict adherence to the existing ACCME Standards for Commercial Support as the best and most appropriate means to manage conflicts of interest, and does not support the proposed amendment that would in effect make professional writers and faculty "commercial interests" and thus exclude them from certified CME activities. We believe the initial statement of the rule, that such persons "cannot control the content" appropriately enables providers to manage any potential bias that may arise in these circumstances, and thus meets the goals of ACCME and the community.

We also note the important fact that the federal government in comparable situations does not exclude participants in critical medical decisions at the National Institute of Health, Center for Medicine (CMS) nor the Food and Drug Administration. Congress itself considered exclusion in debates over management of conflict in FDA Advisory Committees, and rejected exclusion and adopted a management plan instead. If the federal government can manage experts with ties to industry, it seems certain that the CME community can also do so.

The Coalition supports the following application of the existing policy:

> Faculty, consultants, writers and others in a position to influence the content of a CME activity who participate in the creation or presentation of promotional programs on behalf of a commercial interest may participate in accredited CME activities if all potential conflicts of interest are appropriately vetted, disclosed and resolved consistent with current ACCME policies. Providers continue to be responsible for the content of programs. When appropriate, providers should exclude writers and faculty who do not follow the practices and policies of ACCME and the provider. We support the current policy of giving providers the responsibility and discretion to manage potential conflicts and bias in the content of the programs.

Contrary to due process principles, the ACCME poses no clear rationale for this change, nor does it proffer evidence that these possible sources of bias have not or cannot be resolved under the existing policies. It does cite two "recent significant external actions" but does not explain their relevance or applicability here. The first is the consumer fraud settlement voluntarily agreed to by Merck in May of 2008 with 29 states and the District of

Columbia. The most important element of that agreement is the Merck agreement to comply with the ACCME standards of commercial support in its CME grant making process, and the additional promise by Merck to require employees and contractors to fully disclose that relationship in all educational programs, promotional and certified. It further binds Merck to limit its promotional use of faculty that are involved in certified programs. As such, it most importantly supports existing ACCME policy, but does not suggest any action by ACCME here.

ACCME also notes that in July 2008 the Association of American Medical Colleges Taskforce on Industry Funding of Medical Education recommended that "academic medical centers should make clear that participation by their faculty in industry-sponsored speakers' bureaus should be strongly discouraged." This recommendation is not about participation in certified CME, but in promotional education, not a subject within the purview of the ACCME, and not clearly relevant here.

Question 1: Should those who write promotional materials be excluded from having any role in writing CME content?

The Coalition believes writers should not be excluded from writing CME content in a therapeutic area because they have worked on promotional materials for a product in that therapeutic area for several reasons**:**

1. The exclusion of writers from CME would be difficult to enforce because such writers have a multitude of clients with varying connections to commercial interests. Such limits would be extremely difficult and expensive to identify, manage and verify.

2. Promotional education is very different from certified CME. It is strictly regulated by FDA, vetted by the medical and legal teams of the commercial interests, and limited to on label content. The content in promotional programs is more controlled and restricted than in accredited CME.

3. The exclusion of writers from CME would significantly limit the availability of the skilled writers in many therapeutic areas, undermining the quality and value of CME activities. CME providers utilize staff and freelance writers to collaborate with researchers and faculty who may not possess the communication skills and

instructional design expertise to make their presentations relevant and compelling to the target audience.

4. The exclusion of writers from CME would undermine the premise and credibility of the existing standards for commercial support.

We note, also, that the proposal would limit faculty from speaking in a therapeutic area. CME content does not address a 'product' but rather a therapeutic area with various treatment options without regard for the source of commercial support.

Question 2 : Should those who teach in promotional activities be excluded from teaching in independent CME activities?

The Coalition believes that faculty should not be excluded from participation in certified CME programs in a therapeutic area where they have done promotion for these reasons:

1. The exclusion of faculty would be expensive and difficult to enforce.

2. Professional associations may be forced to exclude a majority of their best presenters at their national and local meetings.

3. CME providers, including academic institutions and community hospitals, will face greater challenges finding faculty to participate in CME activities. Academic institutions may encounter difficulties recruiting faculty because of the limits on their academic and economic rights.

4. The overall quality of CME may be compromised because talented teachers will be forced to choose between CME and promotional programs.

5. Research scientists may well resist the limits on their ability to expose clinicians to the results of their findings.

6. The systematic exclusion of some of the best qualified faculty would undermine the premise and credibility of the existing standards for commercial support.

Accordingly, the Coalition believes existing disclosure and conflict management policies are sufficient to address any concerns about bias and conflict of interest.

3. Should certain announcements by grantors be banned, specifically "internal criteria" for grant approval and "topics" of interest?

Background:

The ACCME has called for comment regarding two new statements it proposes as additional conditions to limit interactions between accredited providers and commercial interests to ensure that current processes do not undermine the independence of certified CME. The statements are:

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 (e.g., 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 Support.*

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.

Coalition Position:

The Coalition strongly urges ACCME to withdraw these proposals and instead address these issues as necessary under the existing Standards of Commercial Support (SCS*)*. At present, the ACCME has presented no record evidence that either of these activities undermines the independence of providers and programs, nor has it proffered any evidence that these proposals would further its policies of independence. At the same time, the existing SCS address the issue of inappropriate interaction between accredited providers and commercial interests to prevent any impact or influence on selection of faculty, venue, and the determination of activity content. Further, the ACCME requires all providers to institute strict

policies to identify and resolve conflicts of interest for all involved in program planning and implementation. These are meaningful policies that ensure the independence of CME content.

The Coalition is seriously concerned that the new proposals would increase cost and reduce the likelihood of accredited providers finding adequate grant support without a measurable increase in the independence of CME activities. Virtually all grant-giving organizations have both areas of interest and submission guidelines readily available to all those who seek funding. The ACCME's proposed position would, by suppressing this information, make it harder for accredited providers to find funding. The ACCME's approach requires an increased number of grant submissions and potentially resubmissions as providers attempt to determine exactly what any given commercial interest is willing to support. This would be a significant disadvantage to smaller providers with neither the time nor the staff to undertake such exercises.

The Coalition believes there are additional actions the ACCME could propose in a second call for comment that would better achieve the goal without decreasing the efficiency of the grant seeking process. Consistent with First Amendment guidance by the Supreme Court in the commercial speech area, we believe that the ACCME should consider less restrictive alternatives than the bans suggested, before proceeding to adopt sweeping bans. For example, several narrower, less restrictive alternatives may well address concerns of ACCME, while allowing appropriate and useful communications to continue.

To further the discussion of such less restrictive alternatives, the Coalition offers two such ideas for consideration by ACCME and the entire education community. Because the Coalition has not yet fully vetted these with all Coalition stakeholders, we offer them not as Coalition proposals, but possible alternatives for discussion within the entire CME community before the ACCME takes final action here. Consider the following:

1. To further ensure the independence of CME activities the ACCME could limit some restricted activities by grantors**,** such as sending RFPs to only selected providers or sole source grants. Or, ACCME could encourage increased public announcements and communication by grantors, perhaps enabling all accredited providers and the regulatory community to view the RFPs. An open RFP process, transparent to regulators and other interested parties, may increase the

efficiency of both the planning and grant seeking process. Accredited providers would be able to more quickly identify those commercial interests likely to have funds available for the practice gaps and other unmet needs identified by their research. A more transparent system may operate to prevent potential or perceived opportunities to threaten the independence of CME content.

2. ACCME could further emphasize that needs assessment is the primary responsibility of accredited providers. The ACCME might regulate the use of needs assessment in RFPs, or limit the ability of grantors to specify needs assessment vendors or methods as a condition of receiving grant support.

In sum, the Coalition believes it's appropriate that each accredited provider is responsible for the integrity of its CME program and the activities it certifies. The existing Standards of Commercial Support and conflict of interest policies of the ACCME provide excellent protection for the independence of CME content. We believe that transparency rather than prohibition would better achieve the incremental improvements sought by these latest policy proposals.

If ACCME believes that further rules areas necessary, we recommend that ACCME should propose such rules in a further notice, along with evidence that the proposal would solve the problems specified. We believe that much more narrow alternatives, focused on an open and transparent RFP system might best meet the current needs of the community. The Coalition looks forward to this discussion and debate.

Respectfully submitted,

Brad Bednarz
Marty Cearnal
Mark Schaffer
Education Committee Co-Chairs
Coalition for Healthcare Communication

COUNCIL OF MEDICAL SPECIALTY SOCIETIES

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51 SHERWOOD TERRACE, SUITE M, LAKE BLUFF, IL 60044-2232
(847) 295-3456 TELEPHONE • (888) 611-1400 TOLL-FREE • (847) 295-3759 FAX
WWW.CMSS.ORG

August 15, 2008

Murray Kopelow, MD, MS (Comm), FRCPC
Chief Executive Officer
Accreditation Council for Continuing Medical Education
515 North State Street, Suite 1801
Chicago, IL 60654

Dear Dr. Kopelow:

The Council of Medical Specialty Societies (CMSS), with 32 medical specialty society members, representing more than 500,000 physicians, appreciates the opportunity to comment on ACCME's position that "the manner of interaction between potential commercial supporters, or their agents, and some Accredited Providers may need to be altered."

I. Call for Comment: ACCME will ensure current processes of attaining commercial support will not undermine the independence of continuing medical education: Limiting the Interactions between Accredited Providers and Commercial Interests over Commercial Support

ACCME call for comment item 1:

> "Accredited providers must not receive communications from commercial interests announcing or prescribing any specific content that would be preferred, or sought-after, topic for commercially supported CME (e.g., 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 Support*[SM]."

CMSS position:
The Council of Medical Specialty Societies supports the clarification of the ACCME Standards for Commercial Support as in item 1 above.

Background:
CMSS recognizes that a commercial interest provides commercial support for a CME activity that is often (although not always) within the scope of that commercial interest's business objectives. This is only logical. Even non-commercial interests (organizations that fall outside the definition of a commercial interest as defined by the ACCME) generally support activities that further the mission or the objectives of the supporter. For example, the prestigious Gerber Foundation whose mission is "to enhance the quality of life of infants and young children in nutrition, care, and development" would most likely not support a CME program that addresses Alzheimer's dementia in the older patient.

SCS 1 rightly places the burden of documentation and truth upon the provider to ensure complete independence from commercial interest bias or control. Commercial interests in the pharmaceutical industry have recently changed their behavior to comply with regulation from the OIG, and in so doing, are avoiding communicating desired content areas for grants to be submitted for potential support. In this light, the proposed ACCME clarification would be consistent with current behaviors of commercial interests and CME providers, and of the intent of the ACCME Standards for Commercial Support.

ACCME call for comment item 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.'"

CMSS position:
The Council of Medical Specialty Societies supports the clarification of the ACCME Standards for Commercial Support as in item 2 above.

Background:
The CMSS member organizations invest significant resources, both human and capital, in addressing their missions to provide continuing professional development for their members. To address these missions demands that the organization look beyond the member's dues/CME registration fees to other sources of revenue. Corporate support is one such revenue alternative.

Many, if not most, commercial interests have initiated a grant process that standardizes the application and levels the playing field for fair evaluation of requests. It appears reasonable for potential grantees to seek to understand the criteria for a grant request to comply with grant requirements. Such *process* communication between grantee and grantor is common practice with private philanthropies (such as the Robert Wood Johnson Foundation) and with the federal government (such as AHRQ), as well as with industry, and is considered standard operating procedure.

However, it would be inappropriate for an accredited provider to request, or for a commercial interest to communicate *content* preferences, such as preferred topics (see ACCME 1 above), in discussions prior to submitting a grant. Again, SCS 1 rightly places the burden of documentation and truth upon the CME provider to ensure independence from commercial interest bias or control. In this light, the proposed ACCME clarification would be consistent with current behaviors of commercial interests and CME providers, and of the intent of the ACCME Standards for Commercial Support.

II. **Call for Comment: The ACCME believes that due consideration be given to the elimination of commercial support of continuing medical education activities:**
The proposal is that the commercial support of continuing medical education end.

CMSS position:
The Council of Medical Specialty Societies does not support the proposal that commercial support of continuing medical education end.

Background:
CMSS fully supports the ACCME Standards for Commercial Support and enthusiastically champions the 2004 updates. These Standards require that CME providers, in this case medical specialty societies, clearly and completely separate educational content from commercial bias, which may be perceived as resulting from commercial support. CME providers may offer and physicians may claim CME credit for participating in certified CME activities.

The public and political climate in the United States, particularly concerning the high cost of drugs in the Medicare program, has resulted in intense scrutiny of ACCME, as well as of many CME providers. This climate of fault-finding, blame and threat, couched as inquiry, has understandably stimulated organizations to react, and to sometimes over-correct in immediate response.

The ACCME has current and relevant criteria requiring all CME providers to focus the goals of CME toward improvement of physician practice, thus improving the quality of patient care. These criteria include stronger guidance on complete independence from bias associated with commercial support, as well as stronger procedures for the identification and resolution of conflicts of interest. ACCME is poised to assume a position to strictly enforce its criteria, thus providing evidence to outside pressures that the system of professional voluntary self-regulation works well.

Although there is the potential for added burden to medical specialty societies and other CME providers, the environment, and professional reaction, is stimulating debate in the societies about commercial support. Debate among leaders, executive staff, and members is occurring in many medical specialty societies concerning the levels of industry support they receive for CME activities. Several societies have plans to reduce or curtail industry support and move to alternative types of funding for CME.

CMSS agrees with ACCME "that the profession (taken to mean physicians), the public (taken to mean patients) and the CME enterprise (taken to mean accredited CME providers) weigh in on the subject...with colleagues (taken to mean other accrediting organizations), with other professions (taken to mean nursing and pharmacy), with students (taken to mean participants in the continuum of medical education), with government (taken to mean agencies related to Medicare/Medicaid), and with stakeholders of CME (taken to mean commercial/non-commercial interests related to CME), including the public."

CMSS suggests that the venue for this discussion, with the potential inclusion of additional interested parties, exists in the Conjoint Committee on Continuing Medical Education (CCCME).

The CCCME is a "multi-organizational committee, members of which are key stakeholders in the continuum of medical education." CCCME participating organizations include: the Association of American Medical Colleges (AAMC), Accreditation Council for Continuing Medical Education (ACCME), Accreditation Council for Graduate Medical Education (ACGME), Alliance for Continuing Medical Education (ACME), American Academy of Family Physicians (AAFP), American Board of Medical Specialties (ABMS), American Hospital Association (AHA) , American Medical Association (AMA), American Osteopathic Association (AOA), Association for Hospital Medical Education (AHME), Council of Medical Specialty Societies (CMSS), Federation of State Medical Boards (FSMB), Joint Commission (JC), Liaison Committee on Medical Education (LCME), National Board of Medical Examiners (NBME), and the Society for Academic Continuing Medical Education (SACME).

This Committee was initially convened in 2002 and has sustained an active, stimulating dialog about CME and more broadly, the continuum of medical education in the United States. The CCCME has prepared a report, *Reforming and Repositioning Continuing Medical Education,* that contains recommendations and next steps in seven key areas related to CME: 1) the medical education continuum; 2) self-assessment and lifelong learning; 3) core curricula and competencies; 4) valid content: evidence-based medicine; 5) performance and continuous improvement; 6) metrics to measure and recognize physician learning and behavioral change; and 7) resources and support.

CMSS recommends that the Conjoint Committee on CME be tapped to frame and conduct this debate and examine the three scenarios proposed by ACCME: 1) the status quo with commercial support of CME as an acceptable funding mechanism (governed by tight adherence to the ACCME SCS) 2) the complete elimination of commercial support of CME, and/or 3) a new paradigm (for commercial support of CME as well as other possible scenarios which may emerge from the Committee's discussions).

CMSS further suggests that the CCCME be provided with adequate funding, time, and proper resources to engage this debate in a form and fashion as to realize the end result of settlement of this debate and an action plan for the future. Such funding should include the necessary monies to conduct research into the possible effects of influence and reciprocity on physicians' behavior. CCCME should be asked to begin to address this task as soon as possible.

III. Call for comment: ACCME proposes a new paradigm where ACCME accreditation will continue to reflect only what is in the best interests of the public. The ACCME proposes that if the following conditions were all met, then the commercial support of individual activities would be in the public interest and could continue to be allowed:

1) When educational needs are identified and verified by organizations that do not receive commercial support and are free of financial relationships with industry (eg, US Government), and
2) If the CME addresses a professional practice gap of a particular group of learners that is corroborated by *bona fide* performance measurement (eg, National Quality Forum) of the learner's own practice, and
3) When the CME content is from a continuing education curriculum specified by a bona fide organization, or entity, (eg, AMA, AHRQ, ABMS, FSMB), and
4) When the CME is verified as free of commercial bias.

Alternately, these conditions could provide a basis for a mechanism to distribute commercial support derived from industry-donated, pooled funds.

CMSS position:
The Council of Medical Specialty Societies does not support the new paradigm in its current draft format, as described above, but rather recommends modifications to ensure the separation of bias from commercial support of CME, and further recommends a process for debate and discussion of the proposed new paradigm, so that it may ultimately come to be as universally accepted as are the ACCME Standards for Commercial Support..

Background:

1) **"When educational needs are identified and verified by organizations that do not receive commercial support and are free of financial relationships with industry (eg, US Government), and..."**

   Currently, accredited providers are charged with the responsibility of determining educational needs. Medical specialty societies, in particular, consider it their responsibility to fulfill needs assessment in planning CME for members. It does not seem logical to separate needs assessment from those providers which are in the best position to determine needs, and which are responsible for designing CME to meet those identified needs.

   It appears that the intent of "new paradigm 1)" is to ensure that needs assessment is separated from commercial influence, a premise with which CMSS completely agrees. Divorcing the CME provider, particularly the specialty society, from needs assessment appears to be "throwing the baby out with the bathwater."

2) **"If the CME addresses a professional practice gap of a particular group of learners that is corroborated by *bona fide* performance measurement of the learner's own practice, and..."**

   On January 1, 2005, a "new CME" emerged as Performance Improvement CME, with criteria approved by the three national CME credit granting agencies (AAFP, AMA, AOA). PI-CME is standardized and designed to "address a professional practice gap of a particular group of learners that is corroborated by *bona fide* performance measures of the learner's own practice." PI-CME is offered by a variety, albeit still a few, CME providers, most notably medical specialty societies. Performance measures incorporated into PI-CME are generally, and should be derived from those endorsed by *bona fide* national organizations, such as NCQA, PCPI, NQF and AQA. CMSS recognizes the need and opportunity to facilitate the development of PI-CME among medical specialty societies. This should be a goal of ACCME, as well.

That said, a requirement that any industry-funded CME be based on established guidelines and parameters would eliminate much of the educational programming currently offered and needed. Many conditions do not yet have established practice parameters, as the data necessary to create these care standards are still being developed. Prohibiting commercial support for CME on such conditions would arbitrarily eliminate CME for many conditions for which needs assessment demonstrates a need, which would ultimately have a negative impact on patient care.

It appears that the intent of the proposed "new paradigm 2)" is to ensure the separation, from commercial bias, of the identification of physician practice gaps, as well as the inclusion of performance measures into physician education, a premise with which CMSS completely agrees. Divorcing the CME provider, particularly the specialty society, from identifying practice gaps measured against nationally accepted performance measures appears to be abrogating the CME provider from its educational responsibility in, and ability to offer PI-CME.

3) **"When the CME content is from a continuing education curriculum specified by a *bona fide* organization, or entity, and..."**

While CMSS agrees with the premise in 2) above that *bona fide* organizations should be charged with endorsing nationally accepted performance measures which are incorporated into PI-CME, we recognize that the *bona fide* organizations in the best position to develop educational curricula for medical specialists are medical specialty societies. The role of certifying boards (represented by ABMS) is to certify individual physicians, of state medical boards (represented by FSMB) is to license individual physicians, and of medical specialty societies (represented by CMSS) is to educate individual physicians. The appropriate role for specialty societies is to identify practice gaps of its members, as a group and as individuals, to create an educational curriculum based on practice gaps, and to incorporate nationally accepted performance measures into CME to address identified gaps among its members. This educational design is part of the responsibility inherent in professionalism.

It appears the intent of "new paradigm 3)" is to ensure the separation of commercial bias from the design of educational curricula, a premise with which CMSS completely agrees. Divorcing specialty societies from designing curricula for the education of its members appears to be a Solomonian solution of cutting a whole entity in half, resulting in non-viable educational programming.

4) **"When the CME is verified as free of commercial bias."**

It appears that the intent of "new paradigm 4)" is to ensure that by separating 1) needs assessment; 2) identification of practice gaps of physicians, measured against nationally accepted performance measures; and 3) educational curriculum design, from entities that receive commercial support, even when those entities are in exemplary compliance with the ACCME Standards for Commercial Support for CME, only then can and will the perception of bias be eliminated from CME. Ironically, verification is the desire in this premise. Verification requires assessment of actuality, not design changes (1, 2 and 3 are design changes), and not management of perception.

CMSS does not believe that the proposed extreme solution to the problem of the perception of commercial bias in commercially supported CME, as outlined in the proposed "new paradigm", is appropriate or necessary, as it removes the responsibilities of CME providers, particularly specialty societies, from the design and implementation of CME which is free from commercial bias.

It is important to pause to recognize the practical realities of corporate support. In the absence of support for CME, currently approximately $1 Billion annually, the likelihood that such support will find its way into Direct to Consumer Advertising, and more problematic, into promotional education, is strong. If the goal is to eliminate product bias from the education of physicians, it will be critical to avoid an unintended consequence of stimulating significantly increased product biased education through the mechanism of promotional education.

CMSS considers the concept of pooled funds for the commercial support of CME to be one of a series of potential viable options worth pursuing.

CMSS recognizes that the perception of the incorporation of commercial bias into commercially supported CME is real. We offer the venue of the Conjoint Committee on CME as an immediate vehicle for furthering the discussion, leading to a national solution that is as universally lauded and accepted as are the ACCME Standards for Commercial Support of CME.

Sincerely,

Norman B. Kahn, Jr., MD
Executive Vice President and Chief Executive Officer

COUNCIL OF MEDICAL SPECIALTY SOCIETIES

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51 SHERWOOD TERRACE, SUITE M, LAKE BLUFF, IL 60044-2232
(847) 295-3456 TELEPHONE • (888) 611-1400 TOLL-FREE • (847) 295-3759 FAX
WWW.CMSS.ORG

August 28, 2008

Murray Kopelow, MD, MS (Comm), FRCPC
Chief Executive Officer
Accreditation Council for Continuing Medical Education
515 North State Street, Suite 1801
Chicago, IL 60654

Dear Dr. Kopelow:

The Council of Medical Specialty Societies (CMSS), with 32 specialty society members, representing more than 500,000 physicians, appreciates the opportunity to provide feedback to the ACCME call for comment on the following two questions;

1. Should those who write promotional materials be excluded from having any role in writing CME content?
2. Should those who teach in promotional activities be excluded from teaching in independent CME activities?

In response to these questions, ACCME is considering the following new policy:

- "Persons paid to create, or present, promotional materials on behalf of commercial interests cannot control the content of accredited continuing medical education on that same content."

CMSS position:

Persons paid to create or present promotional materials on behalf of commercial interests (who therefore disclose a conflict of interest) need not be excluded from accredited continuing medical education on the same subject if and only if their conflict of interest can be resolved.

Background:

The ACCME, currently and appropriately, requires accredited providers to implement a mechanism to identify and resolve all conflicts of interest prior to the education activity being delivered to learners (C7, SCS 2.3). Additionally, accredited providers are required to design educational activities that actively promote improvements in health care and NOT proprietary interests of commercial interests (C10, SCS 5). As such, accredited providers undergo additional rigors to ensure that CME activities and related materials promote improvements or quality in healthcare and that CME presentations give a balanced view of therapeutic options.

Since the dissemination of the revised ACCME Standards for Commercial Support of CME, accredited providers have invested significant resources to move beyond identification and disclosure of conflicts of interest, to management and resolution of such conflicts. These efforts have served to ensure that CME activities remain fair and balanced in nature. When conflicts of interest cannot be sufficiently managed and resolved to eliminate commercial bias from CME, then such conflicts are considered irreconcilable. This has particularly been a question when accredited providers, especially in small specialties with small pools of experts, approach individuals considered the "best and the brightest" available to teach physicians, but who disclose relationships that constitute a conflict of interest.

Accredited providers have, however, been creative and successful in implementing at least four interventions to ensure that commercial bias is eliminated from CME. Learning from the experience and demonstrated success of societies in managing and resolving disclosed conflict of interest, CMSS recommends a formalized approach that could be standardized across all providers.

CMSS recommends:

That one or a combination of the following options be considered as universal criteria for resolving disclosed conflict of interest.

- Peer review: members of the planning committee, or other authors/speakers without a conflict of interest, review the content an author/speaker plans to use in a CME program, after which the author/speaker may not change that content.

- Evidence-based presentation: the author/speaker is required to present an evidence-based CME program that conforms to nationally accepted standards of Evidence-based CME (not just having the speaker say "this is an evidence-based presentation").

- Modify content: the author/speaker may present on patho-physiology, research data, and other content, but not make practice recommendations (these are made by another speaker, who discloses no such conflicts of interest).

- On-site monitoring: trained monitors (volunteer physician and staff) attend the presentation and determine if subtle or overt biased crept into the talk, with significant consequences.

CMSS recognizes that the perception of the incorporation of commercial bias into CME is real. We applaud ACCME for requiring accredited providers to identify and resolve all conflicts of interest prior to the education activity being delivered to learners. We believe that the creative experience of accredited providers can be generalized to prevent the incorporation of commercial bias into CME, and thereby protect not only the education of the learner, but the integrity of the CME enterprise.

Sincerely,

Norman B. Kahn, Jr., MD
Executive Vice President and Chief Executive Officer

St. Joseph's Hospital
69 W. Exchange St.
St. Paul, MN 55102
651/232-3000
Fax 651/232-3518

St. John's Hospital
1575 Beam Ave.
Maplewood, MN 55109
651/232-7000
Fax 651/232-7240

Woodwinds Health Campus
1925 Woodwinds Dr.
Woodbury, MN 55125
651/232-0100
Fax 651/232-6888

Bethesda Hospital
559 Capitol Blvd.
St. Paul, MN 55103
651/232-2000
Fax 651/232-2118

HealthEast® Surgery Center–Maplewood
Maplewood
Professional Bldg.
1655 Beam Ave.
Maplewood, MN 55109
651/232-7780
Fax 651/232-7786

HealthEast® Surgery Center–Midway
Midway Outpatient Center
1700 University Ave. W.
St. Paul, MN 55104
651/232-5959
Fax 651/232-5985

Department of HealthEast
St. John's Hospital

HealthEast® Urgent Care–So. St. Paul
724 19th Ave. N.
So. St. Paul, MN 55075
651/232-6348
Fax 651/232-6127

Department of HealthEast
St. John's Hospital

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Murray Kopelow, MD, MS, FRCPC
Chief Executive Officer
Accreditation Council for Continuing Medical Education
515 North State Street
Suite 1801
Chicago, IL 60654

September 10, 2008

Dear Murray,

I am writing as an individual to express my concern in response to the ACCME request for comments regarding the proposal to increase the restrictions for participants in continuing medical education activities. In reviewing the call for comments at our recent Minnesota Medical Association CACME meeting, I felt compelled to add my own personal concerns to those expressed by our committee.

I am opposed to the ACCME proposal to implement the following policies:

> ***Persons paid to create, or present, promotional materials on behalf of commercial interests cannot control the content of accredited continuing medical education on that same content.***

My concern rests around the burden that CME planners would have in implementing this ban. My concern is that a speaker for a CME activity with a slide set that has been reviewed still exerts a significant amount of control over the CME presentation through focusing on certain material, emphasis on recommendations, interpretation of the data and answers to questions from the audience. Without a scripted, tightly controlled presentation, this ban would be impossible to implement with any significant meaning and would restrict organizations from using experts in the field that have some relationships to commercial interests.

The task for CME planners is to identify and resolve conflicts of interest. We already have strict guidelines and high expectations for CME activities. This results in a balanced and fair discussion of the topic with the audience from a speaker who is often an expert or highly regarded in their field. To put a ban on this level of faculty would harm CME greatly and I fear would result in speakers who are either parroting or presenting other peoples' work or the literature.

Our task is to remain diligent about identifying and resolving these conflicts and disclosing these relationships to the audience and then monitoring whether those presentations are objective and free of bias.

I am also opposed to the proposal that:

The commercial support of continuing medical education end.

As a representative of a medium sized healthcare organization with CME responsibilities to a large medical staff and minimal and declining budgets, we do rely on some level of commercial support to present activities with faculty with either a regional or national scope. Without commercial support for some of these activities, I fear that our local education and access to physicians would seriously decline and the hospital based education such as grand rounds, clinically pertinent topics in the local environment, etc would decline or be eliminated.

With the new requirements that CME be more closely aligned with performance improvement activities, demonstrate clinically relevant outcomes, and measure improvements in competence or patient care, these cost for CME activities will not be decreased, but actually increase. Many of the companies have the same stated goal, namely to improve the outcome for the patient and provide better tools and training for the doctors. We need to provide a better mechanism for commercial interests to support these efforts, not restrict their help altogether. I am in favor of a mechanism to pool grants into a general institution fund for activities.

Thank you for your consideration of these comments.

Sincerely,

Robert C. Moravec, MD
Medical Director St. Joseph's Hospital

cc: Donald Piper, MD, Director Medical Education for HealthEast Care System
Bob Beck, MD, Vice President Chief Medical Officer for HealthEast Care System
Craig Svendsen, MD, Chief Medical Quality Officer for HealthEast Care System

Illinois State Medical Society

September 11, 2008

Murray Kopelow, MD, MS (Comm), FRCPC
Chief Executive Officer
Accreditation Council for Continuing Medical Education
515 N. State Street, Suite 1801
Chicago, Illinois 60654

Re: ACCME Call for Comment

Dear Dr. Kopelow:

The Illinois State Medical Society's Committee on CME Activities met, reviewed the three proposals presented for comment by the ACCME and presents for your consideration the following comments.

Should those who write promotional materials be excluded from having any role in writing CME content? Should those who teach in promotional activities be excluded from teaching in independent CME activities?

The committee is concerned that this appears to be a blanket exclusion from all CME activities with no time limit. Additionally, a faculty person may write promotional materials in one therapeutic area but teach in areas unrelated to that subject. The current Standards for Commercial Support (SCS) and due diligence by those planning the activity are adequate to address the concerns.

Accredited providers must not receive communications from commercial interests announcing or prescribing any specific content because such communication would be considered 'direct guidance on the content of the activity. Receiving communications from commercial interests regarding their internal criteria for providing support would also be considered the receipt of 'guidance on the content of the activity or on who should deliver that content".

This is perceived to be an unenforceable proposal. Even if the ACCME had the authority to ban the distribution of communications from commercial interests to those responsible for CME within an organization, others within an organization, e.g., a chief medical officer or a department chair, may share such materials with those involved with the CME program.

If the planning of an activity is done as currently prescribed, the activity's content is in place before funding is sought. Further, it is unlikely that an accredited provider will pursue funding from a commercial interest without a product line specific to a given therapeutic area.

Twenty North Michigan Avenue, Suite 700 Chicago, Illinois 60602 Web site: www.isms.org
Telephone: 312-782-1654 Toll Free: 800-782-ISMS Fax: 312-782-2023

Receiving information should not be confused with *acting* on the information.

The ACCME is proposing a new paradigm where ACCME accreditation will reflect only what is in the best interests of the public. To that end, ACCME proposes four conditions that must be met for all activities for commercial support to be allowed.

