Accreditation Council for Continuing Medical Education

Responses to Call-for-Comment

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

October 2008

ACCME

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

For Comment

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

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

The ACCME requests that the profession, the public and the CME enterprise weigh in on this subject. This needs to be debated by the medical profession and the education community. It needs to be discussed with colleagues, with other professions, with students, the government, stakeholders of CME including the public.

The debate should not go on without discussion of alternatives as nothing would be worse then the deconstruction of a system without the identification of alternatives.

To frame the debate, the ACCME proposes that there are at least three possible scenarios: **1)** the status quo with commercial support of CME an acceptable funding mechanism, **2)** the complete elimination of commercial support and **3)** a new paradigm.

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 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.

Please provide the ACCME with your comments on these possible scenarios. Your ideas for other solutions are also welcome.

In order to comment click here or go to https://accme.wufoo.com/forms/call-for-comment-2/.

(UPDATED 8/6/2008: Comments may be submitted through September 12, 2008.)

RESPONSES TO ACCME Call-for-Comment

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

Response received	Organization Type
My point of view is that the status quo,where commercial support remains an acceptable mechanism,should remain.	Other
August 12, 2008 Dear Dr. Kopelow: [redacted] is pleased to respond to your request for comments regarding the ACCME standard on commercial interest. We believe the current definition of commercial interest ("any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients") is too broad in scope and may ensnare business interests that are free of commercial bias in their provision of CME. [redacted] develops appropriateness of care guidelines for commercial purposes. The guidelines are developed using the principles of evidenced based medicine and our tools are inherently free of bias. Our goal is to improve the quality and efficiency of health care while reducing the potential for unnecessary interventions and potential patient harm. Our clients are the market payors (CMS, MCOs, HMOs) and providers (hospitals); we do not sell our products to the individual physicians for whom we provide CME credits. Medical Directors need to be properly trained to use our decision analysis tools. Our CME activity fills a knowledge gap that enables today's medical director to efficiently and properly perform their professional duties to drive effective, efficient and appropriate health care. The motive of [redacted] in providing CME credit is vastly different from that of a commercial entity whose sole purpose is to sell orthopedists a better drill. We hope that the ACCME will reconsider the scope of the current definition of a commercial entity. The real issue to be addressed is the potential to introduce bias into a CME presentation regardless of whether this is a commercial interest, a government organization, or a seminar sponsored by a medical school. Sincerely, [redacted]	Accredited CME provider
We are not in favor of the complete elimination of commercial support for CME. There has been a sea of change over the years regarding the appropriate use of commercial support, spearheaded by the ACCME's Standards for Commercial Support and the Content Validation Statements. Greater awareness of the potential for bias in CME due to commercial support has come to the CME community and to the nation at large through reports from the lay and medical press, guidance from the IOM, and requests for information from the SFC. The updated SCS from 2004, the October 2007 guidance from the ACCME to eliminate any funder influence on content, and the volume of reporting from influential media such as The New York Times and the Wall Street Journal have positively contributed to greater awareness of the CME grant awarding process and the resulting potential for commercial bias in education. This spotlight on commercial support has resulted in much greater personal and organizational introspection on the potential for bias through commercial support grants, relevant financial relationships between pharma and individuals, and the potential for institutional bias through pharma grants to medical specialty societies, medical schools, and hospital health systems. As a result, the CME community, across all provider types, is expending much effort to ensure that commercially supported CME serve the interest of patient care. The current environment is extremely critical of a lack of transparency between pharma and practitioners, and members of the CME community—including faculty, providers, and funders—have responded with an approach that is risk averse and sincere in its commitment to ensure the validity of CME activities. Regarding the ACCME's New Funding Paradigm New Paradigm Criteria 1 and 2 call for educational needs underlying CME activities to be verified by 1) organizations free of commercial support, and 2) "bona fide" performance measurements. We believe that these are valid needs assessment sources, but that they should not be required needs assessment sources. There have been numerous instances throughout the years of bona fide educational needs that neither government sources identified in a timely fashion nor for which any performance measures existed. In the early 1980s, homosexual men were being admitted to hospitals with pneumonia with the disease that by 1982 would be called acquired immunodeficiency syndrome, or AIDS. The US Department of Health and Human Services published the first guidelines on AIDS in 1998. This is a gap of >16 years between disease identification and guideline publication. The National Quality Forum has not yet published	Accredited CME provider

"Standards for Clinician Level Infectious Disease." Had the ACCME's new paradigm been in place less than 10 years ago, there would have been no commercial support permitted for CME activities on HIV. This example on AIDS education is relevant to the many infectious diseases that have become important public health issues within the last 10 years in the US, including SARS, MRSA, penicillin-resistant TB, and Bird Flu. Oncology is another area in which physicians' performance gaps are not able to be corroborated by "bona fide" performance measurements. There are certainly knowledge, competence, and performance gaps among oncologists that would fit the first 2 criteria of the ACCME's new paradigm for commercial support. However, there are also gaps that don't fit the criteria that are just as valid for education. The guidelines for metastatic melanoma advise enrolling the patient in a clinical trial because there is no standard of care resulting in health care improvements. For oncologists treating patients with this disease, there is no corroboration on performance gaps. No guidelines exist to cover many cancers with specific comorbidities. Therefore, there are no performance gaps that can be measured, nor can they be corroborated. In addition, many cancers are studied in smaller trials rather than the large randomized controlled trials that are more typical for the study of conditions seen in primary care. Oncologists rely on CME—often in the grand rounds setting—to discuss how they can improve diagnoses, treatments, and systems in order to offer the best in care to their patients. New paradigm criteria 1 and 2 are not consistently applicable in the specialty care realm. Adopting these two parts of the new paradigm would direct much commercially-supported CME to the primary care realm, leaving vastly fewer educational dollars on topics of greater relevance to specialists and the patients they serve. Criterion 3 in the new paradigm for commercial support is not clear in its meaning. "When the CME content is from a continuing education curriculum specified by a bona fide organization, or entity, (eg, AMA, AHRQ, ABMS, FSMB)" eliminates many CME providers from the accredited provider pool, including smaller societies, individual hospitals, medical journals, and accredited medical education companies. The ACCME is proposing that the CME content, not the topic alone, must be part of one of these larger organizations' CE curricula. The ACCME is saying that only these larger organizations can appropriately manage commercial support. The evidence shows otherwise, since medical education communications companies demonstrate the highest compliance with ACCME policies, including the SCS. This element as part of the "new paradigm" is not evidence-based. There is risk for inappropriate management of commercial support, including commercial bias, in all provider types. One set of policies should apply to all CME providers. An improved monitoring system from the ACCME would ensure compliance by all provider types. Criterion 4 of the new paradigm will permit commercial support "When the CME is verified as free of commercial bias." This condition already exists as Standard 5 in the current SCS. We use faculty peer review and engage independent content validators to review CME material before it is released. We also ask participants if they perceived commercial bias in the activity. Is this considered verification of freedom of commercial bias? If the ACCME has other verification processes in mind, it should share them with the CME provider community. Again, the ACCME needs to provide an expanded explanation of criterion 4. As for having pooled funds, there are challenges in naming the designated decision-makers who will be in charge of disbursement. The Association of American Medical Colleges (AAMC) recently encouraged academic medical centers to "set up a central continuing medical education (CME) office to receive and coordinate the distribution of industry support for CME activities." Other CME provider types will argue that this establishes a system that will bias commercial support for CME activities provided by those organizations that are members of the AAMC. If there is a designated committee to determine which CME providers receive commercial support, how will they be compensated? Administration means there will be staff; staff means there will be salaries. Will salaries be taken from the pool? Who will establish the criteria for selecting the staff to oversee this grant pool? Many commercial supporters report that they receive >10,000 grant requests a year. How large a staff would this administrative body require in order to review grants in a timely fashion? We perceive the proposal for "a mechanism to distribute commercial support derived from industry-donated, pooled funds" as a way to replace one imperfect system with another. In conclusion, eliminating commercial support now—in today's environment of risk management and transparency—is an inappropriate suggestion. These are times that demand more CME, not less. Eliminating commercially supported CME will drastically lessen quality educational opportunities for physicians from a variety of CME provider types. The Josiah Macy Foundation recently proposed the elimination of commercial support for CME as well, and suggested that "Possible funding sources include the Federal government, foundations, professional groups, and corporations." A scan of recent headlines drives home that these possible funding sources will be neither consistent nor reliable sources of educational funding. The Federal government is in crisis, focused on addressing failing mortgage banks and keeping down CMS costs. Perhaps some foundations and professional groups will fund some CME, but corporations are enjoined to cut costs, even philanthropic costs, rather than take on more expenses during this economic downturn. In an era of pressing educational need to improve the quality of healthcare in the US, it is foolhardy to eliminate commercial support dollars. We believe that proposing the elimination of grant dollars is a politically correct decision driven by the negative press commercial support has received. It is a proposition made by large organizations more economically secure than the local hospital facing slashes in Federal and state support. Commercial support for CME may go away, but the issues in health access and quality will not. Consider this short list, taken from recent 2008 headlines: Grady D. Measles in U.S. at Highest Level Since 2001. The New York Times. May 2, 2008. TB emergency: Drug-	

resistant forms of the disease are widespread, and time and money to fight it are short. Los Angeles Times. February 28, 2008. Abrams J. US ban on visitors with HIV could end soon. Miami Herald. Jul. 16, 2008 Johnson TD. Geriatric Work Force Shortage Risks Health of Aging Boomers. Medscape Family Medicine. July 1, 2008. Rabin RC. Screening for Cancer in Elderly Fuels Fight. The New York Times. July 8, 2008. Ours is an era that demands quality improvement in healthcare performed by competent health care professionals. It is also an era spiraling downward at breakneck speed to general financial crisis in the population at large and in the healthcare environment in particular. It is an inappropriate and irresponsible proposal to suggest the elimination of >$1 billion of educational funding when the need is so critical, and the potential patient outcomes so beneficial.	
For quite some time the ACCME has been presenting accredited providers and the public with speculation regarding the impact of commercial support on the quality and influence of CME. This comment is not to recap the recent evidence to the contrary and the viewpoints of those participating in these programs that are in favor of maintaining the status quo. Rather, I would like to comment on the perception I gathered from reading this proposal. I completely understand the ACCME's desire that "bona fide" organizations should have a role in ensuring that all accredited education is unbiased. The problem is assuming that none of these "bona fide" organizations would have a financial interest in creating educational programming. None of the listed organizations have the time or the resources to dedicate themselves to the degree that you are proposing. It is perceivable that these organizations would focus on a very limited number of disease states. We have seen this in the QI arena, where there are only a small amount of HEDIS measures and a limited number of chronic diseases followed by the NCQA, not to mention the limited number of conditions covered by CMS's Scope of Work processes. So many disease states that are in dire need of evidence-based education would suffer more than they currently do. It is apparent by this proposal that the ACCME has completely given up on accredited providers that are not associated with an academic institution, a medical society or provider association. Most ACCME accredited providers have taken multiple steps to improve the quality of education that they distribute. Educational programming in 2008 is light years ahead of where it was in the 1980s and 1990s. Providers in all arenas have stepped up their game to use technological advancements, more rigorous methods of incorporation of the principles of adult learning and other techniques in an attempt to provide educational value. The problem is that many MECCs have reached a point where their programming is finite. The ACCME knows this; the providers themselves know this and most importantly healthcare providers recognize this. However, to bucket providers such as [redacted], who is moving away from "traditional CME" to focus on Performance Improvement-based CME, and has a firm understanding of what is necessary to create unbiased, accurate and quality education is unfair and a restraint on us in doing business. A process of natural selection is underway within this industry and companies that cannot adapt and improve will be forced out. Unfortunately, if obtaining funding is made more prohibitive, companies that are leading edge may also fall by the wayside. Therefore, [redacted] recommends maintaining the status quo with commercial support of CME an acceptable funding mechanism, but hold all accredited providers to higher standards as they relate to ensuring quality, evidence-based, commercially unbiased programming that provides a true value, not a provider perceived value, to the participant.	**Accredited CME provider**
It would appear to me that the ACCME is trying to standardize all forms of CME. I have objections to this. It seems to place all CME under the command of ACCME. I do not see the need for this. Commercially supported CME has performed well without commercial bias and with excellent content in my opinion. I have always believed in a pleuralistic approach to any educational (or other discipline for that matter)discipline. I believe that one organization controlling all of any discipline is anti-American and largely bureaucratic. I am a semi-retired physician living on a meager income and cannot afford the ever-increasing costs of keeping a medical license and all the other expenses that go along with maintaining an interest in medicine. I believe that the costs would devolve to the consumer and be ever-increasing.	**Other**
Commercial funding of Continuing Medical Education (CME) has been very beneficial to the medical community as a whole and to me in particular. I work for a college health service and my CME budget for a year is $387. Commercial support of the [redacted] conferences alllows me to attend [redacted] for $35 (16 hours CME hours, Category I), where the speakers are mostly [redacted] and other excellent teaching facilities and the [redacted] talks are free of commercial bias. Similar courses at [redacted], with many of the same speakers, run $450 and up for the same number of credit hours and are not accessible to me because of their price. Additionally, commercial funding supports independent CME companies, several of which I have sampled for their CME and found them to be non-biased commercially. I have used them for CME because they are low-cost options for self-study and helpful for people who cannot afford to go to conferences by virtue of the expense, the income lost, or the the remoteness of their practice. The internet, which is so helpful for those who are far from major medical centers, would have far fewer options for obtaining CME credits if the commercial support were cut. I am well aware that there is the potential for bias in commercially sponsored presentations put on by a single pharmaceutical company and I actively look for it when attending one (which I do rarely). With a few occasional exceptions, I have not found the speakers to be pushing one	**Other**

particular product. Generally they give a pretty even-handed approach to treatment and occasionally I have even heard them say they would not recommend a company's product; usually this occurs when there are several sponsors. The removal of commercial support from CME will clearly make it more "pure" but it will also throttle the dissemination of information and it will impose a heavy burden on those MDs who do not receive much allottment for CME but who still need to earn it for relicensure and for keeping current. With the commercial support, it is relatively easy to to stay current, to find CME resources. Lacking commercial support, the CME will be more expensive and not as easy to obtain. I review CME programs for the [redacted]. I am familiar with ACCME and ACCME standards. I understand and appreciate why this question is being raised. In, fact my Department Chairman, [redacted], when I was a pediatric resident in 1980-82, felt so strongly about this issue of bias that he did not permit ANY drug representatives or commercially supported CME to present any conferences in his department at any time. That said, I am also well aware that commercially supported CME, and especially independent CME companies, have been helpful to many and typically give a non-biased presentation . Single company pharmaceutical firms putting on a talk are more suspect, though I have heard several good presentations from that category. I urge you to consider carefully before you abolish all commercial support for CME.	
Commercial support is always needed if not abused. So far my dealings with ACCME has shown well desingned curses without abused of commercial support	**Other**
Commercial support of CME has run its course. Get rid of it. As in other professions, medical professional organizations (e.g., [redacted]) as well as universities should produce and provide CME content, programs, and credit. Also, as in other professions and skilled jobs, such as the law, medical paraprofessional areas, and the insurance industry, practitioners should pay to take the programs. Free, industry-supported CME has only led to a perversion of the intent of such education. The ACCME is certainly not blameless in this matter. The organizations behind it have created a giant bureaucracy and appointed themselves the czar of it through the ACCME. The formation of other, competing accrediting councils would be a good thing to undo the stranglehold that the ACCME exerts over providers of CME. These opinions come from someone who has produced and benefitted financially from CME program. But the system is outmoded and corrupt. Stop corporate influence, and start charging physicians for the value they receive. Reasonable frees would not be an undue burden on them, and the system would not smell so much.	**Other**
Dear Accreditation Council for Continuing Medical Education, Thank you very much for providing an opportunity for public response to the ACCME proposed changes to: •\tlimiting the interactions between accredited providers and commercial interests, and •\teliminating commercial support of continuing medical education activities We strongly believe implementation of this proposal could have a significant and negative impact on the quality and quantity of independent CME, important to ensure practicing healthcare providers have the knowledge necessary to make up to date decisions and appropriately care for patients. One of the main outcomes of CME is to maintain, develop, and enhance practicing physician's knowledge, skills, and performance to improve patient care. As such, complete elimination of commercial support or implementing the new criteria under which commercial support would be allowed to continue could lead to a challenge for practicing healthcare professionals to maintain licensure and certification requirements. Also, there could be a minimal alternative source of funding to CME offerings in medical community, resulting in a paucity of program offerings that could ultimately have an impact on patient care. Despite the controversies surrounding CME activities supported by commercial supporters, we believe that with appropriate oversight and strict adherence to current regulations and guidelines, high quality, scientifically-sound, and fair balanced CME programs can be funded by commercial supporters. We would like to request ACCME to consider the following options to ensure commercial supported CME activities are free of commercial influence and bias: •\trequire greater transparency into speaker disclosures such as disclosing amount of payments received and number of programs conducted in a calendar year, •\tcap or limit the number of programs or total amount allowed to be supported by pharmaceutical industries per calendar year, or •\tdefine specific communications that is allowed and not allowed between commercial supporters and CME providers	**Commercial Supporter**
I believe commercial support of CME is very important for continued medical education. Without this support, practicing physicians, like myself, would have less access to current practices and advancements in medical science. With proper guidelines and oversight, this system can be an important component of Healthcare in the U.S.	**Other**
I am totally opposed to the elimination of commercial support for continuing medical activities . The present requirements of full disclosure of any potential conflicts of interest are adequate if properly monitored. The audience evaluation as to possible bias on the part of the presenter is also adequate.	**Accredited CME provider**

September 12, 2008 Dear Dr. Kopelow, Thank you for the opportunity to provide the ACCME with comments on its proposals to (1) end CME providers' acceptance of commercial support, and (2) to disqualify from CME faculty "persons paid to create, or present, promotional materials on behalf of commercial interests." In my opinion, the wealth of related comments that were expressed at the AMA Reference Committee Meeting on June 15, in opposition to CEJA's similar recommendation to deny industry's financial support of CME, should have satisfied the need for debate among the medical profession and the education community that you identified in your request for comments. Nevertheless, re: the first proposal, I will comment on the three possible scenarios that you offered, and then offer a fourth for your consideration: 1. the status quo with commercial support of CME an acceptable funding mechanism. This option would not satisfy the criticism of the Senate Finance Committee, nor correct the Public's lack of understanding of the invaluable collaboration between CME providers and the research-based pharmaceutical manufacturers that supports physicians' lifelong learning. 2. the complete elimination of commercial support. This was, in essence, the crux of the CEJA recommendation, which was neither acceptable to the leadership of any medical specialty society, nor to the American Association of Medical Students, the Alliance for CME, or the National Task Force on CME Provider/Industry Collaboration. Without public funding to offset the $1 billion currently given by industry to the CME enterprise, the quantity and quality of CME would decline to unacceptable levels. 3. a new paradigm that would allow commercial support 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 of financial relationships with industry (e.g., US Government agencies). This either implies that CME providers are incapable of meeting the requirements for sponsors of certified medical education, or that the ACCME System of Accreditation is flawed. b. 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 Form) of the learner's own practice. This ignores the improvements being made through the AMA's developing requirements for Performance Improvement (PI) activities, and similar initiatives of specialty societies being developed for Maintenance of Certification (MOC) requirements. 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). This also denigrates CME providers' ability to effectively conduct needs assessment for their local area physicians, whose practice gaps may not parallel an aggregate national perspective. d. When the CME is verified as free of commercial bias. This requirement is clearly stipulated in the ACCME Standards for Commercial Support, which have been revised repeatedly to strengthen CME providers' independence to conduct unbiased, evidence-based CME since the Standards' origination in 1992. The alternative scenario we recommend in place of the above three is for the ACCME to empower accredited CME providers by: • raising the Public's awareness of the critical role that providers play, under the capable guidance of ACCME, in ensuring that all physicians are kept up with the leading edge of evidence-based medicine, including that which involves pharmaceutical advancements; • enforcing the Standards for Commercial Support of CME through more commonplace and rigorous monitoring of both live activities and enduring materials, both off- and online. Confirmed infractions, if repeated, should result in immediate loss of accreditation; and • lastly, allowing providers access to the world's largest repository of pharmaceutical information: the research-based manufacturers and their clinical investigators, who often have proprietary information, but who always have the ethical obligation to share that information with peers for the exclusive betterment of patient care. Additionally, knowing that the ACCME will need incremental staffing to implement a thorough monitoring function, and to fund development of an effective Public Relations program, we suggest having accredited providers include an ACCME "surcharge" in budget estimates for certified activities that will be funded by commercial grants. The resulting increased cost to supporting companies should be acceptable, given the alternative of compromising the CME enterprise at the ultimate expense of the patient. Neither research-based pharmaceutical manufacturers nor practicing physicians can remain independently viable in today's increasingly transparent, information rich medical environment unless their seemingly divergent interests unite on patient welfare. To restrict accredited sponsors of CME from providing physicians with leading edge knowledge is not in the Public's best interest. As [redacted] observed years ago, "Principal clinical investigators who direct major research programs and receive substantial economic support from industry must be highly knowledgeable in the area in which they work. They are often aware of confidential information that industry has made available to them. Therefore, clinical investigators uninvolved with industry may be significantly less knowledgeable compared with the individual who receives corporate support."1 [redacted], [redacted], expressed a similar concern: "It is critically important to inform physicians about new research findings. In many cases, the most up-to-date information is held by commercial entities."2 Ironically, it is also the commercially supported clinical investigators from whom most practicing physicians want to learn, either in regulated (commercially sponsored) or unregulated (CME) educational activities. Just for clarification, "promotional" is actually a misnomer, in the context used in your Call for Comments. Both pharmaceutical companies' product-related communications with physicians, as well as CME providers' independent activities, are first and foremost educational. Thank you again for the invitation to contribute proactively to these important issues. We would welcome future opportunity to participate in the clarification of industry's role as supporters of	Commercial Supporter

empowered accredited CME providers. As was mentioned in the CEJA Reference Committee Meeting three months ago, there have been significant advances made enabling CME providers to produce unbiased educational activities that readily withstand expert critical evaluation by the learned participants. That evidence of effective self-regulation under the current ACCME Standards and the resulting benefits to patients should be communicated to the Public. Sincerely, [redacted]	
To Whom It May Concern: I do not believe it will be a benefit to anyone eliminate commercial support for continuing medical education. Who is proposing such a short sighted limitation on doctors anyway? Surely we physicians can use all the help we can get to keep us up-to-date with information that can benefit our patients. We are not millionaires contrary to what the general public , lawyers, and the business world seems to think. Government for instance clobbers the average family physician with all sorts of regulations, taxes, and now mandates for an electronic medical record. There are many that will not be able to afford to continue.... In short I want to say that it has been a blessing for the medical profession to have these contributions toward medical education and in my humble opinion if cutting off help is proposed it can only be coming from someone who doesn't know its like to be in the trenches and walk the walk. I'm all for the ensuring of quality content.... but it doesn't make sense to limit the aid with which to achieve improvements in such quality.	Other
As a solo practicing MD struggling to negotiate arcane insurance company denials AND pay my student loans, I sometimes think about just quitting. I enjoy the online CME I get from [redacted] and [redacted], and I couldn't make it if I had to find an extra few thousand bucks a year to get my required CMEs. [redacted]	Other
CME represents a great benifit for the latest information for patient care. This educational service has been very high quality and has been free of commercial bias. Accordingly, I feel that it needs to be continued.	Other
Continuing medical education is expensive, both for registration and for the lodging and food costs. The increase in the price of travel has added to this burden. Intelligent use of available funds would do well to lessen the cost of those seeking evidence based information. As many medical schools have sought to use CME as a profit center, with mediocre presenters, their monopoly is not acceptable. Any arrangement, without commercial bias would be better than draconian measures to benefit the comfortable.	Other
Dear Council Members: The elimination of commercial support for CME will have a negative impact on the quality and quantity of CME available to practicing healthcare professionals, and therefore negative impact on patient care. The new paradigm scenario under which commercial support would be allowed to continue is not a reasonable remedy. I recognize that the current system can be improved through minor adjustments and therefore I encourage the ACCME to maintain the status quo, with commercial support of CME remaining an acceptable funding mechanism. Sincerely, [redacted]	Other
Gentlemen: I am writing in response to the recent "Call for Comment" by the Accreditation Council for Continuing Medical Education (ACCME) proposing the alteration or elimination of commercial support for continuing medical education (CME) activities. I do not favor making changes to a system which is providing opportunities for me to gain additional information with minimal direct cost to me. This is especially important to those of us who do not reside in major metro areas or near medical schools. As a board-certified medical sub-specialist, I am fully able to sift commercial (and academic) bias. My colleagues seem equally well suited to this task. The consequences of altering the manner in which CME activities are presently funded would have significant effects on learners like me, ultimately resulting in fewer options for learning. Unfortunately, this makes it look as if the major portion of available education would ultimately be of a promotional nature from the pharmaceutical and device companies. Physicians deserve to have a full range of options available to them to maintain currency. Even medical academia is biased, so making this sort of change merely shifts the bias. Additionally, the decision could also limit the availability of activities to address the requirements of Maintenance of Certification and Maintenance of Licensure. I believe this decision could have a significant impact on patient health outcomes in my practice. With more limited CME activities to choose from, especially in smaller communities such as mine, we will have substantially increased difficulty accessing information regarding evidence-based treatment options in disease states where newer interventions may involve off-label uses, or where the science behind novel therapies may soon fit into our patient treatment plans. The decision to eliminate or restrict commercial support could have a great impact both on the quality and quantity of CME available to practicing healthcare professionals, and also on patients, ESPECIALLY IN SMALLER COMMUNITIES where CME is probably more needed than anywhere else. The same can be said for the "new paradigm" under which commercial support would be allowed to continue. I encourage the ACCME to	Other

leave a good thing alone! Allow commercial support of CME to remain an acceptable funding mechanism. Allow the free market place of ideas to remain open. Respectfully submitted, [redacted]	
I think there should not be elimination of this support as an md I find the informaton valuble timely and easily available plus less financial burden on already taxed primary care	Other
I think this medical education program improve our knonledge in very usefull form and in our practice. I believe the importance of continue with the same form of this activities. Thanks.	Accredited CME provider
Not a good idea! A reform designed to eliminate commercial support completely would be couter-productive. Industry is a partner in all health systems and what it offers to physicians is not all evil. I have attended excellent sponsored meetings with no commercial pressure. In addition I cannot see how medical and other scientific journals and societies (that organize their editorial and meetings without commercial biases) could survive.	Accredited CME provider
Physician Assistants are required to have 100 credit hours every two years to maintain our liscense. Many PA's work in private practice and do not have or have limited employer paid CME expense accounts. Without the pharmaceutical sponsorhip of education activities keeping the cost of cme at a reasonable level, it will be financially impossible for most PA's to maintain their liscense. Seven years ago I founded the [redacted] group. Its major purpose was to provide quality continuing medical education to this group of [redacted]. At that time it was difficult for [redacted] PA's to access the educational activities specific to our field. I have been responsible for planning six annual [redacted] cme conferences and many cme dinner meetings. There is a strict code of ethics in terms of non-biased presentation of information. We program developers take this duty seriously. Lectureres are well aware of this standard and are required to maintain this despite having a financial connection to the sponsoring company. Also, it is paramount to understand that the attendees are well educated and experienced as to what is and is not acceptable at these functions. They demand a full spectrum of information including all treatment options. The designers of these changes have taken a paternalist view towards the provider/pharmaceutical company interaction. I'm offended at the notion that patients would benefit from 'protecting' the providers from the undue influence of pharmaceutical companies. I don't write prescriptions depending upon what pharmaceutical's company's name is on the pen in my lab coat pocket. The current pharma guidelines work well. Further restrictions in this area are counterproductive.	Accredited CME provider
Please continue the current policy. The information is a helpful summary of current drug information. Thank you [redacted] one of many physicians in private practice who try to learn from all sources what can be of help for the patient.	Other
September 12, 2008 Board of Directors Accreditation Council for Continuing Medical Education 515 N. State Street Suite 1801 Chicago, IL 60654 RE: Call for comment on the independence of sponsored CME To the ACCME Board of Directors: The purpose of this letter is to respond to the ACCME “Call for comment” on the independence of sponsored Continued Medical Education (CME) programs, and to submit a potential solution for ACCME consideration. I am a physician, educator, and clinical investigator. I have participated extensively in CME programs as both a learner and a presenter, and therefore I have insight into the current state of sponsored CME from both perspectives. It is axiomatic that effective CME for medical practitioners is vital to healthcare improvement. However, producing high quality CME programs is very expensive, and industry sponsors now bear most of the financial burden. Recently, certain groups (including the Senate Finance Committee) have suggested that financial conflicts of interest between industry sponsors and presenters are a major threat to the integrity of CME, and the presence of commercial bias in CME presentations could potentially influence the care provided to patients. According to the June 11, 2008 “Call for comment” announcement, it is the position of ACCME that: (1) new methods for verifying that CME presentations are free from commercial bias are needed; and (2) the “manner of interaction” between parties (e.g. sponsor, CME provider, and presenter) “may need to be altered”. I agree with this assessment, and I applaud the ACCME for taking action to eliminate any concerns over CME integrity. The “Call for comment” announcement also indicated that the ACCME was seeking submission of alternatives (a “new paradigm”) for commercial support of CME. The purpose of this letter is to propose the core elements of a new model for sponsored CME that not only represents a viable alternative to the current model, but perhaps could also serve as the new paradigm that the ACCME is looking for. I believe that the ideal model for sponsored CME must incorporate a separation between a presenter and commercial interest sponsor in which the presenter is BLINDED to the identity of the sponsor. Ideally, the presenter would be blinded to the identity of the sponsor throughout the entire process (i.e. until the presentation has been delivered). If, however, this would not be possible or desired in the eyes of the ACCME, then the presenter should (at a minimum) be blinded to the identity of the sponsor until the content of his or her presentation has been determined and finalized. Anticipated Question #1: Why is blinding the presenter necessary? The process of “full disclosure” (i.e. full	Other

disclosure of the source of sponsorship) is simply not enough to eliminate bias or the appearance of bias. The inherent and fatal flaw with the full disclosure model is that the presenter will always know who the commercial interest sponsor is when he or she is creating or delivering the content, and the presenter could potentially be influenced by this. It can be very challenging to detect if any bias, either consciously or subconsciously, has infiltrated a presenter's presentation. Even if a presenter is able to maintain balance in a CME presentation, it is impossible for the presenter to be unaffected by knowledge of the commercial interest sponsor. The essence of the program has been fundamentally changed (i.e. biased) by the knowledge of the identity of the sponsor. Therefore, under the current paradigm for CME sponsorship, a sponsored program can be balanced, but by definition it cannot be unbiased. Alternatively, if the presenter is blinded to the identity of the commercial interest sponsor when the content is finalized or delivered, the potential for bias is effectively reduced (or even eliminated). This is the fundamental principle of the blinded sponsorship model that I propose. Anticipated Question #2: From a practical standpoint, how could effective blinding be accomplished? There are multiple potential (and feasible) methods for implementing a model of blinded CME sponsorship. Because this web-based mechanism for online submission of comments to the ACCME does not allow for inclusion of figures, drawings, and other supporting documents, I am not able to submit a detailed description of my practical vision for a blinded sponsorship model. However, I have done a great deal of work in this area, and I have devised very specific ways of executing the blinded sponsorship model using, for example, a web-based interface that could serve as a separation between a source of funding and the presentation being sponsored. I would be happy to elaborate on my work in this area if so desired. In conclusion, I would like to thank the ACCME for the opportunity to submit these comments, and I hope that my insights will be of use to the ACCME in its efforts to help ensure CME independence. Although I am not a member of your organization and I can only make suggestions for your consideration, I fully recognize that effective CME is a vital element of healthcare improvement and therefore I would welcome the opportunity to collaborate with the ACCME on new solutions to protect CME integrity going forward. Please do not hesitate to contact me. [redacted]	
Sirs: I respectfully disagree with the proposed changes to the ACCME policies for accreditation. As noted in the proposal, "some conflicts of interest are irreconcilable". The most concerning episodes of bias in both research and CME activities of late have been due to either blatant dishonesty (lack of candor in reporting data or in reporting potential conflicts of interest) or simple error. Neither of these causes will be corrected by the proposed policy. The solution to the issue is to continue to require complete transparency in the development and presentation of CME accredited programs. The current policy defines potential causes of conflict of interest and sources of bias, but this should be expanded to include the examples given in the policy explanation as well as all other sources of bias (eg funded research, vanity publications etc.). Allow physicians to sort out the reliability of the information based on the source rather than further limiting the sources. Bias, per se, does not mean that the information is incorrect.	**Other**
To whom it may concern: My comments are in response to your request for opinion regarding the proposed elimination fo commercial support for CME activities. After careful thinking and analysis of the proposal,it is my desicion to recommend that commercial support for CME activity is NOT ELIMINATED. Having been a receipient of many learning programs funded through commercial support, I can truly report that these were very beneficial to my medical education progress and to keep me aware of the latest evidence base medicine data and the latest updates on standards of care. Perhaps some adjustments to the current system may be in order but to eliminated altogether would be, as the expression goes, "throwing the baby with the bathwater". Please consider my comments when arriving to a decision on this important subject which has significant repercussions on healthcare providers such as myself. Respectfully, [redacted]	**Other**
Without commercial support,many professional,no matter what field of expertise would be very short changed in educational oppurtunities currently being provided. Commercial support provides experts in the fields requiring continual updated information to continue keeping current in professional areas (medical,for example). Everything educational oppurtunity can not be taught by sitting down in front of a computer. Live presentations provide back up to information from Internet offerings. Also, time away from is very limited to current budget crunches so oppurtunities offered by commercial support are very welcomed. I attend many of these offerings throughout the year when my schedule allows and I am always impressed by the presentation offerd to me. I would very much prefer this commercial support to continue as currently being provided. Thank you for this oppurtunity.These offerings are the only learning oppurtunity that is available to me because me employer is very selective as to what we attend.	**Other**

"We are writing to voice our disagreement with the proposal by the ACCME that the commercial support of continuing medical education end. We agree with the statements made by the Council of Medical Specialty Societies and the Alliance that the elimination of commercial support for CME will result in more unregulated promotional education aimed at physicians and less high quality continuing medical education. We believe that properly administered and supervised commercial support of CME is important to the success of many accredited CME programs. Without this support, the education opportunities for physicians will decrease, possibly significantly." [redacted]	**Accredited CME provider**
•\tComments by [redacted] supports the first scenario 1) the status quo with commercial support of CME as an acceptable funding mechanism with more transparency built into the process. At this point there does not seem to be a Plan B for some accredited providers who receive commercial support, e.g., in the state of Texas, constitutional rule does not allow continuing education to be a line item in a medical school budget. o\tRegarding the proposed new paradigm (scenario 3) for situations that could receive commercial support from pooled funds, it doesn't seem realistic to limit commercial support funds to topics or projects that meet the criteria of specific organizations. The data and guidelines of these organizations can certainly be utilized; however, many providers develop CME based on professional practice gaps of their own learners assessed through in-house quality data or system failures, for example, and provide education that results in improved patient care. o\tCommercial interests should be encouraged to set aside funds for topics not related to a therapeutic area of their respective company. o\tIt appears that commercial interests are changing processes to reduce potential bias, e.g. online grant applications and compliance with new PhRMA Guidelines.	**Accredited CME provider**
•\tSuch a consideration undermines the current rules and regulations already established by the ACCME to prevent and control perceived bias in our CME activities that all accredited providers diligently abide by. •\tIt is as though legitimate, "play by the rules" providers are being penalized for those companies that are not following the current standards and guidelines. This change in policy regarding commercial support should only apply to those that are caught not following the rules, not to all providers. •\tNot enough time has elapsed since the new policies and accreditation criteria have been in place for an objective assessment of whether these new policies are eliminating bias in CME; why is there such a crisis? •\tIn the proposed new paradigm, we reject the notion that other agencies that do not receive commercial support–which we would be required to use as a basis for identifying needs—would be considered unbiased b/c they are free of financial relationships with industry. •\tIf the new paradigm were in place would the ACCME eliminate its new proposed increase in provider fees and personnel for the purpose of oversight of companies receiving commercial support? •\tThe new paradigm limits the following: the breadth and depth of current/future CME providers; innovation in types of activities developed; breadth of therapeutic areas covered for CME activities [ie, less education on orphan-type diseases and more on the top diseases: cancer (mostly solid tumors), HIV, etc]—ultimately, it will be the patients who suffer because their health care providers will not have access to state-of-the-art, meaningful, and free education that is relevant to their needs, clinical practice and improved patient outcomes. •\tHas consideration been given to conducting a study of any countries that have adopted a "government run" education plan for healthcare providers/physicians (eg, New Zealand)? Perhaps an evaluation of such countries and their healthcare systems or whether physicians go outside of their country to find useful/quality educational programs may shed some light on what would happen in the United States if such a new paradigm were adopted. •\tWe suggest that certified providers forge relationships with government agencies, medical societies, and other disease advocates to develop sound educational programs. The certified providers have dedicated resources necessary to develop and implement timely educational initiatives. We can also provide the necessary support to these agencies, societies, and advocacy groups to obtain funding from multiple supporters, which include grant writing, web-site submissions, needs assessments, validation with experts, etc. The groups noted above have a wealth of information that would be helpful in identifying the need, the audience, demographics, and preference of learning styles.	**Accredited CME provider**
1. The cost of CME is continuing to rise as is the cost of transportation to go to these and the associated hotel cost. I believe that the need to keep these fees as low to physicians as possible is important. 2. Are there any other professional that don't allow advertising boothes at their conventions? Even teachers and attorneys have these. I believe the current system works well and you should not change it. We, as physicians, can make common sense decisions and wed out the commerical support.	**Other**

1.Status quo with commercial support of CME an acceptable funding mechanism. We believe that commercial support of CME should remain an acceptable funding mechanism. ACCME has spent significant time and effort in the development of Standards for Commercial Support. Many providers have spent significant time and effort developing processes that support the SCS. In our opinion, providers should continue to diligently work within the SCS and ACCME should use the existing SCS to measure compliance. In the report ACCME commissioned, The Relationship between Commercial Support and Bias in Continuing Medical Education Activities: A Review of the Literature, ACCME reports that there is no evidence to support assertions that commercial support of CME produces bias. Therefore, there doesn't seem to be a need to completely eliminate commercial support at this time. We all need to be cognizant of the perceptions concerning commercial support, but we also need to demonstrate that accredited CME is independent and in the best interest of the public. 2.Complete elimination of commercial support. We are directed to use evidence-based information as content in our CME activities. Based on the ACCME-commissioned report, there is no evidence to support assertions that commercial support of CME produces bias. In our opinion, we should not force complete elimination of commercial support. 3.A new paradigm where ACCME accreditation will continue to reflect only what is in the best interests of the public. 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. a.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 b. 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 c. When the CME content is from a continuing education curriculum specified by a bona fide organization, or entity, (eg, AMA, AHRQ, ABMS, FSMB), and d.When the CME is verified as free of commercial bias. 4.Alternative to #3. Mechanism to distribute commercial support derived from industry-donated, pooled funds. We feel it is unnecessary to change the paradigm of accredited CME at this time. The current Bridge to Quality paradigm focuses on improved professional competence and performance and improved patient care. Based on the overall healthcare environment, including Joint Commission, CMS initiatives, etc., it seems we would be best served focusing our efforts in this direction. Ultimately, we may need to modify some things along the way, but we don't feel that the CME paradigm should be changed to address perceptions that don't apply to the majority of accredited CME. The best interests of everyone may be met by focusing our attention on meeting the criteria of the current ACCME model. In our opinion, it would be more beneficial to demonstrate the benefits of accredited CME. This evidence will significantly help to dispel \tmisperceptions of those outside the industry.	**Accredited CME provider**
ACCME Call for Comment On Industry Funding of CME Activities [redacted] Response Submitted by the CME Subcommittee 9/12/2008 There is no place for commercial bias in the practice or science of medicine as the ACCME frequently emphasizes The [redacted] echoes these sentiments strongly not just by statement but by practice. Within the past few years, sweeping changes have been made in the organization to ensure that we reach the goal of an organization devoid of industry influence as much as possible. Examples of the [redacted] drive to achieve this goal include: 1.\t1). Virtually 100% compliance with an online conflict of interest survey for all presenters at [redacted], including all authors in a string. 2.\t2). Through the [redacted] CME subcommittee, every educational activity sponsored by the [redacted] undergoes a careful review from inception to completion and follow-up not only for educational activity content but for conflict of interest. This includes written work, oral presentations and online activities. 3.\t3) Initiation of CME programs is by members or educational organizations (medical schools and centers); when the program is established, the [redacted] then seeks potential support. 4.\t4). A detailed means of guarding against and correcting real or perceived COI is carefully documented and utilized within the organization in order to avoid commercial bias. On the other hand, to completely dispense from accepting industry support for medical activities is self-defeating. It is not our belief that all industry represents an evil empire where their only mission is the sales of product at any cost, even at the sacrifice of virtuous medical practice and research. To completely remove industry support is to create the potential for serious consequences involving vital education for health-care providers. For example, in times when leaders in the medical field bemoan the end of academic medicine, in no small part because of trepidation of investigators losing research support, industry supplies a potentially valuable resource for keeping research careers alive. Another example includes the high cost of educational activities in terms of attracting top medical educators from far distances to lecture, and the price and complexity of organizing complex educational venues such as in symposia or meetings. Furthermore, many of the important breakthroughs and research in medicine come from industry and to silence their contributions by so completely excluding them may in fact hurt rather than improve medical care. As a result, the [redacted] feels that a new paradigm is the only means with which to continue to improve our education and training program is with industry as a partner rather than a foe and yet without their potential of commercial bias. The [redacted] has taken many steps to ensure this. Currently, proposals are being tested using a general contribution fund from industry which we will fund all educational programs regardless of topic and speaker. This will achieve greater separation of an individual company from a desired speaker. An [redacted] internal speakers' bureau has been proposed and is being evaluated: all [redacted] speakers will belong to a single speakers' bureau funded by a general industry contribution pool rather than attaching	**Accredited CME provider**

specific speakers to specific companies. Finally, the [redacted] feels that without engaging the opinion of industry leaders, these important policy decisions about commercial funding are being made in a vacuum. Toward this end, the [redacted] is proposing a joint conference among industry, the [redacted] and ACCME leaders to have frank interchange on this important subject. It seems reasonable to conclude that industry leaders do not want to be seen as corrupters of medical practice and research any more than we want to allow them to assume this role. Indeed, the fundamental rules of decision making and derived personal benefit make it difficult if not impossible to completely avoid a conflict of interest. The [redacted] agrees with the ACCME in the inexorable pursuit of eliminating COI but in the form of a relationship with new, clearer parameters. Such a shift in practice should be implemented on a schedule with clear parameters for grandfathering support received prior to the new rules taking effect. Industry offers valuable tools to medicine; the current debate should be about deriving these benefits within reasonable boundaries, to the benefit of improved patient care.	
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.\tWhen 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.\tIf 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.\tWhen 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.\tWhen the CME is verified as free of commercial bias. [redacted] 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 [redacted] mission is to educate our members — [redacted] – this is one of the four strategic objectives of the organization. [redacted] 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 [redacted] 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: [redacted] 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: [redacted] 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 [redacted] 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: [redacted] 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, [redacted] 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, [redacted] 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	**Accredited CME provider**

provide appropriate quality care for their patients; and to offer patients anything less would be socially and professionally irresponsible. Additionally, [redacted] 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. [redacted] 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.	
ACCME should not adopt the proposed criteria at this time. The recent review of literature commissioned by the ACCME examining the presence of bias in commercially supported CME activities does not support nor refute the notion that bias exists in those activities. Data does not exist to suggest that the current Standards for Commercial Support are not effective for the majority of CME providers. A ten percent non-compliance rate should be of concern. But does this suggest more restrictive regulations should be adopted at this time? If CME is to be a “Bridge to Quality” perhaps the ACCME should approach the issue utilizing quality improvement science. That would suggest first examining the system to see if it is in control. In that examination some variation will be found. Some of that variation will be special cause variation. Systems and processes should not be changed to address special cause variation. Changing systems by addressing only special cause variation is tampering not improving. If there is a consistent source of variation in the system that variation needs to be “fixed” first. That means addressing the part of the 10% non-compliance that is not special cause variation. With this done the system could be found to be in control. Only systems in control can be systematically improved. There are very robust tools available from improvement science to use in improving systems and the component processes that comprise the work of systems. If that important work has not been done any suggested changes as sweeping as that suggested by the ACCME has to be viewed as tampering and not improvement. Don’t go there.	**Other**
Agree	**Accredited CME provider**
Although the formation of a "pooled fund" from industry to support CME activity would be a clear separation of industry/CME, industry must be given some "carrot" to entice them to do this. This "carrot" may come in the form of display time/space that would not be pre-advertized but would offer them access to specific groups participating in the CME activity which parallels their interests/products. To simoply have an amorphous "pool of funds" with no access to participants would be a formula for failure. CME acitivities are expensive now: this would drive the costs to unattanable levels	**Accredited CME provider**
As a clinician and educator I find it rather disturbing that the ACCME would consider that, elimination of industry support for CME may improve the end product i.e.disemination of unbiased medical education. If this misguided regulation of medical education comes to pass,we will then be left with pharmaceutical company sponsed programs to educate the vast majority of community based physicians. Over the years as in any industry I have an opportunity to work with many CME companies which receive support from the pharmaceutical industry.The majority of these providers have delievered valuable unbiased CME programs to many community clinicians whom have little opportunity to leave their small pracitces to attend weekday CME venues. I would propose that a more appropriate consideration would be for the ACCME to develop a working relationship rather than an adversarial relationship with both industry and CME providers. In the end the most important outcome should be to education our providers of care regardless of the source of support.	**Accredited CME provider**
As a medical specialty society, we feel the proposed criteria are very troubling because they would disqualify much of the educational venues our members have enjoyed and need. Eliminating commercial support will make it very difficult to provide the scope of educational activities our society provides to our members and the medical community as a whole. Our members are involved in the creation of the evidence that becomes the basis for evidence-based care guidelines and performance measures as well as the writing of the measures themselves. But many of the conditions our members treat – which can have serious consequences for those affected – do not yet have a wide enough knowledge base to have established performance measures and care guidelines. In some instances these therapeutic areas can present a greater need for physician education because of the limited knowledge available. By making it impossible for continuing education in sub-specialty areas to receive commercial support, specialty and sub-specialty care could ultimately suffer. Furthermore, as we are in the era of Maintenance of Certification for physicians, we need to provide more opportunities for busy physicians to earn CME and participate in a variety of accredited activities. Of course we believe in and support the concept that these activities are devoid of commercial influence, but the requirements listed above are too strict and will seriously imperil our mission as a professional society.	**Accredited CME provider**

As a physician responsible for accrediting CME content, I wish to comment on your “new paradigm.” 1)How can you imagine that “government agencies” (and academia as well, for that matter) are “free of financial relationships”?!!? Our industry has already given a green light to direct providers of medical care (hospitals and clinics) for similar fanciful ideas. Believe me, there is no philosopher-king out there who is above Congressional accusations, unless it is Congress itself. Shall we hand the entire industry over to the Senate Finance Committee? 2)Is the mechanism in place to transfer all needs assessments to a small group of “bona fide” performance measurers such as the National Quality Forum (Your article says “Form”) and assure that they are and remain unsullied? 3)Are the “bona fide” entities you list prepared to “specify,” in a timely fashion, the content of every CME curriculum presented to them? I thought this was the function of the ACCME. And how will their integrity be verified? Does this requirement subsume a dramatic reduction in the quantity of CME activities? 4)What exactly is a “continuing education curriculum”? Is it an MedEd company that has been accredited by the ACCME, or is the entire ACCME accreditation process to be scrapped and rebuilt under some other initials? Or perhaps it is every single activity that must be “verified as free of commercial bias” by yet another gaggle of bureaucracies with impressive initials. Certainly the entire industry is running scared from Senator Grassley, but should we commit suicide to avoid death by bureaucracy? As our representatives, the ACCME and associated initials have an obligation to negotiate as little change in our direction as will keep the “omnipotent moral busybodies” off our backs. What you need is an honest and open discussion (behind closed doors) with the commercial supporters. Go where the money is. How far back do they intend to pull to deflect Congressional scrutiny? How can we more exactly focus on their needs, which should be to educate when they have a better product and advertise when they have a “me, too” product? What is their stake in objective CME (like the Merck Manual)? How important (in dollars) is the goodwill they generate from unbiased educational activities? You cannot just imagine solutions on your own. Collaborate with the drug and device industry; do a needs assessment; ask your lawyers how to bamboozle Congress; budget out a solution in dollars and cents; buy a few politicians. Ending commercial support for CME is throwing the baby out with the bath water, and it is the death of the ACCME as well as many MedEd companies. (The opinions expressed here are solely those of the writer and do not necessarily represent the company for which he works.) Regards, [redacted]	Other
As a practicing clinical physician, Director of Medical Education at my local community hospital and a member of several speaker bureaus, I have a unique perspective on Commercial Support issues. I believe Commercial Support does have its place in CME activities. The proposals would have unintended consequences and, beginning with # 1, do not seem like a good idea to me. What specifically am I concerned about? 1) Use of government agencies to regulate CME on a micromanagment or approval level is a terrible idea. Think about it, do you really want a third party to regulate what consistutes CME? The same way a thrid party already regulates payment and delivery of medical services? This would add more bureaucracy and distance clinicians from information needed to care for their patients. We see how efficient the government already is at solving healthcare issues and we invite them to do more??? 2) The money for CME has to come from somewhere. Given the efficiency of corruption developing in our government, I would think that somewhere in the government chain of regulation may be an inroad for undue influence on CME, ie., someone in the agency overseeing CME may be paid by a lobbying group for pharma or by specific pharma companies to allow exceptions to support or to allow support to occur in hidden ways. The FDA has already been under investigation for undue influences by pharma in their rate of drug approvals before the Cox-2 debacle. 3) Imagine how the government will have to approve your CME program... ie., I cannot think of any good outcome for this to allow a local community hospital to substitute a last minute CME program change when there is a cancellation of speakers. I know how long it takes our state medicaid to process a Prior Authorization for a medication -- do we want the same headache for CME approval when we have to make changes in plans??? No, this never occurs in a CME Grand Rounds program, right??? 4) Letting the government agency decide CME basically abdicates our responsibility to our patients. If we do this, I fear the consequences will be similar to letting a third party decide what tests are necessary for patient care and what drugs may be given... I have many other thoughts on this matter, but the above will suffice for now, thanks. Please note that opinions expressed are NOT on behalf of my affiliated community hospital (an accredited CME provider), only for myself. [redacted]	Other
As a provider, I get quite a few updates and inservices on medications by medical professionals thru sponsors. We are all busy individuals and attending seminars is not always an option.	Other
As a semi retired physician the cost of CME's can be prohibitive but I still need them to stay licensed. I have been using [redacted] and found the articles to be fair and balanced, unlike Fox News. They do their own screening and we submit comments as to the objectivity of the learning. I do not want to lose this support and as other independent teaching companies will take over and change exorbitant fees for their CMES as they have in the past. I used to spend upwards of $1000.00 per year to get these credits. If one is not near a teaching institution than they have to pay big time for credits. Thank you.	Other