This proposal can only be interpreted as providers being seen as inherently violating the SCS and guilty until proven innocent. The committee had the following questions:

1. What is the difference between conditions 1 and 3?
2. What is meant by the "best interests of the public"? As defined by whom?
3. How would a provider verify that a need was identified by an organization that does not receive commercial support? Even the AMA and some governmental agencies receive funds from commercial interest.
4. What is the definition of a "bona fide organization'?
5. If a CME addresses a professional practice gap of a group of physician learners, why would it need to be corroborated by "bona fide performance measures"?

This proposal is seen as unnecessarily burdensome and duplicative of the SCS. If learners have a need, ensuring that the content is "from a continuing education curriculum (Note: CME curriculum is not specified.) from a bona fide organization" is unreasonable and represents a far reaching new paradigm.

Sincerely,

Robert L. Buckley, M.D., Chair
Committee on CME Activities

RLB:rl

cc: Peter E. Eupierre, M.D.
Shastri Swaminathan, M.D.
Robert L. Milam, M.D.
Alexander R. Lerner

Twenty North Michigan Avenue, Suite 700 Chicago, Illinois 60602

Illinois State Medical Society

September 12, 2008

Murray Kopelow, MD, MS (Comm), FRCPC
Chief Executive Officer
Accreditation Council for Continuing Medical Education
515 N. State Street, Suite 1801
Chicago, Illinois 60654

Re: ACCME Call for Comment

Dear Dr. Kopelow:

The Illinois State Medical Society's Committee on CME Accreditation has reviewed the three proposals presented for comment by the ACCME. We appreciate the opportunity to offer comments on these proposals.

Should those who write promotional materials be excluded from having any role in writing CME content? Should those who teach in promotional activities be excluded from teaching in independent CME activities?

The providers must comply with the Standards for Commercial Support (SCS) which require that providers ensure CME content is bias-free, making this proposal unnecessary. A blanket policy like this does not take into account that people may stop participation in promotional activities and what the process would be to "certify" their eligibility for participation in CME activities. Providers and their activity files are subsequently reviewed during the accreditation survey to ensure compliance with SCS. This appears to be micromanagement of providers and faculty without defined outcomes.

Accredited providers must not receive communications from commercial interests announcing or prescribing any specific content because such communication would be considered 'direct guidance on the content of the activity. Receiving communications from commercial interests regarding their internal criteria for providing support would also be considered the receipt of 'guidance on the content of the activity or on who should deliver that content".

The provider's sources of information on commercial interests are diverse and, as such, a provider has no control over who chooses to send them communications. Commercial interests may also use outside companies for promotion and a CME provider may be on any number of those mailing lists. This is not an enforceable nor measurable proposal.

Twenty North Michigan Avenue, Suite 700 Chicago, Illinois 60602 Web site: www.isms.org
Telephone: 312-782-1654 Toll Free: 800-782-ISMS Fax: 312-782-2023

The ACCME is proposing a new paradigm where ACCME accreditation will reflect only what is in the best interests of the public. To that end, ACCME proposes four conditions that must be met for all activities for commercial support to be allowed.

A new paradigm is proposed where activities will reflect 'only what is in the best interests of the public'; why and as defined by whom? What is the definition of a "bona fide organization'? The committee notes that even the AMA and some governmental agencies receive funds from commercial interest.

Lastly, the paperwork for documenting and reviewing compliance with the four proposed conditions would be onerous for providers and accreditors.

We appreciate the opportunity to provide comment and look forward to the outcome of these proposals.

Sincerely,

Ronald L. Johnson, M.D., Chair
Committee on CME Accreditation

RLJ:rl

cc: Peter E. Eupierre, M.D.
Shastri Swaminathan, M.D.
Robert L. Milam, M.D.
Alexander R. Lerner

Twenty North Michigan Avenue, Suite 700 Chicago, Illinois 60602

KU THE UNIVERSITY OF KANSAS
Medical Center

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ACCME

September 9, 2008

Murray Kopelow, MD, MS, FRCPC
Chief Executive
Accreditation Council for Continuing Medical Education
515 North State Street
suite 1801
Chicago, Illinois 60610

Dear Dr. Kopelow:

First, let me thank you for talking with Dr. Joseph Kyner and me last week regarding our letter to you of July 29. We certainly appreciated your call and your clarification on several issues.

In regard to ACCME's call for comments on issues posed in June, we put the issue before physicians with whom we routinely work here at the University of Kansas Medical Center and also sent a memorandum to our statewide CME advisory board members. Those solicitations for input were sent out in the last week of July.

Attached is a representative sample of the comments we received from physicians. They are reproduced exactly as sent and only edited slightly for spelling.

Following is also a synthesis of comments that represent the collective opinions of our CME program staff here at KU Medical Center.

Elimination of Commercial Support: There is an absence of empirical data that supports or refutes the notion that commercial support from pharmaceutical companies and device manufacturers biases CME and results in influence of prescribing and/or purchasing (of medical devices) behavior. CME is a data/evidence-based driven enterprise. Likewise, we need good data on this question.

For those who say that commercial support of CME is just wrong for ethical reasons, the question begs, "why"? On what do they base that opinion?

ACCME has in place a rigorous set of requirements that address conflict of interest and the acceptance of commercial support. We suspect that the majority of providers are vigilant in adhering to those requirements and we recommend that ACCME stick by their requirements until hard data is acquired that supports or refutes the notion that commercial support biases CME.

If commercial support is eliminated, it must be phased out over time in order to give providers the opportunity to: 1) secure funding from other sources; 2) gradually increase the fees for CME activities to participants.

Given that much CME has been partially subsidized by pharmaceutical companies and device manufacturers, participants have been sheltered from the real cost to produce quality CME activities. If providers passed along those costs in the form of fees and did so abruptly—as opposed to doing so incrementally—we would anticipate considerable price resistance and deterioration of participants.

Continuing Education
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The call for elimination of commercial support coincides with ACCME's requirements that focus on measurable change in behavior and healthcare quality improvement. We applaud these requirements. However, acquiring the advanced levels of skill in assessment and measurement—either through staff or consultants—will translate to increased costs. Anticipated increases in staff and operations cost also come at a time of economic downturn coupled, at least in Kansas, with state budget reductions that directly affect state supported universities.

Comments on proposed conditions for acceptance of commercial support.

Overall, our view is that these proposed conditions are reactionary and that potential ramifications of these measures have not been sufficiently evaluated for unintended consequences. Again, let's not take hasty steps related to commercial support unless warranted by sound data.

Verification of educational needs by organizations that do not receive commercial support. In our opinion, this requirement somehow casts aspersions on the integrity of CME professionals and suggests that we are incapable of doing an unbiased assessment of our learners or that we are unprofessional enough to bias the results of our assessments.

If CME addresses a professional practice gap, it must be corroborated by bona fide performance measures. There are a number of practice gaps in education for health professionals that, to date, cannot be corroborated by bona fide performance measures. For example, the recommendations of the Institute of Medicine around team-based medicine and patient-centered care are often behavioral and, to our knowledge, do not have established measures.

When CME content is from a CE curriculum specified by a bona fide organization, e.g, AMA, AHRQ, etc. This is somewhat disturbing—what is the assessment criteria a provider is to use to determine what is bona fide and what is not? Could this requirement not limit developing activities that are immediately responsive to identified needs of a set of learners.

When CME is verified as free of commercial bias. Who, or what agency, is going to verify this. Isn't this why we have the standards of commercial support?

We appreciate your review and consideration of comments from the University of Kansas Medical Center and our CME providership. Again, we wish to thank you for your time last week in talking with us regarding our comments and concerns addressed in our July 29 letter.

Cordially,

Joseph Kyner, MD, Professor of Medicine
Associate Dean of CME

Dale Grube, MA, Associate Dean, Continuing Education
Director, CME

ACCME CALL FOR COMMENTS 8/11/08 – COMMERCIAL BIAS IN CME

Submitted to: Murray Kopelow, MD, MS, FRCPC
Chief Executive
Accreditation Council for Continuing Medical Education

Submitted by: Michael Fullmer
President and CEO
Medical Communications Media, Inc.

COMMERCIAL BIAS IN CME: HOW SERIOUS IS THE PROBLEM AND WHAT SHOULD WE DO?

The Accreditation Council for Continuing Medical Education, the American Medical Association and the Senate Committee on Finance have all been closely examining the issue of commercial bias in CME-certified education and are attempting to assess the degree to which there is a problem and determine the best path to insuring that CME provides fair balance, and scientific rigor, and is in the best interest of physicians and the patients they serve.

HOW MUCH BIAS REALLY EXISTS?

There has been much discussion about commercial bias in CME. Unfortunately, there has been a sense of urgency to fix a perceived problem without first obtaining credible evidence of the extent of the problem in today's CME environment. Recent discussions seem to be flawed in two areas:

1. Assumptions of commercial bias are generally based on anecdotal information or accounts that pre-date the 2003 OIG Compliance Program Guidance for Pharmaceutical Manufacturers and the revised 2004 ACCME Standards for Commercial Support.
2. Discussions (e.g.: Recommendation of the Council on Ethical and Judicial Affairs for the AMA) very often combine CME-certified education with non-CME-certified promotional events such as speakers programs and dinner meetings.

Recently, an independent ACCME-funded study, by Ronald M Cervero, PhD and Jiang He, MPA examined the literature and concluded: "Although it has been speculated that commercial support produces bias in CME activities, there is no evidence to support or refute this assertion."[1] Since we are all called to utilize an evidence-based approach when developing content for CME, should we be any less committed to using the same approach when assessing and attempting to address commercial bias?

[1] Cervero, R; He, J: The Relationship between Commercial Support and Bias in Continuing Medical Education Activities: A Review of the Literature, June 2008

As far as certified CME activities vs. non-certified activities, it is clear that certified activities are bound by a stringent set of rules as defined by the ACCME and OIG guidelines, both of which were designed specifically to insure, quality, fair-balance and scientific rigor. Non-certified activities are not similarly bound and must therefore be separated when attempting to assess commercial bias in CME.

Survey of US Physicians on Commercial Bias

On July 30, 2008 Medical Communications Media, Inc. sent an e-mail to 23,434 physicians in its proprietary database inviting them to participate in a survey on the topic of commercial bias in CME. This database consisted of registrants of its dedicated website www.CMEcorner.com or previous participants in CME activities. Between July 30 and August 6, 2008 379 physicians responded. The questionnaire asked 7 closed-end questions and invited comments on question 8. It is important to note that this was not a scientifically designed and validated study and was not intended to be the basis for decisions on this topic. It does, however, provide a flavor of physician attitudes on this subject. To follow is a summary of the results.

1. Please rate on a scale of 0 to 10, 0 being no bias and 10 being completely biased, the degree to which you believe today's certified CME programs are biased by commercial entities such as pharmaceutical and medical device underwriters:

Mean Rating	Response Count
2.98	379

2. Please rate on a scale of 0 to 10, 0 being no bias and 10 being completely biased, the degree to which certified CME programs were biased by commercial concerns prior to institution and implementation of the revised *ACCME Standards for Commercial Support issued in April of 2004 and the OIG (Office of the Inspector General) Compliance Program Guidance for Pharmaceutical Manufacturers* issued in May of 2003:

Mean Rating	Response Count
4.11	379

3. Please rate on a scale of 0 to 10, 0 being no bias and 10 being completely biased, the degree to which today's promotional (non-CME) education programs (e.g.: lunch-and-learns, speaker or dinner programs) are biased by commercial sponsors:

Mean Rating	Response Count
5.37	379

The first three questions dealt with perceived commercial bias 1) for CME-certified programs today, 2)) for CME-certified programs prior to the 2003 OIG guidelines and 2004 ACCME revised Standards for

Commercial Support and 3) for non-certified promotional education programs such as speaker's programs or lunch and dinner programs. The mean score for today's CME-certified programs suggest that physicians do still perceive some bias, but it is at the mild end of the range. Question 2 suggests that we have made progress since the 2003 OIG guidelines and 2004 ACCME revised Standards for Commercial Support have been released, but there is still work to be done. Question 3 shows a clear increase in bias for promotional, non-CME-certified programs. This further supports the need to separate CME-certified programs from non-certified promotional programs when conducting discussions on the issue of commercial bias in CME.

It is important to note that the term "commercial bias" was not defined by the survey; nor were the respondents asked to define what they considered to be "commercial bias". For example, if a CME-certified program presents favorable data on a commercial supporter's product because of its inherent benefits, is that program perceived as biased? We also don't know to what degree commercial bias from the past creates a residual effect on today's perceptions. These and other questions need to be explored more thoroughly in future research. This research should include both surveys and in-depth physician interviews or focus groups.

4. Do you feel there would be an advantage to having a standard disclaimer on the 1st page of all invitations or promotional flyers for promotional (non-CME) live programs to clearly identify them as "promotional"?

Yes	No	Not Sure	Response Count
60.7% (230)	26.9% (102)	12.4% (47)	379

One area that was explored was the potential benefit of a new standard requiring notification if the education is a promotional event. Almost two thirds of those surveyed favored this approach and 12% were unsure.

5-7 Questions 5, 6, and 7: Commercially supported certified CME (e.g. supported through a pharmaceutical or medical device company educational grant) currently represents about two thirds of available CME. What impact to you think the elimination of all commercial funding might have on future CME offerings? (Please select one answer for each area in Questions 5, 6, and 7)

5.	Improve Quality of CME	Hurt Quality of CME	Have No Impact on the Quality of CME	Response Count
	20.3% (77)	54.9% (208)	24.8% (94)	379

6.	Increase the Quantity of Available CME	Decrease the Quantity of Available CME	Have No Impact on the Quantity of Available CME	Response Count
	6.1% (23)	88.4% (335)	5.5% (21)	379

7. Accessibility in	Increase Access	Decrease Access	No Impact on Access	Response Count
Rural Areas	7.4% (28)	83.9% 318)	8.7% (33)	379
Urban Areas	5.5% (21)	68.6% (260)	25.9% (98)	379
Suburban Areas	6.3% (24)	77.3% (293)	16.4% (62)	379

Questions five through seven dealt with the perceived impact that the elimination of commercial support would have on CME. On quality, over half felt that it would hurt the quality of CME, 20.3% felt it would improve the quality of CME, 24.8% felt it would have no impact.

On the issue of quantity of available CME programs, 88.4% felt that the number of available programs would decrease, 6.1% felt it would increase and 5.5% felt it would have no impact.

Looking at accessibility in various settings, more than two-thirds of the physicians surveyed felt that it would decrease access in all settings with the biggest concern being in rural areas. This is not surprising given the role of large urban-based universities and hospitals in providing CME activities in and around their centers.

Perhaps the most interesting finding from this survey relates to question #8, which simply stated “Other Comments” and had a space for open-ended comments. Of the 143 comments received, 116 (81%) voiced their support for continuing with commercial support of CME, 6 (4%) voiced their support for discontinuing commercial support of CME and 21 (15%) touch on other areas related to the survey. Those voicing support for continued commercial support were quite direct, at times voicing very strong feelings. The overwhelming voice of support for continuing support fell into four primary categories:

Sample Comments

Category 1 - Physicians are discerning enough to manage bias if it occurs (37 comments)

1. *As a physician I recognize that bias will never be completely eliminated when commercial entities are providing information. However my scientific training and sense of professional skepticism are always on*

alert; consequently I do not believe that I have been or will be unduly influenced when commercial sources of CME are used.

2. *I think most physicians are intelligent enough to detect and consider bias.*
3. *What an insane proposal! I've retired after 30+ years of practice. I greatly benefited and learned from CME which was supported by a variety of commercial entities. At NO time did I change any professional behavior because of such support. To imply that I could be 'bought' with a pen, breakfast or lunch is maximally offensive. It is simply political correctness run pathologically amok. Thanks for the opportunity to comment on the silliness.*
4. *Physicians are a fairly intelligent group, and are sophisticated enough to discern potential bias. We frankly don't need paternalism from ACCME nor the AMA. Eliminating commercial sponsorship will only serve to concentrate information dissemination within the hands of academics and professional societies---and, let us be frank: that's hardly a step up on the 'bias ladder'. Thanks, but I can fend for myself.*
5. *As a licensed physician with both an undergraduate and medical degree and 6 years of post graduate training that I think I am smart enough. Leave things be. No competent physician can be influenced unduly.*

Category 2 - Concerned about the impact that the elimination of commercial support for CME would have on cost, availability and quality (43 comments)

1. *The biggest problem is finding affordable CME. I couldn't possibly afford the required 50 credits a year w/o industry support. I only get $1,000 a year for registration , hotels and travel.*
2. *Commercial support is essential to be able to provide good quality and variety CME program.*
3. *If educational grants are not available to pay speakers then it will be hard to find qualified speakers who will donate their time to give lectures. Large teaching institutions will carry on CME as a part of their mission. Intermediate and smaller hospitals will not be able to afford CME without support.*
4. *Elimination is a poorly thought out, reflex type of solution. I call it the brain dead solution. More disclosure, oversight, etc. perhaps, but this banning movement is ridiculous and threatens large amount of extremely informative CME, and several learning opportunities (eg. simulators, hands on training) would disappear almost entirely.*
5. *What plan does ACCME have for funding CME if there is no commercial funding?*

Category 3 – CME is Generally Fair and Objective (10 comments)

1. *In my experience there's minimal bias in CME programs sponsored by commercial interests*
2. *Virtually every CME course commercially sponsored bends over backwards to be fair and objective.*
3. *Pharma has in the past provided ethical continuing education. I would challenge those seeking to eliminate or restrict even more industry sponsored CME to propose a cost-effective alternative.*
4. *Would hate to see CME go away and really feel it is rarely biased.*
5. *Academic purist over-estimate both bias in CME and their own importance in preventing it.*

Category 4 – Other Comments Favoring Commercial Support of CME (26 comments)

1. *CME is important today - and commercially sponsored, non-biased CME helps improve the quality of patient care.*
2. *This effort is pandering to the politicians and to the worst instincts of the public*
3. *It would be helpful if their critics would realize that drug and device companies are not only not evil but actually responsible for many of the health benefits we enjoy today. This process of demonization is short-sighted, counterproductive, and very unlikely to do anything to improve patient care.*
4. *Physicians need to be fully educated, we really don't care who supports it, we just want to learn.*
5. *Commercially supported certified CME is absolutely essential to general medical learning today. It not only should not be eliminated, instead it should be expanded and is extremely helpful to the general practice of medicine and quality of patient care.*

There were 6 respondents, of the 143 physicians offering comments on question 8, who used it to express their desire to eliminate commercial support for CME. All six comments are listed below:

1. *Let's get commercial support out of CME. Commercial support did not occur during medical school, but has a heavy presence in CME. If commercial support is not engaged in medical school education why is it allowed in postgraduate and CME?*
2. *Strongly favor elimination for the sake our professional image*
3. *Pharma sponsored CME are high tech infomercials.*
4. *a blatant conflict of interest that needs to be addressed proactively by professionals. Industry supports CME to sell a product-even if it's not the best for the patient, we must stand up for the patient, not our pocketbooks or stomachs...*
5. *Physicians have become beggars, taking money and gifts wherever they can get them. Academic physicians are particularly guilty of selling themselves, possibly because they wish to try to emulate private practice incomes.*
6. *Commercial bias in "CME" is a stain on the integrity of the medical profession. It has permeated throughout the profession like a plague. I strongly urge ACCME to ban commercial support of CME, and help bring integrity back to the medical profession.*

While the 6 respondents who favored the elimination of commercial support for CME were equally as passionate, it is difficult to ignore the sheer numbers, with 116 favoring the continuation of commercial support for CME and only 6 favoring its elimination.

Commercial Bias Question – Program Evaluations

Current CME guidelines require that each program evaluation include a question to determine if participants perceive commercial bias. Steps are required should a provider determine perceived bias based on these evaluations. Medical Communications Media, Inc. employs two methods for this assessment as demonstrated from the recently completed CME/CE-certified live and online programs listed below.

Was the activity free of commercial bias?

2007 - 2008 Commercial Bias Summaries (All Professions)
4-Strongly Agree…1-Strongly Disagree

Year	*Type*	*Program Name*	*Responders*	*Mean Score*
2007	Grand Rounds	Malignant Gliomas, Hope Life: Using Biology to Refine Treatment	662	4.0
2007	Grand Rounds	Comprehensive Management of Ovarian Cancer: Current Treatment and Maximizing Quality of Life	554	4.0
2008	Grand Rounds	Advances in the Management of Myelodysplastic Syndromes	227	4.0
2008	Grand Rounds	Advances in the Management of Recurrent Ovarian Cancer: A Case-Based Approach	158	4.0
2007	Audioconference	ADHD Across the Lifespan: Managed Care Strategies for Optimizing Patient	409	3.7

		Care		
2007	Audioconference	ASTHMA IN MANAGED CARE Improving Clinical Outcomes	425	3.7
2007	Audioconference	ASTHMA IN MANAGED CARE Optimizing Healthcare Resource Utilization	398	3.6
2007	Audioconference	The Management of Bipolar Disorder in Managed Care: Enhancing Function and Productivity	263	3.8
2007	Audioconference	The Management of Bipolar Disorder in Managed Care: Improving Adherence to Therapy	229	3.8
2007	Audioconference	Update on the Management of Chronic Constipation in Long-Term Care	1013	3.7
2007	Audioconference	Contemporary Management of Chronic Constipation in Long-Term Care	427	3.5
2007	Audioconference	Reducing Peptic Ulcer Complications in the Elderly	561	3.7
2007	Audioconference	Insomnia Management in Long-Term Care: Challenges and Opportunities	287	3.7
2007	Audioconference	Managing Insomnia in Primary Care: Practical Tools for the Busy Practitioner	286	3.7
2008	Audioconference	Optimizing the Continuum of Care in Elderly Residents With Anemia and CKD	354	4.0
		TOTAL	***6253***	***3.8***

Was the activity free of commercial bias?

			Yes	***No***
2008	Online	Management of Gliomas: A Case-Based Approach	52	4
2008	Online	Maximizing Metastatic Breast Cancer Treatment and Outcomes Through Cell-Based Disease Monitoring and Anemia Management	26	2
2008	Online	The Neurosurgeon's Evolving Role in the Management of Malignant Gliomas	11	4
2008	Online	Balanced Pharmacotherapy: A New Strategy to Minimize Risk and Maximize Efficacy in Acute Coronary Syndrome (ACS)	105	2
2008	Online	Malignant Gliomas, Hope & Life: Using Biology to Refine Treatment: Podcast Program 1	11	1
2008	Online	Malignant Gliomas, Hope & Life: Using Biology to Refine Treatment: Podcast Program 2	9	0

2008	Online	Malignant Gliomas, Hope & Life: Using Biology to Refine Treatment: Online Program 1	20	2
2008	Online	Comprehensive Management of Ovarian Cancer: Current Treatment and Maximizing Quality of Life	18	0
2008	Online	Malignant Gliomas, Hope & Life: A Forward-Looking Discussion	64	3
2008	Online	Malignant Gliomas, Hope & Life: Using Biology to Refine Treatment: Online Program 2	33	2
2008	Online	Malignant Gliomas, Hope & Life: A Forward-Looking Discussion	21	1
2008	Online	Malignant Gliomas, Hope & Life: Using Biology to Refine Treatment: Podcast Program 3	5	0
2008	Online	Malignant Gliomas, Hope & Life: Using Biology to Refine Treatment: Podcast Program 4	4	0
2008	Online	Controversies in Neuro-Oncology: A Conversation About Managing Primary & Metastatic Brain Tumors	8	2
2008	Online	Controversies in Neuro-Oncology: A Case-Based Discussion on Managing Primary & Metastatic Brain Tumors	25	0
2008	Online	Rhinitis & Beyond: Managing Associated Comorbidities	21	0
2008	Online	Optimizing Chemotherapy Outcomes in Early & Advanced Breast Cancer: A Case-Based Discussion	15	2
2008	Online	Optimizing Chemotherapy Outcomes in Early & Advanced Breast Cancer: A Case-Based Monograph	14	0
2008	Online	Rhinitis & Beyond: Managing Associated Comorbidities	13	1
2008	Online	Rhinitis & Beyond: Managing Associated Comorbidities	55	0
2008	Online	Rhinitis & Beyond: Managing Associated Comorbidities	37	1
2008	Online	Management of Persistent, Recurrent, and Refractory Ovarian Cancer	17	0
2008	Online	Management of Persistent, Recurrent, and Refractory Ovarian Cancer	15	0
2008	Online	Optimizing the Continuum of Care in Elderly Residents With Anemia and CKD	11	0
2008	Online	Primary Malignant Gliomas: Current Practices & Future Directions	2	1
			612	28
		TOTAL PERCENTAGE	***96%***	***4%***

This represents only a random sampling of recently completed live programs and completions to-date for online programs introduced in 2008. These are also from a single medical education and communication company. It does, however, suggest that today's healthcare professionals perceive the CME/CE activities to be largely unbiased. It also points to the readily available data that could provide immediate insight regarding physicians' attitudes on this subject.

Recommendations:

1. *Gather from providers combined data on the commercial bias question for all programs that were completed between 1/1/08 through 6/30/08. Have providers separate data into groups based on funding source, with "commercially funded" being one of the groups. Assess the extent of reported commercial bias and the differences between the groups based on the source of that funding.*
2. *Conduct scientifically designed research with physicians, including in-depth interviews, to better understand their perceptions and attitudes on this subject*
3. *Be certain to separate CME-certified activities from non-certified activities in all discussions of commercial bias in CME.*

INSURING FAIR-BALANCE AND SCIENTIFIC RIGOR

One of the troubling aspects of recent conversations on commercial bias is that it fails to recognize the strong leadership that the ACCME has provided which has resulted in a major evolution of CME over the past 15 years. To adequately insure that CME activities are free of commercial bias, the ACCME has understood that it is essential to build proper firewalls. This has, consequently, become a key underpinning in today's CME guidelines. The changes that the ACCME and the OIG have initiated have been many and have been significant. They include:

1. Regulatory
    - The establishment of *Standards for Commercial Support* in 1992 and revision of those standards in 2004.
2. Structural
    - The separation of CME staffing from marketing staffing within the structure of pharmaceutical underwriters. This separation includes the separation of budgets and marketing's control over those budgets.
    - The separation of staffing and financial structures within companies providing both CME-certified educational services and promotional services (advertising and promotion).
3. Contractual
    - The requirement of a legally-binding letter-of-agreement between the accredited provider and the commercial underwriter that clearly states the roles of the respective parties and the contractual agreement of both parties to comply with all current educational guidelines.
4. Communication
    - The institution of guidelines that prohibit discussions related to faculty or content between the accredited provider (includes their agents) and a commercial underwriter.

- The institution of guidelines that prohibit requests by the accredited provider (including their agents) of the commercial underwriter for information.
- The institution of guidelines that prohibit medical accuracy reviews by commercial underwriters.

5. Disclosure
    - The establishment of comprehensive guidelines to determine and address potential conflicts-of-interest with faculty of CME-certified activities

6. Enforcement
    - An increase in the number of probations issued from about 1% in the past to about 10% of current providers seeking reaccreditation[2]
    - Increased scrutiny and compliance with requirements for accredited providers that receive a large percentage of commercial support, or present CME whose content may need further validation or CME providers that offer only jointly sponsored activities with non accredited organizations[2]

Each of these steps was taken to prevent the risk of commercial bias. Providers and their agents have adjusted quickly to insure compliance. Grant request processes have become web-driven and more automated. Access to the staffs of commercial underwriters has been restricted to CME professionals only and access to these individuals has become less frequent with discussions limited to financial issues regarding the grant extension and outcomes related information at the completion of the program.

STRATEGIES FOR THE FUTURE

Current strategies under discussion assume that significant commercial bias exists and that this bias requires a significant response beyond current and planned guidelines and practices. While evidence of significant commercial bias has not been established, the following strategies are currently under consideration by the ACCME:

<u>The Status Quo</u>

Alternative #1 – Continue with the Existing System

As we all continue to strive for the highest possible quality, fair-balance and scientific rigor in CME, it is a given that we will continue to evolve and that the ACCME will lead us in that process. As long as commercial bias exists in any form, the status quo will never be an acceptable option and further changes or refinements will be required.

[2] ACCME: Accredited CME is Education That Matters to Patient Care; June 2008

A Complete System Overhaul

Alternative #2 – Complete Elimination of Commercial Support

While the elimination of commercial support for CME would certainly decrease the risk of commercial bias , should it be proven to exist to a significant degree, the implications of this change would be far reaching and potentially damaging to our efforts to provide quality CME to physicians and optimize care to their patients. While the following is not an exhaustive list of the potential implications, it does point out potential consequences worth considering.

Limiting Resources

1. Commercial funding represented 63% of CME funding in 2006[3]. This estimated 1.2 billion dollar gap would need to be bridged by medical societies, medical universities, accredited hospitals and/or the physician audience, if we are to maintain our current level of CME support.
2. The medical societies depend on commercial grants not only to fund their role in supporting their CME activities, but also to support education not funded by other sources (e.g.: practice management, regulatory updates) and other activities designed to support their physician constituency. Without this support there would likely be cut-backs in society staffs and services. These cut-backs would likely not be limited to CME services. It is not surprising that the Council of Medical Specialty Societies took an official position against this very same proposal in a letter addressed to the AMA Council on Ethical and Judicial Affairs dated June 5, 2008.[4]
3. There are 849,542 US physicians according to the AMA[5]. If the costs of CME currently being provided by commercial support (estimated at $1,238,820,965 [3]) were passed on to and shared equally by these physicians, the cost per physician would be just over $1,400.
4. A more likely scenario is a substantial reduction in national initiatives and the more expensive technology-based educational platforms such as interactive web applications, web conferences and handheld applications.
5. There are 325 medical education companies listed in the 2007/2008 PMD directory[6]. Most medical education and communication companies have a full complement of highly trained staff including: medical directors, medical writers/editors, project managers, meeting managers, programmers/webmasters, designers and database managers. Assuming that the current level of CME activities is maintained to meet the ongoing CME needs of the US physicians, these same responsibilities would need to be absorbed by medical societies, medical universities and accredited hospitals, most of which currently carry minimum staffs for this purpose. Would these individuals migrate to these organizations and how would their positions be funded?

[3] 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

[4] Letter from Council of Medical Specialty Societies to Mark Levine, MD, CEJA, American Medical Association, June 5, 2008

[5] American Medical Association – Specialty by Type of Practice list; Medical Marketing Services website (www.mmslist.com); July 3, 2008

[6] Pharmaceutical Marketers Directory, 2007/2008, Haymarket Media, Publisher

6. A recent report from the ACCME indicated that there are 729 ACCME accredited providers of which 425 (58%) received $100,000 or more in commercial support for their CME activities in 2006[3]. What impact might it have on CME if a significant portion of these providers were no longer financially viable?

Regionalization

1. One possible outcome of the elimination of commercial support, as mentioned previously, is the movement away from large-scale national programs and towards regional and local CME activities. Would such a movement result in a tendency to select faculty experts from a regional area, thereby limiting access to highly respected national experts, who are often involved in major national or international studies for major research-driven organizations (e.g.: NIH, American Cancer Society or the Juvenile Diabetes Foundation)?
2. Regionalization might also move many of the CME activities to major urban areas where most of the medical schools and major hospital systems are based. Might this impact rural physicians and their access to CME activities?