As the Pharma funded CME has allowed world wide and medical activities through the Medical industry funded CME improves the curriculum of learning. The commercial support to continue to be allowed. CME activities are presently funded would have a profound effect on learners like myself. Newer novel therapies that may soon fit into our treatment armamentarium will be highlighted through to the doctors and Web conferencing to be also to be under the way. Quality and Quantity of CME available to practicing healthcare professionals While I recognize that the current system can be improved through minor adjustments, I encourage the ACCME to maintain the status quo, with commercial support of CME remaining an acceptable funding mechanism.	Accredited CME provider
[redacted] finds the criteria biased toward major national health initiatives, leaving areas that have room for clinical improvement but are not necessarily “certified practice gaps” without this funding source. This would skew the affordability of such programs, thereby limiting the availability of such programs and stifling communication and discussion on innovative solutions to clinical problems. This represents but one of many unintended consequences that may arise with changes to the commercial support mechanism. [redacted] respectfully requests that the ACCME continue to engage in dialogue to conduct significant surveys of all stakeholders (including physician attendees) prior to making any sweeping policy changes. [redacted] asks whether there is truly a need to move from the current policies. ACCME admits that it is improving its monitoring system and taking a more proactive approach. Would it not be more wise to collect data through this monitoring system, analyze the data and determine if there are deficiencies caused by the current policy and them make policy changes based on the outcomes? Discussions of policy changes based on perceptions, rather than facts, should be tabled. Discussions on how to best collect data and analyze the situation should take the forefront.	Accredited CME provider
August 21, 2008 To: Whom it may concern From: [redacted] Re: Funding Question on CME My name is [redacted] I am a Family Medicine Physician who practices in rural New Mexico. CME is a constant challenge for me. I have to travel long distances to attend meetings, at a significant cost. Commercial support for CME allows the option of having CME at home or at the office. Also, this support allows my state organization to secure quality speakers when I do attend the meetings. My desire would be to adjust the current system to eliminate the perceived problems and maintain the help and support of the commercial companies. Thank you. Sincerely, [redacted]	Other
August 22, 2008 Dear ACCME: In this time of declining funding for CME's, I find it very strange that there is a movement to eliminate a potential source. The government certainly is not going to increase its funding. There has been and there will always be commercial bias in CME activities. I think I speak for my colleagues that we are not children. We all have independent thoughts regardless of any commercial bias in any CME's, real or perceived. Besides we need to see and work with pharmaceuticals as friends and colleagues, not as enemies kept at a far distance. After all both of us cannot survive without the other. I most strongly oppose any proposal to eliminate commercial support for CME's. [redacted]	Other
[redacted] If pharmaceutical support for CME, which is now almost always channeled through companies that plan and carry out educational program, is eliminated, there will be a dramatic reduction in CME. It is naive to assume that non-profits such as medical schools, hospitals, and governmental agencies will be able to respond to the loss of funding by the pharmaceutical companies. Additionally, not only will such a ban have a significant negative impact on individual CME programs, but many major meetings sponsored by our large societies (in my case, [redacted] will be faced with drastic reductions in support. The irony of this proposed ban on pharma support for CME will be that "speaker's bureau" lectures will be the only educational programs offered to practicing physicians. I agree completely that oversight of CME must be enforced, and in my experience it is, and that companies that carry out CME programs must be continually vetted, as it seems they are now. However, to simply ban pharma support of CME will be an extreme example of throwing out the baby with the bath water.	Other
C.M.E activities have to be for the benefit of society, with scientific evidence. If they are totally free of commercial motive, they can be supported by funding from any agency. World wide scientific knowledge dissemination is preferable to knowledge access for limited groups, financially capable of such access.	Non-Accredited CME provider
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.\tThe status quo with commercial support of CME an acceptable funding mechanism [redacted] comments: [redacted] supports the ACCME’s 2004 Updated Standards for Commercial Support (SCS) and the AMA	Accredited CME provider

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.\tThe complete elimination of commercial support [redacted] 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.\tProposed 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.\tWhen 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.\tIf 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.\tWhen the CME content is from a continuing education curriculum specified by a bona fide organization or entity, (eg, AMA, AHRQ, ABMS, FSMB), and 4.\tWhen the CME is verified as free of commercial bias. [redacted] 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 [redacted] 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.	
CME support from the pharmaceutical industry is essential for many physicians to get affordable education not otherwise attainable.	**Other**
Comment #2 The [redacted] strongly disagrees with this proposal for blanket elimination of commercial support of CME activities. The [redacted] agrees that the ACCME should lead a dialog that results in a new paradigm for a more appropriate role for commercial support of CME. The [redacted] has participated in the comments created on this subject by CMSS. Our rationale and all suggestions are embedded in those comments. \t	**Accredited CME provider**
Comment from [redacted] While some Texas CME providers have opted to eliminate support for CME from commercial interests for their own organizations, the consensus of the [redacted] was that removing commercial support from the CME enterprise would do little to promote the health of the country. The reality is that accredited CME is the most balanced forum for education, transfer of knowledge, and performance improvement. The commercial support dollars currently invested in CME would be allocated elsewhere – to promotional meetings that tend to be less objective, to direct to consumer advertising and other areas, with less altruistic ambitions. ACCME improved the Standards for Commercial Support℠ in 2004 which have provided an excellent foundation for the separation of promotion and educational content. At a time when CME providers are being rewarded for forming alliances with stakeholders and bridging gaps, this initiative to drive away the companies that develop cures seems naïve and counterproductive. The [redacted] members polled agreed that utilizing the current Standards for Commercial Support℠ with some changes was the most plausible plan. The [redacted] favored the use of additional resources to self-verify educational needs against bona fide performance measures, however felt that requiring approval from unidentified designated agencies would greatly hinder the approval process in terms of time, productivity and financial burden. Rather, conflicts of interest and bias in CME programs should be resolved through increased transparency of all steps in the grant submission and allocation process. Utilizing the proposed mechanisms of audits and verification, the ACCME could more clearly	**Other**

identify the need for specific correction and improvement. At this time, there is no published data that covers the CME enterprise since the full implementation of the updated Standards for Commercial Support℠. In the spirit of continuous professional development, [redacted] suggests a study be conducted by a group (outside of the ACCME) to uncover gaps in compliance. Utilizing the information collected from closer scrutiny of select providers (considered high-risk), studies could be conducted to determine the identified problems of developing quality content with commercial support. Once these gaps are documented, they should be shared with the accredited providers for a full understanding and training. Further measures could then be developed to increase accountability and to mitigate the appearance of impropriety.	
Comment from [redacted] on the ACCME Proposal that Due Consideration be Given to the Elimination of Commercial Support of Continuing Medical Education Activities [redacted] is committed to providing continuing medical education (CME) that is balanced, not influenced by commercial interests, and is in the best interest of patients. The [redacted] appreciates the opportunity to comment on the ACCME proposal to consider the elimination of commercial support of CME. The [redacted] supports the ACCME Standards for Commercial Support (updated in 2004) which provide safeguards to ensure CME is delivered without influence from a commercial entity and includes regulations that require providers to control the content development and decision-making process and to resolve potential conflicts of interests. These standards ensure certified CME contains clinical recommendations which are evidence based, unbiased and in the best interest of the public. Professional organizations are the "trusted intermediaries" for providing educational activities for physicians and other healthcare professions as well as the public. These organizations have members and staff that are experts in their respective medical areas who through full disclosure, resolution of conflicts of interest, and content validation ensure that CME does not contain promotional messages or in any other way present biased information. Insufficient time has elapsed to determine the success or failure of the ACCME Standards for Commercial Support. A need to evaluate the effectiveness of the ACCME Standards for Commercial Support was identified in the report titled, "The Relationship between Commercial Support and Bias in Continuing Medical Education Activities: A Review of the Literature" published June 2008 at www.accme.org. In this report, it was stated that "no studies that directly addressed the question of whether commercial support produces bias in accredited CME activities" have been found. The report further states that the efficacy of the updated standards for commercial support in preventing bias have not been evaluated. It should also be pointed out that elimination of commercial support for certified CME-activities would not eliminate promotional activities produced by FDA-regulated companies. In fact, funds currently earmarked for support of CME activities would almost certainly be re-directed to promotional activities. Based on these conclusions, it is the Academy's position that sweeping changes to the current model not be made until the effectiveness of the ACCME Updated Standards for Commercial Support are measured and deficiencies, if any, are identified. We encourage ACCME to conduct these evaluations to ensure that future recommendations can be supported by necessary data on efficacy. Respectively submitted, [redacted]	**Accredited CME provider**
Comment of [redacted]. on ACCME Proposal: "The ACCME Believes that Due Consideration be Given to the Elimination of Commercial Support of Continuing Medical Education Activities" [redacted] appreciates this opportunity to comment on the new proposals by the Accreditation Council for Continuing Medical Education (ACCME) regarding interactions between accredited providers and commercial interests over support. As the [redacted] has a strong interest in the availability of high quality, objective medical education that is free of commercial bias. We believe strongly that CME should be balanced and objective. However, the ACCME's proposals are so broadly drafted that they will unduly restrict the appropriate interaction between CME providers and the healthcare industry, without improving the delivery of CME. I.\tThe Proposed Restrictions are Premature, Absent Evidence of Bias ACCME has proposed either banning all commercial support for CME, or creating a "new paradigm" in which commercial support would only be permitted if four restrictive conditions are met. As described further below, [redacted] believes that each of these proposals sweeps far too broadly and that rather than addressing the specific concern ACCME seeks to remedy – potential for commercial influence or bias -- they would severely degrade both the quality and availability of CME. A more nuanced approach can better maintain the availability of CME, while also creating better protections against potential commercial influence. As discussed further below, [redacted] recommends that the ACCME: (1) give time for its recent increased enforcement activities to take effect and allow it to better measure the state of CME; and (2) coordinate its effort with industry groups such as PhRMA and AdvaMed, which have their own codes on how their members may support CME, to develop a more comprehensive, and more focused, set of rules than the ACCME could create on its own. The ACCME itself acknowledged, in a recent letter to the Senate Special Committee on Aging that it "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 bias is found	**Other**

in the medical education or regulatory literature." In the absence of any such evidence, the drastic changes that ACCME has proposed are premature. [redacted] recommends that the ACCME: (1) pause in finalizing or implementing any new proposals on CME, to take time to determine whether there is in fact undue commercial influence, whether it has been mitigated by the May 2005 implementation of the 2004 ACCME Standards for Commercial Support; (2) evaluate the results of its recent increased enforcement initiative; and (3) confer with representatives of industry, to determine what collaboration is possible, and to develop more focused, targeted standards for both CME providers and commercial supporters that can improve objectivity and quality without reducing availability of CME. [redacted] supports constructive attempts to improve the objectivity and quality of CME. However, [redacted] opposes a ban on all commercial support for CME. As the ACCME stated "nothing would be worse" than deconstructing the current system without identifying alternatives, or carefully considering the implications of such a radical step. Drug and device manufacturers represent a significant, if not the most significant source of funding for CME. It is not clear what, if anything, could take its place if it were eliminated. It is for these reasons that the American Medical Association recently rejected a proposal by its Council of Ethics and Judicial Affairs (CEJA) recommending that individual physicians, medical institutions, and professional organizations cease accepting industry funding to support professional education activities. Similarly, in a poll conducted by [redacted], a large majority of physicians opposed a ban on industry support of CME. The better course is to consider what improvements or additional safeguards might be put into place for the current system of commercial support. II.\tThe Proposed Restrictions are Impractical, and Would Not Improve the Quality or Objectivity of CME ACCME's proposed alternative of four conditions that commercial support would have to meet is so sweeping as to amount to a de facto ban. Moreover, it is not clear that they would improve the quality or objectivity of CME. The first condition would require that educational needs be verified by organizations that do not receive commercial support and are free of financial relationships with industry, such as the U.S. government. This would eliminate from the process virtually all organizations currently involved with identifying educational needs, including physician societies, whose leadership and members often have financial relationships with industry. Academic medical centers also often have financial relationships with industry that would render them ineligible under the proposed standard. ACCME does suggest the Federal Government as a source to verify educational needs, but it is not clear that this would improve either the quality or objectivity of CME. We are not aware of any coordinated or concentrated effort by the Federal Government to gauge medical education needs across the broad range of practice areas that currently exist. Nor is the government likely to be nimble or responsive enough to continually monitor and update changing needs. Moreover, since the government does not itself develop new technology, and has only limited involvement in treating patients, it will have little first hand experience on where educational needs are likely to arise. Instead, it will find itself reactive, relying on information developed by third parties, and/or from the very physicians, physician societies and others, i.e., the very groups whom the proposed condition would prohibit from identifying educational needs to CME providers directly. Education is much better served when proposals and recommendations for topics can come from a wide range of sources with a wide range of perspective and views. It is also worth noting that the Federal Government is not itself free of potential conflicts of interest. As one of the largest payors for medical technology, the government has an interest in limiting the use and discussion of newer and potentially more expensive technologies. It would have a potential inclination towards CME programs that favored less expensive technologies and discouraged newer technologies, and that might downplay improvements in safety and efficacy. Turning over identification of educational needs to the government alone would merely substitute one perceived bias for another. The second and third proposed conditions – CME must address a practice gap corroborated by bona fide performance measurements such as the National Quality Forum, and have content from a continuing education curriculum specified by a bona fide organization, such as the AMA – would also impose undue rigidity on a system that requires flexibility and responsiveness to doctors' interest and changes in medical and scientific needs. A one size fits all curriculum for content will preclude many important CME topics. Moreover, it is not clear how those limitations would themselves reduce potential commercial influence on individual programs. [redacted] has no objection to the fourth proposed condition – that CME be verified as free of commercial bias – but ACCME should clarify how this broad requirement would be implemented. Certainly ACCME cannot individually verify every CME program conducted in the United States each year. However, a requirement that CME providers must, as part of their accreditation and renewal, affirm in writing that each CME program they conduct is free of commercial bias in accordance with ACCME standards seems an appropriate step. III.\tACCME Should Suspend Development of New Standards, to Evaluate the Effect of Increased Enforcement [redacted] questions whether additional standards are necessary at all. As noted above, the ACCME has not identified any actual evidence of inappropriate commercial bias in CME, so the need for new requirements is conjectural at best. The ACCME already has detailed standards in place governing the development and delivery of CME and curtailing the input of commercial supporters. These standards are supplemented by longstanding guidance from the Food and Drug Administration, policy statements from the HHS Office of Inspector General, as well as industry codes and the internal policies of individual companies. [redacted] believes that the ACCME's standards for commercial support – which already prohibit commercial interests from suggesting speakers or topics, or reviewing program content in any way, and which soon may prohibit industry from even announcing areas in which it believes CME programs are appropriate – should,

when fully adhered to, adequately address any potential for conflict, or undue influence. To the extent shortcomings exist – and as ACCME stated in its letter to Congress, it is not at all certain that they do – they likely arise more from a lack of enforcement of these existing standards than a need for stricter policies. ACCME has itself admitted that its enforcement of current standards has been lackluster. It should allow time to bolster that enforcement role, and gauge the results, before embarking on a dramatic new paradigm or cessation of commercial support. For example, ACCME has set a goal of requiring CME providers found not to be in compliance with its standards to establish improvement plans within weeks of the findings, and verify improvements within a year. In addition, it has committed to a tenfold increase in the percentage of CME providers put on probation. These changes themselves will likely have a significant effect on CME providers. ACCME should pause in its plans to revamp existing standards, and instead allow for a two to three year observation period to assess the impact of increased enforcement effort (since non-compliance findings and improvement plans issued now may take a year to verify, a shorter period will not give an accurate reflection of the changes' impact). At the end of this time, ACCME can better determine whether increased enforcement can itself achieve the goal of improving the objectivity and quality of CME. It will also gain a much more detailed understanding of where any shortcomings in the current system lie. To the extent ACCME concludes that additional standards are needed, the added enforcement experience will better enable it to gauge what specific steps will lead to improvement. [redacted] proposes that during this interim period, ACCME coordinate with associations representing industry, such as PhRMA and AdvaMed, which have their own codes on how their members may support CME. This will lead to the development of a more comprehensive, and more focused, set of rules than the ACCME could develop on its own. ACCME cannot directly manage the activities of commercial sponsors of CME. Therefore, it has proposed terms that are broad and absolute, in an effort to restrain manufacturer activities over which it does not have direct authority. However, commercial sponsors can themselves set voluntary codes of self-regulation to modulate their activities with regard to CME in a more focused way. If the ACCME and industry collaborate to each develop standards, they can develop a system that is both stronger and more workable, which limits commercial influence while still preserving the availability of funding and the free flow of information.	
Comments: 1.\tIf "conditions" are to be adopted at all, it seems the order of the "conditions" is wrong. Shouldn't the first "condition" be related to practice gaps? If there is not a practice gap it seems there would not be an educational need. No educational need suggests that no educational intervention is required. If there is not the expense of developing an educational intervention commercial support is a mute point. 2.\t "Condition" 2 speaks to "professional practice gaps of a particular group of learners". Does that absolve the accredited provider from the responsibility of identifying and assessing practice gaps in their own target audience? And what about the educational needs that may address the gap(s)? Or are we to assume that one size fits all? Variation will exist in practice gaps even among the particular groups of physicians. The probable variability will exist for a number of reasons. Educational needs will also differ within those groups based on the variability in the practice gaps. One size may seem to fit all but there are likely to be enough differences to merit tailoring professional development activities to take into account those differences. Setting a condition for commercial support on this assumption does not seem well grounded. 3.\t"Condition" 1 assumes there are organizations that do not receive commercial support and are free of financial relationships with industry exists that are identifying and verifying educational needs for every physician group in medicine. I don't think that is the case. Does this mean that CME activities for those groups of physicians should not receive consideration for commercial support? Too restrictive. 4.\t"Condition" 2 assumes there are bone fide performance measures of learners' own practices fro every physician group in medicine. We know that is not the case. Too restrictive. 5.\tDoes "Condition" 3 absolve the accredited sponsor from selecting content for its CME activities that receive commercial support? "Condition" 3 assumes there are continuing education curricula specified by bona fide organizations or entities for every physician group in medicine. We know this is not the case. Does this mean that CME activities for those groups of physicians should not receive consideration for commercial support? Unrealistic. 6.\tI agree with "Condition" 4. There is merit in each suggested "condition". Having to meet all four "conditions" to "qualify" for commercial support is too restrictive and unrealistic for some segments of the physician community.	**Other**
Commercial CME should be continued	**Other**
Commercial funding should continue. This funding makes more education available. With the proper restraints and acknowledgements, I as a medical professional believe I have the training education to discern the difference between what works and what does not. We are the ones who see what is happening at the clinic level and we take the moral responsibility of patient safety seriously. We owe to researchers et al to try their solutions or drugs, but we owe it to our patients to stay educated to keep them safe. If a certain article biases a particular method or medication perhaps it would behoove the sponsoring company to also offer content from the opposing view. I believe this is pretty much the case as I have been able to find this info and balance the hype.	**Other**

Commercial providers of education require that it survive. The providers will not survive if they are deemed to be biased, inappropriate or ineffective. I think government or government approved educators will simply provide the government line. Competition is helpful. Most medicos are not so nieve as not to see bias or promotion.	**Other**
Commercial support is critical to ongoing medical education efforts. Unrestricted educational grants are critical to professional societies, most of which are not-for-profit organizations with a large number of academicians. These organizations would not be able to provide a comprehensive CME program without grant support from commercial sources. The [redacted] acknowledges that abuses have occurred in some CME programs, but believe firmly that the vast majority of CME programs, including those co-sponsored by professional organizations, have presented fair, accurate information. It is unclear that accredited CME programs, as well as professional organizations, have not all developed methods to insure the presentation of balanced, valid data. Rather than a new paradigm, we suggest that the ACCME work with stakeholders to develop a set of policies that seek to prevent bias from all CME presenters and organizers. [redacted] is concerned that the new paradigm proposed by the ACCME is impractical and does nothing to address bias from non-commercial sources. In Condition 1, ACCME suggests that: an organization like the federal government decides the educational needs of the medical field. Vetting educational needs might be reasonable when CME aims to provide standard of care information, but it is unclear that CME aimed at specialized fields of medicine, especially those with a heavy focus on basic research, can be assessed in a timely manner by individual who are not active participants in the field. Such assessment is currently performed through co-sponsored educational program that combine CME accredited programs and professional, non-profit medical societies. This allows the most knowledgeable individuals in a given field and to define the most appropriate educational programs with oversight by accredited CME organizations programs. This has been a highly successful partnership with the vast majority of CME programs presenting unbiased work. Even if the US Government agreed to assume this role, it is unclear that any single agency would possess sufficient knowledge to rule on all medical specialties, that decisions by individuals within the government would be free of bias, nor that decision could not be provided in a timeframe that does not inhibit the most innovative fields of medicine. Conditions 2 and 3 cannot be met for educational program that focus on basic science and early Phase clinical trials. To make this a requirement would appear to conflict with the ACCME goal of fostering education in these areas. It is also unclear that the bona fide organizations listed have expertise in defining CME content for basic research and early phase clinical trials; moreover it is unclear that these organizations are not without their own biases. Condition 4, the presentation of CME free of commercial bias is a goal [redacted] shared with the ACCME. Again, [redacted] asks the ACCME to draw on the experience of CME accredited programs, professional organizations, and those experience in peer-review to create policies that prevent biased presentation while preserving free exchange of industry-sponsored medical research and early phase clinical trial data.	**Accredited CME provider**
Commercial support is very important to keep CME's going. I know I depend on the free online CME's. I find them very informative and educational. They allow me to enhance my nursing knowledge at a time and place that fits best in my schedule. I am a full time Mom and a part time nurse and I depend on opportunities like this to keep me up to date on changes occuring in the medical field. Please continue to suport these worthy programs for myself and my fellow collegues who rely on these valuable opportunities. [redacted]	**Other**
commercial support of CME does NOT inapprropriately influence medical practise and is necessary to get CME activity participation to the maximum number of physicians	**Other**
Commercial support of CME is a valuable resource to the quality improvement of the overall healthcare system and patient care that cannot be ignored. No reliable data currently exists that commercially-supported CME is biased, is planned and produced any differently from CME that is not commercially supported, or is under the influence or control of the commercial supporter. There is also no available evidence on the effect the ACCME's 2004 Updated Standards of Commercial Support have had on actual commercial interests' influence on the content of CME. As such, the appearance of impropriety alone has sparked a debate about whether to eliminate commercial support from the CME enterprise. It seems that this is a premature discussion not grounded in actual, identified gaps or needs supported by credible evidence. It also presumes that the elimination of commercial support will eliminate all presumed attempts by commercial interests to influence the activities and practices of CME providers. As a first step, the industry ought to identify ways it can measure the effects, if any, of commercial support on CME and as specifically applied to the various types of accredited providers. Then and only then can the industry engage in a discussion where it can legitimately weigh the costs and benefits of allowing commercial interests to support CME, whether of all types of providers or even of a limited few, and make an informed decision about its continuation. Even assuming, however, that some benefits might be gained by eliminating commercially-supported CME, the costs of doing so to the greater healthcare system can already be envisioned. Monies previously available to	**Accredited CME provider**