Restructuring the Needs Assessment Process

1. Most major MECCs have in place medical directors and outcomes managers dedicated to complex process of collecting and analyzing needs assessment and outcomes data. The needs assessment process typically includes: literature reviews, conversations with key opinion leaders, surveys with samples of the intended audience and reviews of needs assessments data from medical societies and organizations representing specialty groups. Outcomes can include in-person surveys, electronic surveys, or more detailed practice habit or attitudinal evaluations. Are medical societies, medical schools and accredited hospitals equipped with the staffing and expertise necessary to absorb these tasks for the 1.2 billion dollars in education that is currently commercially supported? Would these individuals from the MECCs migrate to these organizations and how would their positions be funded?
2. Some of the major MECCs have developed large physician databases which they use for electronic communication with physicians during the needs assessment process. Will the process be impaired if MECCs which possess these resources redefine themselves by moving away from CME or closing their doors?
3. Is there an advantage to having 300+ medical education companies simultaneously and independently researching physicians' educational needs vs. a much smaller group?

Promotional vs. CME Funding

1. If commercial funding of CME is prohibited, it might be assumed that a large portion of these dollars would be moved into promotional activities and direct-to-consumer advertising. What might this do to the balance between promotion and education?

Alternative 3 – Needs Assessments by Organizations Free of Financial Relationships with Industry" (eg, US Government agencies); Content Developed by Bona Fide Organizations (i.e.: AMA, AHRQ, ABMS, and FSMB)

1. Does the government currently have the staffing and expertise to support needs assessments for approximately two-thirds of currently available CME?
2. Is there currently a budget or plans for a budget to support that staffing?
3. Are the bona fide organizations such as the AMA, AHRQ, ABMS and FSMB currently staffed to support approximately two-thirds of the currently available CME?
4. If not, where will the funding come from to hire these staff?
5. Will these organizations be willing to forgo all commercial support (CME or otherwise) to insure that the risk of commercial bias does not simply transfer to these organizations? This would include significant research grants by industry to universities and advertising in journals of the named organizations.

Recommendation

Refinement and Evolution

Alternative 4 – Increased Enforcement and Further Refinements

This obvious alternative seems to have been missed among the alternatives currently under review. This alternative might include a number of changes listed below, many of which have already been identified and are in the process of being implemented by the ACCME:

1. *A comprehensive independent study to determine how much, if any, commercial bias exists in current certified CME activities and the causes for that bias.*
2. *Collection and analysis of data from evaluations on perceived commercial bias from program participants.*
3. *An expanded definition of "commercial interest" and increased scrutiny of organizational types and business models regarding eligibility for accreditation.*
4. *An expanded and more comprehensive ACCME database of CME activities based on required reporting from providers, ACCME monitors and program participants.*
5. *A specific action plan for specific CME-certified programs that have reported program bias over a given threshold.*
6. *Required violation reporting by accredited providers along with the intended resolution plan. The source of the violation could be an underwriter, joint-sponsor, faculty member or provider staff*
7. *Significant increases in staffing at the ACCME for more frequent site visits and increased communication with providers.*
8. *Surprise visits to accredited providers for spot checks on compliance.*
9. *Tougher and timelier penalties for non-compliance.*

10. *Continued dialog and collaboration with providers, non-accredited MECCs, underwriters and other CME stakeholders to establish clear goals, refine processes and insure quality, fair-balanced education.*

Potential ACCME-Recommended Refinements

Refinement 1 – Prohibit Freelance Writers from Writing Both for Promotional & CME Projects - Commercial bias certainly needs to be addressed at this level. This specific recommendation would help reduce the risk of commercial bias, but it might also be considered a prevention of trade by this class of professionals. An alternative might be to restrict freelance writers from serving for promotional writing and medical writing (CME) for the same commercial concern .

Refinement 2 – Prohibiting Potential Faculty Who Teach in Promotional Activities from Serving as a Faculty Members for CME Programs - If we are to eliminate financial connections that faculty have that might increase the risk of bias, it would seem illogical to randomly select only one type of relationship (i.e.: involvement in promotional activities). There is no published evidence that demonstrates that involvement in promotional activities increases the risk of bias any more than serving as a consultant on an advisory board or receiving a research grant. To eliminate potential faculty with any financial ties to commercial supporters, on the other hand, would virtually eliminate all nationally and internationally recognized experts from involvement in CME activities.

It is also important to consider that for each financial tie one of these experts possesses, there is typically a counter-balancing financial tie to a competitive commercial concern, since experts tend do work for all of the companies with an interest in their area of expertise. If there is disproportionate support by one commercial concern, this is uncovered in the financial disclosure process. Credit providers then have remedies to address this issue including the option of disqualification. Bottom line, the current disclosure process was designed specifically to address this issue and is working, unless there is solid evidence to the contrary.

Final Reflections

Because the patient's health is ultimately at stake, it is critically important that we do our homework on this matter and not respond impulsively to outside forces that may, or may not, completely understand the world of CME. This is true, no matter how passionate, influential or well-intentioned these groups may be.

Before we go any further down this path, it will be essential that we ask ourselves these questions:

- What is the true extent of commercial bias in CME?
- If it occurs in a significant way, what are the causes?
- Are physicians able to discern and manage commercial bias when it does occur?

- If our purpose is to serve physicians and the patients they serve, have we fully engaged the physicians in our discussions about commercial bias in CME?
- Have we fully considered the implications of the elimination of commercial support for CME on access, availability and quality of future CME programming?
- Do we have a viable alternative plan in place should it be eliminated?
- Is it well thought-out and is it financially viable?

NAAMECC
North American Association of Medical Education and Communication Companies, Inc.

July 30, 2008

BY E-MAIL

Murray Kopelow, MD, MS, FRCPC
Chief Executive
Accreditation Council for Continuing Medical Education
515 N. State Street, Suite 1801
Chicago, IL 60654

Re: **June 11, 2008, ACCME Policy Announcements and Calls-for-Comment**

Dear Dr. Kopelow:

We are writing on behalf of the North American Association of Medical Education and Communication Companies (the Association) to request that the Accreditation Council for Continuing Medical Education (ACCME) (1) issue a public announcement stating that all written comments received in response to the ACCME's June 11, 2008, Policy Announcement and Calls-for-Comment (the Package)[1] will be posted publicly to the ACCME's web site as soon as possible after receipt, and (2) granting an extension of time to the later of (a) August 25, 2008, or (b) two weeks after the ACCME issues *both* (i) the promised clarification of its initiative on closer scrutiny of so-called "high risk" providers[2] and (ii) clarification of its proposed four part test for determining when "commercial support of individual activities would be in the public interest and could continue to be allowed"[3], in which interested persons may file written comments on the Package. Our reasons for these requests are as follows:

1. **Public Disclosure of Written Comments on the Package.**

In a July 9, 2008, conference call with members of the Association, you stated that written comments on the Package would not be made public by the ACCME. At the same time, you stated that based on an evaluation of these comments, the ACCME would announce its positions and final policies on the matters covered in the Package at a later date to be determined.

The Association and its members are seriously concerned about the lack of transparency in a process in which only the ACCME is able to assess the evidence and arguments submitted by all continuing medical education (CME) stakeholders in response to the Package. Some may

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[1] *Available at* http://www.accme.org/index.cfm/fa/news.detail/news_id/c7b2d7ee-854d-4440-9b87-265746af2495.cfm.
[2] *Id.*, "*ACCME Monitoring and Surveillance: Measurements during the Term of Accreditation, For Information, Initiative #1—Closer Scrutiny of Select Providers*".
[3] *Id.*, "*The ACCME Believes that Due Consideration be Given to the Elimination of Commercial Support of Continuing Medical Education Activities*".

conclude that this amounts to a closed and secretive proceeding designed to achieve a predetermined outcome that is squarely at odds with the ACCME's own firm commitment to disclosure as a way of ameliorating concerns about potential bias.[4] We submit that for the ACCME process to have enduring credibility with affected constituencies and with the public at large, it should and must be conducted in the sunshine. Our members need and want to know whether the decisions ultimately reached by the ACCME in this critical proceeding are based on evidence and solid argument or, conversely, are based on predisposition and belief. This means that all written comments received on the Package should be disclosed publicly by the ACCME. We are not asking for a seat at the table during the deliberative process when ACCME Staff and the ACCME Board evaluate the comments and determine what final action to pursue.[5]

Governance in the sunshine is a way of helping to insure the fairness and integrity of the entire ACCME process. This principle of openness is an aspect of administrative due process when the regulatory body is a government agency. Given that the ACCME operates as the functional equivalent of the government in setting standards for continuing medical education (CME), which in turn are incorporated into state medical licensing statutes, there is every practical reason to apply the same transparency rules here.

Moreover, non-governmental organizations (NGOs) recognize the value and importance of transparency to the integrity of the organization's decision making and to the public trust, or lack thereof, that it engenders. For example, the World Association of Non-Governmental Organizations has adopted a Code of Ethics and Conduct for NGOs that imposes a number of transparency obligations.[6] One of the Guiding Principles on "Transparency and Accountability" is the proposition that "An NGO should be transparent in all its dealings with the government, ***the public***, donors, ***partners***, beneficiaries, ***and other interested parties***, except for personnel matters and proprietary information."[7] Likewise, the Guiding Principle on Public Trust says that "*Trust is the lifeblood of an NGO . . . To develop and maintain trust each NGO should exhibit and maintain public accountability and* ***transparency****, and should be honest in the information it makes available to the public.*"[8] Accordingly, and even if transparency principles do not apply here as a matter of law, the ACCME should apply them simply as a matter of principle.

We submit that there is no principled reason why the written comments on the Package, including those from the Association, should not be divulged by the ACCME as soon as possible after they are filed.

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[4] *See e.g.* ACCME Standards for Commercial Support, Standard 6, *"Disclosures Relevant to Potential Commercial Bias", available at* http://www.accme.org/dir_docs/doc_upload/68b2902a-fb73-44d1-8725-80a1504e520c_uploaddocument.pdf.

[5] We reserve the right to request an opportunity to make an oral presentation to ACCME Staff and to the ACCME Board before final action is taken on the Package.

[6] *Available at* http://www.wango.org/codeofethics.aspx?page=0.

[7] *Id.* (Section I.E. (emphasis and italics supplied)).

[8] *Id.* (Section VI., Preamble) (italics in original; emphasis supplied).

2. **Extension of Comment Period to August 25, 2008.**

With respect, we hereby formally request an extension of time to the later of (a) August 25, 2008, or (b) two weeks after the ACCME issues *both* (i) the promised clarification of its initiative on closer scrutiny of so-called "high risk" providers, and (ii) clarification of its proposed four part test for determining when "commercial support of individual activities would be in the public interest and could be continue to allowed", in which interested persons may file written comments on the Package. Indeed, given the importance and complexity of the issues raised by the ACCME and the potential impact on Association members, and even if the ACCME were to issue these clarifications immediately, it would be appropriate for the ACCME to provide time through and including Labor Day for the submission of written comments, but we are not specifically requesting that long a delay. Our request for a postponement of the comment period is based on a number of factors.

First, while we appreciate your participation in a lengthy conference call about the Package on July 9, 2008, the clarity that was intended to have been provided during that call has actually engendered yet additional confusion and uncertainty, not less. We need more time to articulate clearly what areas of uncertainty remain and why we believe these uncertainties should be resolved in one direction or another.

Second, one of the crucial elements in the Package is the ACCME's conclusion that, absent any empirical evidence of biased content, an accredited provider who nevertheless receives a large percentage of commercial support is presumptively "high risk" and hence must verify to the satisfaction of the ACCME that its interactions with commercial supporters from inception to CME presentation are being conducted independent of commercial interests.[9] As you acknowledged during the July 9, 2008, conference call, this presumptive determination is highly stigmatizing and engenders substantial time and effort to rebut, without any assurance that even a persuasive rebuttal process would be successful in removing the initial stigma associated with the "high risk" accusation. Moreover, you specifically stated on July 9 that this approach does not represent the views of the ACCME, but does reflect the views of some other interested stakeholders. Further, you promised that you would issue a public announcement the same or the following week clarifying that the ACCME itself does not share these views on "high risk" provider status but is merely reflecting what some others may think. In addition, you stated that you would provide a breakdown by provider type of the organizations that have tentatively been identified as "high risk" based on this approach.

To date, however, the ACCME has not issued any public clarification that the presumptive designation of "high risk" status does not reflect its own views. Nor has the ACCME yet provided a breakdown by provider type of which organizations have been tentatively identified as "high risk". Absent this information, it is difficult, if not impossible, for the Association to evaluate whether and to what extent the reputation of its members is tarnished by the ACCME's proposal on "high risk" providers and to develop meaningful comments in response. For this reason alone, an extension of time is warranted.

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[9] *See fn. 2* above.

Third, and relatedly, several key members of the Association have been distracted from focusing on preparing written comments on the Package by the need to prepare a response to the ACCME's inquiry into compliance with the 2004 *Standards for Commercial Support* directed to their individual companies.

Fourth, the ACCME's proposed four-part test for determining when "commercial support of individual activities would be in the public interest and could continue to be allowed"[10] provides little if any detail about how this would work in practice. Absent specific clarification of both the substantive standards and procedural steps that would apply in assessing each of these criteria, the ability of the Association and its members to weigh the implications of the proposal and to provide meaningful comments is seriously eroded. Put differently, the ACCME is poised to develop a new paradigm for commercial support for CME in response to comments on the Package, and perhaps to eliminate commercial support entirely, yet the ACCME's notice fails to provide sufficient detail to allow for the submission of meaningful comments. This process seems fundamentally unfair.

Fifth, it has taken the Association more time than originally envisioned to organize itself to undertake the critical review and analysis of the Package necessary to provide meaningful comments that might be of substantial value and importance to the ACCME. We are sure you can understand how difficult this organizational undertaking can be, particularly with many competing priorities.

Sixth, it is the summer with attendant vacations and the like, which makes all of the foregoing even more difficult.

We are sure you will agree with us that proposals of this magnitude deserve considered thought and attention by the affected community. Indeed, we suspect that others, in addition to the Association and its members, would appreciate additional time to respond.

* * *

[10] *See* fn. 3, above.

We ask that you bring this request to the attention of the ACCME Board of Directors and advise us accordingly when you have done so. In asking that you notify the Board, we are honoring your request that you serve as the conduit for these communications. At the same time, we are providing copies of this request directly to the liaison for each of the ACCME's member organizations, as shown below.

We appreciate your consideration. Best personal regards.

Respectfully submitted,

Michael R. Lemon, MBA, CCMEP
President

Stephen M. Lewis, MA, CCMEP
President-Elect

Richard F. Tischler, Jr., PhD, FACME
Treasurer

Sandra T. Weaver, MS
Secretary

Karen M. Overstreet, EdD, RPh, FACME, CCMEP
Past-President

cc American Board of Medical Specialties
Member organization liaison: Jan Simon, RN, MHSA (jsimon@abms.org)
American Hospital Association
Member organization liaison: John Supplitt, MPH, MBA
(john.supplitt@heart.org)
American Medical Association
Member organization liaison: Alejandro Aparicio, MD, FACP
(alejandro.aparicio@ama-assn.org)
Association for Hospital Medical Education
Member organization liaison: Charles Daschbach, MD, MPH
(cdaschb@chw.edu)
Association of American Medical Colleges
Member organization liaison: David Davis, MD (ddavis@aamc.org)
Council of Medical Specialty Societies
Member organization liaison: Norman Kahn, MD (nkahn@cmss.org;
also c/o jkersten@cmss.com)
Federation of State Medical Boards of the U.S., Inc.
Member organization liaison: Carol Clothier (cclothier@fsmb.org)

NAAMECC
North American Association of Medical Education and Communication Companies, Inc.

August 12, 2008

BY E-MAIL

Murray Kopelow, MD, MS, FRCPC
Chief Executive
Accreditation Council for Continuing Medical Education
515 N. State Street, Suite 1801
Chicago, IL 60654

Re: **June 11, 2008, ACCME Policy Announcements and Calls-for-Comment: ACCME Response to NAAMECC July 30, 2008 Requests**

Dear Dr. Kopelow:

The North American Association of Medical Education and Communication Companies (the Association) appreciates the extension to September 12, 2008, of the time for providing written comments in response to the June 11, 2008, Policy Announcements and Calls-for-Comment (the Package) from the Accreditation Council for Continuing Medical Education (ACCME). We also appreciate the ACCME's clarification that there is no evidence to support the belief that commercial support for accredited continuing medical education (CME) has placed the entire CME system at high risk for commercial bias.[1]

At the same time, however, the ACCME has now profoundly expanded the scope of the rulemaking by proposing yet additional criteria for defining the independence of accredited CME providers.[2] In order to provide a meaningful response to this latest request for comment, these proposed new criteria will need to be evaluated both for their procedural and substantive merit, as well as their business impact. Moreover, we need to analyze how all of these elements fit into the new four-part paradigm that the ACCME is considering in order for commercial support for CME to remain a viable option. Indeed, the ACCME's stated inability to clarify this new paradigm absent additional details and examples from the Association about what it wishes be clarified, not only places the burden of clarity on the wrong party, it also makes it difficult if not impossible for the Association to assess how the numerous pieces of this puzzle all fit together. We and our members have the strong sense that we are shooting at a moving target, which fundamentally undercuts the fairness of the entire process.

Moreover, we remain troubled by the ACCME's tepid response to our request for public release of all written comments filed on the Package. For example, we do not comprehend why certain

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[1] *See* ACCME August 5, 2008 Letter Regarding Special Inquiry, *available at* http://www.accme.org/index.cfm/fa/news.detail/News/.cfm/news_id/fd384ed8-5a4b-44d0-acdd-c77ce900b7a6.cfm.
[2] *See "ACCME Proposes Additional Features of Independence in Accredited Continuing Medical Education", available at* http://www.accme.org/dir_docs/doc_upload/d64b68f6-9525-43af-9074-719f92ad7c97_uploaddocument.pdf

information will be made public but only "without attribution". Surely, in order to assess the credibility of the comments, it is important to know the identity of the commenter. Otherwise, how else, among other things, can the commenter's own possible bias and potential conflicts of interest be evaluated? Further, we do not comprehend why only "summaries and extracts, as opposed to verbatim submissions" will be made public. Transparency means openness. The Association has no objection to public disclosure of its forthcoming written comments in their entirety and seeks the same degree of transparency for the comments to be submitted by all others. Indeed, such total openness would obviate the delay in posting that the ACCME acknowledges will occur on account of the need to prepare summaries and extracts. In addition, posting the written comments *in toto* will free up ACCME staff time for the important task of evaluating the comments themselves, as opposed to summarizing and extracting them.

Moreover, and perhaps most fundamentally, a process in which the ACCME unilaterally decides what is summarized or extracted and what is not, and how these summaries and extracts are prepared, places too much control of the information in the hands of the ACCME itself. It will only serve to erode the trust and confidence of the regulated community in the integrity of the entire regulatory endeavor. The ACCME's point that the comment and evaluation process is not a vote, even if true, is largely beside the point insofar as transparency is concerned. We seek openness not in order to "count the votes", but in order to assess the validity of the underlying arguments. Also, and even if votes are not being counted as such, it does seem highly relevant to know the extent to which commenters supported and opposed particular points of view, as well as the level of overall interest in the debate.

Lastly, and even if, as the ACCME contends, it is not the "functional equivalent of the government", the fact remains that the standards we are proposing are straightforward principles of fairness and transparency. Moreover, the ACCME's protest about its status is belied to a considerable extent by, among other things, the fact that the ACCME is proposing to import into the "independence" determination the very standards that were part of a governmentally coerced settlement with a major pharmaceutical company.

Respectfully submitted,

Michael R. Lemon, MBA, CCMEP
President

Stephen M. Lewis, MA, CCMEP
President-Elect

Richard F. Tischler, Jr., PhD, FACME
Treasurer

Sandra T. Weaver, MS
Secretary

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cc American Board of Medical Specialties
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Member organization liaison: John Supplitt, MPH, MBA
(john.supplitt@heart.org)
American Medical Association
Member organization liaison: Alejandro Aparicio, MD, FACP
(alejandro.aparicio@ama-assn.org)
Association for Hospital Medical Education
Member organization liaison: Charles Daschbach, MD, MPH
(cdaschb@chw.edu)
Association of American Medical Colleges
Member organization liaison: David Davis, MD (ddavis@aamc.org)
Council of Medical Specialty Societies
Member organization liaison: Norman Kahn, MD (nkahn@cmss.org)
Federation of State Medical Boards of the U.S., Inc.
Member organization liaison: Carol Clothier (cclothier@fsmb.org)

BEFORE THE ACCREDITATION COUNCIL FOR

CONTINUING MEDICAL EDUCATION

In the matter of:	)
June 11, 2008 ACCME Policy Announcements and Calls-for-Comment; August 6, 2008 Further Call-for-Comment	)

COMMENTS OF THE NORTH AMERICAN ASSOCIATION OF MEDICAL EDUCATION AND COMMUNICATION COMPANIES, INC.

September 12, 2008

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BEFORE THE ACCREDITATION COUNCIL FOR

CONTINUING MEDICAL EDUCATION

In the matter of:	)
June 11, 2008 ACCME Policy Announcements and Calls-for-Comment; August 6, 2008 Further Call-for-Comment	)

COMMENTS OF THE NORTH AMERICAN ASSOCIATION OF MEDICAL EDUCATION AND COMMUNICATION COMPANIES, INC.

EXECUTIVE SUMMARY

The North American Association of Medical Education and Communication Companies, Inc. ("the Association") strongly supports the enablement of quality continuing medical education (CME) in the United States. We commend the Accreditation Council for Continuing Medical Education (ACCME) for providing all CME stakeholders with this forum for discussion and debate about issues central to the on-going viability of the CME enterprise and consequently to post-graduate education of licensed physicians and the resultant health and well-being of patients across the country. At the same time, the Association is concerned that the ACCME's proposals will work at cross-purposes with these laudable objectives. For example, the ACCME's proposal to categorically ban commercial support for CME is seriously flawed and, if adopted, may well cripple the ongoing viability of the CME enterprise. The ACCME's alternative "new paradigm" for commercial support is ambiguous and unworkable and, in any event, beyond the ACCME's authority. Proposals of this magnitude should be adopted, if at all, by bodies more representative of the entire stakeholder community. Likewise, the ACCME's proposed new

"independence" standards, including the categorical prohibition on (a) suggestion of topics, (b) provision of requests for proposals (RFPs), and (c) CME faculty members speaking at promotional meetings that are subject to regulation by the U.S. Food and Drug Administration (FDA), are equally unnecessary. The ACCME's *Standards for Commercial Support: Standards to Ensure the Independence of CME Activities*, as currently formulated, adequately address concerns about bias occasioned by commercial support. If problems persist, they should be addressed through more aggressive monitoring and enforcement by the ACCME. Moreover, the ACCME is a "state actor" subject to norms established under the U.S. Constitution. Many of the procedural steps and substantive criteria embodied in the proposals violate these standards.

For these reasons, and the others recounted here, we urge the ACCME to reconsider its proposals and to withdraw them. In their stead, we propose that the ACCME create an operational framework that follows the practices of other well-respected regulatory and oversight bodies. The ACCME should also reach out to leading organizations in each provider group and work at grass-roots levels to engage in issues identification and consensus building around needed changes. In this way, the ACCME can ultimately put forth guidance, together with any related regulatory changes, that is fair and addresses the needs of all stakeholders, while at the same time building a platform for growth and development fundamental to the effective maturation of the CME enterprise. The Association is prepared to work closely and collaboratively with the ACCME in such an endeavor.

I. INTRODUCTION.

The Association appreciates this opportunity to provide comments in response to the ACCME's June 11, 2008 Policy Announcements and Calls-for-Comment[1], and the ACCME's August 6, 2008 further Call-For-Comment[2] on a proposed new policy regarding the independence of CME[3] from commercial influence (collectively, "the Package"). The Association represents, advocates for, and educates medical education and communication companies ("MedEd companies") in order to foster important learning, public policy, and commercial objectives.[4] We support the enablement of quality CME in the United States and we share fully the ACCME's objective to preserve the value of and to improve CME, even though we may disagree on how best to accomplish these goals. The Association appreciates the discussion stimulated by the Package and commends the ACCME for providing a forum in which these issues can be meaningfully debated. In itself, this is an important contribution to the public health.

In addition to submitting these written comments, the Association requests an opportunity to make an oral presentation to the ACCME Board of Directors before any final action is taken by the Board on any element of the Package. Such an oral presentation by the Association—and other stakeholders recognized to represent a majority of ACCME-accredited providers, and others—is particularly called for here given the multiplicity and complexity of the fact, public health policy, and related legal questions raised by the Package, the numerous stakeholders that are potentially affected by the ACCME's proposals, and the far-ranging potential impact of the

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1 *Available at* http://www.accme.org/index.cfm/fa/news.detail/news_id/c7b2d7ee-854d-4440-9b87-265746af2495.cfm.

2 *Available at* http://www.accme.org/index.cfm/fa/news.detail/News/.cfm/news_id/ac4a519e-a2d3-4cd7-80d8-9695ce98179f.cfm.

3 In these Comments, we generally use the term "CME" to refer to certified CME provided by an ACCME-accredited provider.

4 *See By-Laws of the Association* (Amended as of May 24, 2005), §1, *available at* http://www.naamecc.org/Portals/0/NAAMECC_Policy_Procedure.pdf (at 29).

Package, if adopted as proposed, on CME in the United States and, consequently, on the health and well-being of the American public.

Moreover, and in addition to the points raised below, the Association reiterates the concerns it voiced in letters to the ACCME dated July 30, 2008[5] and August 12, 2008[6], respectively, as well as in verbal communications between the Association and ACCME leadership, about problematic aspects of the process employed by the ACCME in initiating and pursuing this rulemaking proceeding, particularly its lack of transparency. The Association renews its call that the ACCME provide greater transparency to this process, including, particularly, disclosure of *all* comments received on the Package in their entirety and without summarization or extraction of the kind the ACCME has said it intends to employ in lieu of full disclosure.[7] Surely, given the self-evident possibility that implementation of the Package may well have a serious impact on the CME enterprise generally, and will disproportionately affect one ACCME provider category—MedEd companies—it does not seem like not too much to ask that we (and everyone else) know what is being said, by whom, and based on what evidence. This elementary kind of fairness and transparency—"due process", if you will—which is required in this rulemaking as a matter of law in any event because of the ACCME's status as a "state actor"[8], at least provides

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[5] *Available at* http://www.naamecc.org/downloads/public_disclosure.pdf. *See also* ACCME's Undated [August 6, 2008] Response Letter (to the Association's July 30, 2008 Letter), *available at* http://www.naamecc.org/downloads/ACCME%20Response%20to%20NAAMECC%20July%2030.pdf.

[6] *Available at* http://www.naamecc.org/downloads/NAAMECC%20Response%20to%20ACCME%20August%206.pdf.

[7] *See* ACCME's August 6, 2008 Response Letter.

[8] Despite the fact that the ACCME "does not accept" the view that it is the "functional equivalent of the government" and asserts that it is merely "a private organization established to conduct professional self regulation" (*see id.*), there are strong grounds on which to conclude that the ACCME is a "state actor" subject to constitutional norms. *See* Section VI. There is no incompatibility between the ACCME's status as a private organization, on the one hand, and its status as a "state actor" for constitutional purposes in certain circumstances, on the other. *See e.g. Brentwood Acad. v. Tenn. Sec. Sch. Athletic Assoc.*, 531 U.S. 288, 295 (2001) ("[T]he deed of an ostensibly private organization or individual is to be treated sometimes as if a State had caused it to be performed."); *US v. Stein*, No. 07-3042-cr, Slip Op. at 36, *et seq.* (2nd Cir. Aug. 28, 2008) (KPMG, a private accounting firm, nevertheless a "state actor" in the circumstances presented).

an opportunity for the public, including the Association, to review, evaluate, and directly assess all of the evidence and arguments being advanced in response to the Package. Only this kind of "sunshine" can provide the degree of public confidence and legitimacy that the ACCME's ultimate conclusion here, whatever it is, represents a valid and validly supported outcome or conversely, and somewhat ironically, is the product of preexisting bias and predetermined beliefs.

II. THE ASSOCIATION STRONGLY SUPPORTS CME AND UNDERSTANDS AND APPRECIATES ITS IMPORTANCE TO THE PUBLIC HEALTH.

We do not address here the importance and value of CME to the medical profession and the public at large, as there appears to be absolute agreement on all sides of the debate about this foundational premise. The Association strongly supports the goal of promoting continuous improvement in physician competence and clinical knowledge through life long learning with the ultimate aim of helping patients obtain the best possible medical care. MedEd companies understand the critical role that we and other CME providers play in this process. The current controversy is not about whether to retain CME, which we all agree should and must be preserved, but about how best to optimize its value. Accordingly, we do not address here the substantial body of evidence that establishes the value of life long learning for physicians and its profound consequent impact on the health and well-being of the American public.[9] Rather, we address here aspects of the Package that, in our view, undercut that laudable objective without adequate justification. As a result, and if adopted as proposed by the ACCME, the Package

[9] *See e.g. "CME As a Bridge to Quality: Leadership, Learning, and Change Within The ACCME® System"*, at 2, *available at* http://www.accme.org/dir_docs/doc_upload/e2843247-7cae-40fe-a0eb-27a982b8fcc0_uploaddocument.pdf ("IN THIS FRAMEWORK, ACCREDITED CME IS ONE OF OUR NATION'S STRATEGIC ASSETS FOR IMPROVING CARE.") ("*Bridge to Quality"*).

would have a serious adverse impact on the public health, on the CME enterprise generally, and on the more than 80 generally small businesses that comprise the Association.

III. THE PROPOSAL TO CATEGORICALLY BAN COMMERCIAL SUPPORT SHOULD NOT BE ADOPTED.

The centerpiece of the Package is the ACCME's proposal that commercial support for CME end.[10] This proposed ban would apply even to CME whose content is free from commercial bias and which otherwise meets the laudable and widely accepted independence criteria established under the ACCME's 2004 *Standards for Commercial Support: Standards to Ensure the Independence of CME Activities.*[11] As an alternative to the complete elimination of commercial support for CME, the ACCME proposes a four-part test for determining when "commercial support of individual activities would be in the public interest and could continue to be allowed."[12] We address the proposed categorical ban on commercial support first as implementation of such a ban, as the ACCME itself acknowledges, may have the practical effect of deconstructing a system without identification of alternatives and "nothing would be worse" than that.[13] In fact, the *Standards for Commercial Support*, which the Association strongly endorses, are working as intended to address any legitimate concerns about the independence of CME content, and the requisite absence of commercial bias in CME, and the ACCME has said so repeatedly. If problems persist, the answer lies in additional monitoring and enforcement of the existing requirements by the ACCME and not in adding yet additional layers of regulatory prohibitions.

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[10] See "The ACCME Believes that Due Consideration be Given to the Elimination of Commercial Support of Continuing Medical Education Activities", fn. 1 above at 6-7.

[11] *Available at* http://www.accme.org/dir_docs/doc_upload/68b2902a-fb73-44d1-8725-80a1504e520c_uploaddocument.pdf ("*Standards for Commercial Support"*).

[12] *See* fn. 10 above.

[13] *Id*.