the CME industry from commercial interests would naturally be driven to increased promotional activities in an attempt to influence physician behavior. Monies would also be driven to increased direct-to-consumer advertising in an attempt to predispose the public at large to the commercial interest's products and services. Patient care and improved quality healthcare would no longer be the target of these financial resources and could be jeopardized by their redeployment. Available outlets for quality CME would be reduced, as would the actual number of quality CME programs available to healthcare professionals. CME providers would have the tendency to become lax in their accountability to outside third parties and the public at large regarding their educational methods, development processes and outside influences generally. Elimination of commercial support from the CME enterprise cannot be the solution to a problem that no reliable evidence even supports. There is nothing to suggest that the current system (labeled the "status quo" in the call for comment) does not work. Conversely, there is also nothing to suggest that it does work. We do not know what we do not know. Therefore, the first step must be to assess which processes and procedures are working and which ones are not working. Then we can address specific problems as they are identified. Changing the system on the assumption that the current system is not working will do nothing to ensure that the new system will meet the challenges, if any, faced in the current system. Certainly, improved evidentiary standards could be considered and implemented to provide greater proof as to the effect of commercial support on the content of CME. This would allow the CME industry to reach a more informed conclusion as to whether the current system in place is effectively managing the CME enterprise outside the influence of commercial interests. While it is premature to consider a new paradigm, the one suggested, presumably designed to address a problem we have not yet identified or defined, would certainly be a significant strain on the CME community. Additional strain or burden on the CME community may be justified, but because we do not know the problem, we cannot yet know the benefit to be gained from the change, and we cannot weigh the benefit gained against the increased burden. What, specifically, though, would the strain on the CME community be? Basing educational activities on identified educational needs of government agencies is desirable, but requiring verification of educational needs by government agencies would effectively be to turn the CME enterprise over to the government agency itself, which would be inefficient, costly and unduly burdensome. Further, to require that all commercially-supported CME be based on bona fide performance measurements or on content from bona fide organizations would be to limit the content of CME to the therapeutic areas and findings for which measurements exist and on which consensus on guidelines have been reached. The new paradigm would delegate commercially-supported CME to government-identified standards that do not include the most recent findings in medicine. The CME enterprise should be looking for ways to determine the effects of commercial support, if any, on the content of CME activities. The results from that process should drive changes, if any, in the funding mechanism of CME. In addition, solutions to improve the public's perception of the CME industry should be evaluated and considered, including increased transparency of the grant writing and awarding processes, strengthening of activity audits through increased evidentiary requirements of providers, accreditation by the ACCME at the activity level instead of at the provider level, increased accountability within the medical professional communities regarding the CME they attend and for which they claim credit, and employing outside third-party auditors to attend CME activities unannounced.	
Commercial support to continuing education is necessary, however of the three choice - continue as usual, eliminate or provide with the 4 stated guidelines I believe in the 3rd choice. Each professional medical and/or allied health organization should certify that there is no commercial bias and that the courses fill a gap. With the support of medical equipment/pharmaceutical/ exercise equipment/ disease specific associations, etc the availability and quality of continuing education course will possibly diminish significantly. This will limit healthcare professionals in their goal of ongoing education to keep abreast of new areas / findings in their respective fields.	**Other**
Commercially supported venues are an appropriate means of facilitating provider educational activities. These activities do NOT necessary assure that a specific product and/or medication(s) will be prescribed by a provider. Certainly, new technologies offer patients increased choices of health care options, and providers would do well to be as informed as the consumers. It is often difficult for providers to attend meetings other than on their own time. This means attending meetings in the evenings or on weekends. Of course, providers may be asked to pay for food; that is certainly a possiblity. However, eliminating all commercially supported activities is inappropriate. In addition, numerous providers are employed in venues where there are specific formularies, so they may not be able to offer commercially sponsored products. One of the problems I do have with these activities, however, is that often the speakers receive large honorariums...and that is a problem; these are the people who do prescribe those products.	**Accredited CME provider**

Commercially unsupported academic education by university based providers may be just as biased as those provided by commercially supported programs. Both forms of education are pure businesses with different agendas. Centers of excellence have touted themselves with the same zest as the drug and device manufacturers to draw patients and fundings, burnish reputations and provide life long careers for those so privileged to be the leaders in medicine. It must be accepted that clinicians are not trained in the more esoteric exercises in statistical models and methods. Statistics are however general guidelines to groups of patients and may be totally not applicable to the indiviidual patient. Statistics do not lie; liars do. It must, however be accepted that some logical guideline other than hearsay or theoretical guideline must be used. The elimination or suppression of industry supported programs serve only to eliminate debate that the unsupported or even supported industry would engage in. Jurrors in court are not experts as expert witnesses testify, but with testimonies are able to make a decision with fair accuracy. As a clinician with a " hard science background", I find the paternalism by ACCME offensive. It is with comic relief when human weaknesses are revealed by either party. More voices should be included in continuing medical education , not less.	**Other**
Commerical support is vital to sustain CME lectures. The removal would limit physician education opportunities and ultimately hurt patient care. Please do not limit commerical support for CME activities. [redacted]	**Other**
Complete elimination of commercial support for CME is fraught with difficulty for a number of reasons: 1. Many physicians get all of their CME from commercially funded free CME programs; the suggestion that commercially funded CME be eliminated does not consider this aspect. 2. There are numerous accredited providers and MECCs that are making very strong efforts to comply with all the ACCME guidelines and to try to show that CME funded by industry can result in improved patient care. There are also many accredited providers and MECCs that are not adhering to these goals and standards. Completely eliminating commercially funded CME punishes the good providers because of the actions of the bad providers. Enforcing the current standards are more than adequate in insuring fair-balanced CME which is free from bias. 3. Educational needs can be identified by accredited providers if they have sufficient infrastructure in place. To state that only large organizations with no relationships with industry can conduct an assessment of educational needs is unproven, since there are accredited providers that carry out thorough needs assessments to plan educational activities. 4. Professional practice gaps need not only come from professional organizations. One can read the literature and see that it is rife with articles which demonstrate gaps in the treatment of many common diseases. 5. CME content does not need to come only from a large professional organization. Accredited providers with policies in place to write CME content can provide content of similiar quality. Industry has funded CME for many years and has collectively contributed billions of dollars to CME. Most companies now have in place mechanisms to separate themselves from accredited providers. I think that we need to give the current regulations and mechanisms a chance before we eliminate commercial funding for CME. The elimination of commercial support for CME would decimate an entire industry of professionals working in it. Before this is done, I urge that we make sure that this is really necessary.	**Accredited CME provider**
CONFIDENTIAL [redacted] RESPONSE: [redacted] supports the status quo for accepting commercial support of CME activities. Eliminating the ability of medical societies and other similar associations to accept support of educational programming will result in a sharp decrease in the quality and number of CME activities. With respect to the new paradigm proposed by ACCME, the [redacted] stands opposed to the first three of the four conditions suggested by ACCME: 1 – The first condition would prohibit any professional medical societies and other similar organizations from conducting CME Needs Assessment for its members when commercial support might be sought. ACCME provides rules and guidance on the how to conduct Needs Assessments. Like many medical societies, the [redacted] Needs Assessment processes are evidence-based and transparent. Needs Assessments are: •\tVolunteer-Member generated •\tBased on current evidence and literature •\tReviewed in a blinded fashion by the [redacted] Education Committee In addition, the [redacted] conducts a systematic Conflict of Interest Review of all educational offerings to ensure programs are free of commercial bias. 2 – Eliminating CME that is not identified by performance measures greatly diminishes the number and variety of CME programs likely to be offered both because of the limited number of scientifically validated performance measures, and the even more limited range of organizations and institutions meeting the proposed ACCME standards for producing such performance measures. While [redacted] agrees with the concept in principle, applying these standards rigidly at this point in the evolution of our knowledge of measures of medical performance is far too limiting. 3 – [redacted] understands the theoretical desirability of CME content coming “from a continuing education curriculum specified by a bona fide organization, or entity, (eg, AMA, AHRQ, ABMS, FSMB),” however, such is not yet practicable since few bona fide organizations produce such curriculum, and those that do have produced only limited numbers of curricula. With respect to the fourth principle that “CME is verified as free of commercial bias,” [redacted] completely agrees with this requirement. In summary, the new paradigm proposed by the ACCME is based on standards for Needs Assessment and CME that don’t exist today. The [redacted] does not support this new	**Accredited CME provider**

paradigm.	
Considering the costs of outside continuing education, I would strongly encourage the ACCME to maintain the status quo. Patients will suffer considerably and an undue financial burden would be placed on us providers should you discontinue the current system.	**Other**
creo conveniente el apoyo de de estas pero si eliminarlas	**Other**
Date: July 8, 2008 To: ACCME Murray Kopelow, MD MS(Comm) FRCPC, Chief Executive, ACCME From: [redacted] RE: Response to ACCME's Call for Comment Dated 6/11/08 Call for Comment: The ACCME believes that due consideration be given to the elimination of commercial support of continuing medical education activities. The [redacted] would like to make the following observations in reference to the above mentioned call for comment: The [redacted] acknowledges the public pressure that the ACCME has endured regarding its accreditation criteria and realizes that many of these new criteria are being proposed in response to that criticism. However, the [redacted] feels strongly that the existing Standards for Commercial Support are an adequate means of addressing issues related to the proper management of commercial support. We also think the ACCME is better positioned to enforce existing regulations, rather than adding new regulations, which will invite equal opportunity for criticism if they are not enforced. That said, we will entertain the call for comment below. The [redacted] agrees that the debate about industry funding should not go on without discussion of alternatives to garnering this support. However, the [redacted] does not consider any of the proposed funding models to be a 'viable' means for continued funding. Pooling resources would create many difficult scenarios regarding who would manage the pool and, perhaps most challenging, how funding for educational programs would be prioritized, given the wide variety of educational needs and providers. Given the diverse educational audiences we serve, gaining consensus on priority projects would be nearly impossible, leaving many groups with inadequate funding. Additionally, pooling resources from industry will likely result in a shift of resources away from accredited CME education, where they can have the most positive impact, in favor of more direct marketing to both physicians and patients. Item two in this call for comment states: support of individual funding would be allowed, if the CME addresses a professional practice gap of a particular group of learners that is corroborated by bona fide performance measures of the learners own practice. The [redacted] has serious concerns about the reference to bona fide performance measures. Currently, quality measures cover a small percentage of medicine as it is practiced today; to require that all 'fundable' education evolve from quality measures would leave many educational needs unmet. Specifically within the field of [redacted] many treatments do not have established quality measures due in large part to the difficulty in creating effective measurement tools. Additionally, while the [redacted] agrees that the quality measurement movement will affect physicians' practices over time, we are cautious about quickly selecting one measurement model to tie education to; we suspect that systems measures will prove to be as important as individual physician quality measures, and that it is too soon to restrict funding to the latter. As the debate continues to evolve on performance measures we must not restrict ourselves to a narrow definition of quality. Additionally, prohibiting CME funding for new and emerging technologies that lack performance measures may lead to an unintended consequence. Early adopters of new technology are usually small in number. Educating these small groups adds financial risk to non-profit educational products, making the financial viability nearly impossible for such products. A funding ban for this important element of education would limit the amount of training a professional, non-profit organization could offer, leaving the new and emerging technology 'education' to marketing or sales representatives who do not possess the requisite skills and are often prone to the very bias we and the ACCME strive so carefully to avoid. Item three calls for a curriculum specified by a bona fide organization or entity. We observed that the examples provided as bona fide organizations do not include a medical specialty society. The [redacted] believes strongly that the [redacted] and Board of a given specialty should have equal opportunities to define a curriculum for a specialty. Additionally, roles and responsibilities vary among specialties, making it equally likely that a specialty society would assume a leadership role in curriculum development. Therefore, we advocate strongly for an expansion of this list of bona fide examples to include medical specialty societies. Items three states that CME must be verified as free of commercial bias. The [redacted] seeks clarification regarding who would verify the existence of bias and at what point in the program development process such verification would occur.	**Accredited CME provider**

Dear ACCME, [redacted] appreciates the opportunity to comment on this proposal. As an accredited CME provider, we fully understand and appreciate the importance of keeping educational activities independent of the influences and opinions of commercial entities. This proposal concerns us, however, because the lack of commercial support would jeopardize our ability to provide CME to physicians in the field of clinical laboratory medicine. Funds from commercial support supplement registration revenues received for our CME activities. With these combined revenues, we are able to present CME activities with (1) reasonable registration fees; (2) on-site refreshment breaks during which attendees can participate in networking and exchange of ideas; (3) handout materials to facilitate the learning process; (4) high quality and expert faculty members; and (5) on-site staff to ensure the activities proceed smoothly and that the ACCME standards are being met. We think that the ACCME standards for commercial support provide a sufficient safeguard for ensuring that the interests and influences of commercial entities do not encroach upon the planning, developing, implementing, or evaluating of CME activities. Therefore, [redacted] is strongly in favor of scenario 1 ("status quo with commercial support of CME an acceptable funding mechanism"). [redacted] strongly objects to scenario 2 ("the complete elimination of commercial support") as explained above. Without support from commercial entities, the costs of sponsoring CME activities would have to be passed on to our members in the form of increased registration fees. These higher fees will deter potential attendees from registering for our CME programs. [redacted] also strongly objects to scenario 3 ("a new paradigm"). We feel there may be organizations or individuals not covered by the paradigm conditions that would be more effective in identifying, verifying and/or corroborating educational needs, particularly for sub-specialty areas of medicine. Furthermore, it's critical that new developments and findings be disseminated to physicians as expeditiously as possible. The requirement to fulfill all of the criteria listed in scenario 3 would impede the deliverance of CME activities, thus having a negative impact on patient outcomes. In conclusion, [redacted] hopes that this proposal will be withdrawn and that commercial support will continue as an acceptable mechanism for funding CME activities. Sincerely, [redacted]	**Accredited CME provider**
Dear ACCME: Unfortunately, the consequences of altering the manner in which CME activities are presently funded would have a profound effect on learners like myself. Limiting providers' ability to develop effective CME activities will mean that fewer options for learning will be available. Further, the major portion of available education would be only of a promotional nature from the pharmaceutical and device companies. Lastly, the decision could also limit the availability of activities to address the requirements of Maintenance of Certification and Maintenance of Licensure. In the end, however, I believe this decision will have an even more profound impact on patient health outcomes. With limited CME activities to choose from, learners like myself will be hard-pressed to understand evidence-based treatment options in disease states where cutting-edge interventions involve off-label usages, or the science behind novel therapies that may soon fit into our treatment armamentarium. In short, the decision to eliminate commercial support could have a great impact both on the quality and quantity of CME available to practicing healthcare professionals, and also on patients. The same can be said for the new paradigm scenarios under which commercial support would be allowed to continue. While I recognize that the current system can be improved through minor adjustments, I encourage the ACCME to maintain the status quo, with commercial support of CME remaining an acceptable funding mechanism. Yours truly, [redacted]	**Other**
Dear Gentlemen and or Ladies: The current thinking about educational activities and advertising by commercial groups is bizarre. Advertising by commercial entities should be eliminated on the airwaves, in journals, in the office and in educational activities to make things "pure". No more drug company advertising or support. Nothing else will do. If this does not seem to be a viable (reasonable) plan, then come up with something reasonable that allows support of journals, continuing medical education, detaining and samples, ect. Surely you do not believe your are actually addressing (the problem) which is that everything is for sale for the right amount of money. Nothing other than a global plan to reign in the commercial groups will help. Take off your blinders!!!!!	**Accredited CME provider**
Dear sir, CME is an important tool for exactly continuing medical education. I believe that commercial support is needed , and it will be the grown doctors and students to know the balance in between , and to know how to eliminate the commercial issues and to remain with pure medical issues . Yours , sincerely .	**Other**
Dear Sirs, I strongly believe in maintainning the status quo, mainly because it is of mutual interests of us in the medical profession and the pharmaceutical companies. Pharmaceutical industries take a great risk in investing in research to develop an original drug, which is eventually turned into a generic after the patent expires.	**Other**

Dear Sirs: The consequences of altering CME funding could have a real impact on professional education, and could in fact have the opposite effect of what is intended. By eliminating commercial support for unbiased CME activites, the major portion of available education would be only of a promotional nature directly from the pharmaceutical and device companies. Limit the availability of CME activities is antithetical to the freedom for which we stand in this country. In addition, eliminating commercial support of unbiased CME activities would limit options for completing the requirements of Maintenance of Certification and Maintenance of Licensure in my specialty. Further impact will be felt by patients themselves. With limited CME activities from which to choose, professionals like myself will be hard-pressed to keep abreast of evidence-based treatment options and cutting-edge approaches. The restriction on access to pharmaceutical representatives has already taken a toll on patient care and safety. I have only recently found out about a new option for treatment of Attention Deficit Disorder that improves effectiveness and reduces the chance for abuse; however, I only received this information by seeing an advertisement in the lunch room of a colleague's office and asked my colleague for more information. Surely we will not be reduced to random drug company information as our source of information about new medications? I realize that the current system can be improved, I encourage the ACCME to continue to allow commercial support of unbiased CME as an acceptable funding mechanism. Sincerely,	**Other**
Dear Sirs: Elimination of commercial support for CME will have a disasterous impact on affordable CME and will hinder learning in academic centers as well as stand alone CME events. Medicine continues to evolve but it is difficult for practicing physcians to keep up with the new scieince that underpins many of the new agents. The science that they learned in their training is in some instances wrong and in others oversimplified and reversing this (or unlearning) can be a very difficult process. If local programs are not available to such physicans, the likelihood of their updating their knowledge base is gratly reduced and they will be forced to get CME at national or reginal meetings unless the practioner is close enough to an academic center. Withdrawal of commercial support to national and regional meeting will make these meetings much more expensive to the learner and will likely limit the programs to speakers closer to the location of the particular of that meeting. Learning will be concentrates to a few days 1-2 times per year and may not be well retained in that context. Even academic centers are better able to offer a wide range of lecturers if commercial support is available than is possible when only drawing on local talent. Commerically supported CME has maintained a hands off procedure and has adhered to ethical standards that justfy continuation.	**Accredited CME provider**
DIRECT, BRANDED "education" is a farse. We all know that. It is marketing. But, frankly, it is rather harmless. Physicains, despite the fondest hopes of big pharm are not stupid or gulible or eaily moved by a polished speaker/salesperson - and certaintly not by the stupid pens and mugs they litter our offices with. HOWEVER, those CME programs that are FUNDED by Pharma or other commerical interests, but NOT BRANDED are amoung some of the best, most usesful, most effecient CME activities I have attended. Those put together by a 3rd party - themselves a for profit or even an independed non-profit - survive in the market place, ONLY becasue they provide EXCELLENT, USEFUL, information geared to the PRACTICAL neeeds of their audience (most often primary care specialists). Selling space in a nearby auditorium to various sponsors does not compromise their utillity to the practicing physician and helps defray the cost. Those confrences sponsored by acadmeic institutions for which I have paid hundreds of dollars several times over are NOT as effective. The accademitians do not need to "win" or keep my interest or my patronage, the tend to talk to themselves and love to share "war stories" of how wonderful and tallented they are with their near unlimited budget and equpment. They live in a different world. Please do NOT throw out the excleent "babby" of CME consolidators with the "bath water" of educational "sales talks.	**Other**
Does this mean that commercial support of all the big national meetings will be eliminated also? The various colleges, the [redacted], etc all accept commercial support. Should we be eliminating pharmaceutical company involvement in randomized clinical trials? Where exactly is the line to be drawn?	**Accredited CME provider**
Education is valuable and we need to upgrade, havind said that they should eliminate luxeries especially wine and dine (a little snak and refreshements such as water is sufficent)	**Other**

Eliminating commercial support for CME is like throwing the baby out with the bath water. My concern is that this would significantly reduce the # of CME programs and reduce information delivery substantially. The current system is already very regulated and most commercial bias has been squeezed out. Enforcing the current rules concerning commercial involvement in content is more than adequate in controlling bias. I don't think that the group that is suggesting this alternative has thought the issue through very well. I'd like to know where the funding will come from if not from commercial sources. The [redacted], CME organizations, doctors? I think that each of these sources is extremely unlikely. Should presentors be asked to educate for free--I don't think so. This proposal is purportedly to reduce the potential bias of commercial input, but it simply suggests a lack of confidence in the current rules and lack of confidence in presentors and organizers--this lack of confidence is offensive and lacks foundation in the current climate. It occurs to me that the bias is not on the commercial but that the bias is on the "anti-commercial at all costs side". The diehard anti-commercial side of this argument should fully disclose its bias and get out of the decision making process.	**Other**
Elimination entirely of CME support from the pharmaceutical (or other commercial) industry. Thanks [redacted]	**Accredited CME provider**
elimination of all commercial support for CME activities would unfortunately diminish participation in such activities by practicing physicians since the costs of attendance would certainly rise significantly. Conferences with variable commercial support that I have attended have been well balanced with presentation of alternative approaches to therapy.Hopefully, most of are also aware that some bias may be present and and consider this in our decisions.Measures to oversee content for balance(by perhaps panels of recognized authorities from eductional institutions and specialty societies,etc.) could be further developed. Pooling of funds from various commercial entities to be allocated by a separate professional body might also be a means of diluting the commercial influence.	**Other**
Elimination of commercial support for continuing medical education activities is an unfortunate idea. Good quality educational activities are expensive to develop. Who will support development if commercial entities are prohibited from doing so? If commercial support is eliminated, the quality of education available to clinicians will decline. It is hardly possible to imagine a situation more favorable than ACCME than the current one, in which commercial grantors pay for development, yet have no input on content. Please do not throw out the clean baby of today with the murky bathwater of years past.	**Other**
Elimination of Commercial Support of CME activites will greatly lesson the amount of CME's obtained. It is expensive to maintain a practice, and I, for one, am looking at closing my practice if there are any further expenses. Thank you for your time.	**Other**
First ACCME should demonstrate adverse consequences from having CME sponsored by commercial entities. We would expect no less than such evidence-based processes to go into our decisions for medical interventions. It is important that we're consistent. IF data show clear and convincing adverse consequences outweighing benefit, then it will be important to be consistent, i.e. no national or local meeting could get any commercial support of any kind, including unrestricted educational grants. It will be important also to be certain that no full-time academic faculty participate in such a decision, since there will be an obvious conflict knowing that there will be few other places to get CME other than academic institutions. Those institutions will need to charge substantial amounts to divert faculty to satisfy the huge increased demand from physicians requiring CME to retain their licenses and unable to get it from sources that relied heavily on commercial support.	**Accredited CME provider**
For primary care physicians like me, commercial cme is essential. It gives me the opportunity to access free cme on a vareiety of topics. It helps me maintain my required cme for licensure and credentialing. For small practices like mine, being able to alleviate the cost of cme is crucial. Please do not fix a system that is not broken. [redacted]	**Other**
For those of us dealing with patients with Ultra orphan diseases there would be no CME at all of the current support model is terminated. As we deal will small patient numbers there is no support from non commercial sources as the population is deemed too small to justify politicians or education departments to invest in these patients. This will significantly change the opportunities for patients to benefit from possible new products as late diagnosis will become the norm rather than the exception again.	**Other**