A. There is No Empirical Evidence to Support the Proposed Categorical Ban.

On several recent occasions, the ACCME has explicitly acknowledged the absence of any empirical evidence to support the proposition that commercial support, in and of itself, creates a high risk of commercial bias in CME.[14] Most recently for example, in its letter regarding the Special Inquiry on so-called "high risk" providers, the ACCME stated that "[t]here is no evidence to support [the] belief" that commercial support unilaterally compromises the independence of CME, particularly because "we are not operating in an unregulated system" and because the current system, "based on the ACCME Standards for Commercial Support™", has "an effective set of internal controls".[15] Accordingly, the ACCME itself has publicly and unequivocally concluded that the current system "ensure[s] learners and the public of the high quality, the independence and the scientific integrity of accredited continuing medical education."[16] As the Society for Academic Continuing Medical Education (SACME) stated in

[14] See e.g. July 11, 2008 ACCME Letter (transmitting "Information from the Accreditation Council for Continuing Medical Education (ACCME) for the Special Committee on Aging of the United States Senate", at 17), available at http://www.accme.org/dir_docs/doc_upload/6d4d0864-2f45-4185-975c-cd8954feb966_uploaddocument.pdf ("No data demonstrating commercial content bias is found in the medical education or regulatory literature.") ("ACCME Senate Committee Submission"); see also June 11, 2008 "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", at 11, available at http://www.accme.org/dir_docs/doc_upload/151305e9-cb64-4bac-8539-fe010b640527_uploaddocument.pdf. ("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 IOM Submission"); June 11, 2008 ACCME Funded Final Report by Ronald M. Cervero, Ph.D., and Jiang He, MPA, titled "The Relationship between Commercial Support and Bias in Continuing Medical Education Activities: A Review of the Literature" at 3, available at http://www.accme.org/dir_docs/doc_upload/aae6ecc3-ae64-40c0-99c6-4c4c0c3b23ec_uploaddocument.pdf. ("Although it has been speculated that commercial support produces bias in CME activities, there is no evidence to support or refute this assertion.").

[15] *See* ACCME August 5, 2008 "Dear CME Colleagues" Letter, *available at* http://www.accme.org/dir_docs/doc_upload/d2bc4716-6e9a-41bb-a289-9b7fe4d7b1b5_uploaddocument.pdf.

[16] *Id.*

its comments on this rulemaking: "We fully reject the premise that merely receiving a grant creates an inherent conflict *as there is no evidence that this is true*."[17]

Inasmuch as CME providers are required by the ACCME to use an evidence-based approach when developing CME content, it seems only reasonable for the ACCME itself to utilize a similar evidence-based approach when determining if sufficient *evidence* exists to demonstrate that commercial support for CME that otherwise meets all applicable indicia of independence in and of itself results in commercial bias that somehow undercuts the integrity of the ensuing CME. There is no such *evidence* and the ACCME has repeatedly acknowledged as much. The absence of any empirical evidence to support the proposed ban on commercial support would itself render any ensuing adoption of the proposal purely arbitrary and hence not sustainable either as a legal or policy matter.[18]

In fact, any neutral review of the many ACCME pronouncements and policies, and extensive documentation, evaluations, audits, reports and the like required by the ACCME to substantiate the "independence" from commercial bias of CME[19], including additional proposals on the subject that are included in the Package, reveal a profoundly robust system of ACCME monitoring and enforcement capable of ensuring the independence from commercial bias of CME. In the absence of any *evidence* on which to conclude that commercial support in and of itself is *per se* biasing, there appears to be no factual predicate for the ACCME's proposal to categorically ban commercial support. In fact, the first principle of medicine is to "do no

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[17] *See "SACME Response to ACCME Calls for Comment"* at 3 of attachment to SACME September 5, 2008 Letter (emphasis supplied), *available at* http://www.accme.org/dir_docs/doc_upload/68b2902a-fb73-44d1-8725-80a1504e520c_uploaddocument.pdf.

[18] *See e.g. Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (agency factual determination not based on *evidence* is arbitrary and capricious and therefore unlawful). This is also a "due process" principle that is applicable to the ACCME as a legal matter in view of ACCME's status as a "state actor".

[19] *See e.g.* Items Listed in ACCME *"Documents and Forms Library", available at* http://www.accme.org/index.cfm/fa/home.library/home.cfm.

harm"[20]. The ACCME has already acknowledged the potentiality for harm that is likely to ensue from a categorical ban on commercial support given the absence of documented evidence of its inherently biasing characteristics, and particularly in the absence of any validated regime to take its place—in the ACCME's own words, "nothing would be worse" than that. SACME put it this way: "[E]liminating all commercial support from CME programs poses a very real threat to the viability of CME within the current academic environment."

B. There Is No Stakeholder Consensus To Support The Proposed Categorical Ban.

Moreover, the absence of a stakeholder consensus on the wisdom of categorically eliminating commercial support for CME likewise reveals the imprudence and impropriety of the ACCME unilaterally adopting such an outright ban at this time. For example, the American Medical Association's (AMA's) Reference Committee on Constitution and Bylaws recently rejected a proposal from the AMA's own Council for Ethical and Judicial Affairs proposing that the AMA adopt a resolution categorically banning all commercial support of CME.[21] In fact, the Council of Medical Specialty Societies (CMSS), which is an ACCME-member organization[22], voiced its own strong objections to CEJA's proposal.[23] CMSS identified a number of existing conflicts management tools that serve to ensure that the educational content of CME is "clearly and completely separate from commercial support".[24] These management tools include the ACCME's *Standards for Commercial Support*, which the Package proposes to modify further

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[20] *Primum non nocere* ("First, do no harm."), *available at* http://en.wikipedia.org/wiki/Primum_non_nocere. ("Since at least 1860, the phrase has been for physicians a hallowed expression of hope, intention, humility, and recognition that human acts with good intentions may have unwanted consequences.")

[21] AMA 2008 Annual Meeting.

[22] *See* ACCME Board of Directors and Member Organizations, *available at* http://www.accme.org/index.cfm/fa/about.directors.cfm.

[23] *See* CMSS June 5, 2008 Letter to CEJA, *available at* http://www.cmss.org/index.cfm?p=readmore&itemID=1335&detail=News%20Items.

[24] *Id*.

in several respects; the pharmaceutical and device industries' own guidelines on the subject that affirmatively require such separation[25]; enforcement action by the Office of the Inspector General of the Department of Health and Human Services, which "has put teeth into compliance by industry, as the penalties for non-compliance include very large fines and potential incarceration"[26]; Congressional oversight by the Senate Finance Committee[27]; and the U.S. Food and Drug Administration's (FDA's) standards for ensuring the independence of CME, which, while adopted by the agency primarily to address the use of CME as a subterfuge for "off-label" promotion, nevertheless establishes standards for ensuring the independence of CME from commercial influence.[28] CMSS concluded that, collectively, these tools provide the requisite assurance of independence of CME from bias created by commercial support and that a categorical ban on commercial support is not warranted.

C. There Are Unintended Negative Consequences From the Proposed Categorical Ban.

Perhaps the predominant unintended consequence of the proposed categorical ban on commercial support is its likely effect in diminishing the quantity and quality of CME. If that happens, then this would likely result in increased clinical mistakes and misjudgments that may well compromise patient care substantially. Such a result would indeed be a sad and unfortunate byproduct of the proposed categorical ban on commercial support. In fact, and as the Coalition

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[25] *See* Pharmaceutical Research and Manufacturers Association *"Code on Interactions with Healthcare Professionals"* (revised July 10, 2008), *available at* http://www.phrma.org/files/PhRMA%20Marketing%20Code%202008.pdf; Advanced Medical Technology Association, *"Code of Ethics on Interactions with Healthcare Professionals", available at* http://www.advamed.org/NR/rdonlyres/D96644D9-7FA9-4DCC-B944-F00A8351FE57/0/AdvaMedCodeofEthicswithFAQ.pdf.

[26] See also e.g. "OIG Compliance Program Guidance for Pharmaceutical Manufacturers", 68 Fed. Reg. 23731 (May 5, 2003) ("OIG Compliance Guidance").

[27] See e.g. "Committee Staff Report to the Chairman and Ranking Member: Use of Educational Grants By Pharmaceutical Manufacturers", S. Rept. 110-21, 110th Cong., 1st Sess. (April 2007), available at http://www.senate.gov/~finance/press/Bpress/2007press/prb042507a.pdf.

for Healthcare Communication ("the Coalition") observes in its September 12, 2008 Comments[29]: "Commercial funding accounts for a far greater portion of innovative CME activity that is focused on improvement in patient care . . . Commercial support often funds new designs for educational programs to address practice gaps and has been a driver in creating non-traditional learning venues such as e-learning and other Internet-based activities." In fact, the ACCME's Annual Report Data 2007[30] support this conclusion. They show that MedEd companies, which rely to a greater extent on commercial support than other provider types, have funded and created the revolution on how CME is made available, accessed, and used by an overwhelming majority of clinicians in the United States and around the world. MedEd companies have created innovative, interactive multimedia programs that are engaging, that clearly fill an educational need, and that support life long learning.

In its submission to the AMA[31], and harkening to the underlying rationale for the "do no harm" first principle of medicine, CMSS expressed profound concern about another "potential unintended consequence" of a categorical prohibition of commercial support for otherwise "independent" CME:

"The elimination of commercial support for certified CME will significantly reduce the availability of certified CME, produced by accredited CME providers, such as medical specialty societies. We expect the funds previously devoted to this support will be channeled by industry to promotional activities, including promotional educational activities for physicians . . . [T]hese activities [are] not governed by standards to separate promotional bias from education . . . [T]he

[28] See "Guidance for Industry: Industry-Supported Scientific and Educational Activities", 62 Fed. Reg. 64094 (Dec. 3, 1997).
[29] At 8.

result of adoption and implementation of CEJA['s] recommendation . . . will likely be a rebalancing of education for physicians, with significantly less unbiased certified CME and significantly more biased promotional education." In its August 15, 2008 comments to the ACCME on the Package, CMSS reiterated the point in the following terms: "If the goal is to eliminate product bias from the education of physicians, it will be critical to avoid an unintended consequence of stimulating significantly increased product biased education through the mechanism of promotional education."[32]

The ACCME's proposal to ban commercial support for CME does not analyze or even address *any* "unintended consequences" from its adoption.[33] Indeed, it does not specifically address or even consider the straightforward proposition advanced by CMSS in its recent AMA submission and ACCME comments that such an outright ban would have the inevitable counterproductive effect of shifting industry support from independent CME to promotional activities that by their nature are not intended or required to be independent. After all, they are *promotional.* In fact, in its August 15, 2008 comments to the ACCME on the Package[34], CMSS reiterated what it previously said to the AMA—"*The Council of Medical Specialty Societies does not support the [ACCME] proposal that commercial support of continuing medical education end.*" The absence of a consensus on the subject among the ACCME's own membership should be sufficient reason, in and of itself, for the ACCME not to adopt the proposed ban. Moreover, CMSS's views should be accorded especially significant weight not only because of its status as

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[30] *Available at* http://www.accme.org/index.cfm/fa/home.popular/popular_id/127a1c6f-462d-476b-a33a-6b67e131ef1a.cfm. If requested, we can provide the ACCME with a written explanation for how we derived this conclusion from the Annual Report Data 2007.

[31] At 7.

[32] *Available at* http://www.cmss.org/index.cfm?p=readmore&itemID=1341&detail=News%20Items, at 7.

[33] In its comments in this proceeding, SACME identified a number of unintended consequences from the proposed ban, including a decrease in the number and scope of CME activities and consequent reduction in the number of clinicians educated.

an ACCME member organization, but also because its constituent medical specialty societies, and hence CMSS itself, represent a substantial segment of non-commercial providers of CME in the United States.

Further, there are additional collateral implications from the ACCME's adoption of a ban on commercial support beyond those identified by CMSS that likewise deserve consideration. If all conflicts in medical education must be eliminated rather than managed, is the same prophylactic standard to be applied to a variety of other interactions that society tolerates—indeed encourages—where the potential for bias exists yet is deemed to be managed through disclosure and other techniques? For example, does it mean that any physician who receives industry funding for biomedical research should resign from all medical school faculty appointments lest the commercial relationship be deemed categorically to bias the content of her curriculum? If so, how will this affect the quality of medical education going forward, as some of the best and brightest minds withdraw from teaching medical students? Conversely, what does this do to the quality of biomedical innovation if all medical faculty terminate all paid relationships with industry instead of resigning their faculty appointments?

Examples from contexts that relate directly to personal physical health and well-being and personal financial health and well-being are also relevant. Under the Federal Food, Drug, and Cosmetic Act, the government permits advertising of prescription drugs to physicians subject to a variety of statutory and regulatory disclosure obligations intended to ensure that the communication is truthful, not misleading, fully substantiated and fairly balanced. If commercial support is inherently biasing, then it might reasonably be argued that the law should be modified to categorically prohibit all-but-government-sponsored advertising for medical products.

[34] At 3 (emphasis in original).

Likewise, under the Securities Laws, commercial financial instruments are permitted subject to detailed disclosure and filing requirements designed to ensure that the selling materials are truthful and not misleading. If commercial support is inherently biasing, and could not be addressed through conflicts management tools, then it might be argued that the Securities Laws should be modified categorically to prohibit all-but-government-sponsored communications about financial instruments. Other examples abound. The point is simply that in a variety of conflicts contexts that are arguably analogous to, and at least equally as important as, the CME context, we as a society have concluded that conflicts management tools, not categorical prohibitions, are the better way of achieving socially desirable objectives. If someone violates these conflicts management rules, we punish them. But we do not simply discard conflicts management principles in favor of outright prohibitions simply because of the *possibility* that there will be rule-violators. Otherwise, we would have a governmental and regulatory regime of total suppression, as opposed to one that favors the open, but regulated, exchange of information and ideas. As former U.S. Supreme Court Justice Sandra Day O'Connor recently stated in discussing commercial free speech rights in *Thompson v. W. States Med. Ctr.*[35]: "If the First Amendment means anything, it means that regulating speech must be a last—not first—resort."

D. Conflicts Management Tools Are More Appropriate Than Categorical Prohibitions, And The ACCME Has Said So Itself.

It is important to observe that the ACCME's proposal to ban commercial support for CME represents a conclusion that potential conflicts cannot be managed and must be eliminated entirely that is at odds with other thoughtful recent recommendations from highly respected organizations in analogous contexts. Indeed, it is directly at odds with FDA's and NIH's conclusions that management tools, such as disclosure, are better suited to address potential

[35] 535 U.S. 357, 373 (2002).

conflicts in clinical research rather than are outright prohibitions.[36] In fact, several recent ACCME public presentations to the CME provider community endorse the proposition that conflicts of interest can and should be managed through conflicts management tools and should not be categorically prohibited.[37] What has changed, empirically, over the last few months that would justify such a dramatic shift in the ACCME's position? The ACCME's overall credibility is seriously eroded when, unexpectedly and without any evidence in the interim to support the change, the ACCME reverses course 180 degrees and announces that due consideration be given to banning commercial support altogether because, now, conflicts of interest can no longer be managed. Such an abrupt change of position also compromises the ACCME's credibility and effectiveness and suggests that it is acting in response to political pressures. Reactions of this kind are viewed by many in the CME stakeholder community as a distraction from what the ACCME has tasked us to do—conducting CME that matters to doctors and hence matters to patient care.

Moreover, for example, in February 2008, a Joint Advisory Committee of the American Association of Medical Colleges (AAMC) and the American Association of Universities (AAU) issued general guidelines on conflicts of interest that utilize conflicts management tools to address problems of bias without creating the total elimination of commercial support that the ACCME here proposes. Likewise, in June 2008, the AAMC adopted a Task Force Report on medical education that does not seek a total ban on industry funding of CME and that looks to conflicts management tools, such as the ACCME's preexisting standards on commercial support,

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[36] *See* 21 CFR Part 54 (FDA); 42 CFR Part 40 (NIH).

[37] *See e.g.* ACCME IOM Submission at 12 (ACCME "manages" interactions between commercial supporters and CME providers) ; ACCME Presentation at the AMA National CME Task Force Conference, "*Accredited Continuing Medical Education as a Strategic Asset: The value-added of CME from within the ACCME system"* at

(continued…)

as a way of ameliorating concerns about commercial bias.[38] While the Macy Report[39] admittedly recommended an end to commercial support for CME, the ACCME itself, together with two other accrediting organizations, took issue in very strong terms with virtually every aspect of that report, including, notably, the absence of an evidentiary basis for any of the Report's conclusions and recommendations.[40] Relatedly, the Institute of Medicine of the National Institutes of Health (NIH) is considering a broad array of questions concerning CME, including whether and to what extent commercial support for CME that is otherwise "independent" should continue to be permitted and the ACCME itself has likewise responded in that proceeding.[41] It seems entirely appropriate and important for the ACCME and others to await the conclusion of that process before moving forward with proposals to eliminate commercial support that, while sounding high-minded, may have a serious adverse impact on the overall CME enterprise if adopted.

E. The ACCME Lacks the Authority to Adopt a Categorical Ban.

The involvement of so many other thoughtful organizations in the debate about conflicts of interest generally, and conflicts of interest in CME potentially created by commercial support *per se*, suggests yet an additional reason why the ACCME should not adopt the categorical prohibition it has proposed. This has to do with the serious question that exists about whether the ACCME has, or should have, the authority unilaterally to pronounce National policy in this

printed page 10 of slide deck (October 2007) (describing management tools used by ACCME, including independence, transparency, and separation of promotion from CME).

[38] *Available at* http://www.aamc.org/research/coi/start.htm. On the use of management tools to address conflicts of interest in lieu of outright prohibitions, *see generally* Bernadette M. Broccolo and Jennifer S. Geetter, *"Today's Conflict of Interest Compliance Challenge: How Do We Balance the Commitment to Integrity with the Demand for Innovation?"*, American Health Lawyers Association Journal of Health & Sciences Law, Vol. 1, No. 4 (July 2008) at *1 et seq.*

[39] See "Continuing Education in the Health Professions, Proceedings of a Conference [Sponsored by the Josia Macy, Jr. Foundation in November 2007]", published 2008, available at http://www.josiahmacyfoundation.org/documents/pub_ContEd_inHealthProf.pdf.

[40] See generally "Chief Executives of the ANCC [American Nurses Credentialing Center], ACPE [Accreditation Council for Pharmacy Education], and ACCME Respond to the Josia Macy, Jr. Foundation" (June 19, 2008), available at http://www.accme.org/index.cfm/fa/news.detail/news_id/5834283e-b17e-487f-8b4a-4e32cfdb5a67.cfm.

area. We submit that the ACCME's institutional mandate is only to provide a mechanism for monitoring and enforcement of criteria for accredited providers that develop valid CME, but was never intended to, and does not, encompass profound questions of National policy about whether and to what extent commercial support *per se* should be deemed to be a categorically disqualifying factor for CME. In analogous contexts, and no matter what their own view of the policy justifications for the underlying proposals, courts will compare a regulatory agency's actions against its underlying statutory mandate and will overturn them if found to exceed the scope of the agency's authority.[42] Analogous principles apply to so-called *ultra vires* acts of corporate Boards of Directors when they take action in excess of the underlying rights conferred in the corporation's charter or by-laws.[43] We believe that National policy on conflicts of interest with such profound ramifications should be undertaken, if at all, by a representative body able to determine a National consensus on the subject, and not by the ACCME. Such a radical change is unquestionably beyond what anyone ever conceived to be the scope of the ACCME's authority in this area. Indeed, Congress is now considering legislation that would effectively codify the categorical disqualification of any recipient of commercial support from developing educational materials for physicians.[44] Whatever one believes about the wisdom or constitutionality of this kind of prohibition, the fact remains that it is a matter far better suited for Congressional

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[41] *See* ACCME IOM Submission.

[42] *See e.g. Assoc. Am. Physicians & Surgeons, Inc. v. FDA*, 226 F. Supp. 204, 222 (D.D.C. 2002) ("This court does not pass judgment on the merits of the FDA's regulatory scheme. The Pediatric Rule may well be a better policy tool than the one enacted by Congress; it might reflect the most thoughtful, reasoned, balanced solution to a public health problem. The issue here is not the Rule's wisdom . . . The issue is the Rule's statutory authority, and it is this that the court finds lacking.")

[43] *See e.g.* §3.15, Illinois Business Corporation Act of 1983 ("Defense of *Ultra Vires*"), 805 ILCS 5/3.15.

[44] *See* S. 3396, 110th Cong., 2nd Sess., July 31, 2008, proposed "Independent Drug Education and Outreach Act of 2008", *available at* http://www.thomas.gov/cgi-bin/query/D?c110:2:./temp/~c11013NgiD:: (proposing, among other things, to add new §904(b)(2)(B) of the Social Security Act to provide for grants or contracts to "eligible entities" for "the development and production of educational materials" for healthcare providers, and requiring that in order to be so "eligible" an "entity *shall . . . receive no support* from any entity that manufactures products . . . or from any organization funded by such entities . . . ") (Emphasis supplied).

determination by a representative National assembly than it is for determination by the ACCME in this rulemaking proceeding.

In fact, CMSS makes an analogous point in its August 15, 2008 comments on the Package.[45] It proposes a "national solution" that would be developed under the aegis of the Conjoint Committee on Continuing Medical Education (CCCME), which is a multi-organizational committee consisting of key stakeholders across the continuum of medical education. Whatever the merits of this specific proposal by CMSS that CCCME, which includes only select representation from the CME stakeholder community and notably fails to include any representation of MedEd companies of the kind who are members of the Association, CMSS could equally well have framed its proposal as a fundamental lack of authority on the part of the ACCME to legislate unilaterally a categorical ban on commercial support of CME. However framed, the primary point that CMSS is making is the same as ours—the ACCME lacks any underlying institutional mandate to pursue such a profound policy change on its own, and the ACCME's suggestion that it may do so is not appropriate.

F. The Proposed Categorical Ban Violates The First Amendment And Is Otherwise Problematic.

Moreover, and in view of the ACCME's status as a "state actor"[46], a categorical prohibition on commercial support for CME that is otherwise independent and unbiased raises "free speech" concerns under the First Amendment to the U.S. Constitution. These concerns are analogous to those dealing with discrimination against disfavored speakers based merely on their identity and without regard to whether the underlying speech is truthful and not misleading.[47] The

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[45] At 3-4, 7.

[46] *See* Section VI. below.

[47] *See e.g. First Nat'l Bank of Boston v. Belotti*, 435 U.S. 765, 777 (1978) ("The inherent worth of the speech in terms of its capacity for informing the public does not depend upon the identity of its source, whether corporate,

(continued…)

categorical prohibition on commercial support for CME, in the absence of any evidence of actual commercial bias, further amounts to a kind of viewpoint discrimination that also raises serious First Amendment questions.[48] In fact, the proposed ban on industry funding may even be less justifiable than discrimination based on a particular viewpoint or against particular speakers, such as commercial speakers, inasmuch as it represents a categorical prohibition on *all* commercial support no matter what the underlying content of the CME communication and no matter how independent and free from bias that content can be proved to me. Hence, and even if not technically required to comply with the First Amendment as such, the principle of access to all voices in the marketplace of ideas, that animates First Amendment jurisprudence, should nevertheless quite clearly apply here as a matter of policy.

Moreover, and ironically, the categorical exclusion of commercial funding for CME, even if it otherwise meets all applicable criteria on independence, amounts to the kind of blanket censorship that is at odd with the principle of academic freedom. After all, the ACCME sees CME, as we all do, as a form of academic learning. We can all agree that academic discourse of this kind should be open to all manner of ideas, even those that are currently out of favor politically and even those supported by commercial interests, assuming they are independent and

association, union or individual.") While we agree that the ACCME's definition of "commercial interest" properly includes companies that produce, market, resell, or distribute health care goods or services consumed by or used on patients (*see* ACCME August 2007 "*Policies and Definitions To Supplement 2004 Standards for Commercial Support*" , *available at* http://www.accme.org/index.cfm/fa/Policy.policy/Policy_id/9456ae6f-61b5-4e80-a330-7d85d5e68421.cfm), other entities not deemed by the ACCME to be "commercial interests", such as for example, health insurance providers and others, may well introduce "bias" into CME comparable to or even more problematic than the "bias" that the ACCME is concerned about in the case of defined "commercial interests". If potential "bias" in CME is the concern, then the justification for such disparate treatment of different organizations is not readily apparent and may raise "equal protection" concerns that are beyond the scope of these Comments but that the ACCME as a "state actor" should nevertheless be sensitive to.

[48] *See e.g. Rosenberger v. Rector & Visitors Univ. of Va.*, 515 U.S. 819, 829 (1995) ("When the government targets not subject matter, but particular views taken by speakers on a subject, the violation of the First Amendment is all the more blatant.").

otherwise lack bias.[49] It is also fair to observe that there is simply no need for the ACCME to promulgate categorical rules banning commercial support, as the marketplace itself will adapt to the changing environment and as organizations adopt policies and procedures that they believe are best suited to their own particularized needs.[50]

IV. THE PROPOSED "NEW PARADIGM" IS A PARADIGM OF AMBIGUITY. COMMERCIAL SUPPORT SHOULD NOT BE CONDITIONED ON ADOPTION OF THE "NEW PARADIGM".

In lieu of banning commercial support altogether, the ACCME proposes as an alternative what it characterizes as a "new paradigm". This proposed "new paradigm" consists of demonstrating compliance with a four-part test for determining the acceptability of commercial support; if all conditions are met, "then the commercial support of individual activities would be in the public interest and could continue to be allowed." But the contours of the new paradigm relate primarily to the criteria for determining the validity of CME *content* and do not relate directly to determining its *independence* from commercial support. Accordingly, there is a threshold question that needs to be asked and answered about the nexus between the problem that the ACCME is purporting to address—independence from commercial support—and the solution it is proposing in the new paradigm. The absence of a direct nexus between the problem and the solution is highlighted by the fact that, in addition to proposing a new paradigm governing CME content, the ACCME is separately proposing a variety of additional modifications to the independence criteria in its *Standards for Commercial Support*.[51] Even assuming, *arguendo*, that

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[49] "Scientific and academic speech reside at the core of the First Amendment." *Washington Legal Foundation v. Friedman*, 13 F. Supp. 2d 51, 62 (D.D.C. 1998), *appeal dismissed and judgment vacated in part by, Washington Legal Foundation v. Henney*, 202 F. 2d 331 (D.C. Cir. 2000) (citation to U.S. Supreme Court authority omitted).

[50] *See e.g.* Stanford University School of Medicine, "*A New Policy on the Use of Industry Support for Continuing Medical Education (CME)"*, The Dean's Newsletter (August 25, 2008), *available at* http://deansnewsletter.stanford.edu/#1. The Association's citation to this new policy at Stanford should not be understood or interpreted as our endorsement of it.

[51] *See* Section V below.

the proposal for a new paradigm in lieu of a total ban on commercial support is not entirely incompatible with the ACCME's proposal to establish additional standards for determining independence, it nevertheless represents a kind of duplicative "piling on", particularly given, as we demonstrate above, the absence of any empirical evidence to establish the bias inherent in commercial support for CME.

As a further threshold matter, and as the Association observed in its July 30, 2008 letter, there is a fundamental lack of clarity about the substantive standards and procedural steps that would apply in assessing each of the proposed criteria in the new paradigm. Nor has the ACCME been helpful in that regard as, in response to our request for greater clarity, the ACCME, in its August 5, 2008 letter, asked the Association for additional details and examples of what we wish to have clarified. As we said in our letter of August 12, 2008, the ACCME's unwillingness or inability to provide additional detail absent more information from us places the burden of clarity on the wrong party and itself speaks volumes about the ambiguity of the proposal.

Put differently, the ACCME is poised to adopt a new paradigm for commercial support for CME in response to comments on the Package, and perhaps to eliminate commercial support entirely, yet the ACCME's notice fails to provide sufficient detail to allow for the submission of meaningful comments on the "new paradigm". This process is fundamentally unfair. It departs from well-settled principles that apply to agencies that engage in comparable rulemaking. In other words, a notice of proposed rulemaking must provide adequate "notice" of the terms of the proposed rule and how it will operate in practice in order, in turn, to provide affected parties and the public at large with a meaningful opportunity to comment on the proposal.[52] Absent such

[52] *See e.g. Ethyl Corp. v. EPA*, 541 F. 2d 1, 48 (D.C. Cir. 1976) (Under Administrative Procedure Act, notice of proposed rulemaking must be "sufficiently descriptive" so that "interested parties may offer *informed* criticism and comments" (emphasis supplied)).

specificity, the Association is effectively shooting at an unidentified target. Whether these principles of administrative "due process" apply directly to the ACCME, which they do because the ACCME is a "state actor"[53], or whether instead they are applicable only by analogy, the fundamental point is the same—we cannot be expected to provide meaningful comments absent the requisite level of specificity from the ACCME.

A. The Requirement for Third Party Identification and Verification of Educational Needs Is Ambiguous.

For example, Part 1 of the "new paradigm" would condition commercial support on, among other things, identification and verification of educational needs by organizations, such as U.S. Government agencies, that do not receive commercial support and that are themselves free of financial relationships with industry. What criteria would be applied to the identification and verification of these educational needs? How if at all would these criteria be the same as or different from the needs assessment criteria that apply under the ACCME's current validation paradigm? Why is the current paradigm inadequate to establish the validity of the educational needs, especially in light of the recent statement by the ACCME that it " . . . believes that our system has an effective set of internal controls, based on the ACCME Standards for Commercial Support, that ensure learners and the public of the high quality, the independence and the scientific integrity of accredited continuing medical education."[54] What agencies of the U.S. Government would be involved? Are there any such agencies that, in fact, are free of any financial relationships with industry by way of grants, contracts, and the like? What are the standards and procedures for seeking identification and verification of educational needs by any such agency? Will these be established by notice-and-comment rulemaking by the agency? Will

[53] *See* Section VI below.
[54] *See* ACCME August 5, 2008 "Dear CME Colleagues" Letter, fn. 15 above.

there be a case-by-case adjudication to identify and verify educational needs? How would that process work? What impact would either rulemaking or case-by-case identification and verification of educational needs have on the commercial support approval or grant process? Would commercial supporters remain willing to contribute to CME in this new paradigm of delay? What does the ACCME propose to do about the serious economic impact that the resultant delay will unquestionably have on the commercial viability of the CME operations of medical education providers, including MedEd companies, academic medical centers, specialty medical societies, and others? And perhaps most importantly, how will this delay impact the creation and delivery of CME addressing new models of care and medical innovation generally and what will be the impact of such a delay on the public health?

Moreover, and as CMSS observes in its August 15, 2008 comments on the Package[55], the CME provider is in the best position to determine needs and in fact is responsible for designing the CME to meet those needs. Accordingly, "[i]t does not seem logical to separate" the two, and "[d]ivorcing the CME provider . . . from needs assessment appears to be 'throwing the baby out with the bathwater.'"[56]

B. The Requirement for Third Party Corroboration of Practice Gaps Is Ambiguous.

Likewise, Part 2 of the "new paradigm" would condition commercial support on corroboration of a professional practice gap of a particular group of learners by *bona fide* performance measurements (e.g. National Quality Forum) of the learners' own practice. It is not apparent why or how this corroboration relates in any way to the propriety in the first instance of commercial support for CME. Nor is it apparent what are the universe of sources for

[55] At 7.
[56] Id.

determining professional practice gaps and who determines their *bona fides* and on what basis. On what basis does the ACCME conclude that CME should be used exclusively to fill practice "gaps"? How if at all can this be harmonized with the proposition that CME is about life long learning? How can the proposed requirement for independent corroboration of practice gaps be reconciled with the American Medical Association's (AMA's) Physician Recognition Award (PRA) and Credit System that awards so-called PRA Category 1 credit for internet point-of-care or other physician CME "lookup" or self-directed study options?[57] Assuming *arguendo* that CME is only about learning "gaps", what role if any would the views of the highly motivated prospective physician learners have in determining the validity of a learning "gap"? If a group of physician learners wants information on a particular topic is that, in itself, inadequate to establish a *bona fide* learning gap? If so, why? Will the ACCME adopt social utility criteria in assessing whether professional practice gaps have been adequately corroborated in order to justify commercial support? For example, will a professional practice gap for dermatologists be deemed to have been adequately corroborated only if it relates to treatment, say, of diseases such as skin cancer, whereas, by contrast, and even if there is a need and desire on the part of dermatologists to learn about dermal fillers for cosmetic use, will that be deemed categorically inadequate to corroborate a gap as determined by *bona fide* performance measurements? If so, why?

Moreover, and as CMSS observes in its August 15, 2008 Comments on the Package[58], "divorcing the CME provider" from identifying practice gaps amounts to "abrogating the CME provider from its educational responsibility", which seems entirely inappropriate. Likewise, and given the fact that many conditions do not yet have established practice standards as the data

[57] *See e.g.* 2006 Revision at 11, *available at* http://www.ama-assn.org/ama1/pub/upload/mm/455/pra2006.pdf.

required to create them are still being developed, foreclosing commercial support for CME for such conditions "would arbitrarily eliminate CME for many conditions for which needs assessment demonstrates a need, which would ultimately have a negative impact on patient care."[59]

C. The Requirement For Third Party Establishment of CME Curricula Is Ambiguous.

Part 3 of the "new paradigm" suffers from similar ambiguity. It fails to articulate, for example, how the CME curricula are going to be established by the so-called *bona fide* organization or entity and whether and how that curriculum setting process will be open and transparent, or, like much of this ACCME proceeding, will be conducted out of the sunshine and behind closed doors. Moreover, the design of educational curricula, as CMSS observes, is "part of the responsibility inherent in professionalism", which should not be removed from the purview of CME providers. While CMSS admittedly makes this point in the context of medical specialty societies serving as CME providers, the same principle is equally applicable to other provider types. So long as the provider is "ACCME accredited", it is neither logical nor appropriate to distinguish the "responsibilities inherent in professionalism" as between the differing categories. Again, to quote CMSS's thoughtful comments in the broader context of all CME providers: "Divorcing [CME providers] from designing curricula for the education of its members appears to be a Solomonian solution of cutting a whole entity in half, resulting in non-viable educational programming." We agree.

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[58] At 6.
[59] Id.

D. The Proposed Requirement That CME Be Verified As Free From Commercial Bias, While Valid, Is Circular.

This brings us to Part 4 of the "new paradigm" which, on examination, shows the apparent circularity of the ACCME's reasoning here and why the absence of detail is fatal to the proposal. This criterion would permit commercial support if Parts 1 through 3 of the "new paradigm" had been satisfied, *and* "the CME is verified as free of commercial bias". Of course, the freedom from commercial bias criterion is part of the existing ACCME validation paradigm and is the *sine qua non* of "independent" CME. But, presumably, under the new paradigm, the CME would not be verified as free of commercial bias, unless Parts 1 through 3 of the "new paradigm" had also been satisfied. The ACCME has failed to explain or even to address the interplay between the respective elements of the "new paradigm" and whether and how the proposals in the August 6, 2008 further call-for-comment do or do not impact the "new paradigm" which, after all, was proposed in June and, apparently, without regard to the concepts in the August 6 notice. Like CMSS, we "do not believe the proposed extreme solution to the problem of the perception of commercial bias in commercially supported CME, as outlined in the proposed 'new paradigm', is appropriate or necessary, as it removes the responsibilities of CME providers . . . from the design and implementation of CME which is free from commercial bias."

E. The Adoption Of A New Paradigm For CME Is Beyond The ACCME's Authority.

Several points deserve emphasis. The kind of profound change represented by the "new paradigm", whatever its specific contours and however it works in actual practice (which, as we demonstrate above, are not apparent in the proposal) again represents a fundamental shift in National policy on CME. This kind of shift—"new paradigm", in the ACCME's own terminology—seems well beyond the scope of the ACCME's underlying remit for all of the same reasons, and others, that establish why unilateral elimination of commercial support is

beyond the scope of the ACCME's authority. Indeed, one can speculate, with a high degree of certainty, that the practical effect of conditioning commercial support on compliance with the "new paradigm" would be the elimination of commercial support altogether, which may well be its intended purpose. But the point is simply that such an outcome should be accomplished, if at all, through a much more representative National consensus process than the seriously flawed rulemaking process initiated here by the ACCME. Whatever the merits of the "new paradigm", and they are few, these should be determined by institutions such as the U.S. Congress or, as proposed by CMSS by the CCCME. Moreover, an examination of the ACCME's own recent statements about the integrity and comprehensiveness of the current regime in establishing the independence of CME themselves belie the need for a "new paradigm" as an additional constraint on commercial support.

* * *

In sum, we believe, as did many SACME members[60], that adoption of the "new paradigm" would be time consuming and burdensome and create needless additional bureaucracy and that it suffers—ironically—from the flaw that many of the third party validators that would be accorded special status themselves have their own biases and may not even know or understand the CME needs of individual physician learners. We believe that the current ACCME *Standards for Commercial Support*, if properly monitored and enforced by the ACCME, fully and completely preserve the independence of CME and that no demonstrable need exists for adoption of the "new paradigm" as a condition for commercial support of CME.

[60] *See* SACME Comments at 4-5.

V. THE PROPOSED NEW INDEPENDENCE STANDARDS SHOULD NOT BE ADOPTED.

The Package includes several proposals intended to eliminate "influence" by industry on CME on the theory, presumably, that any commercial "influence" necessarily erodes the "independence" of the ensuing CME. For example, the ACCME proposes that commercial interests cannot communicate with accredited providers about any "sought-after topic" for commercially supported CME, including not only suggestions of CME topics about a particular "product line" but also suggestions about topics such as "therapeutic areas" or "patho-physiology" of disease. Likewise, the ACCME proposes that commercial interests may not communicate with CME providers about their "internal criteria for providing commercial support", as this would be deemed to be the receipt of "guidance, either nuanced or direct, on the content of the activity or on who should deliver that content" and hence prohibited by the ACCME's *Standards for Commercial Support*. Relatedly, all parties are admonished by the ACCME "to pay close attention to what are known as 'requests for proposals' [RFPs] for CME activities as they may be a point for insertion of influence by industry."

Further, the ACCME, in its August 6, 2008 call-for-comment is proposing to establish what amounts to a categorical ban that would exclude any "thought leader" in any field of medicine or science, or any medical writer, or anyone else for that matter, from being paid to participate in the creation or presentation of promotional information on behalf of a commercial interest and, at the same time, creating or presenting information for CME on the same content, even if the CME content is otherwise independent and free of commercial bias. In other words, thought leaders and others who wish to participate in the development and presentation of CME content will have to declare in advance whether they are on the "side" of promotion or on the "side" of education. If they pick the promotional side of the line, then, under the ACCME's proposal, they

would be categorically prohibited from crossing the line to the other side, apparently forever, at least with respect to particular content.

These proposed new independence standards are not in the public interest and should not be adopted.

A. The Proposed Prohibition on Suggestion of CME Topics and Provision of RFPs By Commercial Interests Should Not Be Adopted.

It is revealing that ACCME cites no evidence to support the proposition that "influence" and "bias" are functionally equivalent concepts. Why is it inappropriate for a commercial interest to "influence" the topics to be presented in a CME activity that it funds, so long as it does not "bias" the content, and particularly if there is valid and independently derived evidence of clinical practice gaps and identified need? After all, if I am spending money to support something, then at a minimum I should at least be able to have a voice in what topics I am interested in funding without at the same time in any way trying to "control" what is said on the subject? The ACCME's proposal is like telling someone they can contribute to charity, but then prohibiting them from deciding which charity to contribute to because, by designating the "topic" of my beneficence, I am somehow controlling the disposition of the funds. This makes little sense except as a kind of "absolute" vision of rectitude unencumbered by any concept of practical reality. It would convert commercial support for CME into sort of a charitable undertaking where the donor cannot decide what charity it should fund, even though the donor demonstrably refrains from attempting in any way to influence how the designated charity spends the donated funds. Further, directing commercial support into an anonymous fund of some kind to be awarded at the discretion of an oversight body such as the ACCME is simply not workable. This is likely to have the consequence of limiting the amount of commercial support for CME with an unknown present and future effect on the viability of the entire CME

enterprise. And equating a commercial interest's suggestion of a *topic* or equating a CME provider's knowledge of a commercial interest's RFP standards, to *control* of the ensuing CME *content* by the commercial supporter is an unjustified leap by any measure.

By way of analogy, if a professor teaches oncology at a medical school, adoption of an ACCME-like approach would mean that she may assign a mandatory research paper to her students but is foreclosed from telling them what topics are permissible subjects because, if she does, this would effectively amount to controlling the content of the research paper. Medical students would be left to guess whether a paper on breast cancer would count for course credit or whether only papers on lung cancer or some other form of the disease are acceptable. This charade seems quite unnecessary. So long as the professor does not control the content of the paper, the fact that she suggested the topic seems perfectly reasonable—indeed appropriate. Suggestion of the *topic* by the professor in no way demonstrably biases the *content* of the communication. Likewise here, the entities who provide the funding should have every right to suggest a topic, but without controlling the content. Otherwise, CME providers are left to scour a company's web site or the literature generally to divine what topics a company is and is not likely to fund, which seems like a large waste of everyone's time. Just because I tell you what is of interest to me does not mean that the content of my ensuing communication is necessarily biased. Where is the social science evidence to support that proposition? Certainly the new mandatory clinical trial posting regime under the Food and Drug Administration Amendments Act of 2007 and the greater transparency that commercial interests are now routinely providing about their areas of research interest will give CME providers more *clues* about what CME programs a company *might* be interested in funding. But why should everyone be spending their time on guesswork?

Rather, they should be spending their time on developing high quality CME activities that have the kind of rigor the ACCME, the Association, and most others in the CME enterprise seek.

Likewise, the use of RFPs, in and of itself, seems entirely appropriate and unproblematic. In fact, government agencies, such as the National Institutes of Health, routinely use RFPs to inform interested parties that funds are available to support education or research, to provide context about why the funds are available, and to explain how applications should be submitted and what information is required to be included. This use of an RFP-type process saves time and resources that are better spent on the development of the underlying CME content.

If the concern about suggestion of topics and about the use of RFPs is that they are points at which to insinuate commercial *bias* in the ensuing CME content, that concern is amply addressed by the current *Standards for Commercial Support.* If violations of these standards are taking place, then enhanced monitoring and enforcement by the ACCME is in order. Violators should be caught and punished. However, additional regulatory prohibitions that would foreclose suggestion of CME topics by commercial interests or the use of RFPs are unnecessary and potentially counterproductive. As SACME put it in its comments, "[A] lack of a transparent approach would likely lead to hidden agendas, a waste of time and resources and unnecessary increase in the cost associated with accredited CME to cover the inefficiencies created by such a policy."[61] We agree.

B. The Proposed Categorical Ban On CME Faculty Speaking at Promotional Meetings On The Same Content Should Not Be Adopted.

The ACCME's proposal to categorically ban CME faculty from speaking at promotional meetings on the same content would effectively require thought leaders and any other CME faculty members to "take sides" on CME content. They would effectively be required to declare

in advance whether they are on the side of promotion or on the side of education, apparently forever, at least with respect to the same and closely related content. This "crossover" prohibition would apply even if the CME faculty members promotional presentation is truthful, not misleading, fully substantiated, fairly balanced, and "on label", as required by FDA. It would presumably mean that a thought leader who makes such a promotional presentation could not thereafter teach at a CME activity about emerging data and innovative models of care on the same general content area. This seems like a profoundly misguided policy.

Oddly, in proposing a categorical crossover ban, the ACCME does not explain or even address why the ACCME's *Standards for Commercial Support* are inadequate to address and resolve any conflicts of interest that might be created by these dual roles. In fact, Standard 6 currently requires disclosure to learners of potential conflicts of interest created by relevant financial relationships. And Standard 2 defines relevant financial relationships to include a financial relationship in "any" amount during the preceding 12 months. Coupled with the overarching requirement that CME be independent and free from commercial bias, such a disclosure regime appears to be adequate in itself to address the problem the ACCME seeks to remedy and the ACCME does not explain why it isn't.

Moreover, the proposed crossover prohibition applicable to CME faculty appears to be just an indirect way of categorically prohibiting commercial support for CME even if the CME is otherwise independent and free from commercial bias. The proposition that one should not be able to accomplish indirectly what one may not accomplish directly, which is a relevant constitutional principle for example under the First Amendment[62], seems applicable in this

[61] At 2.

[62] *See e.g. Grosjean v. Am. Press Co.*, 297 U.S. 233, 250 (indirect regulation of speech through taxation of newspapers unconstitutional).

context as well. All of the reasons discussed above why a categorical ban on commercial support for CME should not be adopted are equally applicable to the proposed CME faculty crossover ban. A policy with such profound National implications seems quite clearly beyond the purview of the ACCME and should be considered and adopted as National policy, if at all, as in the case of a proposed ban on commercial support for CME, by a more representative body.

Moreover, the "authority" cited by the ACCME fails to support the proposed crossover ban. First, the ACCME says that the ban is supported because a group of state attorneys general "won" a judgment against a major pharmaceutical company imposing a comparable prohibition. But this use by the ACCME of the term "won" suggests that a neutral third party, such as a judge, evaluated the evidence and arguments on all sides of the matter and concluded that a crossover prohibition should be ordered. In fact, the crossover prohibition in that case, which nevertheless applies only for a limited duration for any particular CME faculty member, is part of a government coerced settlement agreement, and was not "won" by the state attorneys general in a fully litigated proceeding. Indeed, as anyone involved in this kind of litigation knows, "fencing in" provisions like this are sometimes imposed as part of a settlement in a particular case based on the specific underlying facts of the matter and cannot and should not be interpreted as necessarily establishing policy in other, unrelated contexts.[63]

Moreover, the ACCME's citation to the June 2008 *AAMC Task Force Report* as support for the proposed crossover ban is incomplete and somewhat misleading. It is true of course, as the ACCME says, that the Task Force recommended that academic medical centers (AMCs) "strongly discourage" participation by faculty members as speakers at promotional events. At the same time, however, the Task Force specifically acknowledged that AMCs may "choose" to

allow participation of faculty members in "industry sponsored, FDA regulated programs".[64] If they "choose" the latter, then the Task Force suggested that AMCs "require full transparency and disclosure by their personnel to the centers *and when participating in such programs*" and "require that payments to academic personnel be only at fair market value."[65] In other words, and contrary to the impression created by the ACCME in the proposal, the AAMC Task Force did not recommend a categorical crossover prohibition of the kind the ACCME is proposing. Indeed, the Task Force acknowledged that this matter is best left to institutional "choice" and that if the choice is to permit such participation, then conflicts management tools, such as transparency and disclosure, are adequate to address the matter.

The ACCME's proposed categorical crossover ban has the potential to seriously impair and weaken the quantity and quality of CME in the United States. It may well deter significant numbers of physicians, including some who are the most interested and qualified to participate as CME faculty, from engaging in promotional relationships with commercial interests, or, alternatively from participating in CME altogether.[66] Either result seems unfortunate, as it may well remove some of the most qualified individuals, including key "thought leaders", from participation in one or another of these important activities.[67]

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[63] The ACCME's proposed importation into its own criteria of standards mandated in a government coerced settlement agreement itself belies the ACCME's assertion that it is not a "state actor".

[64] *See* AAMC Task Force Report, *available at* https://services.aamc.org/Publications/showfile.cfm?file=version114.pdf&prd_id=232&prv_id=281&pdf_id=114 at 20.

[65] *Id.* (Emphasis supplied).

[66] *See "White Paper: Merck Settles Vioxx® Litigation with State Attorneys General: an Analysis"*, McDermott, Will & Emery (May 29, 2008), at 5, *available at* http://www.mwe.com/index.cfm/fuseaction/publications.nldetail/object_id/25354abe-4d4d-4f08-846c-55f05f96f1af.cfm.

[67] Id.

C. The Proposed Categorical Prohibition On Medical Writer Crossover Is Duplicative and Unnecessary.

The ACCME's proposed new independence standards, as applied to CME crossover by medical writers who work on promotional programs in connection with the same content, is duplicative and unnecessary for yet an additional reason beyond those articulated above in connection with crossover by CME faculty (e.g. disclosure and use of other conflicts management tools). This has to do with the ACCME's extant August 2009 deadline that already requires significant institutional firewalls between agencies that create promotional programs and accredited providers who produce CME activities. In itself, this will likely have the effect that the ACCME is seeking to achieve by the proposed CME crossover prohibition. It is unfortunate that the ACCME does not address or even identify the overlap between the forthcoming separation of functions requirements and the proposed crossover prohibition as applied to medical writers (and other staff and freelancers that work on content).

In fact, most commercial interests who provide CME grant funding already require that the provider not be working in both promotion and CME, and will refuse to provide CME grants to entities involved in promotional programming. Data from the most recent (2007) survey of MedEd companies[68] demonstrates that this provider sector is moving swiftly into a certified education-only model from the mixed promotional/certified CME model that was prevalent before the issuance of the OIG Compliance Guidance in 2003. A great deal has changed in the CME environment since then, and MedEd companies and other stakeholders have continued to adapt as rules and regulations, including the ACCME's own *Standards for Commercial Support*, new accreditation criteria, and recent policy revisions, have evolved. MedEd companies have

changed their internal organizational structure through separation of the unit involved in CME and through the erection of stringent internal firewalls. The data demonstrate for example that all MedEd companies who deliver certified CME have firewalls that separate education from promotion and that substantial progress is being to ensure the adequacy of these firewalls through an array of controls (e.g. separate project teams; separate communications systems; separate office space; etc.).[69] None of the organizations who responded to the survey reported sharing staff that controls content (e.g. writers, medical directors) between the education company that produces certified CME and the affiliate that produces promotional activities.

VI. THE ACCME IS A "STATE ACTOR" SUBJECT TO CONSTITUTIONAL NORMS.

There are strong grounds to conclude that the ACCME is a "state actor" and hence subject to constraints, such as due process and First Amendment free speech requirements imposed by the U.S. Constitution. We demonstrate above how a number of the ACCME's proposals violate these constitutional norms. The ACCME should carefully analyze the "state actor" issue and how it affects the current rulemaking, as ACCME may well be called upon to do so later in any event, particularly given the highly charged current atmosphere. In the attached State Actor Appendix, we provide some thoughts for consideration by the ACCME on this exceptionally important question.

VII. CONCLUSION.

The ACCME has a fiduciary responsibility not only to all segments of the provider community, but also, and most importantly, to physicians and to the American people to consider well the

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[68] *See* Peterson ED, Overstreet KM, Parochka JN, Lemon MR. "*Medical Education and Communication Companies Involved in CME: An Updated Profile.*" Journal of Continuing Education in the Health Professions (In Press).

[69] *Id*.

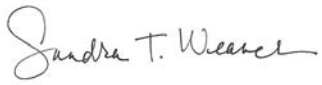
impact of its proposals, particularly the unintended consequences from their adoption that are likely to seriously and adversely affect the overall CME enterprise and consequently the public health. The first principle of medicine is to "do no harm". As we demonstrate above, promulgation of the Package as proposed by the ACCME is not in the public interest and may well do serious harm to post-graduate education of physicians in the United States.

Respectfully submitted,

Michael R. Lemon, MBA, CCMEP
President

Stephen M. Lewis, MA, CCMEP
President-Elect

Richard F. Tischler, Jr., PhD, FACME
Treasurer



Sandra T. Weaver, MS
Secretary

Karen M. Overstreet, EdD, RPh, FACME, CCMEP
Past-President

cc American Board of Medical Specialties
Member organization liaison: Jan Simon, RN, MHSA (jsimon@abms.org)
American Hospital Association
Member organization liaison: John Supplitt, MPH, MBA (jsupplitt@aha.org)
American Medical Association
Member organization liaison: Alejandro Aparicio, MD, FACP (alejandro.aparicio@ama-assn.org)
Association for Hospital Medical Education
Member organization liaison: Charles Daschbach, MD, MPH (cdaschb@chw.edu)
Association of American Medical Colleges
Member organization liaison: David Davis, MD (ddavis@aamc.org)
Council of Medical Specialty Societies
Member organization liaison: Norman Kahn, MD (nkahn@cmss.org; also c/o jkersten@cmss.com)

Federation of State Medical Boards of the U.S., Inc.
Member organization liaison: Carol Clothier (cclothier@fsmb.org)

STATE ACTOR APPENDIX

The ACCME Is a "State Actor" Subject to Constitutional Norms

There are strong grounds to conclude that the ACCME is a "state actor" and hence subject to constraints, such as due process and commercial free speech, imposed by the U.S. Constitution. In our main comments, the Association demonstrates how a number of the proposals in the Package and the process employed in this proceeding violate these constitutional norms. Here we address some of the reasons why we believe that in the context of this rulemaking the ACCME is a "state actor".

Most state medical regulatory authorities either directly or indirectly incorporate ACCME accreditation requirements into their CME regimes. The AMA's PRA program, with its "Category 1" credit system, has been adopted by forty-three states and the District of Columbia as either the sole CME credit acceptable under state rules or as a significant feature of the mandatory CME regime.[70] For example, California requires an M.D. to secure 100 CME credits during a given four-year period, with all 100 of these consisting of AMA PRA Category 1 credits, and the state licensing board has the statutory authority to deem any courses that meet certain content standards and receive accreditation from either the ACCME or the California Medical Association to satisfy state CME requirements.[71] Similarly, Florida, while requiring a varying number of CME credits for each license renewal based on a multiple-year cycle, mandates that the credits come either from AMA PRA Category 1 courses or from certain other sources, and the licensing board advises doctors that Category 1 providers "are either accredited

[70] A current table summarizing state requirements is *available at* http://www.aad.org /education/relicensure/_doc/StateLicensureRequirementsRevised.pdf.

[71] Cal. Bus. & Prof. Code § 2190.1(e). *See also e.g. "The California Medical Board, Continuing Medical Education, Option Available to You", available at* http://www.mbc.ca.gov/licensee/continuing_education_options.html.

by the [ACCME] or intra-state by the Florida Medical Association."[72] Likewise, Illinois requires 150 CME credits over a three-year cycle with at least 40 percent of the credits coming from Category 1 courses, and the licensing board notes that the ACCME is the organization responsible for accrediting CME providers.[73]

There are other indicia of substantial entwinement between the ACCME and state medical licensing boards. For example, the Federation of State Medical Boards[74] is a member organization of the ACCME and has a seat on its Board of Directors.[75] "The FSMB is working to assure the pertinence of accreditation of CME as a trusted source *on behalf of its member boards* that require CME and utilize ACCME."[76] (Emphasis supplied). In fact, the ACCME itself, in its *Bridge to Quality*, quite convincingly makes the "state action" case by demonstrating that CME is an essential requirement for maintenance of licensure and recounting, chapter and verse, the "pervasive entwinement"[77] among the ACCME, the FSMB, and individual state medical boards.

While it is true the states do not necessarily adopt the ACCME's standards directly, many indirectly require ACCME-accredited coursework by mandating that physicians take courses under a CME regime that uses ACCME accreditation as a baseline. In this respect, therefore, the ACCME is serving as a surrogate for the state medical licensing boards in developing,

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[72] Fla. Dep't of Health, *Continuing Medical Education (CME), available at* http://www.doh.state.fl.us /mqa/medical/me_ceu.html (information updated for reporting period ending Jan. 31, 2008).

[73] Ill. State Medical Soc'y, *Medical Licensure & Relicensure in Illinois, available at* http://www.isms.org /physicians/licensure/licensure_a.html.

[74] The FSMB, although not in and of itself a government entity, represents the 70 medical licensing boards of the U.S. and its territories, and its mission is to improve the quality, safety, and integrity of health care through developing and promoting high standards for physician licensure and practice. *See "About FSMB", available at* http://www.fsmb.org/aboutFSMB.html.

[75] *See ACCME Board of Directors, available at* http://www.accme.org/index.cfm/fa/about.directors.cfm.

[76] *See 2008 Annual FSMB Meeting, Agenda Item 13A, Tab 2* (at page 6 of 6), *available at* http://www.fsmb.org/pdf/annualmeeting_2008/hod_agenda/item_13a_tab_i_accme.pdf.

[77] See *Brentwood Acad.* at fn. 8 above.

implementing, and policing its CME accreditation standards. This surrogacy, as well as other areas of pervasive entwinement among the ACCME, the FSMB, and the state medical licensing boards demonstrates that there are strong arguments for characterizing the ACCME as "state actor" subject to the same constitutional principles that would be applicable to the Government itself were it regulating CME directly. As the Coalition puts it in the comments it is filing in this rulemaking: "[T]he process, procedures and substance of the ACCME system of accreditation is inextricably tied to the official, governmental process of professional certification."[78] And whether or not the ACCME is itself a "state actor", there are substantial arguments that a state medical licensing board, by incorporating by reference ACCME standards (and the process used to develop those standards), which would be unconstitutional if adopted by a Government body itself, likewise is subject to a constitutional challenge as a consequence of the ACCME's actions here. In other words, to the extent that a state medical licensing board indirectly incorporate the ACCME's standards, which have been adopted using constitutionally flawed procedures, there is a compelling argument that they are subject to challenge as a result. This possibility is something to which the ACCME should likewise be attentive.

There is no clear single formula for determining whether and when a private or semi-private association, such as the ACCME, is nevertheless a "state actor" for constitutional purposes. The Supreme Court itself has noted that it is an "impossible task" to "fashion and apply a precise formula" to this question.[79] "What is fairly attributable [to the State] is a matter of judgment, and the criteria lack rigid simplicity."[80] As a general matter, however, the Supreme Court has noted

[78] September 12, 2008 Comments at 2.
[79] Burton v. Wilmington Parking Auth., 365 U.S. 722 (1961).
[80] *Brentwood Acad.* at 531 U.S. at 295.

a number of factors that may be relevant in any given case in deciding whether state action is present:

- Did the activity result from the state's exercise of "coercive power"?
- Did the state provide "significant encouragement, either overt or covert"?
- Did the private actor operate as a "willful participant in joint activity with the State or its agents"?
- Is the nominally private actor controlled by an agency of the state, or is it exercising a public function delegated to it by the state?
- Is the private actor "entwined with governmental policies," or is the government "entwined in its management or control"?[81]

Private actors will be held to constitutional standards if "there is a sufficiently close nexus between the State and the challenged action of the regulated entity"[82] The determination of whether there is a "sufficiently close nexus" looks, among other things, to the standards listed above, and whether the state provided "a mantle of authority that enhanced the power of the harm-causing individual actor."[83] Notably, the Supreme Court has suggested that a state agency, by "embracing" rules promulgated by an association, may well transform those rules into state rules such that the association itself, i.e. the ACCME in this case, becomes a "state actor." Given the pervasive degree of entwinement between the state medical licensing boards, the FSMB, and the ACCME, among others, and given the extent to which the ACCME's rules have been "embraced" by a panoply of government actors, including not only by state medical licensing boards but, as also, as the Coalition observes in its comments[84], by FDA and even by state legislatures in contexts that do not relate directly to medical licensing but relate to regulation of

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81 *Id.* at 531 U.S. at 296.
82 *Id.*
83 *NCAA v. Tarkanian*, 488 U.S. 179, 192 (1988).
84 *Id.* at 194.

industry behavior[85], there is an unquestionably tight "embrace" between what the ACCME does and how it does it, and what the state does and how it does it.

For these reasons, and others not recounted here, the Association believes that strong grounds exist for concluding that the ACCME is a "state actor" subject to constitutional norms. Equally as important, state medical licensing boards, who unquestionably are state actors, may well also be liable for breaches of constitutional norms occasioned by the ACCME's actions in this rulemaking.

[85] *See* e.g. §14 of Massachusetts S. 2863, adding Chapter 111N, and requiring, in new §2(3), that the State Department of Health adopt a marketing code of conduct for pharmaceutical and medical device companies that would prohibit, among other things, industry "sponsorship or payment" for CME "that does not meet the Accreditation Council for Continuing Medical Education Standards for Commercial Support." *Available at* http://advamed.org/NR/rdonlyres/AEAF3DC5-356E-49DF-BD69-5CA048624AB1/0/ma2863.pdf (beginning at line 791). To the extent that the process employed by the ACCME in this rulemaking and the substantive standards that emerge are constitutionally flawed but are ultimately incorporated into the ACCME's *Standards for Commercial* Support nevertheless, these flaws may well be imputed to the State in the context of legislation like this. The ACCME should be sensitive to this possibility.

Pfizer Inc
235 East 42nd Street
New York, NY 10017-5755

September 11, 2008

Accreditation Council for Continuing Medical Education
515 N. State Street, Suite 1801
Chicago, IL 60654

Dear Dr. Kopelow,

In response to both of the recent requests for comments, Pfizer is pleased to provide the following commentary.

June 2008 Policy Announcement and Request for Comments

Issue 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 .

Response:

If the intent of ACCME's proposal is that no form of communication will be allowed by commercial supporters that identifies where funding may be available, then we disagree with this proposal. We do, however; support any policy revisions intended to ensure specific content is not communicated or controlled by commercial interests either directly or by proxy.

It is appropriate for commercial interests to clearly communicate areas of available funding in order to benefit providers' search for a balance of available funding support resources. If efficient mechanisms are not available for providers, a great deal of operational efficiency is lost by both the provider and commercial supporter community. In addition, providers are much

more likely to become overly dependent on fewer sources of commercial support funding if these efficient transparent mechanisms are not encouraged.

A lack of transparency also contributes to a culture where "business development" models of engaging industry gain a strong advantage over "educational support" models of communication. Any policy that discourages transparency will have the unintended adverse consequence of encouraging practices that are more highly dependent on personal interactions between provider business development personnel and commercial supporters. These business development practices, which may employ financial incentive systems that potentially overshadow patient health concerns, pose a much greater risk to content validity and issues around independence than transparent communications. Finally, it remains important to honor provider independence by recognizing they have a choice about whether to pursue funding, and to optimize their ability to seek balanced funding for programs.

There is a spectrum of risk in terms of what is being defined by terms like "topic", and a great deal of heterogeneity around the use of this term. The spectrum as we define it is outlined in the table below. Ultimately, what is appropriate should be defined by what is in the best interests of patients. The table is intended to be a general guide where the accurate decision can only be determined by the patient-centric facts and circumstances of the situation. In general we view the first three levels as consistent with ACCME standards and therefore appropriate in descending order of preference while those that follow are almost universally inappropriate.

Funding Area Statement Type	Example	Risk of Content Control	Provider Benefit (Efficiency)	Comment
1. Performance gap based on publicly available measures	Patient non-adherence to treatment plan as measured by HA1c	Low	High	Program level communications where commercial interests identify evidence based gaps in healthcare performance around which mutual patient-centric interests might align represent the optimal balance

				between risk and efficiency. This does not focus on content at all but encourages providers to seek funding for PI CME initiatives much more efficiently. We believe that commercial supporters using this framework can most effectively function within the spirit of Standard 1 of the SCS.
2. Clinical area	Diabetes	Low	Moderate	Appropriate to efficiently communicate budget support areas for providers but still leaves them "guessing" about specific areas of diabetes support. This in turn wastes grant application resources.
3. General Topic	Current update on treatment options for diabetes	Moderate	High	Appropriate in most cases if they are not specific to a method of treatments, but can blur the line if not carefully delineated
4. Prescribed Topic	*Update on specific therapeutic option (compound specific) or an exclusive focus on a single content focused learning objective that is associated with a new drug launch (ex: mechanism of action)*	*High*	*High*	*Inappropriate in most cases when topics prescribe specific content in a manner that does not reflect what is new, true and/or important to patients or where there is not an opportunity for a broad fair balanced discussion of all available options*
5. Prescribed Content	*Anything specific from learning objectives to content elements*			*Unless externally mandated by government agencies to address public safety concerns, we can not envision a scenario where this would be appropriate*

6. None Allowed	*No information available*	*Low at the activity level, but potential for high at organizational COI level*	*Low*	*Undermines transparency and favors providers who expend greater resources to determine funding areas through business development rather than educational development practices.*

Issue 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.'