For those of us who are retired, or semi-retired, and do not have funds or funding to attend expensive CME venues and who do not have hospital privileges at institutions with CME programs, in order to meet the continuing medical education requirements of our various licensing agencies we must rely on various forms of free CME, most often on the internet. Most of the sites which provide free CME appear to be unbiased and free from interference by the entities which provide the funding for those sites. It would appear the the four criteria proposed for Option 3 would be extremely difficult to meet and would introduce the interference of the Federal government in the choice of which programs would be available. It would appear very doubtful that sponsoring organizations would jump through these expensive hoops in order to continue to support free CME and the choice of cubject matter would diminish significantly. I find that the current spectrum of subject matter available to me gives me a wide choice to determine which programs fit my individual needs and believe that Federal determination of subject matter or having to rely on the determinations of various professional organizations will limit my ability to obtain CME which fits my needs. Please keep the curret format.	**Other**
Funding options need to be available. Not all accredited providers can afford content experts or develop materials. I think commercial support should be allowed, but not directly requested from pharma/medical device companies. Pharma/medical device companies generate revenue from health care industry, so should share the burden of educating physicians, nurses and staff since they develop products that change the face of health care. However funding needs to contributed to the education process in a benign way. Similar to taxes and distribution of budget to agencies by the government. I think there should be buy in from interested parties (pharma co, medical device co, etc) to contribute a standard percentage to evidence based education. However this money should be provided to a fund that is overseen by the AMA, AAFP and ACCME,etc. That entity should divide the funds into by region and by topics. Then take requests for support from providers. Those overseeing the fund and evaluating the grant requests from providers should have no financial relationships with any contributor. This would allow companies to still contribute to evidence based education, but remove any direct association or influence with regard to funding. Funding availability needs to exist. Granted it could become burdensome and beauracratic, but objective.	**Other**
Having been out of medical school 35 years now, I have come to appreciate the value of having some commercial support for CME activities. I am a volunteer (i.e., noncompensated) faculty member at my local medical school. Without some commercial support, our activities will be curtailed. Providing a basic meal in the evening helps attract busy doctors to attend and interact with our residents, providing seasoned critiques for journal clubs. This also encourages nonsalaried faculty to become acquainted with the residents, invite them to participate in surgery and office and gain valuable additional experience they might miss if they are only exposed to the fulltime faculty.	**Other**
Hello in this life science and money they not the same road But still you can spend money to get the science. continuing medical education is must for all health professionals. the only way now to get money through commercial support providing not to affect the quality , type or the quantity of the education so I am with that elimination regards.	**Non-Accredited CME provider**
Hospital based CME activities are in the depths of cost reduction in budget expenditures. Eliminating commercial support will negatively impact the hospital based organization from providing larger scale or nationally recognized speakers.	**Accredited CME provider**
I AGREE WITH CONTINUED COMMERCIAL SUPPORT. WITH NO BIAS TO PRODUCTS.	**Other**
I agree with NO elimination of commercial support of continuing medical education activities	**Accredited CME provider**

I agree with only item # 4. I do not "trust" bureaucratic stratures in government or imbecile organisations like AMA anymore than I "trust" pharmaceutical companies. Having said that, "commercial support" of CME activities provides needed services. Yes, pharmaceutical companies are likely to support only CME activities that have to do with the diseases that they are selling medications for and not other very worthwile subjects that they have no financial interests in...so what...as long as the speakers / CME content is "free of commercial bias." I could smell "commercial bias" easily. My "commerical bias" detection sensor is quite sensitive. If I attend an event or program that smells "commercial bias" I would not attend those events or programs again. I organize educational meetings for our local endocrinologists club. These educational meetings are supported by pharmaceutical companies who "pay for the speaker." Although I do not seek CME accreditation for these educational meetings, I insist to both the sponoring companies and the speakers on "pure" educational content and no commercial biases. If I dectect commercial bias, that speaker will never be invited back to speak to us again. Eliminating "commerical support" of CME would not help those "doctors" who do not have a sense of smell for "commerical bias". They will be biased by sales rep, detailing, throw away journals, biased articles in respected journals including NEJM, and journal advertisements. You could not help these "doctors" by elimatining "commercial support" of CME activities. The only solution is to eliminate such "doctors" (now a days includes N.P and P.A.s) from medical school periods. That is the place to clean house. Not after the fact. Formal CME activities now are getting more and more expensive: CME registration fee, hotel fee, travel cost, time off practice...etc. If I go to Boston, San Franciso, Behtesda, or Phildelphia...etc for a one week conference, I have to spend more than $2500 just on travel and hotel. I am an endocrinologist who sees an avearge of 12 patients a day because I guess I am "old fashioned" and spend a lot of time with my patients. I simply could not afford these expenses all the time. I welcome "commercial support" of CME. I use my "commercial bias" sensory detector to tell me which ones to attend and which ones to avoid. We should embrace more "commercial support" with clear stipulation of NO "commercial biases", like the way I runs our endocrine club.	**Other**
i agree with the new paradigm	**Accredited CME provider**
I AGREE WITH THIS tHANK YOU FOR YOUR INTEREST IN UPDATE US [redacted]	**Other**
I agree. I do not suggest that anyone has evil intentions but my experience with commercial CME is not that what is taught is so bad but only that the PROPORTION of topics is not proportional to what we need. That is, out of 10 mental health talks, 9 are likely on atypicals and new drugs: rather than more balance. My concern is not so much with content as with the agenda. Thank you. Let's get medical education back in the hands of physicians: we have not done our job and should not pay someone else to do it (or worse, ask patients to pay for it by way of inflated drug prices)	**Non-Accredited CME provider**
I agreed with the enclosed letter and looking forward and ready to defend your CME goal to us as a medical practitioner in this country. I hope this conflict will resolve as soon as possible because we need your help to be better equiped and knowledegeable clinician in our respective field. Thank your for your help and keep it up!!! Sincerely [redacted]	**Other**
I am a child neurologist practicing in a rather rural setting. It seems to me that the majority of the CME I get for free online or from mailings is of good quality. It usually addresses enough OTHER information that ther is real value. An article on Bells Palsy typically will address History, Pathology, demographics.....and treatment, not necessarily pushing the non-generic meds. Offerings generally from university sites; from [redacted]; [redacted] neurology; [redacted]; and [redacted] have both been useful and informative. In my rural existence, these kinds of articles are far more pertinent than anything I can get elsewhere. I think that inevitably there is bias, as there is in everything. Grand rounds in [redacted] city pertinent to me occur in one hospital Wednesday AM's, in another on Friday AM. Either way at minimum I would loose 1/2 day in the office for 1-2 hours of credit; the selection of topics of interest is limited. I am annoyed that I get no, or very little CME when I spend an hour or two trying to determine something like if the sisters I take care of who have both Mondini abnormalities AND Hereditary Sensorimotor neuropathies are related at some genetic level give me no credit. I can give more examples of such complex issues. I do think that there is more influence at the level of what topics are offered than influence on the nature of what is IN the content of an article Thus, areas wehre there is a lot of renumerative medication or treatment have lots of CME available.	**Other**

I am a general surgeon in a small town, [redacted], Nebraska. Where I live I am a good four hour drive from the major cities, [redacted] and [redacted], where the most educational activities are available. It is very difficult for me to take time away from my practice to go that far away or further to take a course or attend meetings. Therefore I rely heavily on educational materials that can be obtained on the internet or courses provided by companies that publish CME courses. I have not found that these courses are commercially biased. Limiting provider's ability to develop effective CME activities will mean fewer options for learning will be available to persons like myself. I encourage the ACCME to continue to allow commercial support of CME to be an acceptable funding mechanism.	**Other**
I am for status quo, where commercial support remains an acceptable funding mechanism.	**Other**
I am in favor of continued commercial support/ funding for educational activities in general. Many healthcare professionals, patients and community at large benefit as a result. Please reconsider the strengths these offerings provide.	**Other**
I am in favor of continuing 'status quo'. As health professionals, we are aware that presentations of sales representative must be examined and comparisions of various products evaluated.	**Other**
I am in support of the elimination of commercial support for all continuing medical education activities realizing, that in doing so, it will not guarantee the elimination of commercial bias. The Standards for Commercial Support have been revised and improved, but everyone acknowledges that it is nothing more than money laundering. The documentation requires that potential faculty disclose their affiliations. CME departments collect and disseminate the information to the participants but there is no guarantee that the presenting faculty has been honest and we accept them at their word. However, even without commercial support, we have no guarantee that faculty will present a fair and non biased view or be honest in their disclosure information.	**Accredited CME provider**
I am not in favor of this but rather that the support be given to a fund established in a accredited provider's organization to serve as support for bona fide courses that have been developed by the CME entity and that a panel my evaluate based upon criteria to determine eligibility. I do not believe that MECCs and commercial companies should receive commercial support funding.	**Accredited CME provider**
I am speaking on my behalf and not on the behalf of the society. I am involved in multiple medical education efforts in the local (hospital) regional and national level. The need for rducation and especially of the primary care physician and allied health is tremendous. Please do not touch CME anymore Keep the status quo. Today medical Education is available throughout the US and is relatively inexpensive. Eliminating commercial support will make medical education beyond the reach of the larger medical community. Replacing sponsors with government or large chain insurances/hospitals/pharmacies will even be worth than today. High quality education is very expansive. Separating grants processes from marketing, inhibiting the commercial presence in the location of the education is already in place. Do not take back education to the dark ages where you may benefit small groups (primarily universities, few societies) and make a 1 unit of CME cost $200-800. Third party MedEd companies, though competing, at times with societies like ours serve a very important function and especially in the country and the periphery. the large majority that I encounters are true professionals. Do not put this very important issue of education in the hand of beginners and volunteers. PRESERVE the System it hgas been damaged enough!!!!!!!!!	**Accredited CME provider**
I am strongly against elimination of commercial CME. I see no reason to eliminate commercial CME in favor of a single organization to rule over CME. This rings of expanding beaurocracy and more and more laws. Being a physician of 32 years, I resent the attitude that commercial support is the only consideratiion in my selecting what organization I choose to provide me with CME. I also get CME from several commercial and non-commercial sources. I also wish that CME remain mostly free of cost, because I feel that the spread of information should be free and easy to obtain.	**Commercial Supporter**

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. I am also opposed to the proposal that: \tThe 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.	**Accredited CME provider**
I believe it is important to have commercial support for continuing medical education activities. With the costs of medicine increasing and the amount of money a physician can earn decreasing it is important for physicians especially for those physicians in solo practice or small groups to be able to obtain CME credits from this source. With the elimination of commercial support of CME many physicians will be unable to afford to take CME. The CME activities I have participated in have been educational and unbiased. I truly appreciate these CME activities. Commercial Support of CME activities is important and critical to the further education and continuing education of physicians. Thank you for your consideration of this matter.	**Other**
I believe tgat commercial support of CME is possible, neseaaary financially, and wokable for the common good, if strict rules of ethics are followed. The relationship between commercial enterprise and the Medical Profession is one of the backbones of the continual improvement in the health care we render to our patients.	**Other**
I believe that both of the proposed changes outlined in ACCME's Call for Comment—the outright elimination of commercial support for continuing medical education (CME), or the "new paradigm" for commercial support—would be harmful to CME and more generally to American physicians. Over a long career in medical education and medical publishing, I have watched hard-working, dedicated professionals strive to continuously improve the quality of medical information delivered to practicing physicians. I am proud of their work, and I believe the medical education provided by my organization, working under the current standards and guidelines of the ACCME, is of the highest quality and strongly beneficial to clinicians. While obviously no one individual can have visibility of all CME activities provided with the $594 million in commercial support to publishing and education companies flagged in ACCME's 2007 data, I truly believe that the great majority of CME providers have diligently worked to improve their processes and offerings along with the ever-improving standards of the ACCME. It is greatly in the national interest to have well-informed physicians and other clinicians. Never has the need been greater: the burden of chronic disease is growing along with demographic and lifestyle changes in the American population; there is an ever-changing flow of "new" or newly-recognized disorders; there are no "silver bullets" for serious illnesses that affect tens of millions of Americans; and there is intense research into new diagnostic, therapeutic, and prevention strategies that practitioners must understand and, where appropriate, fit into patient care. Yet never has the need been harder to meet: Today's regulation, paperwork, and pressure to see more and more patients make it all the more important that education address true practice gaps and be delivered in creative and efficient ways that best communicate key concepts. With leadership and prompting from the ACCME and others, the CME endeavor in the United States has been continually enhanced. Today it is clearly focused on identifying true needs and practice gaps, trying to apply adult learning principles and creative ideas to increase effectiveness, and seeking improved ways to measure outcomes. Further, CME providers (and pharmaceutical companies as well) recognize the need for fair balance and the importance of separating content and faculty decisions from influence by commercial supporters. Toward that end and fully consistent with ACCME's goals, careful processes have been put in place and are, in fact, followed in practice. Even in research commissioned by ACCME, for-profit CME providers working with grants from commercial supporters have a 95% level of compliance with ACCME Standards for Commercial Support—in fact, a higher level of compliance than any other category of CME provider. Surveys reported by Professional Postgraduate Services and other groups show that physicians clearly believe they benefit from the quality of CME activities certified today. Against this background, it is very difficult to see any way in which elimination of commercial support would benefit our healthcare system. Quite the contrary, it would reduce the availability and quality of education to the practitioners who need it to improve patient care. According to ACCME data, commercial support for CME amounted to about $1.2 billion in 2007. That funding has allowed excellent education to be delivered in clinical areas of great national importance—diabetes, Alzheimer disease, asthma and COPD, cardiovascular	**Accredited CME provider**

disease, and so on. I have heard no credible suggestions as to how that funding would be replaced. Certainly in today's high-deficit, tax-cut--focused political environment, the Federal government is unlikely to step in, nor will states provide significant funding. As an alternative to elimination of commercial support, ACCME has also postulated what the Call for Comment describes as a "new paradigm" in which those organizations that receive commercial support would be moved to a lesser role. Identification and verification of educational needs and practice gaps would be reserved for other organizations; content would be from curricula specified by certain "bona fide organizations" (presumably from a list to be approved by the ACCME). This "new paradigm" is equally problematic. First, it too is based on the unsupported premise that commercial support precludes independent CME activities that address true professional gaps in a fair-balanced, evidence-based manner. Second, it forces CME providers into a convoluted and bureaucratic system of interactions with multiple organizations. The added costs inherent in this process will immediately reduce the number of CME activities delivered with a given level of funding. And the funding level is not likely to remain a "given": Realizing there's a kernel of truth in the old cliché that "a camel is a horse designed by a committee," it is unlikely that many commercial supporters would wish to provide grants for the work of a disparate grouping of organizations rather than selecting, through a rigorous grant review process, a single provider of known levels of quality and compliance. Third, the "new paradigm" relegates for-profit providers into essentially a role of logistical support. This removes the initiative and creativity that these providers currently bring to the process of designing CME activities that best address practice gaps. It further can be expected to push many or most for-profit CME providers out of business. In short, ACCME's Call for Comment postulates two measures—elimination of commercial support, or a convoluted "new paradigm" for commercial support—that will fail to solve any documented problem, and that certainly will work to the detriment of practicing physicians, the CME enterprise, and in fact the American health care system. These are the realities of the CME enterprise in the United States today, in my opinion. If one of ACCME's key motivations for its proposals is the fact that, as is so often the case in public discourse, the perception in some quarters may lag reality, then ACCME should focus its efforts on measures that would correct those misperceptions rather than disrupt the real progress that has been made. For example, steps could be taken to enhance the frequency and detail of auditing and enforcing compliance to reassure critics that there are teeth in the rules, without harming the ability of CME providers to deliver quality educational activities. Thank you for the opportunity to comment.	
I believe that eliminating of commercial support of CME would play a major role on how I keep up with quality CME avaliable to praticing physicians. Not only that and even more so, it would have a profound impact on patient health outcomes. Outstanding information is being delivered via these means and to eliminate it for be a travesty for all of us, patients and health care providers.	**Other**
I believe that is a bad idea when most physicians are unable to maintain cost of practices and will significantly reduce places where where these CME can be obtained. It insults me to believe that ACCME feels that as a Physician I would have difficulty in seperating the sales pitch and the substance of the activity.	**Other**
I believe that the total elimination of commerical support could be detrimental to the industry and cause a number of companies to go out of business. I do like the idea of a "new paradigm" for commercial support; however, I would like to see another change made to ACCME accreditation. The company I work for does not receive commercial support from anyone, at anytime, EVER. We don't even charge physicians to attend our seminars. Yet, we are required to adhere to the stricter and stricter regulations relating to commerical support. Following these changing rules and regulations often feels redundant and unnecessary. Perhaps there could be two levels of accreditation - accreditation for those who accept commercial support and accreditation for those who do not. Make the accreditation for those who do not accept commerical support more attractive by requiring less red tape and charging lower fees. Perhaps the appeal of fewer "hoops" to jump through will cause more providers to stop accepting commerical support.	**Other**
I believe that unbaised continuing medical education even if supported by a pharm. company should be an option for physicans. My past experience tells me that the information has been helpful to me and of benefit to the patients that I treat.	**Other**
I believe that with disclosure rules for speakers or companies, commercial support of CME is a viable and appropriate way for CME funding.	**Other**

I believe the ACCME is being too restrictive on this topic and should re-consider its prohibitions on physicians contact with pharma. Many of the advances in medicine have come about because of pharma's research over the years, so that the length and quality of life have advanced in this country, and we have treatments for many life-threatening diseases such as AIDS and cancer. In addition, pharma has been important in funding CME activities, meetings, grand rounds, etc. , when insurance funding and academic centers could no longer fund these important activities. They were unrestricted grants and brought in the best minds in the field, not just speaking on the drug company products. Now because of a public outcry and media misperception, we are jumping overboard to cover ourselves by cutting off any reasonable relationship. I think more objective people should be part of this discussion. Many things touted as CME may be no more than propaganda for the companies; what we need is an organization which can really screen to make sure the funding is for a scientific and unbiased activity, rather than say it cannot be done unless regulated by some government or professional organization.	**Accredited CME provider**
I believe the proposed new paradigm for allowing CME support by commercial entities should NOT include condition #2. That is, there should be no requirement that a physician performance gap be identified, for two reasons: 1. the proof of an performance gap is not directly related to chance that the CME activity will include a commercial bias. 2. Some vital CME activities have content that does not address a performance gap (e.g. the use of new anticoagulants for prophylaxing DVT may be learned by a set of providers who are already expert at providing standard DVT prophy). Commercial support should be available for these as well. [redacted]	**Accredited CME provider**
I believe this is a foolish proposal without consideration as to where future funding of CME will come from. It is akin to television companies or any other major companies turning away sponsors of their programs. Current CME's are of high quality and are actually bias free if one actually takes the time to experience them. I challenge those who brought this proposal to show us how future CME will be funded. Where will the funding come from? The government/tax payers? This type of proposal should not be considered unless those questions can be answered. This is political correctness gone too far! I strongly urge the ACCME to maintain the status quo as this relationship is beneficial to both parties.	**Accredited CME provider**
I believe to remove such support would have a devastating effect on the availability of CME courses and materials to physicians and other licensees. If there is concern about undue influence then perhaps various rules may have to be modified and make it acceptable. Personally,I have taken many CME programs sponsored by pharmaceutical companies and I don't believe they adversely influenced me. One of the basic tenets of economics in this country and indeed the world is the concept of subsidies which has become essential. Just look at your TV commercials without which there probably be no TV. I think the drug companies should be lauded for making free CME activities available to the many physicians who participate and without which many phyicians would do without. Do not eliminate commercial support for CME activities because it would be hypocritical and have a markedly negative effect on such activities	**Other**
I can see the rationale for industry donating funds to a large pot and then grant requests being made to respond to needs. But as you said, there is no evidence that they current system for support of activities is broken. In your new paradigm, the individuals who will make the decisions to award funding are human and their professional relationships, beliefs, and biases will directly affect which providers receive the awards. You and I both know that the industry will become dominated by a certain group of providers who are well-connected and know how to wordsmith very well, plus they have the people and resources to respond to many educational opportunities. They will create a very nice business for themselves and will likely add to their NIH funding and other resources. What will prevent these providers from injecting their biases into the programming? I can assure you that they will somehow be well-connected within the pharmaceutical industry. Thus, the new paradigm will not necessarily create a better educational system, just different educational system. It might even be harder to identify and eliminate bias. You really need to determine how to identify and eliminate those providers who inject bias into the current system rather than just change the system. Especially if the current system is generally not broken as you have stated. Changing to a new paradigm my get legislators off of your back for a while, but it will do nothing to further eliminate bias and might make it harder to identify. It strikes me that ACCME becoming much more confrontational with providers and directly attending and reviewing activities for bias and interviewing participants directly is a better approach. Once identified, confronting those who do inject bias and rescinding their accreditation will get them out of the business. Let's really attack bias and get rid of those greedy souls who are just doing this for the money.	**Accredited CME provider**
I disagree with ACCME in regard to their plans to eliminate Commercial Support of Continuing Medical Education Activities. Commercial Support of Continuing Medical Education Activities is an invaluable way of having a broad range of CME opportunities.	**Other**

I disagree with this premise. Providers are intelligent enough to understand when Commercial bias is present. Even commercial information is valuable. You will interfere with the ability of each provider to get good CE as cost will go up. More commercial activities will occur that are not CE but still influential. Access to good new information about new products and uses of products will be limited. Please do not change the present process for approval of CE activities. Thank you, [redacted]	Other
I disagree with this proposal. It is so expensive to obtain CME's without undue expense, especially for Middle Level Practitioners such as myself. I do not receive that large of a salary that I can afford to travel frequently in order to pay substantial sums for lodging, food, not to mention the program itself. The continuing education credits that I have obtained through the various free sources on the internet and through the mail has made it viable for me to continue as a PA-C who does not make much money as a Federal employee. I beseech you to reconsider this approach which assumes that all who partake of the CME provided in such a manner are weak minded enough to be swayed by any possible slant presented. However, in defense of the programs, I have not seen any nefarious attempts to sway people, such as myself who depend upon such sources to flesh out our knowledge bases and to obtain CME credits in a financially responsible fashion. My employer has had to cut almost all CME monies due to an overall cut in funding.	Other
I disagree. I believe that commercial support for CME events should be allowed as long as guidelines are followed that prevent any "influence".	Other
I disagree. In two decades in this field I see weaknesses at the state levels and hospitals. The hospitals don't develop staff and old ways and forms continue. Staff are only educated at the state accreditors level who often don't know the link between their accreditor and the ACCME. A way to eliminate inappropriate behaviors would be to make all forms the same, all steps for approval of applications, if applications are used, the same....When ACCME develop tools, make them mandatory usage. You are developing the RULES, you know what your purpose and what you want to accomplish is, the provider doe not. So, please develop the tools and don't just recommend them, make them mandatory for all to use. There are still people out there having disclosure forms completed the day before the event. They never saw the ACCME Letters to Identify RELEVANT Financial Relationships. The rule makers in their state society were not at the Alliande meeting when the tools were presented. They work, they are great... Regulation is not democratic, it has to be enforcible and leave no room for deviance to the process and no room for subjective interpretation or feeling. Make sure surveyors understand that if there are not disclosures, there are any deviance, although the activity happened, people cannot be awarded credit and they need to enforce this at their own place of work as well. Thanks for asking!	Accredited CME provider
I do believe it to be Arbitrary and unnecessary. Why are Doctors assumed to be the easiest Professionals to be Corrupted. Sincerely [redacted]	Other
I do encourage the ACCME to maintain the status quo, with commercial support of CME remaining an acceptable funding mechanism. With limited CME activities to choose from, learners like myself will be hard-pressed to understand evidence-based treatment options in disease states where cutting -edge interventions involve off-label usages or the science behind novel therapies that may soon fit into our treatment armamentarium. The deciaion to eliminate commercial support could have a grat impact in both the quality and quantity of CME available to practicing healthcare professionals.	Other
I do not agree with the elimination of commercial support of CME. I believe it will decrease to a great degree the opportunity for physicians to continue to keep up with the advances in medicine. Please reconsider the consequences of this.	Accredited CME provider
I do not understand why the ACCME would even consider the elimination of commercial support of CME activities. I find the invaluable to my practice and my continuation of education. My patients benefit also as the CME activities are a valuable resourse for me to address their issues. The Commercial support of CME acctivies are of great assest for those physicians like myself that are in private practice and do not have an organization that support CME activites. [redacted] Child Psychiatrist	Other