Response:

This proposal raises two issues. The first is the *nature* of the commercial supporter's criteria being referenced here. The second is the *transparency* of the actions of commercial supporters in this regard.

Certainly criteria established by commercial supporters that attempt to influence content in any way are inconsistent with the spirit of the Standards. Beyond these kinds of attempts to influence providers, we believe that commercial supporters can and should set out precepts that embody their philosophy about quality CME; Pfizer is currently doing this. We also think that full transparency is central to avoiding the traps that internal, opaque criteria can create. To that end, we support the principle of transparency wherever it can be practically implemented. In our view, commercial interests have internal criteria whether they are public or not. Without transparency, there is no opportunity to understand if the criteria are appropriate. In addition, today's system creates an un-level playing field that disenfranchises many "duty of care" providers who simply do not have the administrative resources to understand the basics of such "black box" systems.

The lack of transparency is part of the culture that has contributed to the creation of a "business development" rather than "educational model" of interaction. It rewards those providers who invest in business development personnel who spend time developing relationships with commercial supporters. In our view, this approach has more universally succeeded in understanding what is in the "black box" of criteria in a manner that creates an unfair advantage for these providers. This in turn contributes to an issue we believe still remains at the core of the more serious conflict of interest issues currently facing the CME community where provider financial incentives can potentially overshadow public health concerns. We would suggest that providers should only be allowed to seek support from commercial supporters who are publicly transparent about their criteria for decision-making coupled with transparency about the decisions they have made.

With respect to the specific issue of Requests for Proposals or Calls for Grant Applications, we also feel this is an effective mechanism to more efficiently align resources with public health needs in a manner that is transparent. In an ideal future state, CGAs should not be necessary when there is a clear emergence of robust national needs and corresponding proposals, but that is not today's reality. Prior to the use of CGAs, it was extraordinarily rare to receive a grant request for performance improvement CME. Almost universally, the only grants received have been "one and done" didactic lectures of limited benefit to patients. We do think CGAs need to be based on some very clear principles.

- Limited to defining the evidence based performance gap where funding is available. Anything beyond this infringes on provider independence with respect to all of the other areas of educational planning.

- Universally available to all providers. The prior selection of which providers will receive these creates its own set of potential bias issues.

We would also encourage ACCME consideration of endorsing acceptable independent review standards for CGA responses. The CGA mechanism modeled after NIH type RFP's is an efficient vehicle to more clearly communicate the availability of resources and encourage performance improvement approaches. The only criticism we have heard of this practice has

been the perception that the recipients may be pre-determined. That could be handled by requiring that CGAs are sent out broadly. We would like to address that by transparently posting all responses in the future, but the provider community has not been universally supportive of that to date. Short of a future independent review mechanism, ACCME might consider this transparent disclosure a mandatory requirement for any provider responding to an RFP or CGA.

Under separate cover, we are sending examples of two Calls for Grant Applications along with all responses received.. One is for the area of smoking cessation and the other is for improving patient adherence to treatment plans. We hope you find them useful in your review.

Issue 3:

The ACCME Believes that Due Consideration be Given to the Elimination of Commercial Support of Continuing Medical Education Activities

*The ACCME proposes that if the following conditions were **all** met, then the commercial support of individual activities would be in the public interest and could continue to be allowed.*

1) When educational needs are identified and verified by organizations that do not receive commercial support and are free of financial relationships with industry (eg, US Government agencies), **and**

2) If the CME addresses a professional practice gap of a particular group of learners that is corroborated by bona fide performance measurements (eg, National Quality Forum) of the learners' own practice; **and**

3) When the CME content is from a continuing education curriculum specified by a bona fide organization, or entity, (eg, AMA, AHRQ, ABMS, FSMB), **and**

4) When the CME is verified as free of commercial bias.

Alternatively, these conditions could provide a basis for a mechanism to distribute commercial support derived from industry donated, pooled funds.

General Statement:

Fundamentally, we believe that using commercial support as a resource to improve performance around professional practice gaps, is clearly in the public's interest and we have enthusiastically aligned our processes and procedures behind those standards. This transformational approach to viewing industry support in the context of performance improvement initiatives holds great promise to more effectively manage current issues related to commercial support. We do not believe that either the status quo or the complete elimination of industry support is in the best interests of patients. If; however, the profession determines that commercial support does not contribute to patient care, then industry should respond with reallocating these funds to other areas as rapidly as possible.

Response to Specific Conditions:

Condition 1: We do not feel that needs assessments need to be free of commercial support. The issue is management of conflict of interest. There are limitations to an approach where all educational needs are identified and verified by organizations that do not receive commercial support and are free of financial relationships with industry. Needs assessments conducted by NGOs rarely address the multiple levels of data needed by the CME community in order to devise strategies for planned change. Most do little to address domains of learning that include the various attributes contributing to the learner's motivation.

Often, NGO type needs assessments may be based only on an epidemiologic view. They can also contribute to the lag in translating new evidence based research into practice if not conducted on a very timely basis. To this end, we feel that one of the more important contributions commercial support can make is to provide funding for needs assessments that are more tailored to the needs of the professional CME community. These kinds of assessments must span the horizon from traditional epidemiological data to barriers and facilitators of care. They need to take into account the availability of public domain resources that may be of help to CME planners. Realistically any nationally based needs assessment must be viewed as but one cell in a complex matrix of assessments that includes regional and local inquiries that align to form a framework for educational intervention design. A typical example of this may be statewide quality improvement initiatives where commercial support is sought.

We are attaching a Call For Grant applications in the area of adherence along with the responses we received to illustrate one such approach. We do believe that better mechanisms need to be found to avail the CME community of this type of support in order to avoid both real and perceived risks of bias. One option might be to include an external independent review board; another is to solicit an existing organization like SACME to take on this role. To that end, we would enthusiastically endorse any approach that could set up an independent review mechanism for aligning commercial support resources with the development of needs assessments.

A foundational principle to industry support of needs assessment work is that the same standards applied to clinical research should apply here. For example, it should be mandated "a priori" that any needs assessments funded in this manner are to be part of the public domain. Anything less is unacceptable and represents a clear risk to introduce bias into the provision of needs assessment data.

Condition 2: Completely concur with number 2 where those measures exist. In areas where they do not exist, the principle remains the same that commercial support should be restricted to areas that can improve professional competence.

Condition 3: We agree that CME content is ideally established from a continuing education curriculum established by a bona fide organization. The major potential gap in the above approach relates to the clarity of defining what level of curriculum is being referred to. If the level is defined too low in the structural hierarchy, then delays in incorporating new science into formal curricula could result. As long the level of detail being referred to in the curricula relates to objectives found higher in the hierarchy that define professional practice gaps, then this approach would not erect barriers to translating new science into practice. If however, the understanding was that the curriculum was explicit in all of its content without regard to the latest evidence, then the subsequent delays of incorporating new science into education would not be in the public interest.

We also take a broader view of the CME content development process. We believe the content element goes well beyond the construct of a curriculum. We envision that content development

takes into account all the elements referred to in the competencies of the ACGME for instance. In addition, practice will be influenced by external expectations of governmental bodies and others considered stakeholders in the quality of healthcare. In our view of this element great care should be taken to be inclusive of both multiple stakeholders and multiple sources of information so that the most robust and dynamic product emerges. .

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Condition 4: It is important that all CME is managed for conflict of interest. If supplemental mechanisms can be developed like the ones proposed, it would have the additional benefit of streamlining grant review, where monitoring for COI has been a necessary and major focus. The elements that need to be incorporated into such a mechanism need to move beyond the process - driven current system: one in which the activity files may be entirely in order-- yet the risk for real bias existed within the actual framework of planning. From a commercial supporter perspective, we have experienced what we considered bias from providers whose paperwork was apparently exemplary. Therefore, an important element of any new system that may emerge is to ensure that commercial support does not go to organizations that have a CME structure that potentially puts financial considerations ahead of public health concerns.

Additional issues:

In addition to the issues outlined by ACCME, balanced funding is an important principle for the profession and the public. We believe that balanced funding is a strong surrogate for proposals to pool funds. Further we assert that additional mechanisms are needed to ensure appropriate utilization of commercial support both at the organizational and activity level. It is our view that support from any one commercial entity should not exceed 50% for a major activity (non-RSS) and that any organization that relies on too high a percentage of commercial support for its overall activities should also not be eligible to receive this support. In addition, we believe that commercial support should increasingly be understood as inappropriate for supporting non-educational expenses that are not directly beneficial to learning. Today, no standards exist upon which we can develop informed policies for balanced funding requirements.

August 2008 Additional Request for Comments

Should those who write promotional materials be excluded from having any role in writing CME content?

Yes. We currently expect firewall provisions to include this separation, but it is hard to evaluate and monitor from a commercial supporter perspective.

Should those who teach in promotional activities be excluded from teaching in independent CME activities?

Our definition of promotional activities is all of those where faculty involvement is governed under FDA regulatory requirements and therefore directly controlled by commercial interests. We believe this is a discussion where views will continue to evolve over time on the basis of additional experience and discussion, and that ultimately it is a question for the medical profession to decide. We do feel that the confusion between independent continuing medical education and FDA regulated promotional programs has been a large contributor to the continuing confusion and subsequent criticism of industry's role in support of CME. We offer the following three suggestions that if implemented soon would largely ameliorate the concerns being addressed while the larger debate around this issue continues within the medical profession:

1) Minimally, strengthen disclosure requirements by requiring more specificity with respect to participation in promotional programs. While current disclosure requirements help the learner understand the general nature of potential conflicts of interest, they do not currently illuminate the issue of greatest concern relative to ensuring that the learner realizes the faculty may have given a promotional talk on a related topic within the same trip as the current activity is occurring. More specific disclosure of these elements would add clarity to the confusion between education and promotion and more fully inform the learner of potential bias issues.

2) Institute a mandatory separation in time and place between promotional programs and independent activity involvement. The most frequent example of a practice we would encourage ending occurs where a promotional speaker gives the same content area talk in the context of independent education within the same geographic area on the same trip. Even when commercial supporters have policies prohibiting this, faculty continue to occasionally encourage it through their own direct contact with providers. Many providers find this acceptable because they save on travel expenses. We think it contributes to the confusion between independent education and promotion.

3) Recognize educational efforts as exemplary conflict of interest management practices for elements related to this standard. Continuing professional development efforts for faculty who participate in both independent education and company sponsored speaker's bureaus in order to insure they demonstrate a competent understanding of the difference offer enormous potential to manage this issue more effectively. For example, the effort that will be launched by the Alliance for Continuing Medical Education and the Society for Academic CME later in 2008 to address this gap in CME practice may serve as a useful mechanism for providers to manage this potential conflict of interest.

Finally, we would like to express our appreciation for your proactively encouraging responses from all stakeholders to include commercial supporters.

Respectfully,

Pfizer Medical Education Group
US External Medical Affairs

Mike Saxton, MEd, FACME
Maureen Doyle-Scharff, MBS, FACME
Sarah Krug
Jacqueline Mayhew
Robert Kristofco, MSW, FACME

PhRMA

September 11, 2008

Murray Kopelow, MD, MS, FRCPC
Chief Executive
Accreditation Council for Continuing Medical Education
515 North State Street
Suite 1801
Chicago, IL 60654

ACCME Calls for Comment

Dear Dr. Kopelow:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to submit comments in response to Call-For-Comment 1, Call-For-Comment 2 and Call-For-Comment 3 on the proposals announced by Accreditation Council for Continuing Medical Education (ACCME) related to commercial funding of continuing medical education (CME). PhRMA is a voluntary nonprofit organization representing the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier, and more productive lives. PhRMA companies are leading the way in the search for cures.

PhRMA appreciates the opportunity to provide these comments to ACCME. PhRMA supports independence in the medical education conducted by ACCME- member educational providers (referred to generally as Providers). We also support ACCME's efforts to ensure that Providers conduct their own needs assessments and develop their content for their educational activities. At the same time, we believe that recent changes made by both ACCME and PhRMA in our respective Standards for Commercial Support and Code on Interactions with Healthcare Professionals further promote the independence of CME from commercial bias and that more time is needed for full implementation and assessment of their impact before further changes relating to commercial support of independent education are contemplated. ACCME's Standards for Commercial Support already contain very valid criteria and we believe appropriate monitoring and enforcement of those criteria are important before further refinement is considered.

In response to ACCME's Calls for Comment and as described in greater detail below, PhRMA recommends:

1. ACCME allow Providers that conduct their own needs assessments to receive general information from commercial interests on the general topics, such as therapeutic areas, that a commercial supporter might choose to fund; provided such communication is disseminated widely through request for educational grant applications (or their equivalent) or through websites.

2. ACCME confirm that manufacturer websites or requests for educational grant applications that include general application requirements similar to those that would be required by any other grant making entity such as the National Institutes of Health (NIH) do not constitute "internal criteria" that would constitute inappropriate guidance".

3. ACCME allow the revised PhRMA Code on Interactions with Health Care Professionals and the ACCME Standards for Commercial Support and other related ACCME accreditation criteria policy changes to take effect and be fully implemented before making further changes to its Standards for Commercial Support. These new changes do constitute a new paradigm and further change is not yet warranted, particularly when those changes could have a detrimental effect on physicians and patients.

4. ACCME reconsider its proposal to ban physicians from serving as speakers for promotional speaker programs and for CME that may include a discussion of the same product or related disease state.[1] Transparency and conflict management are the hallmark of all other guidance in this area and should be maintained by ACCME.

I. Introduction

A. Purpose of CME and importance of independence

CME is a critically important mechanism for physicians and other health care providers to obtain information and insights that enhance their knowledge and skills and improve patient care and clinical outcomes. It is vital that such

[1] We note that ACCME's proposal would ban physicians from teaching CME on the same product. However, as noted in our letter, CME is not offered on a particular product but may be on a range of treatments in a particular clinical area.

education be current, address knowledge, competence, and performance gaps of learners, and be free of commercial bias.[2]

B. Industry funding of CME

Pharmaceutical manufacturers may support CME for a wide range of reasons. Central to their support is a belief that they are participants in the healthcare system, and therefore should participate in the educational process by which physicians and other health care professionals remain current. The pharmaceutical industry is an evidence-based industry, and thus it supports inclusion of all evidence-based scientific exchange to promote optimal patient care. Such support of activities is critical to the industry's mission and should not be construed as an intention to create bias or control the content of educational activities.

There is also a great deal of literature on the underutilization of medicines, and barriers to adherence and noncompliance with treatment regimens. To the extent that Providers independently identify specific performance gaps or barriers, and educational activities can address some of these issues directly or indirectly, patient outcomes are improved and there is evidence that overall health care spending could be reduced.[3]

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[2] We note that there are many factors that can influence physician prescribing and patient use of medicines, such as peer reviewed research and payor coverage, formulary, and utilization management decisions. See, e.g., D.P. Goldman, et al., "Prescription Drug Cost Sharing: Associations with Medication and Medical Utilization and Spending and Health," *Journal of the American Medical Association*, July 4, 2007; S. Soumerai et al., "Use of Atypical Antipsychotic Drugs for Schizophrenia in Maine Medicaid Following a Policy Change," *Health Affairs*, April 1, 2008; and H. Huskamp, "The Effect of Incentive-Based Formularies on Prescription-Drug Utilization and Spending." *New England Journal of Medicine*, December 4, 2003. In fact, IMS Health reports that in 2007, 67 percent of all prescriptions filled were generic (IMS Press Release, "IMS Reports U.S. Prescription Sales Grew 3.8 Percent in 2007, to $286.5 Billion," March 12. 2008).

[3] M. Sokol et al., "Impact of Medication Adherence on Hospitalization Risk and Healthcare Cost," *Medical Care*, June 2005 (improved adherence to medicines for diabetes, hypertension and high cholesterol yields between $4 and $7 in savings for every additional dollar spent on medicines during the one year period studied by Medco); D. Cutler, et al., "The Value of Antihypertensive Drugs: A Perspective on Medical Innovation," *Health Affairs*, January/ February 2007 (Harvard and MIT researchers estimated that if all patients with high blood pressure were treated to guidelines with antihypertensive medicines, an additional 89,000 premature deaths and 420,000 hospitalizations could be avoided annually); M. Cloutier, et al., "Asthma Guideline Use by Pediatricians in Private Practices and Asthma Morbidity," *Pediatrics*, November 2006 (a program designed to improve asthma care for children led to a 47% increase in the use of medicines that prevent asthma attacks, a 56% reduction in outpatient visits, and a 91% decrease in emergency room visits for treatment of asthma).

Providers have an obligation under ACCME accreditation standards to assess the outcome of their activities on learners and understand the educational value of the activities and whether they meet their objectives. Outcomes measurements may also provide information on new or remaining educational needs among activity participants. These assessments are beneficial but add cost to the activity. Industry support can provide an additional source of funding to conduct these assessments.

We also note that manufacturers have medical education departments, staffed with professionals whose sole focus is to ensure that educational funding is provided to support the company's patient care driven mission. To further strengthen and promote the independence of these departments, the revised PhRMA Code on Interactions with Healthcare Professionals, discussed below, calls for company grant-making functions to be separate from sales and marketing departments. Many companies may already have taken that action after the OIG Compliance Program Guidance for Pharmaceutical Manufacturers in 2003 (the "OIG Compliance Program Guidance") made such a recommendation. Companies have policies and procedures in place to assure compliance with regulatory guidance and industry standards. Companies conduct internal training with respect to their grant-making functions. For these reasons, we hope that ACCME understands that the grant-making function is consistent with industry's overall mission to help patients.

C. PhRMA Code on Interactions with Healthcare Professionals

In 2002, PhRMA adopted its current Code on Interactions with Healthcare Professionals (the "PhRMA Code"). The PhRMA Code covered a wide range of topics relating to interactions between pharmaceutical manufacturers and health care professionals, including support of CME. The PhRMA Code provided that funding should be given to the Provider and not to the physician, that the Provider should determine the content, faculty and educational methods, materials and venues of the activity and that payment should not be made for non-faculty healthcare professionals attending the CME or to compensate for the time spent by healthcare professionals attending the CME.

Nevertheless, in response to recent concerns by policymakers and others, PhRMA determined that it was time to review the PhRMA Code, and on July 10, 2008, announced the adoption of the revised PhRMA Code that will take effect in January 2009 (the "Revised PhRMA Code"). The Revised PhRMA Code has been positively received by various stakeholders. It includes a number of new provisions specifically related to industry funding of CME. Those provisions include:

- Funding should be intended to support a full range of treatment options and not to promote a particular product.

- A company should separate its CME grant-making decisions from its sales and marketing departments.

- A company supporting CME should respect the independent judgment of the CME provider and should follow standards for commercial support established by ACCME or other entity that accredits the CME provider.

- Companies should not provide any advice or guidance to CME providers regarding content or speakers for a particular CME activity, even if asked by the CME provider.

- Companies should not provide meals or receptions directly at CME events. A CME provider, at its own discretion, may apply the financial support provided by a company's grant to provide meals for all participants at a CME activity.

In addition, PhRMA strengthened its section on Adherence to the Code which now includes that all companies that engage in pharmaceutical marketing should:

(1) publicly state their commitment to abide by the Revised PhRMA Code;

(2) self-certify annually with signatures of the Chief Executive Officer and Chief Compliance Officer that they have policies and procedures to foster compliance with the Revised PhRMA Code; and

(3) authorize PhRMA to post names and contact information for company Chief Compliance Officers.

In addition, companies are encouraged to obtain periodic, external verification of their compliance policies and procedures. PhRMA will post on its website the names of companies that indicate a commitment to abide by the Revised PhRMA Code, the status of annual certification, and when a company has sought and obtained external verification of compliance policies and procedures. Thus, the Revised PhRMA Code is enhanced both with respect to its specific provisions on industry support of CME as well as its provisions that encourage adherence to the Revised PhRMA Code and public accountability.

In light of the Revised PhRMA Code, the ACCME Standards for Commercial Support, the OIG Compliance Guidance, the FDA Guidance on Industry Supported Scientific and Educational Activities, we offer our comments on the specific proposals made by ACCME.

II. Proposal 1: Manner of interactions – Call for Comment 1

A. Receipt of Communication

ACCME proposes: "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 Support."

Providers Need to Conduct Their Own Needs Assessments and Commercial Supporters Should be Permitted to Communicate General Topics, Within Therapeutic Areas, They Will Support

We agree with ACCME that Providers must independently determine the need for education among prospective audiences. It appears that ACCME is concerned that Providers do not conduct their own needs assessments to determine topics that might be appropriate for educational activities and instead adopt commercial interests' funding topics as their own. We understand that ACCME is concerned that the resulting CME activities could be skewed toward those topics that will be commercially supported and thus undermine the Provider's role or miss important educational needs.

We would also be concerned with such potential bias if Providers were only adopting commercial interests' funding topics. However, in our companies' experience, Providers generally do conduct their own independent needs assessments and gap analyses, develop objectives, and identify topics to address those educational needs independent of commercial interests, as currently required by ACCME. It is clearly the Providers' responsibility to conduct such needs assessments, and we support ACCME's efforts to monitor Providers and enforce such requirements to ensure that they do.[4] In addition, there should

[4] At times, manufacturers may conduct their own rigorous independent needs assessments to determine what gaps exist in health care provider education and performance to determine where funding might be most needed and against which to evaluate a Provider's needs assessment. Those should not be substituted for independent assessments performed by the Provider.

not be confusion between a commercial interest providing a list of different general topics that it might choose to fund and Providers' identification of topics and control over the content of any educational activity selection based on their independent needs assessments. ACCME should verify that a needs assessment has been conducted by, or under the direction of, the Provider as part of its accreditation process and in order to verify compliance with the "direct guidance on the content" standard.

Under the Revised PhRMA Code that mirrors ACCME policies in this regard, companies should not provide any advice or guidance to Providers regarding content or speakers for a particular CME activity, even if asked by the Provider. However, the Revised PhRMA Code permits manufacturers to publicize general topics in which they have funding available to support education.[5] This information might be communicated in different ways such as requests for educational grant applications[6] or websites. There is a range of information that a manufacturer could convey as a general topic for which it has funding to support educational activities. For example, broad therapeutic areas such as asthma, breast cancer, epilepsy, oncology, Parkinsons or Type 2 diabetes are topic areas that a commercial interest might publicize that it is willing to consider funding. Similarly, general topics might include specific gaps in meeting clinical guidelines identified by government entities, or topics that cover broad gaps in management of disease or that cover multiple pharmacologic or non-pharmacologic approaches. As stated in the Revised PhRMA Code, "financial support for CME is intended to support education on a full range of treatment options and not to promote a particular medicine."

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[5] The Revised PhRMA Code's Question and Answer section includes:

Q21 May a company publicize its interest in a general topic for a CME program for which a grant would be provided?

A. Yes, a company may communicate to multiple CME providers or the public a general topic for a CME program that might be of interest to physicians. For example, a company may publicize that it will consider funding the topics of new treatments or disease management techniques in a particular therapy area such as diabetes or hypertension. However, the company should follow CME accreditation standards considering the nature and specificity of the CME topics that the company may propose, keeping in mind the Code's statement that financial support for CME is intended to support education on a full range of treatment options and not to promote a particular medicine. In addition, the company may not suggest the speakers or review or make any suggestions concerning the specific content of a particular CME program, even if asked by the CME provider.

[6] These Requests could have different names such as funding announcements, requests for proposals, calls for grant applications or similar terms.

These communications should be permitted to continue. Without this information, Providers would be left to guess what areas of activities might be funded by various commercial supporters which would force them to do unnecessary research or submit unnecessary application requests, wasting valuable resources that could be better directed toward education.

In addressing communication between commercial interests and Providers, ACCME should recognize that there is an important distinction between process and content. It may be appropriate for ACCME to limit direct, one-on-one communication between Providers and commercial interests on the content of activities or particular faculty. However, communication on general best practices and education trends as well as logistics may regularly and appropriately occur between Providers and commercial interests. Our members are also supportive of sharing information on educational needs and general topics through broad communication vehicles such as requests for educational grant applications and websites or through other media that may be accessed by any interested Provider.[7]

A company may include information on its website regarding grants to publicize the important role of CME, its interest in supporting CME and to provide transparency into its process. These websites are addressed in companies' overall policies and procedures and are important in maintaining consistency and transparency. The proposed new standard, whatever its intended scope, should not extend to passive communication such as websites. Company websites and other broad communication vehicles should be able to list grant application requirements and the general topics for which activities would be supported.

Prohibitions on such communication methods would, among other things, regulate the commercial interests and not the Providers. Such regulation may implicate important First Amendment principles and therefore is not appropriate. Moreover, such regulation could undermine company websites that have been created to provide greater transparency on independent medical education grants used to support CME activities and other funding activities. A number of companies have announced the creation of websites that list certain grant awards. Those increased transparency efforts have been encouraged by policymakers. As those websites may identify what entities are funded and for what purpose, they could be construed to provide a list of activities a company may have an interest in funding. It would undermine transparency efforts to prohibit Providers from receiving support from manufacturers that list the identity of former grant recipients or grant application requirements, including the need for a full needs assessment and budget, on their websites.

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[7] If a new commercial interest wants to fund activities, Providers will not even know to ask for funding if the commercial interest cannot communicate in some way directly to Providers of its interest in funding CME and the therapeutic areas in which it has funding available.

With regard to the subject of transparency, we ask that ACCME publish and regularly update accredited Providers' status such as accreditation with commendation, suspension or probation. Commercial interests would like to have the ability to verify Provider accreditation status as part of their due diligence on grant applications and are forced to rely upon Provider statements rather than being able to verify status independently through ACCME.

Thus, we suggest that the standard if it is to be adopted, read: "Accredited providers may receive communications from commercial interests on general topics for which applications are requested as long as such topics support education on a full range of treatment options rather than promoting a particular medicine (eg product line)[8], and such communication would not be considered 'direct guidance on the content of the activity' and would not result in Non-Compliance with Standard 1 of the ACCME Standards for Commercial Support."

B. Internal Criteria as Guidance

The second ACCME proposal in this area provides: *"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.'"*

ACCME should clarify what is intended by "internal criteria." It should be appropriate for requests for educational grant applications publicized by companies or websites to identify general topics and that specify broad categories of information needed by the commercial interest to evaluate a grant request such as the Provider's needs assessment, the educational learning objectives, the intended audience, and budget details or use of funds. It should be appropriate to communicate process issues rather than specific content.

The inclusion of application requirements in a request for educational grant application is not unique to commercial interests or industry funding. For example, the NIH funds many different types of grants. NIH publicizes those grant opportunities by issuing funding opportunity announcements in the NIH Guide for Grants and Contracts and on Grants.gov, in Parent Announcements, program announcements (PAs) and requests for applications (RFAs). Its Guide for Grants and Contracts is over 100 pages long with many forms and addenda

[8] We have removed the term "therapeutic area" for the reasons described above. Similarly, the term "patho physiology" is so broad that it has also been removed. Websters online dictionary defines "patho physiology as "the functional changes that accompany a particular syndrome or disease."

and includes among other items, the following components of an application that are necessary to include: Project/Performance Site locations, other project information, senior/key person profiles, budget, research plan, and checklist.[9]

These are just some of the examples of information needed for NIH to evaluate a grant application; similarly commercial interests need to receive information about key elements of each proposed activity in order to evaluate grant requests. It is essential in both cases that the information needed to evaluate the request be publicized to enable potential grant recipients to provide sufficient information to avoid having applications rejected not because they lack merit, but because the grantor cannot verify that the grant, for example, reflects fair market value for the proposed budget components. To that end, requesting certain information may be necessary in order to assure compliance with applicable law, including the federal anti-kickback law.

Similarly, commercial interests should be able to provide general information on the reasons for the denial of a grant request, such as inappropriate venue, unclear learning objectives, or excessive budget.

Both the publication of information required for commercial interest support and the provision of general reasons for denial are consistent with the commercial interests' and Providers' shared interests in compliance with ACCME Standards. Transparency in the general topics for which funding is available to support education, current budget availability, and administrative issues that need to be addressed in the grant application -- not specific content or faculty -- can help Providers avoid wasting time and resources on multiple grant requests. Providers can then spend their time and resources in providing physicians with high quality education that benefits patients.

III. Proposal on the Elimination of Commercial Support of Continuing Medical Education Activities – Call for Comment 2

ACCME proposes at least three possible scenarios with respect to the continuation of commercial support of CME activities: (1) status quo with commercial support of CME an acceptable funding mechanism; (2) the complete elimination of commercial support; and (3) a new method of certification of educational activities for CME which is being referred to as the "new paradigm." PhRMA believes that the changes that have recently been made to commercial support of CME, as reflected by ACCME policies and the Revised PhRMA Code represent a new process for funding CME, and that the alternative proposed as a

[9] NIH Grant Application Guide, Part I: Instructions for Preparing and Submitting an Application, Section 2.5

"new paradigm" by ACCME could be harmful to medical education and adversely impact patient care. PhRMA further believes that these recent changes should be allowed to be implemented fully and results analyzed before further changes are considered. The following comments will address why continued commercial support for CME is the right conclusion and why the other scenarios are not appropriate at this time.

A. Continued Commercial Support for CME is a New Paradigm.

PhRMA released the Revised PhRMA Code in July 2008, with changes to be effective January 1, 2009. As discussed above, the Revised PhRMA Code makes a number of changes with respect to industry support of CME to emphasize the independence between the commercial interests and CME activities.

The Revised PhRMA Code has been hailed by policymakers and some of the pharmaceutical industry's critics as an important step forward. The Revised PhRMA Code follows ACCME changes to its Standards for Commercial Support, which were made in 2004 but became effective in May 2005. As noted in ACCME's recent response to the request from the Senate Committee on Aging, the impact of those new standards "on commercial bias has not yet been measured." The response further notes that "[n]o studies have been reported using data derived from CME planned and presented under the supervision of the [2004 standards]. 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 Standards]." Both the ACCME Standards and the Revised PhRMA Code should be allowed to be fully implemented and assessed before further change is considered.

B. Elimination of Funding Could Limit Education and Impact Patient Care.

The option of eliminating commercial funding of CME would not benefit patients or physicians. There is no conclusive evidence that industry support of CME creates bias in CME.[10] In the absence of such evidence and while waiting for the full implementation of recent changes to the Revised PhRMA Code and the updated ACCME Standards, PhRMA is concerned that elimination of funding may adversely impact physician education and patient care.

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[10] R. Cervero and J. He, "The Relationship between Commercial Support and Bias in CME Activities: A Review of the Literature" (commissioned by ACCME). ACCME acknowledged in its July 11, 2008 response to the Senate Committee on Aging Chairman Kohl's request that despite suspicions of bias resulting from industry support of CME that there is no evidence to support that conjecture.

In fact, the ACCME-funded report raised the question of whether changes in prescribing behavior as a result of CME may lead to better care or not. As noted in the report, there may be multiple reasons prescribing may change after a CME activity, including new information about formulary placement[11] and previous undertreatment for the condition.[12] These changes therefore are not necessarily the result of commercial bias.

The recent work of the Council on Ethical and Judicial Affairs (CEJA) for the American Medical Association is instructive. With regard to CEJA's Report on Industry Support of Professional Education in Medicine, the American Medical Association Reference Committee on Amendments to Constitution and Bylaws referred the recommendation to eliminate commercial funding of medical education for further review after a significant amount of testimony which "stressed a need to consider more fully the role newly adopted accreditation standards play in addressing potential bias in educational content, particularly in continuing medical education,...that the report does not adequately address the potential differential impact and implication of restrictions on industry support across the range of stakeholders in medical education or other potential unintended consequences... [and] that supporting empirical references were problematic."

Thus, any decision to completely eliminate funding would appear to be unfounded and ill-advised based on the lack of evidence of bias and the unintended consequences for patient care that could result.

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[11] Physician surveys consistently report that formularies have a major impact on prescribing decisions. A 2002 survey conducted by the Boston Consulting Group showed that 54% of physicians reported that formularies have a major impact on prescribing decisions. A Tufts Center for the Study of Drug Development also showed a strong impact. In fact, in 2007, 9 of the 10 most frequently prescribed drugs in the United States were generic. IMS National Prescription Audit Plus.

[12] There is a great deal of research on underdiagnosis and undertreatment. A landmark 2003 study conducted by RAND Health found that US patients fail to receive about half of all recommended health care. The study found that medicines are underused in numerous situations for many conditions. Notably for quality standards related to medication, patients on average failed to receive recommended care 30% of the time. E.A. McGlynn et al, "The Quality of Health Care Delivered to Adults in the United States," *The New England Journal of Medicine* 348, no. 26 (26 June 2003); 2635-2645. Another RAND study assessed quality problems in the delivery of pharmacotherapy and identified 50% of all problems as underuse of needed medicines while overuse accounted for 3% of problems. T.P. Higashi, G. Shekelle et al, "The quality of pharmacologic care for vulnerable older patients," *Annals of Internal Medicine* 140, n. 9 (4 May 2004) 714-20.

C. ACCME's Proposed New Certification Requirements for CME Raise Many Concerns.

ACCME's "new paradigm" proposal raises a number of concerns. We have a number of general concerns as well as specific concerns with each of the four conditions.

General Issues

First and foremost, the most significant concern with ACCME's proposal is that the nature of a needs assessments being conducted by government and the linkage to gaps in performance measures will likely not address all developments in science and medicine or innovation in care. If a Provider identifies a gap in knowledge important for patient care, then there should be the ability to conduct a CME activity on the topic and obtain commercial funding without waiting for the government to opine as to whether it sees a need for such an activity. It has not been the business of government in the United States to control the dissemination of truthful information or dictate educational content. This country should not move in that direction today. The ACCME should rely on its current stringent requirement for thorough needs assessments conducted by Providers. If ACCME needs more staffing and resources to enforce its current requirements, then it should obtain more staffing and resources.

Second, even in connection with existing therapies and treatments, it would take considerable time until all new conditions for certification of activities for CME could be operationalized to allow for funding from commercial interests. It is not clear what happens to CME activities and commercial funding in the interim.

Third, national assessments rarely take into account the specific educational needs of healthcare providers found on a regional or local basis. When a Provider conducts a local needs assessment, the Provider can identify particular educational needs in a community or region. National assessments may not be able to identify particular local or regional needs, again having a potential adverse effect on patient care in particular communities.

Fourth, we also have concern that small, rural, and community hospitals might not have the resources to meet these rigorous conditions. Thus, educational opportunities might be reduced in those areas that may already find themselves with limited offerings. Patient care in those areas could be adversely impacted if physicians are unable to fully access all educational activities.

Concerns with Specific Conditions

We now discuss each of the conditions proposed by ACCME for certification of activities supported by commercial interests.

1. *Requiring needs to be identified and verified by organizations that do not receive commercial support and are free of financial relationships with industry (eg US Government agencies).* This condition could dramatically limit the scope of CME activities. Government agencies are not tasked with this type of assessment for these purposes and thus, it is likely that potentially significant needs and knowledge and practice gaps will not be identified. There is also likely to be a significant time lag as issues are raised through the government bureaucracy. Moreover some diseases may impact a small number of people and may not receive the attention of government agencies and other organizations. Nonetheless, it may be very important that CME activities address these disease areas.

2. *CME must address a professional practice gap of a particular group of learners that is corroborated by bona fide performance measurements (eg National Qualify Forum) of the learners' own practice.* Performance measures are developed based on clinical practice guidelines and evaluate the delivery of those clinical standards. The incorporation of new treatments or emerging best practices into clinical guidelines and subsequent performance measures is often a lengthy process which results in a time lag between the adoption of new best practices into use and performance measures that reflect those new best practices and treatments. Moreover, performance measures are not available for every disease or treatment. Therefore, while using performance measures as a guide for CME topics is an interesting idea, it is not clear if such performance measurements are, in fact, available in all circumstances and if so, how effective they are as a measurement of educational value.

3. *When the CME content is from a continuing education curriculum specified by certain bona fide organization or entity (eg, AMA, AHRQ, ABMS, FSMB).* To our knowledge, these entities are not in the business of creating educational curricula. A medical board might develop a statement of competencies but that is far removed from the development of the actual curriculum necessary to achieve those competencies or address educational gaps that exist. It is not clear whether ACCME is proposing to change those entities' core missions. There is concern that even if these entities were agreeable to changing their core missions or assuming this new obligation, unless such criteria were phased in over a long period of time, there would be a moratorium on CME until there is an "official" curriculum for every disease type. Even then, it is likely that diseases that only affect a small number of patients may not get the attention of a full curriculum.

4. *When the CME is verified as free of commercial bias.* It is our understanding that through the current accreditation process, the Provider certifies that its activity is free of commercial bias (among other things) and ACCME accredits the Provider; that ACCME does not conduct a pre-activity verification that this standard is met. It is unclear whether ACCME is proposing to change that process and conduct a pre-activity verification or what is meant by this condition. If ACCME will implement processes that would verify each CME activity prior to its conduct as "free of commercial bias," ensure that Providers conduct a needs assessment and develop a curriculum with appropriate educational content, there is a real question of the need for all of the preceding three conditions in the proposal. Adding on new layers of resources and complexity to precertify will create a backlog of activities awaiting precertification and narrow the educational opportunities to the detriment of physicians and patient care.

There is simply insufficient evidence for the need to shift from the current paradigm, particularly as improved with the Revised PhRMA Code, when there is substantial risk that educational opportunities could be greatly reduced in (1) the scope of offerings with respect to all diseases, (2) the scope of offerings with respect to new developments, and (3) meeting all regional and local needs.

<u>As an alternative to the new conditions for certification of activities to be eligible for commercial support,</u> ACCME could consider using conditions (1), (2) and (3) from its proposal (described above) as part of its verification process. Thus, conditions (1) and (2) from its proposal (described above) could serve as examples of the types of evidence that would be useful in a needs assessment, and condition (3) could serve as one benchmark for verification of curriculum. For example, if Providers use one of these national organizations' curricula (if they exist), they would not need to have their curriculum reviewed as part of accreditation. However, ACCME should not impose these limiting conditions as mandatory conditions when they could ultimately adversely impact patient care if physicians are not able to receive CME based on broader and newer information.

IV. ACCME Proposal on Additional Features of Independence in Accredited Continuing Medical Education – Call for Comment 3

ACCME proposes as a policy to further define the independence of accredited CME: *"Persons paid to create, or present, promotional materials on behalf of commercial interests cannot control the content of accredited continuing medical education on the same content."* In its commentary, ACCME states that "Physicians paid by a commercial interest to do promotional presentations on a

product could not teach in accredited continuing medical education on the same product. Anyone creating content for promotional activities would be excluded from creating content on the same product for accredited continuing medical education, for example."

PhRMA shares ACCME's interest in ensuring that promotional speaker programs sponsored by pharmaceutical companies are separate and distinct from CME and that such distinction is clear to an audience.

As stated in the Revised PhRMA Code, promotional speaker programs play an important and distinct role in pharmaceutical company efforts to communicate about their products and convey new information and developments; "Healthcare professionals participate in company-sponsored speaker programs in order to help educate and inform other healthcare professionals about the benefits, risks, and appropriate uses of company medicines." These company-sponsored events are promotional programs and not CME, but these promotional speaker programs are regulated by the FDA. By way of example, companies must submit all promotional slide decks to the FDA when they are used. The FDA frequently provides comments on such materials and may take enforcement action if necessary. Health care professional speakers are chosen because they meet criteria such as medical expertise, reputation, and knowledge in a particular therapeutic area. They are required by law to present information that is consistent with applicable FDA requirements. Internal legal and medical review is conducted of material before used by a speaker. Under the Revised PhRMA Code, speakers must "receive extensive training on the company's drug products or other specific topics to be presented and on compliance with FDA requirements for communication."

We understand that some healthcare stakeholders have expressed concern that audiences may be confused at times regarding whether a physician might be speaking on behalf of a company at a company sponsored promotional speaker program or as the faculty for CME. Consequently, our Revised PhRMA Code addresses this concern by requiring increased transparency. Section 7 of the Revised PhRMA Code provides: "While speaker programs offer important educational opportunities to healthcare professionals, <u>they are distinct from CME programs, and companies and speakers should be clear about this distinction</u>. For example, speakers and their materials should clearly identify the company that is sponsoring the presentation, the fact that the speaker is presenting on behalf of the company, and that the speaker is presenting information that is consistent with FDA guidelines." (emphasis added)

Similarly, ACCME currently has disclosure requirements as part of its Standards for Commercial Support. The current conflict of interest standards require individuals who serve as CME faculty to disclose any financial

relationship with a commercial interest and require that the Provider manage any potential conflict by defining the role of faculty in developing content related to the therapeutic area in which that commercial interest offers products or services. ACCME has not indicated that the current disclosure/conflict management mechanism is not working and as noted above, both in the report supported by ACCME and in ACCME's response to the Senate Aging Committee's inquiry, there is no evidence that commercial support is creating bias.

Moreover, the FDA, in its Guidance for Industry: Industry Supported Scientific and Educational Activities (the "FDA Guidance") requires disclosure and not a ban in connection with determining whether financial relationships disqualify the independence of industry supported education. The FDA considers "whether there was meaningful disclosure, at the time of the program to the audience of: (1) the company's funding of the program; (2) any significant relationship between the provider, presenters or moderators, and the supporting company (e.g., employee, grant recipient, owner of significant interest or stock); and (3) whether any unapproved uses of product will be discussed." The FDA expressly supported disclosure and rejected a ban in response to a comment to the proposed FDA Guidance that a significant financial relationship should preclude an activity from being independent. Specifically, the FDA responded "[i]t is neither practical nor justified to make a potential conflict of interest an absolute bar to participation in an independent educational activity. Disclosure of such potential conflicts is a workable means to address the potential for bias in medical and scientific contexts, and there is no reason to believe that it will be any less workable in addressing the potential for bias in the context of industry-supported scientific and educational activity."[13] Thus, the FDA Guidance requires disclosure, and not a complete ban. Likewise, ACCME should not institute a ban. ACCME should enforce the provisions of the Standards for Commercial Support, monitor Providers to ensure that they follow the conflict of interest guidelines and resolve any potential conflicts appropriately.

ACCME notes two recent external actions related to this area of concern. In fact, neither support ACCME's most recent proposal.

The first relates to a recent settlement between a pharmaceutical manufacturer and 29 states and the District of Columbia that included provisions regarding speakers who are engaged in promotional activities and also serve as CME faculty. The public settlement (which did not include any acknowledgement of wrongful activity), does not prohibit a physician from serving as both a promotional speaker for the commercial interest and as a faculty member for a CME activity funded by the same commercial interest. Rather, the settlement requires that a physician who serves as a promotional speaker for the company

[13] 62 Fed. Reg 64074, 64085 (December 3, 1997).

must disclose to CME participants orally and in writing the nature of the speaking arrangement if (1) the product promoted was in the same therapeutic class as the subject of the CME activity and (2) the CME activity occurs within 12 months of the speaker performing work or receiving compensation from the company. Thus, the settlement required transparency and does not support a total ban on individuals engaged in promotional activities from serving as CME faculty or providing content for a CME activity and should not be cited as the basis for it.

The second external event cited by ACCME is the recent report issued by the Task Force on Industry Funding of Medical Education of the Association of American Medical Colleges. While the report states "academic medical centers should make clear that participation by their faculty in industry-sponsored speakers' bureaus should be strongly discouraged"[14], the recommendation did not amount to a ban and the report did not attempt to justify the recommendation by citing a concern that participation in speakers programs would bias the academic medical center physician's work or any involvement in CME. Moreover, the Report anticipates that academic medical centers may choose to allow faculty participation in promotional speaker events and therefore includes recommendations that such medical centers require full transparency and disclosure and the receipt of payments that are at fair market value. Thus, the AAMC's recommendation should not be taken out of context to support ACCME's more rigid proposal.

If executed in accordance with applicable FDA regulations and industry standards such as those set forth in the Revised PhRMA Code, company-sponsored promotional speaker programs can provide worthwhile information about the benefits, risks and appropriate uses of medicines. Physicians generally find the information that they receive from pharmaceutical manufacturers to be very useful to them. Physicians may not always have the time to meet with manufacturer sales representatives during the course of their busy day. Moreover, many physicians would rather learn about a product from a peer physician. While the programs are not a substitute for and should not be confused with more broad-ranging CME activities, these promotional speaker programs provide important information for physicians on specific products and their risks and benefits.

The quality of any informational program – be it a promotional speaker program or a CME activity – turns in large part on the expertise and skill of the presenter. It is natural that companies should seek out the most qualified physicians to address attendees at promotional events, and likewise, CME. Providers may independently turn to many of these same experts to serve as

[14] We note that several of our members expressed their disagreement with this Report recommendation.

faculty in a CME activity. he consequence of implementing ACCME's proposed policy is either (1) physicians no longer serve as promotional speakers for companies, which eliminates an important source of information about products for physicians or (2) physicians choose to continue to contract with companies to serve as promotional speakers and no longer serve as faculty for CME activities. Either result is a loss for physician education and ultimately impacts the healthcare patients receive. As long as the message being delivered in each forum is accurate and not misleading and otherwise complies with the applicable laws or rules governing the event, and the audience is provided with sufficient disclosures about the speaker's relationship to the company funding the event, there is no need to force physicians to make such a Hobson's choice.

We urge ACCME to reconsider this change in policy. We believe that ACCME's expressed intent to expand its resources and to increase monitoring of CME activities and to enforce its Standards for Commercial Support are highly appropriate.

* * * * *

We are already in a new paradigm. The Revised PhRMA Code was just adopted and made substantial changes with respect to industry support of CME. This is not the time to make further change. Pharmaceutical companies are key partners of patients and physicians in physician education. Changing the standards at this time sends the wrong message for any efforts for self regulation for any industry, whether it be the pharmaceutical industry, the Provider industry or the physician community. At the same time, these changes proposed by ACCME could have a negative impact on the types of educational activities that might be available for physicians, ultimately adversely impacting patient care.

We agree that ACCME should ensure that Providers conduct independent needs assessments. At the same time, ACCME should allow Providers to receive through broad means of dissemination such as through requests for educational grant applications or website: (1) general topic areas that a commercial interest might choose to fund; and (2) the categories of information that are required in a grant application. In the absence of communication of this type of information, Providers will waste valuable resources submitting grant requests for topic areas that a commercial entity has no interest in funding; and that lack important information for evaluating the request. Such a result would be unfortunate for Providers, physicians and, most importantly, for patients.

Finally, ACCME should reconsider its proposal to ban physicians from serving as speakers for company sponsored promotional programs and also for CME. It is the responsibility of the Provider to require appropriate disclosure of all financial relationships, to manage the conflicts and ensure that the content is

objectively presented. There are many mechanisms available to Providers to fulfill those responsibilities. A complete ban is an unnecessarily blunt tool, which is not supported by any other regulatory or other guidance in this area, and which could ultimately reduce the opportunities for physicians to receive information and education, to the detriment of patient care.

We would be happy to have further discussions with you on these proposals. We look forward to continuing to work with you in this important area. Please feel free to contact us if you have any further questions.

Sincerely,

Diane E. Bieri
Senior Vice President
and General Counsel

Ann Leopold Kaplan
Assistant General Counsel

Comments on ACCME Re: Proposal to Ban Commercial Support of CME (HRG Publication #1842)

September 12, 2008

Accreditation Council for Continuing Medical Education
515 N. State Street, Suite 1801
Chicago, IL 60654

To whom it may concern:

We would like to thank the Accreditation Council for Continuing Medical Education (ACCME) for the opportunity to comment on its Proposed Policy to Support Independence in Accredited CME (Continuing Medical Education). In particular, we would like to comment on the proposal that "the commercial support of continuing medical education end."[i] We strongly support such a proposal because the consequences of the corrupting influence of commercial support on CME are so significant. An outright ban, rather than a compromise that will allow deviations from the objectivity of CME, is therefore justified. Inevitably, in the absence of a ban, there will be conflicts between the educational mission of CME and the financial objectives of commercial companies; no set of voluntary half-measures can assure that the educational objectives will take precedence.

In considering this proposal, it is important to recall that CME was born out of the desire to ensure that physicians remained abreast of advances in medical science. This was and remains the primary purpose of CME. However, in the 1970's, shortly after states began adopting CME requirements as a condition for medical licensure, commercial interests (primarily pharmaceutical companies) seized upon physicians' desire to keep the cost of CME as low as possible and inserted themselves into the CME process.[ii] By assuming the role of financier, commercial interests were able to influence the substance of CME and, presumably, increase the sales of their products. With 48% of all funding for CME (excluding advertising and exhibit income) now provided by commercial interests,[iii]it has become difficult for many to even imagine CME without commercial support.

Yet CME's reliance on commercial support was neither inevitable, nor is it irreversible. Indeed, to a limited extent, it is currently being reversed. With increasing scrutiny from both the public[iv],[v],[vi] and the medical profession,[vii],[viii],[ix] a trend toward developing CME that is free from commercial support is gaining momentum.[x],[xi] Six academic medical centers (Stanford University, University of California at Davis, University of Colorado, University of Kansas at Kansas City, University of Pittsburgh, University of Massachusetts) have banned direct commercial support of CME, but allow companies to contribute to a central pool that supports CME.[xii],[xiii] Memorial Sloan Kettering Cancer Center bans any commercial support for CME.[xiv] On the sponsor end, citing growing concern over conflict of interest, Pfizer, the world's largest pharmaceutical company, announced this year that it would no longer directly support CME offered by medical education and communication companies (MECCs);[xv] Zimmer, a major manufacturer of orthopedic medical devices, announced it would use only independent, third parties to support CME.[xvi] With support from the settlement of a lawsuit for off-label promotion of Neurontin, the Attorney General Consumer and Prescriber Education Grant Program funded the development of an online CME curriculum specifically addressing pharmaceutical company marketing practices.[xvii]

By some measures, CME's dependence on commercial support is actually decreasing. Despite a quadrupling of commercial support for CME over the past ten years, in 2007 the percentage of CME income provided by commercial interests actually decreased to close to 2002 levels (47%).[xviii]

Moreover, there is significant evidence that commercial support affects the integrity of CME. Perhaps the most profound effect of sponsorship is that it influences the choice of topics to be addressed – typically those for which a commercially available product (usually a drug) exists.[xix],[xx]This skews CME away from topics of great public health significance, but which lack a patent-protected therapy. Compared to conferences with no direct commercial support, commercially supported CME symposia present a narrower range of topics and tend to focus on medical conditions for which there are new therapeutic products.19 It also ensures that dietary and behavioral interventions receive short shrift.

In our own research, we were able to demonstrate that commercial booths at an annual professional association meeting, a major source of CME for the attendees, frequently violated the professional association's own codes of conduct. In brief, unprompted discussions with research assistants, drug company representatives at 4 of 24 booths (17%) engaged in illegal off-label promotion of drugs.[xxi]

Finally, commercial support has been associated with the primary objective pursued by sponsors: increases in prescribing. Following three different commercially supported CME lectures about antihypertensive drugs, the rate of new prescriptions increased after two lectures and decreased after one. In each case, the sponsor's share of prescriptions in that class of drugs rose.[xxii]

One relatively new development in CME merits particular mention. MECCs are for-profit firms that organize CME conferences and lectures, often on behalf of commercial sponsors. These companies have grown enormously in the last ten years18,[xxiii] and over seventy percent of their 2007 income originated from commercial sources.3 MECCs are thus not objective providers of educational information, but rather marketing firms with an obvious interest in promoting sales of their sponsors' products.9,24

In principle, several approaches to controlling conflicts of interest in CME could be envisioned: legal restrictions, disclosure, and policy restrictions.[xxiv] The most far-reaching (and the one we favor), legal restrictions would ban commercial support of CME. The advantage of legal restrictions is that they are straightforward and very effective, eliminating the conflict of interest entirely.24 However, the trend in the CME field has instead been toward not rocking the income boat, relying primarily on enhanced disclosure policies with voluntary policy restrictions for the most egregious forms of conflict. But, in effect, disclosure transfers to the consumer of the CME activity the responsibility for interpreting the often complex conflict of interest.24 Policy restrictions attempt to establish specific (typically unenforceable) firewalls while still maintaining a role for commercial support. However, just as only partially blocking a river flowing downhill will cause the water to carve a new path, policy restrictions simply lead to more creative methods of influencing physicians, as demonstrated by the explosive growth of MECCs.7,18,23

Eliminating commercial support of CME could have the downside of losing the single largest funding source of CME. However, since CME would continue to be a requirement for physicians to maintain their state licensure (and thus board certification), the demand for CME would be essentially unabated. Commercial support has shielded physicians from the true cost of CME. Shifting the burden of funding toward physicians (not exactly a group occupying the lower rungs of the earning ladder) would attenuate the effect of lost revenue.

It is also worth noting that CME is not exactly an enterprise operating at the margins of profitability. Whereas in 1998 CME in the U.S. was operating at a 5% profit margin, only 10 years later (2007) the profit margin had skyrocketed to 23%.18 This leaves plenty of profit that could be recycled to offset the loss of commercial support. Indeed, an ACCME policy eliminating commercial support of CME is well within reach.

Eliminating commercial support and with it the conflicts of interest that are currently rife would improve the quality of CME and reaffirm the primary mission of CME - promoting life-long learning and enhancing physician competence. It might also serve as an impetus to move away from expensive, lecture-dominated destination meetings and toward cheaper, more content-intensive forms of CME, such as mail-in and online courses. For these reasons, we support ending commercial support of CME.

Sincerely,

Jonas Hines
Research Associate

Peter Lurie, MD, MPH
Deputy Director
Health Research Group at Public Citizen

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[i] The ACCME Believes that Due Consideration be Given to the Elimination of Commercial Support of Continuing Medical Education Activities. June 2008. http://www.accme.org/dir_docs/doc_upload/d6b96a50-084c-485b-b71a-6b405b9c07d8_uploaddocument.pdf. Accessed September 12, 2008

[ii]**Podolsky SH,** Greene JA. **A Historical Perspective of Pharmaceutical Promotion and Physician Education**. JAMA, 2008;300:831-833.

[iii]Accreditation Council for Continuing Medical Education. Annual report data 2007. http://www.accme.org/dir_docs/doc_upload/207fa8e2-bdbe-47f8-9b65-52477f9faade_uploaddocument.pdf. Accessed September 9, 2008.

[iv]Weintraub A. Teaching Doctors—or Selling to Them? July 31, 2008
http://www.businessweek.com/magazine/content/08_32/b4095026335160.htm?chan=search. Accessed 11 September 2008.

[v] Request for Information from U.S. Senate Special Committee on Aging. June 30, 2008.
http://www.accme.org/dir_docs/doc_upload/4f332029-de8e-4bee-a983-0e05bfcdec0d_uploaddocument.pdf. Accessed 11 September 2008.

[vi]Harris G. Stanford to Limit Drug Maker Financing. New York
Times.August25,2008.http://www.nytimes.com/2008/08/26/business/26drug.html?_r=1&scp=2&sq=stanford%20medical&st=cse&oref=slogin.

[vii]Hager M, Fletcher S. Continuing Education in the Health Professions: Improving Healthcare Through Lifelong Learning. New York, NY: Josiah Macy, Jr Foundation; 2008.

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

[ix]**RelmanAS. Industry Support of Medical Education**. JAMA, 2008; 300:1071-1073.

[x]Pharma-Free CME. http://www.pharmedout.org/pharmafree.htm. Accessed 11 September 2008.

[xi] Independent Experts. HealthNewsReview.org. http://www.healthnewsreview.org/independentexperts.php. Accessed 11 September 2008.

[xii]PharmFree Scorecard. www.amsascorecard.org. Accessed 11 September 2008.

[xiii]Faculty Disclosure of Conflicts of Interest. http://med.stanford.edu/coi/. Accessed 11 September 2008.

[xiv]Kovaleski D. No Pharma Funding. Medical Meetings Magazine. January 1, 2008.
http://meetingsnet.com/cmepharma/cme/no_pharma_funding_012808/. Accessed 11 September 2008

[xv] Pfizer Changes its Funding of Continuing Medical Education in the US [news release]. New York, NY: Pfizer; July 2, 2008.
https://www.pfizermededgrants.com/pfizercme/help/CME_Funding_Change_Announcement.html. Accessed 10 September 2008.

[xvi]Zimmer Announces New Compliance Model [news release].Warsaw, IN. April 17, 2008.
http://www.zimmer.com/z/ctl/op/global/action/1/id/10082/template/CP. Accessed 11 September 2008.

[xvii] Attorney General Consumer and Prescriber Education Grant Program http://www.fsmb.org/re/open/default.html. Accessed 11 September 2008.

[xviii]Accreditation Council for Continuig Medical Education. Annual report data 1998-2007.
http://www.accme.org/index.cfm/fa/home.popular/popular_id/127a1c6f-462d-476b-a33a-6b67e131ef1a.cfm. Accessed September 9, 2008.

[xix]Katz HP, Goldfinger SE, Fletcher SW. Academia-Industry Collaboration in Continuing Medical Education: Description of Two Approaches. J Cont Educ Health Prof, 2002, 22(1).

[xx]Van Harrison T. The Uncertain Future of Continuing Medical Education: Commercialism and Shifts in Funding. J Contin Educ Health Prof. 2003;23(4):198-209.

[xxi]Lurie P, Tran T, Wolfe SM, Goodman R. Violations of Exhibiting and FDA Rules at an American Psychiatric Association Annual Meeting. Journal of Public Health Policy, 2005;26:389-99.

[xxii]Bowman MA, Pearle DL. Changes in Drug Prescribing Patterns Related to Commercial Company Funding of Continuing Medical Education. J Contin Educ Health Prof, 1988;8:13-20.

[xxiii] Ross JS, Lurie P, Wolfe SM. Medical Education Services Suppliers: A Threat to Physician Education. http://www.citizen.org/publications/release.cfm?ID=7142. Accessed September 9, 2008.

[xxiv] Lurie P. Presentation before the Institute of Medicine Committee on Conflict of Interest in Medical Research, Education, and Practice. http://www.citizen.org/publications/release.cfm?ID=7553. Accessed 10 September 2008.

The Society for Academic Continuing Medical Education
www.sacme.org

September 5, 2008

Accreditation Council for Continuing Medical Education
515 N. State Street, Suite 1801
Chicago, IL 60654

Dear Dr. Kopelow,

The Society for Academic Continuing Medical Education (SACME) is pleased to have an opportunity to respond to recent ACCME Calls for Comment on proposed policies. In preparation of the comments, the SACME leadership surveyed our members on the points for each of the proposals. As with any member organization, there was not a unanimous viewpoint, but rather varied opinions based on each organization's situation and circumstances as accredited providers. Based on the survey results, we attempted to glean the most salient points to include in the SACME responses.

As part of this commentary, we are concerned that two such important issues, interactions with commercial supporters and elimination of commercial support, were not presented as separate issues but embedded in a larger document that contained policy and procedural changes for ACCME accredited providers. Presentation in this manner obscures the importance and urgency of these issues. We are much more satisfied with the third Call for Comment (Additional Features of Independence in Accredited Continuing Medical Education) which was released separately.

Attached you will find the responses from SACME to each of the Calls for Comments:

- Limiting Interactions between Accredited Providers and Commercial Interests over Commercial Support with Industry
- Elimination of Commercial Support of Continuing Medical Education Activities
- Additional Features of Independence in Accredited Continuing Medical Education

SACME would welcome the opportunity to work with the ACCME as policies are developed, refined and implemented. We would also welcome any opportunities to further modify and refine the accreditation system and processes to the benefit of both the ACCME and accredited providers and in keeping with the goal of improving patient care. Please feel free to contact me should further information be desired.

Sincerely,

Melinda Steele MEd

Melinda Steele, M.Ed., CCMEP
President, Society for Academic Continuing Medical Education

www.sacme.org
Executive Secretariat
Society for Academic Continuing Medical Education, 3416 Primm Lane, Birmingham, AL 35216
Telephone: (205) 978-7990 Fax: (205) 823-2760 E-mail: sacme@primemanagement.net

SACME Response to ACCME Call for Comment on Limiting Interactions between Accredited Providers and Commercial Interests over Commercial Support with Industry

On June 11th of this year, the Accreditation Council for CME (ACCME) released several announcements and two documents with a call for comment period for each. The Society for Academic CME (SACME) has surveyed its membership and wishes to file this comment related to the document entitled, "Limiting Interactions between Accredited Providers and Commercial Interests over Commercial Support with Industry" also known as Call for Comment 1.

Much attention has been drawn to CME and its independence from undue commercial interest. SACME strongly supports the concept that CME must be evidence-based, supported by education science principles and free of commercial bias. Degree granting institutions of higher education have significant experience with seeking and obtaining commercial support while avoiding undue commercial interest through decades of research and education support. The academic centers have also made mistakes in the past and thus have significant experience to draw upon. Thus the academic accredited CME providers are perfectly positioned to provide comment on this topic.

The call for comment begins by stating that the manner of interaction between potential commercial supporters or their agents and some accredited providers may need to be altered. SACME's position is that if there are concerns about particular accredited providers then those specific providers should be addressed and sweeping changes to the system may not be necessary.

SACME is supportive of the utilization of performance improvement science to help improve the CME system. The science of performance improvement is based upon several simple principles that occur as discrete steps sometimes referred to as the Plan-Do-Study-Act (PDSA) approach. SACME encourages the ACCME to utilize this evidence-based scientific approach for improvement and thus recommends that further changes to the Standards for Commercial Support await evidence of a gap and evidence of efficacious steps for improvement.

The call for comment suggests that;
"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 (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…."

In a recent survey of SACME members, greater than 60% either agree or strongly agree with this statement, approximately 30% disagree or strongly disagree and 10% are neutral. Several respondents commented that the general intent of this statement already exists in the SCS as a commercial supporter cannot provide direction for content. Thus, they support the regulation not because its needed, but because they believe the principle already exists.

Those that were concerned by the statement were concerned for several reasons. These include:

1) The statement starts by saying that accredited providers must not receive communication. In this internet age, avoiding communication may be impossible and being held responsible for receiving what may be unsolicited communication might be simply beyond the provider's control.
2) It is not clear how one would monitor for receipt of a communication.
3) All grant related calls for proposals include information regarding funding domains and there is no evidence that this information causes undue commercial influence in any domain including research and/or education. SACME would agree that a grant that requires a focus on a specific product must be avoided.
4) How would the circumstance be handled when the FDA mandates training for a specific device or procedure?

The call for comment then suggests that **"Receiving communication 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 the content."**

The respondents for this question were essentially split with a slight preponderance disagreeing. The survey results showed that 45% either disagreed or strongly disagreed, 39% agreed or strongly agreed and a significant fraction (16%) was neutral. The survey then asked if the respondents felt it was important to have information regarding internal criteria. An overwhelming majority (>71%) responded that indeed knowing internal criteria are important.

Our membership is concerned that a lack of a transparent approach would likely lead to hidden agendas, a waste of time and resources and an unnecessary increase in the cost associated with accredited CME to cover the inefficiencies created but such a policy. This could then also translate into fewer CME certified opportunities. It is important to note that more than half of the respondents believed that having knowledge of the internal criteria did not cause bias. In addition more than half did not believe that having internal criteria from a commercial interest was any different than having internal criteria from a foundation or the government.