I favor allowing Commercial Support under more stringent guidelines. In developing a proposal for the nation, the ACCME must recognize the needs of community hospitals and their staff, which makes up a large part of the national medical landscape. At [redacted], we have created a number of robust CME series that involves the local physician group. (Our accrediting organization is the [redacted]) We do rely on commercial support to provide ~25% of our operating budget. We assiduously follow the ACCME guidelines. Most of the financial support are in the form of unrestricted grants to our foundation. Our planners, presenters, needs assessments and outcomes are far removed from the sources of support. We provide education to remote areas utilizing our telemedicine network. I see the need for continued suppoort of these activities which is unlikely to be met by the local healthcare organizations, which are struggling with razor thin oprating margins. However, I think the industry created around CME delivery by the "MECCs" provide little added benefit to the education of healthcare providers. Their basic prinicple is to create content that follows the dollars, unlike the content that is created locally to address the specific needs of the local healthcare community.	**Accredited CME provider**
I feel strongly that the current status quo on CME funding is the best approach for those of us in private practice away from metropolitan and university centers. To abolish industry funding would lead to more patient directed advertising and essentially leave practitioners out of the loop.	**Other**
i feel that commercial support of CME is important in keeping us abreast of new therapies plus it is a bit hypocritical for Washington legislators who receive campaign contribiutons from possibly these very same industries seems to be acceptable	**Commercial Supporter**
I FEEL THE EDUCATIONAL OPPORTUNITIES HAVE BEEN AN INTEGRAL PART OF MY CME AND ENHANCING MY PROFESSIONAL KNOWLEDGE AND COMPETENCE IN MY FIELD. ACCESS TO ONLINE LEARNING AT MY DESK AFFORDS ME TIME TO COMPLETE CME AT LUNCH TIME, OR WAITING ON PTS, ETC.	**Other**
I FIND THIS PROGRAM USEFUL.	**Accredited CME provider**
I for one have found the CME programs highly beneficial to my professional development and probably would not be able to go to as many and stay as informed were it not for the sponsorship of the programs and speakers by the pharmaceutical companies.	**Other**
I have attended numerous CME conferences that were largely funded by Commercial Support. I feel that the utmost care has been taken to make the information presented free from commercial influence, and know that the conferences would not have been provided without the funding. I would hope that as physicians we are capable of making educated decisions regarding the use of products, and not simply utilize a product because they gave us a coffee mug at a conference. The education at these programs is vital and unless another funding source is made available, we will loose many valuable conferences. Raising fees for conferences will only deter more providers from attending. Thank you for your consideration in this matter.	**Other**
I have been a medical writer of CME activities for over ten years. My experience is that the funders of these activities are not involved at all in content development. In addition, program planners, faculty, and writers go to great lengths to avoid bias and achieve fair balance, which is then verified--or challenged, if needed--in the final product by peer review. In many cases, I am not even aware who the funder is and which is their product during the development of a CME activity. Pharmaceutical companies are generous in their support of physician's education. The firewalls already built into the system by ACCME, including the documentation and review requirements, as well as physician assessments of integrity in the CME marketplace seem adequate controls against bias.	**Other**
I have been a nurse and nurse practitioner for 34 years and commercially supported continuing medical education activities contributed a great deal to my professional growth and development. Employer support of CME's is limited, and allows me to participate in only one conference a year. By participating in after work hours meetings and post-conference meetings has provided me a great deal of educational material for my patients, and a more in-depth understanding of the clinical management of diabetes and diabetes related compliacations, as well as other disease entities, and cutting edge pharmaceutical and durable equipment products.	**Accredited CME provider**
I have been reading with dismay the debate on funding for CME in particular but also the more general tone of the discussions on the relationships of physicians with industry. Much of the discussions seem to relate to a particular political agenda, while ignoring our commitment to improve patient care. In terms of the latter, it has been very clear to me that innovation in patient care in general and development of new products, not	**Other**

limited to drugs and devices, most of which came from private industry, has transformed our practice of medicine and more importantly has increased both life expectancy and quality of life. Academic – industry partnerships actually need to be encouraged in order to ensure that further developments continue to ensure that the patient's best interest remain at the forefront and independent of political and financial agendas. While there have been clear transgressions of ethical principles and abuses of the system with or without legal implications, many of the arguments against industry relationships and CME support are either out of date or unbalanced and frequently both. Many changes in industry practices have eliminated most, if not all the egregious marketing practices prevalent a decade ago. There is a constant tirade against "off label" use of medications, ignoring the fact that such use is often in a situation where there is not much if anything that one can offer to patients (see below). In contrast, our "not for profit" institutions continue to implicitly encourage expensive procedures (steroid injections and surgery for simple back pain, angioplasty in asymptomatic patients etc) partly, if not entirely to balance the books. In relation to off label use, ironically the case of gabapentin (neurontin) continues to be cited. However, it is important to note that there had been several small and one large multicenter trial to test the effect of gabapentin in painful diabetic neuropathy – a condition that at the time had no approved treatment and caused a significant number of patients immense distress. The trial was done to the highest standards of good clinical practice (which has never been questioned), and the paper published after peer review in JAMA. Was it wrong to discuss results of an appropriately done trial, that has been published in a leading journal, and was for a condition for which there was no approved treatment at the time? Was the audience that then successfully alleviated their patients distress somehow corrupted? The sponsor was bought by a larger company which decided to "settle", rather than debate the issues in court. Most ironic is the fact that soon thereafter, gabapentin became generic and a related compound pregabelin was approved for treatment of the condition. Now it is legal to promote the newer, more expensive compound rather than its generic cousin!! Our anti- industry colleagues continue to decry promotional marketing of gabapentin, ignoring the fact that it works just as well as approved products and is now much cheaper. What happened to the patient's best interests? In contrast, though I believe aspirin prevents heart attacks the recommendation that it be used in most patients with type 2 diabetes is not evidence based. Yet that statement is frequently mentioned in CME programs and nobody objects to "off label" use. One could take the cynical view that it is reasonable to make such recommendations since only generic manufacturers and not big pharma makes money. In summary, the debate on industry physician relationships and CME support is seriously flawed and riddled with the "conflict of interest" of the worst kind because of its subtlety – the of political agenda and careers of those who choose to take an anti- industry view.	
I have done much of my CME through [redacted] online over the last several years. I am able to select topics that are of use for my practice and those that fill in missing knowledge, do the reading and tests at odd hours at home and as my schedule allows. The educational content of CME topics I have chosen has been good and I can turn off any with overtly commercial bias easily (and have fewer qualms about turning off a computer thaan a drug rep). It is economical of my money and time and I believe this format actually improves my education. I still attend conferences every few years. My local hospital offers a weekly speaker but I have found myself attending those far less regularly with more repition of topics and more albeit subtle commercial support for these speakers than I have seen online.	**Other**
I have found that the company supported educational activities give substantive information and are free of commercial bias. They are generally of high quality. I feel that with the cessation of commercial support, there would be decreased CME opportunities that would be necessary to maintain licensure in many states. As such, I support commercial support of CME and feel that it does not detract from the educational validity.	**Other**
I have mixed feelings about this. I am concerned that in the now greater than twenty some years of the Reagan era Republican ideology, that financial support through our long utilized, tried and true funding mechanisms from the federal branches of research and development, have been so depleted on purpose of reliable funding, that profit driven entities such as pharmaceutical companies have stepped into the void, to provide needed research funding. I believe that charitable foundations CANNOT make up the difference. I do not believe that venture capitalists and their firms can be relied upon either as they are just another version of the profit driven world that does not see the wisdom of long term basic research and gradual knowledge building in the worlds of science and medicine. They take the short term view of requiring rapid development of marketable and profitable products rather than pure research efforts. I believe that there are NOT enough wealthy altruists such as Bill Gates, George Soros, Ted Turner, etc., who after having made their billions can also be relied upon to make up the difference that the decrease in federal research efforts has created. But I notice that so much of CME has had to rely on corporate donations to continue. Meetings of most professional groups could not be affordable to the individual practitioner without these sources of support, but I frankly HATE that we have to accept their monies and do not believe as some recent media reports on this issues quoted physicians saying that accepting minor gifts such as ball point pens did not influence their prescribing choices. Baloney. It is all about building brand loyalty and the greatest example of the power of this in America I have witnessed in each of my children, the McDonald's Happy Meal with its tie in's to movie	**Accredited CME provider**

character toys in every Happy Meal makes children a McDonalds loyal customer forever if the parent does not counter-educate. Doctors are no less vulnerable and those who say differently are in denial and being fundamentally dishonest with themselves. I think that all medical schools should buy hard to find out of print copies of some of Vance Packard's books from the 60's and 70's where he talked cogently about the pervasive influence of advertising in our lives and make it REQUIRED reading for every physician in training at all levels. We have turned into a nation of mindless consumer Pavlovian robots. I see one alternative that I enjoy and applaud and those are the private foundations through unversity medical centers such as [redacted] [I think that is the name] that gets supports and makes available good bias free CME on CDs and DVDs and on the Internet. This kind of effort and vehicle I hope will become more prevalent. [redacted]	
I have not found the company sponsored educational activities I participated in to be biased. They make information more accessible and afforadable for CME and CEus.	**Other**
I have participated in supposedly impartial meetings where information presented was at times questionable, and commercially supported meetings where a great deal of effort was made to present information impartially and accurately. I believe physicians are able to make this judgement for ourselves. Restricting access to CME does not do us a service.	**Other**
I have prepared a letter. To whom do I send it?	**Other**
I have zero interest in the idea of pooled funds. The ACCME should consider limiting the percentage of a provider's operating budget that can be obtained from commercial supporters. (And please, lets not play games with regards to where a company ultimately gets its funding. It only makes the ACCME lose even more credibility.) Of course, all providers should be required to meet the Essentials and Standards for Commercial Support.	**Accredited CME provider**
I heartily DISAGREE with the ACCME on its policy to eliminate commercial support of continuing medical education activities. I find the numerous websites that offer free CME to physicians to be relatively unbiased, very topical and meet the educational needs of my practice and the time I have available. Try not to screw up what is working well!	**Other**
I like the new paradigm (and like Stanford's new approach) but wonder how will commercial supporters receive requests from providers for funding into a "pool" when they now have established websites where providers go to request funding for specific activities?	**Accredited CME provider**
I like the new paradigm. But as long as commercial supporters do not influence program content and there are the desired monitoring measures in place, I see no problem with the support. The commercial supporters must subscribe to the standards set but a win win situation must be allowed so that there is ROI for the supporters. Centain types of CME activities are very expensive to run and it would not be in the best interest of the patients if these are not available. Rigerous standards of compliance coupled with vigorous enforcement is necessary. Fairness to all commercial supporters should be ensured as well. Having said all this of course the best of all possible worlds would be total funding independence but money does now shower from the heavens and few organizations can afford to run the programs on their own. Fortunately I work for one such and seeking funding is not one of my problems.	**Accredited CME provider**
I oppose the elimination of commercial support of continuing medical education activities. Over the past years I have attended many continuing medical education activities funded by pharmaceutical companies and other industries and administered by medical schools and other accredited providers of continuing medical education. Programs generally have been outstanding without commercial biases. Most of the CME live programs that I have attended in the past years were continuing medical education activities funded by pharmaceutical companies and other industries and administered by medical schools and other accredited providers of continuing medical education. I have found them to be truly educational. The commercial content is minimal. By abolishing commercial support of continuing medical education activities, you will throw out the baby with the bath water. Please do not eliminate commercial support of continuing medical education activities.	**Accredited CME provider**
I personally think that commercial funding for CME is acceptable. I understand that the companies want to sell their wares so to speak, but it is only on an occasional, isolated program that I have attended in the last 12 years, that I have seen any bias toward the product of the sponser. Most of the programs are unbiased and provide a well rounded presentation. I would hate to see the funding of these sponsers eliminated.	**Other**

I speak in favor of the new paradigm proposed by ACCME. Commercial support can be in the best interest of the public when all 4 of the proposed elements are achieved. In considering element 2 I would like to make the following comment. Professional practice gaps do exist and can be identified with tools presently available to many providers. This is true both at local and more universal (national) levels. However, when examining Quality of care in the learner's own practice this will be problematic. Since the timing of provision of the educational experience is remote from the likely performance changes specific tools well be needed to develop useful data over time. Most of the CME provided under our sponsorship takes place remotely from the site of care delivery and acquisition of data may of necessity come only from the learner after an unknown period of delay. This combination of delay and potential reporting bias may make the resultant data unreliable. It is my opinion that great care must be given to this part of the proposals so that a fair and equitable plan is developed.	**Accredited CME provider**
I strongly disagree with ending commercial support of CME. First, let me state that I receive no compensation from nor have any affiliation with a commercial supplier. I have received a tremendous amount of valuable education from such suppliers. Additionally, as it is often free, I am permitted to pursue more opportunities than I would be afforded under your proposals. I have notice no biases in the commercially supported CME I have taken. Finally, it is farcical to believe that simply because material is generated by professional organizations, it is free from bias. Indeed, most of the academics I have encountered at these organizations have more political and pharma company biases than most of what I have seen that is commercially produced. Please reconsider eliminating this valuable resource.	**Other**
I strongly favor elimination of commercial support for ALL accredited CME activities. Given the absence of data either refuting or confirming the injection of bias in CME by commercial support, I believe the argument can be strongly supported by likely positive effects regarding the face validity of accredited CME and enhanced public perception of the CME industry. Further justification is provided by the social justice considerations regarding covert public support through pharmaceutical and device manufacturers (whose revenues are provided substantially by the public) of continuing education (a cost and professional obligation of being a medical professional) for one of the wealthiest segments of society (physicians). Commercial supporters could use the >$1 billion dollars granted to CME providers to enhance drug compassion programs for those unable to purchase needed medication or assistive devices. The public, if it desires, has a venue to further underwrite CME for physicians through legislative appropriation by elected representatives to CME providers. (The public already provides support to certain "state-supported" universities that are accredited providers of CME to underwrite the cost of the continuum of physician education). The CME industry should be supported by charging registration fees reflective the true cost of the activities. For most physicians, even increased registration fees would contribute a relatively small amount to the true cost of CME which includes the actual and opportunity cost associated with being away from practice. This may decrease the number of CME events but it is speculative that this would compromise healthcare quality or performance. Certain organizations would have to adjust to the absence of commercial support. I speculate that eliminating commercial support could improve healthcare quality and performance by focusing attendees and providers of CME more directly on practice gaps relevant in their learners as opposed to secondary considerations of underwriting other organizational needs and/or acquisition of commercial support . The national CME "curriculum" and enterprise could potentially be altered in ways beneficial to the public. Our operations as CME providers may be greatly simplified if commercial support of CME were prohibited and the operational costs incurred by many CME providers may drop as well. Thank you.	**Other**
I support allowing CME providers to continue receiving financial support from commercial enterprises in the same manner that they do now. When commercial enterprises provide financial support for CME activity, they help to keep down the cost of CME activities that we providers need to maintain certification or licensure and that we need to enhance our medical knowledge and our ability to serve our patients. Financial support of CME programs is a very worthy and beneficial use of the great profits that commercial enterprises realize from their business activity. All CME activities, regardless of the source of financial support, should continue to receive scrutiny to ensure that the information presented is current, relevant, unbiased, and supported by the available research data. Commercial support of CME programs does not ensure that the programs will be biased and unsuitable. I expect that restricting or eliminating commercial financial support for CME programs will result in fewer CME opportunities being available and affordable to me and other providers. That would be an unfortunate loss, and it is a preventable loss.	**Other**

I support and agree with the direction that the ACCME is taking with this policy clarification. I agree that the elimination of commercial support of CME is a laudable goal and that the issue of alternative funding should be part of this discussion. I wonder, however, if the 4 stated requirements will really work, will be enforceable by the ACCME, and will be found to be a workable solution for very many providers. Even now the SCS are complex and poorly understood by many providers. So if they're not understood, then they're not being followed even though many providers believe that they are following them. I think the current proposal adds another layer of complexity that, though well intentioned, cannot easily be understood or followed as the ACCME intends. As such, I think providers will continue to accept commercial support in violation of the policy (most likely due to ignorance or misunderstanding over it) or completely relinquish commercial support in a state of frustration. For the 1st condition, I am unclear what it what it means that an organization does not accept commercial support AND that is is free of financial relationships with industry? Does this proclude the provider who declines commercial support but whose faculty gets research grants from industry? What other agencies besides the US Government might be included in this group? I suspect that the list of orgnanizations that meets BOTH of the conditions set forth under #1 is very short, but I just don't know. I am unclear on what it would look like to be compliant with the 3rd condition. What is a bona fide organization? And what kind of content do they produce that an outside CME provider could use as the content for its own CME activities? Is the ACCME suggesting that the content be developed by the bona finde organization and then accredited by different CME providers? What would that relationship look like? Joint sponsorship with the bona fide organization? As for the 4th condition... how does it vary from or add to the existing SCS? It seems redundant to me given the current SCS. Aren't the current SCS, if correctly implemented, already supposed to verify that CME activities are free from commercial bias? What more does this 4th condition add? And if it does mean something different, then what would that look like in a real situation? In general, to reiterate, while I agree with the premise, I think the requirement to meet all 4 of these conditions is too complex and unworkable for most providers. I would like to see the ACCME articulate another set of conditions or to propose a graduated elimination over time of commercial support from CME. Furthermore, I would like to see the ACCME do even more to ensure that providers have a full and unequivocal understanding of the SCS and that providers have demonstrable implementation strategies of the current SCS. I know that the ACCME has already done a tremendous amount in this regard, and the resources on the Web site are many. However, it remains that many providers are confused, ignorant, or stubborn, and this fact is reason enough to shore up the message, especially in these times of greater scrutiny. I would consider the following types of activities to be better suited to have commercial support while being commercially bias-free: CME whose content is not in any way associated with commercial products or services. These would include activities on bioethics, physician-patient communication, cultural/linguistic competency, and leadership development. I think an even greater problem that is not being addressed by the call for elimination of commercial support is the issue of faculty and others in a position to control content having relevant financial relationships that create a conflict of interest. Even if commercial support were eliminated from all of CME, I think we would still have lots of ambiguity and misunderstanding over the issue of COI and the result would continue to be well-intentioned noncompliance and perceptions of bias in CME activities. This, to me, seems much more complicated and is also worthy of discussion. Finally, I think we allow a "loophole" in the SCS by permitting providers to use monies generated as "drug displays" for educational activities. Drug display fees or exhibit fees do not fall under the SCS and provide a source of financial support for providers. More clarity around this issue would be welcome. Thank you for this opportunity for comment and for reading this long message. I commend the ACCME for standing up to the status quo, always moving CME into a better place, and bringing up these important issues. Thanks again for letting me be a part of this.	**Accredited CME provider**
I support commercial involvement.	**Accredited CME provider**
I support continued commercial funding for independent medical education. It has been very instrumental in faciliating continuation of my medical education. Thank You, [redacted]	**Other**
I support scenario # 1 ("The status quo with commercial support of CME an acceptable funding mechanism"). Why? 1. Commercial entities drive improvements in health care. Traditionally, they have involved practicing physicians in this process, and I believe that should continue. 2. There already exists and exhaustive mechanism to ensure that CME is free of commercial bias. This is rigorously checked on CME accreditation visits. 3. In # 2 of the conditions, the idea of performance measurements of a learner's own practice is entertained. I submit that this is not practical, or even possible to measure accurately. 4. If "commercial interests" are entirely removed from CME, then major journals and meetings will be subject to severe funding deficits, and I believe that the commercial entities will then address more marketing efforts directly at consumers (patients)--a trend that already exists, and I as a physician find very troubling.	**Accredited CME provider**

I support the status quo with continuing use of the disclaimers as to any relationships of the speakers to any drug companies or funded speaking etc. I do not find any biased presentations of continuing education that are not easily discerned by the attendees. The health professionals have adequate education to be able to decide for themselves how to use the data presented at CE programs. I believe that the removal of commercial support for CE would have a strong negative impact on the availability and access to continuing education.	Other
I think this is a great educational opportunity for professionals like myself. With the present demands of thejob as an ARNP I am really dependent on the educatioal opportunities from this CME provider. Please allow them to continue to offer this great service. Thank you. [redacted]	Other
I think as long as commercial funding sources are disclosed, the conflict of interest is minimal. I think as physicians, we are smart enough to see when the presentations are biased. I think commercial fundings are great resources for medical education. It is an insult to physician's intelligence to say that we wouldn't be able evaluate the quality and biases of the education on the bases of it's funding source. I think direct market to the general populaiton is doing much more harm.	Other
I think eliminating commercial support for CME activities will place a burden on health care providers in finding affordable and convenient CME activities.	Other
I think it would be very difficult to sponsor CME activities without the support of pharmaceutical companies. They make it very easy for a nurse that works full time to attned a speaker presentation and get CME. In virtually all of the speaking engagements sponsored by pharma, I rarely have a feeling that I am being sol a particular product.	Other
I think pharmaceutical companies and others who wear a commercial hat are inherently in conflict with the notion of unbiased CME activities and should not fund nor play a role in CME activities. [redacted]	Other
I think that it would be part of a natural progression to national health care. While the dinners are better in commercially supported CME, the information is better from Cochran analysis, and impartial research and reviews. This also comes from my years as a researcher. I was funded by an NIH grant, my friend had worked for a drug company sponsored study. Her findings of tumors on her research animals were suppressed and she lost her job when she did not want to destroy the data. I don't trust data that is commercially supported. I know that we are asked to disclose our commercial sponsorship when we lecture and publish, but I have had lecturers answer my questions secretly, when their sponsors would not like the answer.	Other
I think that private companies and pharmaceutical companies can do unbiased reviews of important topics and offer free CME activities and should be able to continue doing so. Physicians are intelligent learners and can discern things that are clearly biased about a product as they learn. [redacted]	Other
I think this would limit our access to information. Most of the journals are provided free because of commercial support. Many online web based sites also have commercial support. If we don't have quick access to this information it will be difficult to keep up with the ever changing treatment options in medicine. This will hinder the care of patients. I do most of my continuing education through journals and online courses. If these are not available it will be dificult to get the required number of hours. If you take courses from different sources the comersial bias if often eliminated. Ido not have the time to attend enough continuing ED courses to get my required hours. I know that I am not the only one with this issue.	Other
I totally disagree. The CME's I have received that have had Commercial Support has been extremely beneficial. Such a decision will impact the quality and quantity of CMEs available. So I STRONGLY DISAGREE!!!	Other
I tried to submit comments before, but your submission system would not allow me to submit as an approved CME provider - which [redacted] IS If you cannot get a comment submission process to work, how am I supposed to have confidence in the oversight of our CME process?	Other

I use Commercially Supported CME all the time. This is done, naturally enough, to keep me abreast of the current growing edge of medical practice and knowledge. Since I maintain a medical license on the basis of these accumulated CMEs and have such a small practice as to not support directly celf-funded acquisition of CME, the elimination of Commercially Supported CME would jeapardize the continuation of my practice. The CME that I get through the Commercially Supported source is, in fact, the some total of what I do get. I find it unbiased and very fairly presented in interesting and comprehensive formates easy for me to access and participate in. If these activities were made no longer available I would probably continue to practice, but without their help and risking the loss of my license. It simply would not pay for me to support such education independently. Please continue to allow such so that those of us in varying degrees of retirement may not only stay current in our knowledge, but, also, continue to faithfully serve a small group of patients who depend upon our services and wish to continue to do so. As psychiatrist, I often serve as advisor to my long returning patients as to who they might consult for various physical problems and what options are available. Without my CME, I would hardly be in a position to act as such an entry for further appropriate services.	**Other**
I use their services a lot and find them extremely helpful. It would be a shame to eliminate the educational experiences they provide.	**Commercial Supporter**
I vote for a "new paradigm" but not the one put forward by ACCME. There are several problems with the solution put forth in the call for comments: 1) Many US government agencies receive commercial dollars (even NIH and CDC) 2) The committees who help draft policies, guidelines, and reports for the federal government are often made up of key opinion leaders who have many ties to industry. I saw this first hand when I was on the [redacted] 3) Limiting educational needs to organizations that do not take commercial dollars would limit the breadth and depth of CME to clinicians (and this woudl not be in the public's best interest). 4) There are many problems with NQF measures. See this article for just some of the problems: "Public Reporting of Antibiotic Timing in Patients with Pneumonia: Lessons from a Flawed Performance Measure by Robert M. Wachter, MD; Scott A. Flanders, MD; Christopher Fee, MD; and Peter J. Pronovost, MD, PhD". Ann Intern Med. 2008;149:29-32 5) There are many areas of medicine that do not have any bona fide performance measures (i.e., the treatement of cellulitis or the accurate diagnosis of sinusitis). Limiting funding to areas where there are "bona fide" measures is like limiting air travel throughout the world to the airspace over Maine. 6) Since when does the ABMS or the FSMB provide curricula? The business of those organizations is in testing/accrediation/licensing/credentialing. It would be analagous to the ACCME providing a curriculum. Educational organizations like the medical schools and the medical societies should be the ones that create the curricula. The paradigm that I would put forth is to have the decision of which proposals receive commercial support be third parties. This would operate similar to an NIH study section. I am NOT suggesting that all of the drug companies contribute to an independent foundation. I am suggesting that independent bodies/boards make the decisions of which proposals should be funded. National criteria could be derived that would stipulate the criteria for someone to serve on a commercial supporters "grant decision making team". These persons could even be appointed by independent parties (like a referee at a basketball game).	**Accredited CME provider**
I was solicited by a CME vendor to send a modified form letter to you urging that industry maintain a role in CME. "Otherwise, our organization could not exist..." I give many talks to many audiences, and have been impressed by the insidious and pervasive bias that industry funding exerts, especially among endocrinology opinion leaders. Nearly all of these leaders have ties to industry that rpovide them substnatial extra money in their pockets each year. You can review the authors of the ACCORD paper, published June 12, 2008 in NEJM to see that ever author of the article has extensive ties to industry. The diabetes community's resistance to the "negative" findings form ACCORD and ADVANCE (NEJM, June 12, 2008) underscore the degree of conflict of interest that exists between drug comapnies and endocrinology opinion leaders. I woudl urge that industry money be completely disconnected fdrom CME. Another issue is that advocacy organizations such as ADA receive tens of millions of dollars in funds from drug and device manufactiurers each year, and sponsor amssive annhual meetings that are lavishly funded and conspicuously dominated by commercial influence. This creates a conlfict of inteerest that is reflected in the fact that both the ADA and the AACE have long encouraged more aggressive glucose and BP control that what is justified based on evidecne from RCTs. More recnetly, ADA leaders have been strongly resisting efforts to modify diabetes quality measures for glucsoe control to acocmodate new data from ACCORD and ADVANCE, which showed lack of benefit of tight glucsoe control on mortlaity or cardiovascualr events in adults with type 2 diabetes. This sceanrio smacks of conflict of interest, due to the ADAs dependence on industry funds, which likely comproise more than half of the ADAs $200 million a year budget. In additon to reducing industry influecne on CME (at one meeting my colleague was invited to a speaker's beurau and told she could use only the slides provided by the manufacturer of Exubera inhaled inuslin (which was subsequently noted to casue lung cnacer), it would be benficial to publicize the instituional conflicts that exist between ADA (and likely AHA and ACS) and industry. These too lead to undue influence of industry on the community of practitioners. As a	**Accredited CME provider**

perosn who has been an ADA member for about 20 years, and served fore 3 years on the writing group for their national diabetes guideline and currently serve on their grant review committee (and have published over 100 paper son diabetes care, and been an investogator in ACCORD), I have many morre stoires I coudl tell you. If you woudl like me to testify or discuss these issues in more detail, I would be willing to do so.	
I work for a not for profit organization that offers educational programs for physicians. The cost to carry out such events would be prohibitive to our organization if we were not able to get commercial support for our continuing medical education activities. We have the utmost respect for the ACCME's commercial support policies and we take great precautions to make sure that we adhere to your standards. If you were to eliminate commercial support of CME activities, it would make it impossible for us to continue to offer high quality, complex programs to our attendees. I strongly urge you to NOT eliminate commercial support of CME activities. Sincerely, [redacted]	**Non-Accredited CME provider**
I would encourage ACCME to consider seriously alternatives to commercial support for CME. Four years ago, [redacted] adopted a comprehensive conflict of interest policy that eliminated acceptance of commercial support for CME. The benefits of this policy have been overwhelmingly positive. The [redacted] policy states that "the selection of drugs, devices, supplies, equipment and services for purchases, or inclusion in a formulary or Clinical Practice Guideline, must be based on sound clinical (quality, safety and effectiveness) and business (dependability, value, service, price) criteria. Relationships between [redacted] physicians and vendors … must be free of conflict of interest or the appearance of conflict of interest." The policy prohibits physicians from accepting reimbursement from vendors for the cost of travel and/or attendance at product demonstrations, conferences or educational programs, as well as from accepting funding from vendors for CME programs directed at [redacted] physicians. In part, the intent of the policy is to insure that education provided to our 7,000 physicians through 16 state-accredited CME programs is free of industry influence, results in superior care, and is in the best interests of our patients. Viewing CME as playing a critical role in delivering quality and effective care, [redacted] elected to replace commercial support with internal funding. The positive impacts of eliminating commercial support and utilizing internal funds have been many. Educational interventions are now more comprehensive and better designed to address demonstrated gaps in practice and patient needs. The use of internal funding has shifted our focus to systems-based care, delivery of care, and organizational priorities, with less emphasis on treatment modalities. We now demand greater impact from education and more rigorous, higher-level outcomes. Our internal consultation and funding process allows for input and review by leadership, and improved needs assessment, instructional design, and outcomes measurement. Eliminating management of commercial support grants also freed CME staffing time and resources to focus more on the appropriateness, quality, and effectiveness of educational interventions. In the broad context of health care delivery, the cost to our organization of eliminating commercial support has been modest. We estimate that the annual cost of educating our physicians is less than $600 per staff physician. These costs are more than compensated by improvements in prescribing behavior, better targeted education, and improvements in performance and patient outcomes. There is a fundamental question confronting ACCME: "Why does CME need to rely upon commercial support?" No other area of healthcare is supported to this extent in this way by industry. It fuels the appearance and concern, rightly or wrongly, that education is potentially biased. CME must insure that the education is not only free of bias, but delivered in a way that promotes professionalism and practice that is ethical, objective, needs-driven, evidence-based, and patient-centered. One clear alternative to commercial support is to eliminate it and better integrate CME into the core of healthcare delivery.	**Accredited CME provider**
I would not like to see elimination of commercial support for continuting medical education activities. As an RN I participate in some of these activities and find them quite useful. I feel that while there may be some bias placed on certain drugs, that the recipients of these educational materials are able to do comparison and critical thinking to gleen the important messages. Medical and Nursing professionals are able to differentiate and compare and utilize what is available in making decisions. [redacted]	**Other**
I would support the new paradigm that puts forth four criteria that must be met in order for commercial support to continue to be allowed or using the current system and to make minor adjustments but to continue with commerical support of CME remaining an acceptable funding mechanism. I don't believe that we should eliminate the availablity of activities that would limit the requirements to maintain certifications or licensure for individuals working in the medical fields. So much is learned during some of the sessions. Maybe if we could think of ways to keep this learning intact.	**Non-Accredited CME provider**

If an industry-donated, pooled funds approach was taken, it will seriously damage the amount of CE grants given. By not allowing pharmaceutical companies to have a say as to what they would like to support they would be less willing to fund. This will also have a huge impact on MECCs and Accredited Providers in terms of staffing. Less money, less grants, less programs to design and implement, less jobs, less education for HCPs. Also who would be responsible for distributing the fund and how would they determine what to fund. This is replacing a workstream that has been working (after being cleaned up from the late 90s and early 2000) with a structure that is not in anyone's best interest, especially the patient.	**Commercial Supporter**
If one believes (as I do) that CME is a matter of public trust, then what matters is the **perception** of COI. The only way to eliminate the perception of COI, despite all the firewalls in place, is to remove commercial support from CME. It is not unreasonable to ask physicians to bear the cost of their continuing education -- we are in the top 1-2% of income earners and have been afforded many privileges by society. One of the issues is we are not dealing with our 'entitlement' attitude. It would also not be reasonable for organizations to build modest CME support into their budgets (which would involve some cost for payors), but I suspect the public will feel a lot better about supporting "clean" CME. My preference is to remove all commercial support from CME. ACCME's new paradigm is incremental and better than current state, but problematic from my perspective as as stated. For one, MECCs are in theory supposed to function as distributors of pooled funds, but there is clear topic bias in what they develop. In order for the new paradigm to work, I think the distributor of pooled funds needs to be non-profit, with all individuals in a position to distribute funds having absolutely no ties to drug and device makers (they should be disclosed like faculty and planners). I like criteria #1 and #2 in your new paradigm (well done!). Re criteria #3 in the new paradigm -- the AMA and specialty societies should be excluded from the list of bona fide organizations because they have ties to commercial funding. Organizations receiving commercial support for operations or member benefits should be excluded from this list.	**Accredited CME provider**
If you actually do this you can say good-bye to small CME providers - it will turn into big business for a few providers and be extraordinarily expensive to everyone, the ACCME as well as ordinary physicians. We are the only accredited provider of CME in Montana. We are very careful to keep commercial support separate from education. (Remember, we are the home state of Senator Max Baucus, chair of the Senate Finance Committee.) Furthermore, we could not survive without financial support. Without us providing the CME topics extremely rural physicians need, our physicians are forced to leave their practices, patients and families to travel out of state at great expense to themselves to conferences which may not directly impact their practices. Reminder - the internet still does not reach every corner of the world. Please do not do this! Don't let the unethical practices of a few CME providers end support for those who carefully comply. Crack down on those you know who are acting unethically. Commercial support is not/does not have to be totally evil.	**Accredited CME provider**
If you do this, CME will wither considerably. Practicing docs are not going to pay a lot for CME; their incomes are getting constricted as is. You need to distinguish between education given via Speaker's Bureau lectures (which definitely should not be CME) and education developed by faculty independent of pharmaceutical companies albeit the latter provde the resources supporting the actual delivery of the education. I have been on the [redacted] an organization whose activities are supported by pharmaceutical companies through an education organization for [redacted]. We are leaders in the field of [redacted] education and develop our curricula completely independent of pharma. I am also the [redacted] [redacted] summartizes leading articles in the [redacted] literature and is sent to thousands of primary care physicians. That is obviously completely independent of pharma since we select s\articles from the leading journals. [redacted] have both received national awards for our education. Pharma has nothing to do with its content except that it needs to be in the field of [redacted] There can be a fire wall between pharma and good unbiased education, and Lord knows, we docs need all of the education we can get. Most are much too busy to read much literature any more.	**Other**
I'm not supportive of this proposal. Some issues of concern: 1) # 2....how would corroboration occur? By whom? when? who would pay for it? how would the data be shared? what HIPPA laws impact such a decision? will consent be required? will IRB approval be required? 2) # 3...interesting that I don't see academic centers lsited...the group FULLY responsible for all ME and GME! 3) # 4...how does one actually verify free of bias...one can survey for perceptions of bias..but even major medical journals with trained editorial boards and staff have missed it. Picking up acts of commission of bias can be fairly stratightforward, but acts of ommission of data for bias are next to impossible to assay for. Are educators weaker than researchers? ...we need a new system that matches and interdigitates with ME and GME.	**Accredited CME provider**

In a perfect world, this would make sense. Education and commercial payors as a source for funding should be separated. However, looking at the current state of health care and economy this is not practical. Where will funding come from if it does not come from some commercial sources? Universities are having enough trouble funding there own programs and health care institutions are cutting funding for CME to help curtail some of their overhead costs. Removing commercial entities from the arena for funding CME will cause more providers to do the minimal to keep licensure current but will not seek further education if they need to pay out of pocket. Rather than remove the commercial support for CME, the ACCME should look at further criteria to remove the potential for bias in the educational activities until other sources of funding are available.	**Other**
In a time of increasing demands on time and decreasing revenue, changing the CME system as now constituted is short sighted, reactionary, and above all, unnecessary. I have found most programs free from bias and extremely helpful to me and my patients. It works. Leave it alone. [redacted]	**Other**
In america, ours is a free, but commercially driven, society and should remain so. There is no perfect Organized Society. There will always be a need to be watchful for error and misbehavior and this is the charge for its citizens. but we should always avoid any effort to place any strangle holds on our freedoms but we must maintain a watch in order to be free to progress toward continued higher levels of growth and social success. This requires freedom to think and act, but maintain careful vigilence. ALLOW COMMERCIAL INPUT AND SUPPORT BUT BE VIGILENT.	**Other**
In March 2008, the ACCME again expressed the belief that due consideration be given to the elimination of commercial support of continuing medical education. Many stakeholders inside and outside the CME enterprise have expressed their views on this subject. The ACCME recognizes that although CME exists in a data-driven, evidence-based world, many are motivated by firmly held personal beliefs about propriety and professionalism. The ACCME is therefore proposing that the commercial support of continuing medical education end. The ACCME has provided three possible scenarios. First, that the status quo be maintained; second, that commercial support be eliminated completely; and third, that a new paradigm consisting of four components be implemented. The ACCME also proposes that all four components must be met in order for commercial support to be provided for an individual activity. Those four components are: 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 Form) 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. The [redacted] professional society of clinicians, scientists, and other healthcare professionals, [redacted]. [redacted] has an obligation to all its members to provide the best available evidence for diagnosis, therapies, etc. The CME Committee of the [redacted] takes its role to provide such high quality evidence seriously. Therefore, we have conducted surveys of learners' needs, their opinion of the quality of education delivered, and their perception of commercial bias with every accredited educational offering. Thus, it is the opinion of the [redacted] that commercial support not be eliminated. We also do not favor implementation of the "new paradigm." The [redacted] strongly encourages the ACCME to maintain the status quo. With regard to the second scenario, the complete elimination of commercial support, the [redacted] concludes that such a scenario would significantly reduce the amount and variety of CME. Other funding sources, such as the NIH and NINDS, are not in a position to provide the additional funding that would then be needed to support quality subspecialty CME. Consequently, the depth and breadth of offerings would diminish dramatically. In response the scenario three, a new paradigm, the [redacted] asks the ACCME to carefully consider the following. Component one identifies US government agencies as a potential source for needs assessment data. Government agencies are not necessarily unbiased. Reviews of guidelines produced by government agencies have revealed bias to restrict drug and procedure access – government agencies are subject to political influences as well. We ask the ACCME to consider that it is standard practice for government agencies to solicit expert opinion from basic scientists and clinical researchers as well as educators such as those that comprise the membership of [redacted] to compose position papers and lend their expertise to the development of protocols and policies. The [redacted] and NIH already consult with [redacted] members regarding emerging issues in the field and identification of practice gaps as well as for the development of guidelines for practice and research. Hence, it appears that the ACCME would have [redacted] request direction from a government agency that would in all likelihood turn to [redacted] to produce these priorities. Therefore, it is the opinion of the [redacted], that as a subspecialty society of dedicated [redacted] experts, we are in the best position to identify educational needs for our learners. Component two of the ACCME new paradigm states that CME should address a professional practice gap of a particular group of learners that is corroborated by bona fide	**Accredited CME provider**

performance measures of the learners' own practice. The example provided was the National Quality Forum. While organizations such as the NQF and the IHI have expansive data concerning public health issues, they infrequently touch upon issues related to our patient base. Granted, no one disputes the value of reducing medical errors that is so greatly advocated by the five million lives campaign of the IHI. However, restricting our focus in such a way would not provide our learners with content such as the wide spectrum of [redacted] complications of [redacted] in a clinic setting. We ask the ACCME to consider that while healthcare quality organizations may appear to be better suited for corroborating professional practice gaps; like government agencies, they too depend on experts such as those within specialty societies to develop their guidelines and initiatives. Therefore, it is the opinion of the [redacted], that as a subspecialty society of [redacted] [redacted] experts, we are in the best position to identify professional practice gaps for our learners. Moreover, we have already been doing this by means of our Members Needs Assessment initiatives. Component three of the ACCME new paradigm suggests that CME should be derived from a specified curriculum by a bona fide organization such as the AMA, AHRQ, AMBS or FSMB. Again, much like government agencies and healthcare quality organizations, these organizations do not necessarily have the subject matter experts available to support the development of CME content for a subspecialty such as [redacted]. They too would therefore, collaborate with our membership in order to develop this content. In addition, this step implies an inherent assumption that such bona fide organizations would produce curriculum that meets the educational needs of learners they have not identified. This is directly contrary to the process for content development. The [redacted] would have to have the right to refuse content that is inaccurate or contrary to the true educational needs of its learners. Therefore, while collaborating with such entities in curriculum development could be an option, it is best that the [redacted] develop CME content instead of these other organizations, since we already have the expertise and have identified the educational needs of our learners. Further, the patient populations that we care for are already marginalized by their perceived rarity or inevitable degenerative course. National general medical organizations such as the AMA must focus on widely prevalent topics such as infectious disease and cardiovascular disease. They may not have the expertise or desire to consider the care and research needs of smaller groups such as [redacted] [redacted] complications of common illnesses. Yet, each patient group deserves the best possible care and attention to achieving curative therapies. Component four of the new paradigm states that CME is to be verified as free of commercial bias. There are many forms of bias other than direct financial conflict of interest. For instance, intellectual conflict of interest is likely another strong driver of opinion and bias. The standard approach has been to attempt to minimize and potential financial conflicts of interest. The [redacted] [redacted] takes transparency seriously and has done its due diligence in monitoring and addressing commercial bias at all stages of the content development and delivery process. Over the past 6 months, we have strengthened our oversight of this process and changed procedures to ensure compliance with ACCME guidelines. This is a reasonable approach, but there have been issues in implementation. Therefore, remediation should be aimed at improving implementation rather than attempting to single out and eliminate one source of bias. Finally, the objective and mission of the [redacted] has always been to advance the neurological sciences pertaining to [redacted]; to operate exclusively for scientific, scholarly and educational purposes; to encourage research; to provide forums, such as medical journals, scientific symposia and International Congresses, for sharing ideas and for advancing the related clinical and scientific disciplines; and to encourage interest and participation in the activities of the [redacted] among healthcare and allied professionals and scientists; and to collaborate with other related professional and lay organizations. In recent years, there has been tremendous growth in new diagnostic information, pharmacological and neurosurgical treatments for [redacted], as well as a greater understanding of impaired motor control function. The [redacted] offers clinicians and their patients an essential link to this knowledge. Therefore, the [redacted] has an obligation to all its members to provide the best available evidence for diagnosis and therapy, along with quality education in the field of [redacted]. We firmly believe that the [redacted], and not some other organization, is in the best position to do so. Without commercial support, meeting our obligations to our membership would be significantly impeded. The [redacted] has also taken great strides towards the elimination of bias as we now develop opening symposia for our Congress that are supported by multiple commercial supporters and instead of a sole supporter. Thus, it is the opinion of the [redacted] that commercial support not be eliminated; neither should the "new paradigm" be implemented. The [redacted] strongly encourages the ACCME to maintain the status quo.	
In my first submission, I inadvertently added the wrong information, so plesae disregard. The proposal that commercial support of continuing medical education should come to an end. While some legitimate questions have been raised about the best way to ensure that continuing medical education is free for commercial bias, the [redacted] believes that there must be a way to continue the good that it and other commercial companies do in the way of supporting compliant, evidence-based independent medical education. Healthcare professionals and patients benefit from that support. Continuing medical education will suffer without that support. Rather than prohibiting commercial support for all continuing medical education, the [redacted] encourages the ACCME to continue its good efforts through its guidelines and ongoing monitoring to ensure that only appropriate independent commercial support is permitted.	**Commercial Supporter**

In order to keep Continuing Medical Education available to a variety of disciplines, I believe commercial support should remain. Not everyone has the time, availability or funds to remain current with new research, technologies etc. in very dynamic medical areas.	**Other**
In responce to the " call for comment" by the ACCME regarding commercial support for CME activities, I would like to see the first of the three scenarios supported. A status quo with commercial support of CME as an acceptable funding mechanism seems a logical approach to facilitating quality and quanity of contiuing education programs.If the funding of CME activities was restrited with complete elimination of commercial support the availibity of CME/CEU activities would be profoundly effected. All learners must be dicriminating in the information they receive, no matter the source. At this level of professional learners they are very atuned what is a sells job and what is information based on evidence and therapitic practice. To elimate commercial support is short sighted and has the potential for a very negative impact on quality and quanity of CME offerings that enhance knowledge and practice of health care professional. While minor adjustments may be needed, I would encourge the ACCME to maintain the status quo with commercial support of CME remaining an acceltable funding mechanism	**Other**
In response to your Call for Comments regarding the above statment I would like to provide the following: Scenario 1) Commercial support of CME is an acceptable funding mechanism, as long as the activity meets the updated SCS and the company providing it does not meet the definition of a commercial interest. Scenario 2) Complete elimination of commercial support will only serve to handicap physicians and other healthcare professionals in that a) the number of CME activities could be inadequate to fulfill requirements; b) the cost, if passed along to the [redacted] could be a significant burden; c) the variety of topics currently provided could be severely restricted; d) It could severely impact [redacted] ability to stay current regarding medical practice and as a result be harmful to patients. Scenario 3) #1 Doesn't make sense to me....you want to rely on government agencies to identify and verify educational needs....which agency has additional capacity, and how are they going to become experts overnight. If you look at the individuals within the CME exterprise, many of us have 10 - 15 years in this business. #2 We currently identify gaps via literature, surveys, interviews, etc. Why is that not enough? Why an attempt to make it more complicated when there are already established methods for identifying needs? #3 It isn't a bad idea to have an organization such as those listed provide review and sign-off on content. I wouldn't have any objection to a third party review such as the AMA, but I don't agree that content can only come from them. #4 AGREED!	**Non-Accredited CME provider**
In the world of the community hospital, many miles and hours away from the [redacted], the commercially supported CME is the way to get education which is controlled by the standards required of a CME presenter, which not only redounds to the benefit of the practitioner, but to the care we can afford to our patients. I have not noted a bias problem that makes me suspicous of or uncomfortable with the education I have received. And I feel the standards that must be met protects the general public, my patients. I truly believe this is an area where change is not needed.	**Other**
In these times of economic, work productivity, pay for performance, time constraint, family demands, and other pressures, we must not move hastily to "toss out the baby with the bath water". Not all commercial support is negative. Healthcare professionals should be given more credit than they are. We did not become professionals by not using critical thinking skills and judgment. Most of us are capable of recognizing bias in continuing education activities. Commercial support can provide invaluable assistance in getting much needed information to us. Perhaps the emphasis should be more directed toward the participants who should be adept at rejecting bias that can be both obvious and subtle in some activities. The type of commercial support offered/provided should be scrutinized. Those of us who are "low rollers" in healthcare appreciate the mere opportunity that some of these activities provide.	**Other**

Industry influence cannot be banished from CME through the proposed safeguards. The verifying organizations that identify and verify educational needs may not be free of industry influence. Even Federal agencies may have industry ties. For example, NIH is involved in cooperative research and development agreements (CRADAs). Other Federal agencies also have public-private partnerships. And individuals working at NIH and other Federal agencies may have financial conflicts of interest with industry. The requirement that CME content be " from a continuing education curriculum specified by a bona fide organization, or entity, (eg, AMA, AHRQ, ABMS, FSMB)" is vague. More importantly, this list includes entities, like the AMA, that accept industry funds. It seems inconsistent for te ACCME to propose that organizations "that have financial relationships with industry" be excluded from the identification of educational needs, but not the content of the education. The requirement that CME be "verified as free of commercial bias" is untenable. Industry funds many "educational" efforts aimed at market preparation for drugs still in the pipeline, or market expansion for currently sold drugs. Recognition of "commercial bias" in these instances requires not only marketing knowledge but familiarity with therapies in the pipeline of each company. If this sounds like a daunting task, it is. That's why the best way to ensure that CME is free of commercial bias is to refuse industry funding.	**Other**
Industry supports even medical congresses and it is wel accepted by medical comunity if certain rules are followed. Continous Medical Educational acivities are just an example of the same phenomena.	**Other**
Is support the continuation of commercial industry in the CME education	**Commercial Supporter**
Issue 2: The ACCME Believes That Due Consideration Be Given to the Elimination of Commercial Support of Continuing Medical Education Activities "The ACCME takes the position that ACCME proposes that there are at least three possible scenarios relative to commercial support: 1) the status quo with commercial support of CME an acceptable funding mechanism, 2) the complete elimination of commercial support, and 3) a new paradigm." Below is [redacted] response to the ACCME position. Ø [redacted] feels it is our responsibility to comment on the ACCME position. In the last year alone, [redacted] educated over 120,000 US physicians impacting 417 million patient visits. In 2009, [redacted] anticipates similar if not greater reach. Our physician learner communities regularly share their insights or barriers to delivering ideal care, and we are tasked with developing the appropriate educational curriculums to help address these challenges. One of the most consistent challenges we hear about from our learner community is the continuing need to keep updated in their practice area as well as new diagnostic and therapeutic approaches within and/or new to their scope of clinical care. Ø The demands on primary care physicians, as well as specialists, are becoming increasingly complex with the diverse and ever-changing patient populations. CME is what physicians rely on to obtain independent, credible, fair-balanced, objective, and scientifically rigorous information to advance their clinical practice. In 2007, [redacted] awarded more than 1 million credits over nearly 2,000 CME course hours. In the first half of 2008 there has been a significant increase in [redacted] online CME activity with participation up 13% over this same period last year. These data demonstrate that physicians want to get information where they want it, when they want it, and how they want it to fit in with their excessively busy practices and lives. According to one primary care physician who responded to a July 2008 [redacted] member network poll on the need for access to CME opportunities, "We need all the help we can get for any hope of staying current." Ø According to [redacted] research, 74% of PCPs seek product-related treatment information weekly. With [redacted] education, health care professionals can get the information they need in a compressed amount of time, whether it is live, online, or through print. Health care professionals are looking at how they can integrate what they learn in a way that will have maximum impact on their patients, as well as work for their lifestyle. According to [redacted] research, 95% of the information gathered at CME programs is used by physicians to update or refine how they treat their patients. These are the needs that [redacted] seeks to meet and one of the means that we are able to meet the need is through the timely and effective receipt of commercial support based on clinical gaps that are validated by a combination of external third-party data sources and self-assessment data from our learner community. Ø Based on the above, [redacted] does not support the ACCME position detailed in the "Call For Comments relative to the ban on commercial support." 8 Certainly the issue of commercial support of CME is complicated, nuanced, subject to interpretation and misinterpretation, and affects providers, institutions, faculty, and participants in different ways (if at all) and to different degrees. No organization that accepts or provides commercial support for CME, each of which has vested interest in medical decision-making, can be blind to the fact that requests for or acceptance of such funds raises potential for conflict of interest or, perhaps equally as importantly, the perception of conflict of interest. And, also as certainly, providers, provider-associated institutions, faculty, and commercial interests vary in the stated or actual commitment or proficiency in their management of these potential conflicts of interest. Historically, the relationship between institutions and faculty and facilitators of CME is not always as transparent as it could be, and this has cast some doubts on the integrity of the process on the part of some learners. However, these facts cannot detract from the proven tremendous value of CME in disseminating much-needed clinical updates for learners, particularly community-based, primary care practitioners, who may not be in a position to fund their CME/CE efforts on their own. 8 While the current system may not be perfect, the present system of CME delivery	**Accredited CME provider**