In conclusion, SACME is highly supportive an iterative performance improvement approach designed to improve the CME system. SACME suggests that such an approach might include a transparent process for all grants, no matter the source. The transparent process should require that all relevant aspects of a grant be made publicly available. Communication to clarify any of these publicly reported criteria should be permitted. SACME would be happy to work with the ACCME on these critically important and pertinent issues.

SACME Response to ACCME Call for Comment on the Elimination of Commercial Support of Continuing Medical Education Activities

On June 11, 2008, the Accreditation Council for CME (ACCME) released several announcements and two documents with a call for comment on items that have the potential for seriously impacting academic CME. The following is SACME's response to the call for "Elimination of Commercial Support of Continuing Medical Education Activities" and is based on the responses of 86 SACME members who comprise 40% of SACME voting members.

Over the last several years, considerable national debate has focused on the role of commercial support in all aspects of medical education, with a special emphasis on its role in continuing medical education for physicians. The underlying assumption of this debate is that CME supported by industry is inherently biased regardless of safeguards put into place by the ACCME, its accredited providers, and industry. We fully reject the premise that merely receiving a grant creates an inherent conflict as there is no evidence that this is true. We do acknowledge that there have been abuses within the system, but also believe that the entire CME community should not bear the burden of those abuses.

The reality of academic CME is that only a handful of academic institutions do not take commercial support for their CME activities. Most institutions provide minimal or no funding to CME programs and require these programs to be self-supporting. Therefore, eliminating all commercial support from CME programs poses a very real threat to the viability of CME within the current academic environment.

Since the call for Comment on Elimination of Commercial Support of CME Activities contained several different elements, we asked SACME membership to respond to each element.

Commercial support of continuing medical education should end

Overwhelmingly, SACME members who responded to the survey disagreed with the ACCME proposal to eliminate commercial support in continuing medical education. Less than 20% were in agreement with this proposal, and fewer than 10% indicated a neutral position.
When asked about the impact to their CME programs, 77% of the respondents indicated that ending commercial support for CME would have a significant negative impact on their overall CME program. These impacts include:

- a decrease in the number and scope of CME activities
- fewer external speakers used for RSS's
- reduction in the number of clinicians educated
- less CME research
- reduction in staff, or
- complete elimination of the CME program itself.

As one respondent noted, "opportunities to pursue the development of innovative educational and QI applications and rigorous assessment of the resultant outcomes would be severely curtailed."

Elimination of commercial support is a complex issue. Even those respondents who agreed that commercial support should be eliminated felt there would be negative impact to their CME such as a reduction in external programs or an increase in registration fees.

Within the call for comments, ACCME proposed the following three scenarios:

- continuation of the status quo with commercial support,
- complete elimination of commercial support, and
- a new paradigm for CME support.

Less than 10% supported eliminating commercial support entirely, with approximately 30% retaining the status quo, and 60% in favor of a new funding paradigm for CME.

Of those who responded that a new paradigm was needed, there was no consensus on any single model. Examples of two suggested paradigms follow.

- A simple arrangement that allows commercial support to CME programs, but prohibits them from being designated for specific activities. For example, five commercial companies each contribute $10,000 to a hospital's (or medical school's) CME program.

- CME credits should be awarded by accredited degree granting centers of higher education. This would consolidate the accredited provider process to monitoring and management of < 200 providers nationwide.

Given the lack of consensus of those surveyed, any future CME funding paradigm must be well thought out and not put forth as a reaction to pressure from the external environment. The CME system could/should be improved but only if a systematic approach is taken that is responsive to the educational needs of our healthcare provider community and not those who would seek to vilify it.

The ACCME proposed a four-part paradigm for funding CME that would permit commercial support only if all of the following conditions were met:

A. When educational needs are identified and verified by organizations that do not receive commercial support and are free to financial relationships with industry (e.g., US Government agencies), **and**

B. If the CME addresses a professional practice gap of a particular group or learners that is corroborated by *bona fide* performance measures (e.g., National Quality Forum) of the learners' practice, **and**

C. When the CME content is from a continuing education curriculum specified by a *bona fide* organization, or entity (e.g., AMA, AHRQ, ABMS, FSMB), **and**

D. When the CME is verified as free of commercial bias.

Fifty-eight percent of respondents did not believe all components of this model were necessary compared to 22% who did. Twenty-percent indicated they were uncertain about the paradigm presented by the ACCME.

Those who did not support the ACCME proposed paradigm indicated that

- would create more bureaucracy,

- the needs of national organizations differ from those at the provider-level,
- bona fide organizations have their own bias and may not know or understand what the individual healthcare provider needs,
- the model would be time consuming and burdensome, and
- the model suggests lack of provider competence in what the needs of its learners are.

Finally, one comment from a respondent who was uncertain about the ACCME proposed paradigm noted that even some *bona fide* organizations may, in fact, be biased. As noted in a recent article, even the NIH review and grant award process is subject to reader bias. (V.E. Johnson, *Proc.Natl Acad.Sci.USA* doi:10.1073/pnas.0804538105;2008)

Potential Consequences of Adopting the ACCME 4-Part Paradigm

When asked about what the consequences of adopting such a paradigm, there was a wide-range of responses ranging from negative to positive.

- increased bureaucracy and documentation
- limited the range of CME activities
- less innovative CME
- diminished value of local audience needs
- decreased number of activities
- decrease in the number of CME providers
- less commercial bias
- improved CME programs

SACME members who responded to the survey believe that CME providers are in the best position to identify their learner needs and organizations that receive commercial support do manage that support and possible conflicts of interest within the guidelines of the current ACCME Standards for Commercial Support.

Many of those surveyed questioned what a "bona fide" organization actually is and whether or not those organizations are truly free of bias. The reality is that even "mature" review systems such as those in place at the FDA, the NIH, JAMA and NEJM have missed commercial bias.

In summary, we believe:

- The total elimination of commercial support is unnecessary and unjustified.

- The CME system should be improved through an evidence-based approach as a component of a well thought through strategic plan.

- Elimination of commercial support will likely produce significant unintended consequences that have not yet been assessed or analyzed.

- The commercial component of today's healthcare system supports institutions, organizations, research and education. Financial support for education should not be eliminated but managed by appropriate constraints consistent with the medical professionalism.

SACME Response to ACCME Call for Comment on Additional Features of Independence in Accredited Continuing Medical Education

The Society for Academic Continuing Medical Education welcomes the opportunity from ACCME to comment on its proposed policy to further define the independence of accredited continuing medical education. In the continued scrutiny of the CME enterprise we believe it is important to establish mechanisms to further define and ensure the separation of promotion from education and to ensure the independence of accredited CME from commercial interests. As such, SACME supports this proposed policy and agrees with the stipulation that those who are involved with the creation and presentation of content for commercial entities should not also be involved in the control of content of accredited CME. The inherent biases that exist in the involvement in promotional content present conflicts of interest that are not resolvable for accredited CME. We believe this policy will assist to clarify the issues of accredited CME vs. promotion for those who are currently examining CME for bias and conflict of interest.

We wonder, though, if the policy might benefit from clarification in a few areas. First, the policy does not specify any time reference for elimination of such conflicts. Is it intended to be that if one has *ever* produced or presented content of a promotional nature that one is thus banned forever from involvement in accredited CME? Or is the intention similar to other conflicts of interest that such a ban would only refer to relationships or promotional involvement in the past 12 months, allowing one to "cleanse" themselves of such relationships and move back into involvement in accredited CME only after a 12 month period?

Secondly, we believe that the policy when read in isolation and without the ACCME commentary might be strengthened by the addition of non-limiting examples. For instance, at the end of the current statement the addition of "e.g. participation on planning committees, development of content or presentation of content" might add further clarity and meaning when one reads or quotes the policy without benefit of the commentary.

Thirdly, the definition of "promotional" can have many and varied interpretations. The current definition is unclear and we recommend that the ACCME work with the academic community (SACME and AAMC) to define and clarify what the term "promotional" means in the context of this proposed policy.

Additionally, some comments received from our members question how a provider can *verify* whether or not a person has been "paid" to develop or present promotional content. Self report is often less that accurate and without some means of credible verification, this seems to be a critical portion of the policy that providers may not have the means to determine accurately. Would a provider be held accountable if a person did not disclose such information and it is later reported in some manner, for instance on a pharmaceutical web site listing such payments?

We applaud ACCME's efforts to further define and ensure the independence of accredited CME in this particular area. SACME supports the spirit of the policy as stated: "Persons paid to create, or present, promotional materials on behalf of commercial interests cannot control the content of accredited continuing medical education on that same content." We recommend that the policy be further refined with the addition of time frame, non-limiting examples, definition of

the term “promotional,” and verification methods for persons who have been paid for promotional content development or presentation as described above.

COMMENTS

of

WASHINGTON LEGAL FOUNDATION

to the

ACCREDITATION COUNCIL FOR CONTINUING MEDICAL EDUCATION

Concerning

June 11, 2008 Calls for Comment on "Limiting the Interactions Between Accredited Providers and Commercial Interests Over Commercial Support," and "The ACCME Believes that Due Consideration be Given to the Elimination of Commercial Support of Continuing Medical Education Activities"

Daniel J. Popeo
Richard A. Samp
Washington Legal Foundation
2009 Massachusetts Ave., NW
Washington, DC 20036
(202) 588-0302

September 12, 2008

Washington Legal Foundation
2009 Massachusetts Ave., NW
Washington, DC 20036
(202) 588-0302

September 12, 2008

Submitted Electronically:
https://accme.wufoo.com/forms/call-for-comment-1 and **call-for-comment-2**

ACCME
515 N. State Street, Suite 1801
Chicago, IL 60654

Re: June 11, 2008 Calls for Comments on "Limiting the Interactions Between Accredited Providers and Commercial Interests Over Commercial Support" and "The ACCME Believes that Due Consideration be Given to the Elimination of Commercial Support of Continuing Medical Education Activities"

Dear ACCME Members:

The Washington Legal Foundation (WLF) appreciates the opportunity to comment on the ACCME's June 11, 2008 proposal to define appropriate interactions between Accredited Providers of CME and commercial entities that provide them with support, as well as on ACCME's "new paradigm" for commercial support of CME activities. WLF is not commenting on ACCME's August 8, 2008 proposal regarding "Additional Features of Independence" in accredited CME; WLF does not have sufficient expertise regarding the promotional activities of medical professionals to provide useful comments in that area.

WLF is quite dismayed by the June 8 proposals. Both entail wholesale revisions regarding the manner in which CME is provided in this country. One would think that anyone proposing such major revisions would set forth substantial evidence providing justification for the changes. Yet, the ACCME provides virtually no such evidence and only minimal

explanations for its rationales. Basic notions of due process require the ACCME to give a better account of its intent and why its proposed changes are justified. Moreover, because the proposed changes, if adopted, are likely to have massive changes on the industry, fairness requires that those affected be provided a greater opportunity to respond and to suggest alternatives. Finally, WLF believes that the proposed ban on interactions between CME providers and commercial interests raise serious First Amendment concerns. WLF strongly urges the ACCME to re-examine its commitment to constitutionally problematical speech regulation.

I. Interests of WLF

WLF is a public interest law and policy center with members and supporters in all 50 states. It devotes a substantial portion of its resources to defending the rights of individuals and businesses to go about their affairs without undue interference from government regulators. Among WLF's members are doctors and medical patients who wish to receive information about uses of FDA-approved drugs and medical devices, as well as medical patients who wish their doctors to receive such information.

WLF has for many years been actively involved in efforts to decrease FDA restrictions on the flow of truthful information about FDA-approved products. For example, WLF successfully challenged FDA restrictions on commercial speech by pharmaceutical manufacturers. *Washington Legal Found. v. Friedman,* 13 F. Supp. 2d 51 (D.D.C. 1998) ["*WLF I*"], *injunction modified,* 56 F. Supp. 2d 81 (D.D.C. 1999) ["*WLF II*"], *appeal dism'd,*

202 F.3d 331 (D.C. Cir. 2000) ["*WLF III*"]. The district court's ruling included a holding that FDA violated the First Amendment when it attempted to restrict manufacturer support of CME activities at which the manufacturer's products were discussed. *WLF I*, 13 F. Supp. 2d at 73. The court enjoined FDA from "prohibit[ing], restrict[ing], sanction[ing], or otherwise seek[ing] to limit any pharmaceutical company or medical device manufacturer or any other person . . . from suggesting content or speakers to an independent program provider in connection with a continuing medical education seminar program or other symposium . . ." *Id.* at 73-74.[1] On January 29, 2003, WLF filed comments with the ACCME regarding constitutionally objectionable features of proposed revisions to the ACCME Standards for Commercial Support of CME activities.

WLF agrees with the United States Supreme Court that it is "[t]he premise of our system that there is no such thing as too much speech – that the people are not foolish but intelligent, and will separate the wheat from the chaff." *Austin v. Michigan State Chamber of Commerce*, 494 U.S. 652, 695 (1990) (Scalia, J., dissenting). Accordingly, provided that a CME provider maintains its independence, WLF believes that there is no justification for suppressing truthful speech by commercial interests to that provider.

WLF also believes that CME providers are doing a commendable job of supplying

[1] That portion of the district court's injunction was later vacated by the D.C. Circuit as moot, after FDA provided assurances to the appeals court that had absolutely no intention of restricting manufacturer speech with respect to CME, and that its existing guidance documents on manufacturer support of CME were intended to be advisory only.

doctors with valuable medical information. In the absence of evidence that there are serious problems with the industry's integrity – and the ACCME has supplied none – WLF does not believe that there is any justification for a major paradigm shift that could significantly impair the industry's ability to continue to provide first-rate information.

II. ACCME Concern Over Commercial Support Is of Quite Recent Origin

The ACCME's proposals are a continuation of a heightened concern over commercial support of CME, a concern that is of quite recent origin. Indeed, until at least 2003, there was widespread satisfaction with the ACCME standards governing such support. Those prior standards, adopted in March 1992, sought to prevent any bias in CME presentations by, among other things: (1) preventing the manufacturer from "control[ling] the planning, content or execution of the activity"; (2) barring a company from conditioning the provision of financial support on "acceptance . . . of advice or services concerning speakers, invitees or other educational matters, including content"; (3) requiring that any commercial support "be acknowledged in print announcement and brochures" without making any reference to specific products; and (4) requiring all speakers to disclose "the existence of any significant financial relationship or other relationship" they may have had with the manufacturer of a product to be discussed. While evidence of occasional violations of those standards have surfaced, WLF is unaware of any evidence that a significant number of CME providers did not comply fully with the standards.

In the early 1990s, FDA proposed adoption of its own standards for manufacturer

support of CME, and also brought enforcement actions against several manufacturers whose support of CME was viewed as constituting promotion of an unapproved new use of an FDA-approved product. These FDA activities were widely criticized and led directly to the WLF lawsuit cited above. After the district court's 1998 decision in *WLF I*, FDA backed off of its efforts to regulate CME.[2] Rather, FDA let it be known that it was satisfied with the ACCME's regulation of CME; *i.e.,* so long as a CME activity was accredited by the ACCME, FDA was unlikely to closely examine the activity to determine whether a manufacturer may have engaged in improper promotion of one of its products.

In January 2003, an ACCME task force proposed significant revisions to the ACCME commercial support standards, calling for the exclusion from CME activities of anyone who was (due to financial arrangements) potentially biased in favor of a particular manufacturer's products; full disclosures of those biases was no longer deemed sufficient. The January 2003 proposal was similar to the latest proposal in one very significant respect: the task force made no effort to explain why its proposed major revisions were necessary. After opposition to the proposal was expressed by WLF and others, some of the more draconian features of the

[2] Indeed, in its appeal to the U.S. Court of Appeals for the District of Columbia Circuit, FDA explicitly denied that it had any policy whatsoever on manufacturer support of CME. FDA told the appeals court that it viewed its CME Guidance (*see* 62 Fed. Reg. 64093-64100 (Dec. 3, 1997)) as a mere "safe harbor"; *i.e.*, manufacturers who complied with the Guidance could rest assured that they would not be targeted for enforcement action, but failure to adhere to the Guidance could not by itself form the basis for enforcement action. Solely on the basis of FDA's assurance that it would never invoke the CME Guidance in an enforcement action, the appeals court dismissed FDA's appeal and vacated as moot the district court injunction with respect to the CME Guidance. *WLF III*, 202 F.3d at 335-337.

proposal were modified before the current *ACCME Standards for Commercial Support* were adopted in 2004.

The ACCME's June 2008 proposal once again threatens major changes in the way that the industry operates. But once again, the ACCME provides virtually no evidence suggesting that there is a need for such major changes. WLF respectfully suggests that the latest proposal is based on a naive misunderstanding of how CME operates and a misguided faith that reliance on supposed alternative sources of funding would lead to superior educational results.

III. Commercial Interests Supply CME Funding Because They Believe it is in Their Financial Interest to Do So

Underlying much of what the ACCME has written regarding commercial support of CME is its apparent belief that such support is appropriate only if provided solely for charitable reasons. It apparently believes that if, in fact, commercial entities provide such support out of self-interest, then any CME provider that accepts such support is irreparably tainted and the integrity of its CME activity is compromised.

WLF wishes to state the obvious: no medical product manufacturer subsidizes CME based on a philanthropic desire to subsidize the education of underpaid physicians. Instead, they provide support because they believe that doing so will result in increased dissemination of information about their products, and that the increased information dissemination will result in increased sales of their products.[3] Accordingly, if the ACCME succeeds in preventing

[3] Some government officials are wary of manufacturer support of CME for precisely that same reason. They realize that increased product sales may well translate into increased

manufacturers from having any opportunities to suggest topics and content for CME, manufacturers will quickly lose much of their interest in providing financial support. WLF sees much to be gained and little potential harm if manufacturers continue to use their financial leverage to gain some voice in CME programs, so long as the accredited providers continue to exercise ultimate control over program content. Some at the ACCME seem to believe that loss of that funding stream would be a net plus for CME; for reasons set forth below, WLF respectfully submits that the results would be disastrous.

IV. The ACCME Should Continue Its Focus on Independence

Standard 1.1 of the *ACCME Standards for Commercial Support* provides as follows:

> A CME provider must ensure that the following decision were made free of the control of a commercial interest:
>
> (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; and
> (f) Evaluation of the activity.

WLF fully supports Standard 1.1. We believe it is important that a manufacturer not be permitted to turn a CME activity into a one-sided promotion of its product by providing funding for the activity in return for control over how the activity is conducted. The whole

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government expenditures for Medicare and Medicaid. Such officials often focus almost exclusively on the bottom line, with very little heed to whether increased product sales will lead to improved health care.

point of the ACCME accreditation process is to ensure that it is accredited CME providers who makes the final determinations regarding how CME activities are to be conducted. Evidence that an accredited provider is abdicating its responsibility to exercise such control is grounds for revoking that accreditation.

The ACCME now proposes taking the position that an accredited provider is not maintaining independence if it either: (1) receives communications from commercial interests announcing or prescribing any specific content that would be a preferred, or sought-after, topic for commercially supported CME; or (2) receives communications from commercial interests regarding a commercial interest's internal criteria for providing commercial support. That position is not even a plausible interpretation of Standard 1, which focuses on *independence* not *communication*. For the ACCME to state otherwise suggests a bad-faith attempt to disguise the drastic nature of the revision being proposed. Clearly, if evidence indicates that a manufacturer regularly gives a provider "suggestions" regarding preferred content and if in each instance the provider adopts those suggestions without further deliberation, that would be strong evidence that the manufacturer is not operating independently. But there are any number of internal controls that a provider can install to maintain independence, and thereby ensure that no manufacturer suggestions regarding CME content are adopted without first conducting an independent confirmation that the content both meets a perceived educational need and is medically sound. The concept of independent verification is sufficiently established within the medical profession to put the lie to the ACCME's contention that a

provider can never exercise independence if it receives both funding and suggested content from a commercial entity.

Thus, what the ACCME's position really comes down to is a preference that manufacturers provide no input whatsoever in formulating CME content. Precisely why one would have such a preference is difficult to understand, particularly when one considers that a manufacturer's employees and consultants are likely to be among those most knowledgeable regarding the latest medical advances in the fields in which the manufacturer operates. They are also likely to be aware of the topics regarding which doctors are most likely to desire additional information. If manufacturers are not permitted to suggest content, CME programs are less likely to cover as wide a range of cutting edge issues.

Moreover, there already exist self-correcting mechanisms that deter providers from offering biased programs that serve a particular manufacturer's interests but that offer little helpful information to doctors. In particular, doctors are all highly educated professionals who are likely to be able to detect a biased presentation that cannot be trusted. Once a provider develops a reputation for offering biased and untrustworthy CME activities, doctors will be very reluctant to attend that providers events in the future.[4] Similarly, if a provider accepts on faith a manufacturer's suggestion and offers a course for which there is little demand within the medical profession, the provider is unlikely to attract many attendees. Accordingly,

[4] Nor, for that matter, are they likely to prescribe drugs in the manner suggested by the biased presentation.

providers have a strong financial self-interest in maintaining their independence so as to continue to attract attendees.

IV. Adverse Effects on Health Care

WLF approaches this topic with the old adage, "if it ain't broken, don't fix it." There is little to suggest that there are any serious bias problems today in the provision of CME. Moreover, the proliferation of programs means that CME activities cover a multitude of topics. The only sure result of the adoption of the ACCME proposals is a decrease in that variety.

The ACCME's proposed "new paradigm" makes plain, however, that the ACCME is intent on doing away with all commercial support for CME activity. By insisting that four stringent and ill-defined conditions be met before it will concede that commercial support is *ever* in the public interest and could continue to be allowed, the ACCME is attempting to stack the deck to require adoption the outcome it quite evidently prefers: the elimination of all commercial support.

WLF suggests that that outcome would be disastrous for health care. Nearly 50% of all CME is provided through commercial support. If that support is ended, there is no readily apparent source of alternative financing. One of the ACCME's suggested alternatives -- "industry donated, pooled funds" cannot be taken seriously. Manufacturers have no incentive to donate to a pooled CME fund when they have no assurance that the funds will be used to conduct programs that have any relevance to the products they produce.

Nor is there any reason to believe that the government would be an alternative source

of funds of that magnitude. Moreover, there is every reason to believe that funding coming from a single source (*i.e.*, the government) would result in content far less diverse than currently exists. Furthermore, the government has its own biases that it no doubt would bring into play. Governments have an interest in reducing health care expenditures in order to help balance their budgets. Such reduced expenditures, if evidenced-based, may in some cases be good for society as a whole, but it can often be bad for individual patients who are denied treatment based on cost-benefit determinations.

WLF points to the model of continuing legal education (CLE) as one that the medical profession ought not emulate. There are no industry groups with a strong interest in influencing the content of CLE, and thus with an interest in providing subsidies. The result is that most CLE is of very low quality, and lawyers attend when forced to by state licensing requirements -- not because they believe that the courses offer them any meaningful educational benefits. WLF submits that if the ACCME deprives CME of a significant portion of its funding by prohibiting commercial support, the quality of CME will fall to that of CLE. Such a loss in quality and quantity of CME would be a tragic loss to the quality of health care in this country.

V. First Amendment Considerations

WLF only briefly touches on its First Amendment concerns about the restrictions that the ACCME proposes be imposed on manufacturer speech. A number of other commentators have provided strong arguments regarding why the ACCME would be deemed a "state actor"

if its speech restrictions were challenged in court. If the ACCME were deemed a state actor, its restrictions would surely be struck down on First Amendment grounds.

As the U.S. District Court for the District of Columbia made clear in *WLF I*, the types of content-based speech regulations contemplated by the ACCME proposals could not withstand First Amendment scrutiny. As the Supreme Court has held in numerous First Amendment cases, "if the Government could achieve its interests in a manner that does not restrict speech, the Government must do so." *Thompson v. Western States Medical Center*, 122 S. Ct. 1497, 1506 (2002). Because the current "independence" system has worked well to prevent CME attendees from being misled by potentially biased speakers, the First Amendment precludes the government -- or a government-affiliated organization -- from attempting to preclude all speech that is funded by commercial interests.

CONCLUSION

The Washington Legal Foundation respectfully requests that the ACCME withdraw its proposals, unless and until it provides a substantial basis for concluding that the current "independence" system is not working to ensure that doctors receive unbiased presentations at CME activities.

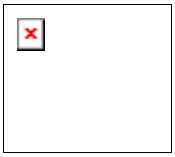
Respectfully submitted,

/s/ Daniel J. Popeo
Daniel J. Popeo

/s/ Richard A. Samp
Richard A. Samp
Washington Legal Foundation
2009 Massachusetts Ave., NW
Washington, DC 20036

From: Betty Daly [bdaly@aace.com]
Sent: Friday, September 05, 2008 2:39 PM
To: Dr. Murray Kopelow
Cc: acebot@aace.com; Board of Directors
Subject: ACCME Proposal to Increase Restrictions for CME Activities

Attachments: image005.jpg



American College of Endocrinology

245 Riverside Avenue • Suite 200 • Jacksonville, Florida 32202
Phone: (904) 353-7878 • Fax: (904) 353-8185 • http://www.aace.com

September 5, 2008

Murray Kopelow, MD, MS (Comm), FRCPC
Chief Executive Officer
Accreditation Council for Continuing Medical Education
515 North State Street, Suite 1801
Chicago, IL 60654

Dear Dr. Kopelow:

The American College of Endocrinology (ACE), a 501(c)3 charitable and scientific organization, is devoted to the promotion of art and science of clinical endocrinology. It activities include a broad scope of continuing medical education programs related to all endocrine disorders.

ACE wishes to submit the following comments regarding the ACCME proposal to increase the restrictions for participants in continuing medical education (CME) activities:

1. ACE agrees strongly that scientific and accredited CME events should be free of commercial interest and influence. However, ACE does not agree with ACCME's proposal to prohibit individuals paid to create or present promotion material on behalf of commercial interest from controlling the content to accredited CME on the same content. This proposal would exclude many academic scholars, including those who are widely recognized for their experience and expertise. Arbitrarily excluding these individuals would seriously limit choices for quality speakers and the conveyance of scientific knowledge.

2. ACE feels that as long as CME providers continue to be diligent in their compliance with existing ACCME requirements in identifying and resolving conflicts of interest and disclosing financial relationships to the audience, there should not be any need for the proposal currently being considered.

3. ACE concurs with the concerns outlined in the comments submitted to you by the American Association of Clinical Endocrinologists that implementing this proposal will have a significant, detrimental impact on physician education:

    - The more knowledgeable and capable educators would be excluded,

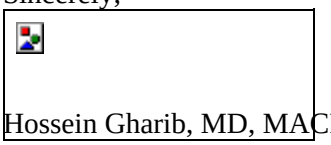
    - Many clinical researchers with the most current and extensive knowledge in their subject area, would no longer be able to participate in CME activities,

    - Moreover, ACE would reiterate the important point presented by the American Association of Clinical Endocrinologists that the presumptions that physicians are incapable of distinguishing the promotional and educational information, and that they cannot give feedback regarding clearly promotional versus educational content are unsubstantiated and that such assertions impugn, unjustifiably, the intellectual integrity of physicians.

ACE strongly recommends that ACCME not adopt this proposal.

Thank you for your consideration of these comments.

Sincerely,



Hossein Gharib, MD, MACP, MACE
President

HG/bd
cc: ACE Board of Trustees
American Association of Clinical Endocrinologists

F/Comm/CME/ACCME/KopelowLtrReACCMERestrictions

Via Betty H. Daly
Executive Assistant to the CEO
American Association of Clinical Endocrinologists
245 Riverside Avenue, Suite 200
Jacksonville, FL 32202
Phone: 904-353-7878 Ext. 143
Fax: 904-353-6755
E-mail: bdaly@aace.com

American Society of
Health-System Pharmacists®

7272 Wisconsin Avenue
Bethesda, Maryland 20814
301-657-3000
Fax: 301-664-8877
www.ashp.org

September 10, 2008

Murray Kopelow, MD, MS(Comm), FRCPC
Chief Executive
Accreditation Council for Continuing Medical Education
515 N. State Street, Suite 1801
Chicago, IL 60654

Dear Dr. Kopelow:

The American Society of Health-System Pharmacists (ASHP) is pleased to submit written comments on the Policy Announcement and Calls-for-Comment, issued in June and August 2008.

Elimination of Commercial Support of Continuing Medical Education Activities

As an ACCME-accredited provider, ASHP is opposed to the ACCME's proposal to eliminate commercial support of continuing medical education activities and to the proposed new paradigm for commercial support of CME activities. CME plays a vital role in the timely dissemination of new research and science to physician learners, and funding from a variety of sources, including commercial support, helps ensure the availability of quality and timely CME. We strongly believe that the reduction in the quality and availability of CME opportunities that would likely result from the elimination of commercial support could have a negative impact on the provision of patient care in the United States. We have the same concerns about the proposed new paradigm for commercial support of CME activities, which is so restrictive as to severely curtail or eliminate support from industries whose science and technology expertise is closely linked to clinical practice.

There is no doubt that the potential, both real and perceived, exists for commercial bias to influence the content of continuing medical education activities. However, this potential exists regardless of whether commercial support is used to fund the activity or not. We do not believe that sufficient evidence exists to confirm there is a higher degree of commercial bias in CME activities funded by commercial support as compared to those where no commercial support is obtained, and therefore do not believe that eliminating commercial support will achieve the goal of preventing commercial bias in CME. We would encourage ACCME to collaborate with the CME community to research the prevalence, causes, and potential solutions to the presence of commercial bias in CME activities so that future policy changes may be based on sound evidence and will achieve their intended goals. And similarly to explore ways by which scientific and clinical evidence from commercial laboratories can be brought into CME activities

ASHP believes it is appropriate to assign accredited providers with the responsibility of preventing bias in their CME activities, as ACCME has done with the revision of the Standards for Commercial Support and further with the revised accreditation standards. Subsequent to the release of the revised Standards for Commercial Support, providers and commercial interests have examined and revised their processes to further reduce the opportunity for introduction of commercial bias in CME. Measures implemented by FDA, OIG, and other organizations further help to prevent commercial bias in CME activities.

Limiting Interactions between Accredited Providers and Commercial Interests

ASHP supports ACCME's efforts to prevent the introduction of commercial bias in CME activities, and agrees that interactions between providers and commercial interests regarding commercial support should be minimal. However, we strongly encourage ACCME not to prohibit providers from obtaining information from commercial interests regarding general subject matter and venues in which the commercial interest may consider funding CME activities. Such a prohibitive policy would again make the process for providers to obtain commercial support very difficult as previously noted. We encourage a more reasonable approach involving general guidance to providers on what type of interactions between provider and commercial supporters are appropriate.

Elimination of Persons Paid to Create or Present Promotional Materials from CME

This proposed policy would disqualify an individual who has presented promotional materials on behalf of a commercial interest from serving as a faculty member, planner, or author for a CME activity, even if the provider limited that individual's control of the content to an area, such as pathophysiology, where the possibility of introduction of commercial bias might be minimal. We believe this policy would result in the elimination of many qualified individuals from participation in the planning of CME activities. ASHP encourages ACCME to instead provide further guidance and direction to providers on its expectations regarding resolution of conflicts of interest. ACCME may also wish to recommend that providers develop their own definitions of irresolvable conflicts of interest, which would specify the conditions under which the provider would disqualify a prospective faculty member or planner.

ASHP urges ACCME to revisit these proposed policies, taking into consideration comments from other stakeholders as well as the potential impact of these changes on the CME community. Thank you for the opportunity to provide comments on these very important and timely issues.

Sincerely,

Henri R. Manasse, Jr., Ph.D., Sc.D.
Executive Vice President and Chief Executive Officer