and, we would put forth, our health care system, relies to a great degree on the financial backing of commercial interests. This is true throughout the entire enterprise and not uniquely or isolated to CME. And in this system the ACCME has put forth an extensive and structured system for accredited education. In this context it is the provider who is responsible for working with contributors to the CME activity to plan, implement, and evaluate activities to adhere to the standard of conduct of education without commercial bias. In 2007, [redacted] asked physicians who attended [redacted] activity to rate us on the comment, “The material presented did not promote a specific proprietary business interest of a commercial entity.” The results showed that commercially supported CME earned a 6.57 on the 7-point scale, a slightly higher rating as compared to noncommercially funded CME activities, which earned approximately a 6.52. These results demonstrate that the perspective of physician-learners to these presentations is that commercial bias did not appear to be apparent in most programs. In fact, most likely due to heightened awareness by the provider and faculty presenter about the need to ensure high compliance with the Standards for Commercial Support, the perceived bias was greater for the non-commercially supported content and presenters compared with commercially supported content. This speaks to the “a priori” effects of the structured communications and responsibilities of providers and faculty already mandated by the ACCME relative to commercial support. 8 These data and other available evidence are the facts. To withdraw the availability of commercial support for CME, in the absence of strong evidence of bias in the system currently and without another system for funding CME in place, jeopardizes the dissemination of important medical updates to learners eager for that knowledge. Rather than calling for the complete withdrawal of commercial support for CME, it would seem most appropriate to modify (strengthen) existing standards, but not in burdensome or limiting ways, and not just to have rules for rules’ sake or create undue burden on providers; but rather, to more fully avoid bias in content and to reward with the highest degree of accreditation those providers that best and most transparently manage all potential conflicts of interest, real or perceived. Independent needs assessment (perhaps by the ACCME or other organizations) and adopting more stringent criteria for documenting how topics of CME are chosen are potential ways to improving the current system. This concept is further described below. o In addition, in the current health care and clinical practitioner environment, commercial support is critical to the affordability of the maintenance of physician knowledge, performance, and patient outcomes. Physicians believe accredited education is critical to their ability to treat patients effectively. When [redacted] asked its member network, “If there were fewer CME opportunities available as a result of the [CEJA] ban, how would this impact your ability to deliver optimal patient care?” On the whole, 92% of the doctors disagree with the ban, and they state three primary ways it will impact them: 8 It will be more expensive to receive continuing medical education, which makes it more difficult for physicians to stay up-to-date 8 The quality of CME will decrease 8 Fewer opportunities available will hurt patient care Actual quotes: “Attending CMEs increase knowledge base, providing new outlook on care and available treatments. Discontinuing industry-supported CMEs would limit the amount of information I receive as a frontline healthcare provider, and negatively impact on my ability to deliver optimal patient care." "It will take longer to get time to read information on new or newer ways to treat patients." \t Commercial interests are not charged with the responsibility of supporting each of the topics that comprise the curriculum of education for the post-graduate practicing physicians. Providers use funds from commercial interests as a means of ensuring that they can expand the educational curriculum by not having to devote financial resources equally to all topics. So, what seems like curriculum bias is just a bias of education that is “reportable” based on its connection with commercial support. Regarding the ACCME’’s “new paradigm” for commercial support, [redacted] submits that the suggested new paradigm is not feasible for the universe of providers for many reasons including: o The updated Criteria for Accreditation and added requirements for monitoring and reporting have significantly increased the resources providers need to plan and execute CME activities. It is fair to say that all CME providers are currently under-resourced to allow for upgrades to their organizational structures. This new paradigm would add such a high level of burden to already over-stretched providers that it could undermine the whole system, produce severe adverse consequences, and potentially cause a collapse of the whole system. o The new paradigm is vague in terms of goals, administration, process data source vetting and updating, and data source utilization, and it is not based on validating or substantiating the “real-time” education needs of physicians and not sufficiently actionable by the universe of accredited providers. o The new paradigm doesn’t appear to have the focus or depth to add to the quality of the CME enterprise. It appears to imply that all providers can fit into a “one-size-fits-all model” in order to provide the ACCME with the ability to assure critics of commercial support that everyone is lining up along one group of politically expedient data sources. The paradigm fails to acknowledge the bias towards government and national groups as the “pre-eminent” data source of gaps and needs, ignoring the fact that these data sources are not collected in “real-time” and do not respond to the real-world, day-to-day, clinical practice needs of physician-learners. Nor does it respond to the uniqueness of the gap analyses conducted by providers and give them the leeway to structure CME in response to their needs assessments and the clinical practice gaps and educational needs of their learner community, which is one of the new updated ACCME criteria. o Reliance on governmental and quasi-governmental sources to define educational need does not represent the most up-to-date compiling of information. It is well recognized that there are data lags and deficiencies to the use of these data sources as a true representative of clinical practice gap/educational needs of practitioners. This model would slow down CME that is critical to the rapid pace of advances in medicine and therefore be

counterproductive. o The updated accreditation criteria of the ACCME have begun to significantly press and test providers. These combined with the myriad of forces (including legal, regulatory, and oversight organizations) are dramatically impacting the ability of providers to do what they need to: planning and delivery of education that matters to patients. There is an extraordinary amount of structure in the ACCME updated criteria. ACCME has now added new reporting and monitoring requirements. Any reduction of commercial support would require institutions to dramatically increase resources needed for CME, and this is not likely given overall resources available. With the elimination of commercial support, where would these funds then come from? The reality is that physicians need CME for their knowledge and for performance enhancement and for patient outcomes; they also need CME to maintain their license. Given the rate of change in the medical areas, in both diagnostic and clinical areas, they need affordable and accessible CME. The approach the ACCME should take is not elimination of CME but rather providing tools and a clear framework in which commercial support can be accepted by providers and whereby the public is assured of that transparency. In addition, if commercial support is eliminated, it is not credible to state or expect that providers can seek and obtain educational grants from private grants and those from government—all of which have limited resources available for CME grants, and the results would generate a major gap in funding available. However, we believe that there are worthwhile elements of the "new paradigm" that could be valuable in updating how commercial support is sought and obtained by providers: o A table of sources of qualified data and information sources can be established by the ACCME that would serve as the basis for qualification for commercial support—a new standard, if you will, that is sanctioned by the ACCME (ability to meet 'levels of evidence') but not dependent on governmental or quasi-governmental sources exclusively or a priori-defined. Such levels of acceptable evidence would be arrayed as follows: \tLevel A—Validated by a national association, national guideline or consensus statement, National Quality Forum, or other source in this level \tLevel B—Regional data, local data, institutional data, proprietary data compiled under the guidance of generally accepted standards for data collection and analysis \tLevel C—Unpublished or unpresented data (i.e., "data on file"), clinical study data alone, personal thought-leader opinion only that was not ratified or validated by other credible sources o In this model, Levels A and B would qualify for support. Level C can be used to support Levels A and B but in and of themselves would not qualify as data sources to validate clinical practice gaps and educational need. o In this model, Levels A and B could be further qualified by use of data evaluation processes such as that reported at http://www.ahrq.gov/qual/iompriorities.pdf. In this model, generated by Institute of Medicine (IOM) and the Agency for Healthcare Research and Quality (AHRQ) to identify the top 20 health care priorities, an evidence-based approach was used and was based on the following criteria which could be used to help inform the above model. o The committee used three closely related criteria—impact, improvability, and inclusiveness—in selecting the priority areas. o The committee recommended use of the following criteria for identifying priority areas: • Impact—the extent of the burden—disability, mortality, and economic costs—imposed by a condition, including effects on patients, families, communities, and societies. • Improvability—the extent of the gap between current practice and evidence-based best practice and the likelihood that the gap can be closed and conditions improved through change in an area; and the opportunity to achieve dramatic improvements in the six national quality aims identified in the Quality Chasm report (safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity). • Inclusiveness—the relevance of an area to a broad range of individuals with regard to age, gender, socioeconomic status, and ethnicity/race (equity); the generalizability of associated quality improvement strategies to many types of conditions and illnesses across the spectrum of health care (representativeness); and the breadth of change effected through such strategies across a range of health care settings and providers (reach). o In this model, the ACCME serves as an educator to providers, whereby they teach and support providers on best practices in data sourcing and analysis, while not placing undue burden on providers by limiting what data and information can be used to qualify clinical gaps and identification of educational needs of physicians. o According to the Macy Report, "A national inter-professional CE Institute should be created to advance the science of CE." In this construct, a percentage of educational grant funds from commercial supporters would automatically be earmarked for the Institute of CME. The funds would be used to create a system of quality improvement in CME and data sources for CME, and provide funding for a group of leaders in CME representing all provider types who could be accessed to address specific questions in education put forth by the provider community, ACCME, commercial supporters or others stakeholders in the CME enterprise. This could be analogous to the IOM or the GAO, which serves as a resource for Congress to advise and engage on specific issues that need support, clarification, or strategic development. Should any "new paradigm" be developed, PMI believes that it should first be piloted and results compared with existing systems to ensure that changes would in fact be based on evidence and need. Such demonstration of ACCME willingness to test a stated path is needed. That is because we feel that the ACCME has already placed many new and, while having merit in theory, still unproven systems for change on accredited providers in the form of the Updated Accreditation Criteria. Let accredited providers be empowered to fulfill their responsibilities without the ACCME proposing additional burdensome requirements before providers have had a chance to demonstrate what they have been able to achieve. Continuing efforts at change are only effective if change can be effected and analyzed. It is not appropriate to propose "changing the rules" without evidence that previously put forth requirements are either not working or manageable. Neither of these are the current circumstances relative to the requirements of

independence from commercial interests. The continued initiatives by ACCME to summarily change rules without seeking input from stakeholders and evidence of need from those stakeholders only serves to confuse providers and diminish the credibility of the ACCME.	
IT is especially important that CME continue to be provided to Midlevel providers that have commercial support since we are growing in use and support to provide care to our aging population. Often financial concerns are present when attempting to continue to update our knowledge base and industry support is greatly appreciated. Please continue to support commercial support to CME for midlevel providers. [redacted]	**Other**
It is important for the ACCME and CME providers to consider the impact of commercial interests and commercial support on CME activities, as independence must be assured for the best interests of patients. Eliminating commercial support from CME may be one option to potentially achieve the removal of commercial bias or influence from CME activities. However, this option seems short-sighted and does not account for the guidance that is already provided by the ACCME through the Standards for Commercial Support. The Standards serve as an effective barrier to unwelcome industry influence and offer a framework for how CME providers and commercial interests may interact to ensure independent, valid, and unbiased CME designed to improve or change physician competence, performance, or patient outcomes. As such, CME providers have developed effective policies and procedures to comply with the Standards, and these efforts must not be disregarded. The Standards leave many opportunities to discover and handle relationships; without them, other infringements that may not be as visible may occur. Useful partnerships with industry can also be forged, and clinical trials are an example. Support of research is good, yet tampering with results is problematic; truth in publishing is more important than banning industry from the educational activities that occur. Moreover, commercial support has contributed to CME providers' capabilities to develop innovative educational activities, such as those related to quality improvement that may not have otherwise been developed without the appropriate financial resources. CME providers and commercial interests have demonstrated that they can work together in accordance with the Standards. It is time to recognize that learners are capable of discerning bias (whether personal or commercial) and will benefit from being in a position to make their own decisions based on the evidence they are given. Banning industry from education will not help this. Rather, an opportunity exists for the CME community to educate physicians on the psychology of influence, how to evaluate scientific evidence, and how to work with the ethics of industry relationships. The ACCME, CME providers, and industry should welcome this. If commercial support were banned from supporting CME activities, it is likely that commercial interests would find other ways to allocate their funds, which may seriously undercut attempts to deliver quality, evidence-based education. Lastly, the [redacted] does not support the concept of pooling industry-donated funds as a mechanism to commercially support CME activities. This structure may offer its own potential for influence on CME activities and would be difficult to equitably manage across CME providers and provider-types. Thus, the status quo should be maintained, with commercial support of CME remaining an acceptable funding mechanism.	**Accredited CME provider**
It is necessary for me as a Doctor of Pharmacy and Physician Assistant currently practicing to maintain Continuing Pharmacy and Medical Education. The opportunities for quality CME/CPhE are dependent on financial and educational support from commercial concerns. Our ability to differentiate between advertisement and educational content is important in our everyday lives and we are good at it. We must have continued access to these resources and I ask you with all urgency to please not only allow but encourage medical education support from pharmaceutical/device companies.	**Other**
IT SHOULD BE SPONSERED OTHERWISE ITS AN EXTRA BURDEN ON PHYSICIANS IN ALREADY INSURANCE CONTROLLED ENVIRONMENT	**Non-Accredited CME provider**
It will be helpful for medical student to learn more and make great progress by continuing medical education activities.	**Other**
It would save drug companies much money. Cost savings should lead to drug price control legislation. Total elimnation of many useless jobs and pieces of mail and e-mail. Harder for societies and associations to support themselves in opulence. Would lower standards of care and require severe limitation of physician and hospital responsibility. New advances may be slower in coming, Overall, I favor such elimination of commercial funding.	**Accredited CME provider**

It's going too far... In an age of evidence-based medicine; please PROVE to me that patients are adversely affected by commercial support for education. Please offer alternative means of funding - who is going to help pay for large CME conferences? Please detail how large PHRMA companies can continue with DTC advertising which HAS BEEN PROVEN to alter prescribing habits. It's not that big of a deal - leave it alone and choose a battle this will TRULY affect patient care.	**Accredited CME provider**
June 11, 2008 [redacted] is accredited by the Accreditation Council for Continuing Medical Education (ACCME). Our mission is to deliver education that brings measurable change in healthcare professional competency with the goal of improving performance and patient outcomes. Given the recent concern and debate over the potential influence of pharmaceutical and medical device company financial support of continuing medical education (CME), [redacted] developed and distributed an e-mail survey to more than 21,000 physicians. More than 5,000 physicians opened our e-mail and more than 18% of these physicians responded to our survey, totaling more than 1,007 responses. According to the data and comments from physician respondents, an overwhelming majority, or 88%, do not believe pharmaceutical and medical device funding of CME should be eliminated. Furthermore,63% of physician respondents indicated that they believe pharmaceutical and medical device support does not lead to bias in education. Following is a copy of the [redacted] survey, including an executive summary of responses with relevant individual comments. If you have any questions regarding our survey or its results, please do not hesitate to contact me at [redacted] June 2008 Distribution: 21,820 physicians Opened E-mail: 5,524 Response Rate: 18.22% or 1007 respondents No Incentive, In-field 4 days Note: Due to rounding, not all percentages total 100% 1. Do you believe pharmaceutical or medical device company support of CME programs leads to bias in CME programs? 24% (244 votes) Yes 63% (633 votes) No 13% (130 votes) Unsure 2. Do you believe pharmaceutical or medical device company support of CME should be eliminated? 6% (64 votes) Yes 88% (890 votes) No 5% (53 votes) Unsure 3. If pharmaceutical or medical device company support of CME was eliminated, would you be willing to pay for your CME? 27% (270 votes) Yes 46% (461 votes) No 27% (276 votes) Unsure 4. Are you an AMA Delegate? 6% (59 votes) Yes 94% (948 votes) No Degree: 92% (924 votes) MD 7% (66 votes) DO 2% (17 votes) Other Comments: It is important to distinguish between certified and noncertified CME (e.g. educational versus promotional). I find CME activities a useful way to obtain information. I make my own judgment as to the use of a medication based upon the data, not what the [manufacturer] gives me. Give doctors credit for having some morals. Pharmaceutical companies provide many valuable services for our fellows in training that we would not be able to support from institutional funds. I understand the inherent bias of pharmaceutical companies but feel intelligent physicians can make independent judgments. Some sponsored CME is biased, some is not. Similarly, much of print media is subtle advertising for products or services. Should we do away with newspapers because of it? No more movies because of product-placement? The responsibility of determining whether CME is biased will always fall on the individual physician, no matter who is sponsoring the CME activity. If pharmaceutical sponsorship is eliminated, we will likely see further decreases in physician education. CME is a key function for treating physicians. Unfortunately there is not adequate funding for CME from sources other than pharmaceutical and device companies. It would be a major loss if this source of funding were eliminated. CME credits are supposed to keep one up-to-date with developments in the field. I appreciate that pharma companies "sponsor" CME -- it does not mean I am obligated to prescribe their product. NO I AM NOT WILLING TO PAY FOR CME CREDITS! Doctors can separate the important news from the biased news. Hospitals can not afford to sponsor talks by the best faculty available on many topics and use the support of drug companies. More and more, doctors are having things taken away from them--their rights in malpractice cases, reimbursements, the list goes on. This will discourage students from applying to medical schools as well. We need to fight for what little is left for physicians in this nation. Physicians do have higher ethics than it seems anyone will give us credit for. By denying the use of those Billion+ dollars, CME as we know it will cease to exist, including just about every national academy meeting, etc. This is just a bad idea!!! Unlike the non-CME Certified dinner lectures, I cannot recall a single instance where I could have identified a sponsoring company or product from the content of the CERTIFIED CME program. The entire issue regarding support by pharmaceutical or medical device companies is ridiculous. Surely physicians should be intelligent enough to assess data in a reasonable manner and to understand who is presenting it and what potential issues there might be present. I really enjoy taking online CME and CME at various conferences. I don't know how such opportunities would continue without industry support. Given my student loan and practice startup loan burden, I need all the help I can get. THIS TYPE OF QUESTIONING, WITH THE INFERENCE THAT PHARMACEUTICAL COMPANIES ARE A BAD INFLUENCE, IS INCREDIBLY INSULTING. (BOLD INTENTIONAL) GIVE ME A MODICUM OF CREDIT! I MANAGED TO MAKE IT THROUGH 12 YEARS OF FORMAL PRIMARY SCHOOL, 4 YEARS OF COLLEGE, 4 YEARS OF MEDICAL SCHOOL, AND 3 YEARS OF RESIDENCY BEFORE STARTING MY OWN PRIVATE PRACTICE. PHYSICIANS ARE NOT MINDLESS DOLTS. THERE ARE MORE THAN ENOUGH REGULATIONSON THE MEDICAL PROFESSION AS IT IS. Primary care doctors are being reimbursed by Medicare and other insurers so drastically low that we have no disposable	**Accredited CME provider**

income. I am not sure that the leaders in the AMA, State and local medical societies really know how disgracefully little the primary care doctor is earning. I am allegedly retired and read medical journals 8 or more hours daily and can't keep up. If I were still in full time practice I would have zero reading time because I would have to see many patients to survive financially. I love practicing medicine very much. We are now, in my estimation, the least desirable professions to be in. There is a serious loss of respect for the Internist or GP. I do not believe the AMA should be given the power to delegate what, where, how much, and how physicians get there CME for certification and state requirements. I am disturbed enough by this thought that I may reconsider my support of the AMA in the future. First it's PhRma and now this. Concentrate less on the where are the funds coming from and more on the accreditation and quality assurance that goes into the programs! The present's system is excellent, and very helpful in supporting unbiased Continuing Medical Education for Physicians. If it's not broken don't try to fix it! The ultimate decision to accept or decline any CME due to bias rests with the individual health professional. To absolve him or her of this responsibility makes keeping up almost impossible. I believe that there are sufficient safeguards in place in the current CME environment to prevent the influence of industry on CME content or faculty and allow for unbiased learning environments. I do not believe that funding exists to replace the millions of dollars currently furnished by industry to support CME. Physicians are so stretched and strained that the education made easily accessible only stands to improve care. Rapid dissemination of advances in medicine and standards of care is best achieved through active industry involvement. Physicians have a responsibility to maintain a balance in educational resources but to exclude corporate sponsored education would reduce education not enhance it. Reputable companies put on GOOD programs. It is easy to see where bias may exist in some of the data presented, but please, we are trained physicians familiar with bias, and yes, we will make our own decisions about which products to use. I have attended dinner/lunch/weekend conferences with experts that I probably would NOT have had an opportunity to meet otherwise, and in smaller venues where a more personal connection can be established and nurtured. I strongly urge you to not allow the AMA sub-comm on this topic recommend the discontinuation of this type of CME. Elimination of pharmaceutical funding support for continuing education would be a short-sighted, Draconian action that would have a detrimental long-term effect on medical education. Good quality educational programs can lead to more widespread guideline application, regardless of source of funding. This is particularly relevant given the well documented treatment gaps that exist today, due to underutilization of evidence-based data. The emphasis should be on quality rather than source of funding. Physicians' ethical and analytical skills should not be underestimated in such a degrading manner. Once again the integrity of the individuals in our profession is impugned by the implicit accusation that we are corruptible, immoral people just waiting to be led astray by abject bribery. Give me a break! This is another example of the rapidly degrading quality of life associated with the practice of medicine. The synergy which exists between practicing physicians and makers of pharmaceuticals and devices requires each doctor to use his own moral and ethical judgment regularly while seeking to advance their own practice of medicine in the best interests of their patients. I feel I am able to recognize this and interpret things accordingly. If necessary I would pay for CME, but as a relatively new doctor, this can become very expensive and prohibitive when added to loan payments and other expenses. CME programs sponsored by various pharmaceutical companies is an excellent and cost effective method of providing me with my educational requirements. Discontinuation of these programs would be a significant impediment to my ability to stay current with new and important information. I think the proposal to eliminate these programs is ridiculous. I am sick and tired of hearing how physicians are being "bought" by pharmaceutical and medical device companies. I feel very comfortable listening to someone present information about a product and deciding for myself whether "that" product will be helpful to my patients or useful to me in providing care for a patient. Many times the information is educational and actually benefits my patients by my being able to provide a treatment or procedure not previously available. I cannot remember anything provided to me by a rep in my nearly thirty years of practice that has swayed me to change my treatment or management if I did not think it would benefit my patient. It would seem to me that if physicians are adequately trained to analyze medical information and medical education material, then why would Industry-supported CME be an issue? I am INSULTED that some of my medical colleagues seem to believe that I cannot make decisions about whatis the best possible care for my patients because I have attended an education activity sponsored by a Pharmaceutical Co. I believe that pharmaceutical or medical device company support of CME stimulates knowledge, understanding and interest, and helps physicians remain current in their areas of practice. It is an interesting and enjoyable way for physicians to hear what the experts in different areas think as well as providing an opportunity to hear what their colleagues feel. It stimulates thought, productivity, and better medicine. I have followed the CEJA pronouncements with great interest and I find them patronizing and offensive. I don't need an ethicist to help me determine what CME is biased. I'm disappointed and disgusted with the AMA and will never give them another penny if they continue to legislate CME morality. I believe that there is some bias in CME due to the pharma support. I do not believe that it is extreme or causes more problems than it helps. The future health care of our country is too important to make fast and unresearched decisions. Do not throw the baby out with the bath water. We are not that easily influenced. This would hurt the process of medical education. Patients trust us with their lives, we take that seriously. Trust us to decide for ourselves. I only prescribe meds that I feel are safe and efficacious. I am not swayed by CME dinners or lunches. I feel those settings help provide needed information for doctors who are too busy to read all the

mail they get concerning new medications/devices, and I feel most doctors will make intelligent decisions concerning what to prescribe. I attend CME events at a local hospital which are sponsored by pharmaceutical and medical device companies. The speaker makes the appropriate disclosures and the talks are given. I have not seen a bias in the presentations I have heard. I think that axing the funding will be highly detrimental to the education of physicians practicing in the community. We must all realize that physicians and industry are to a large part partners in the provision of healthcare to patients and must work for the benefit of the patient and not ourselves. CME is expensive. I have been in academic medicine for 11 years and private family practice for 20 years. Pharmaceutical support of CME helps everyone. Physicians are intelligent enough to detect bias, if it exists. This bill would be a mistake! Let's face it, the average practitioner often has a hard enough time taking time off practice to attend a seminar and then to have to pay more! Fortunately cheap CME is available over the internet, but meetings often provide other benefits such as MEETING other physicians, networking and frankly, the chance to ask questions of a lecturer is invaluable. The assumption that well-trained physicians cannot understand drug/device company's support of CME and eliminate such biases (real or perceived) is an absolute insult to the medical profession. We did not invest our lives and a professional reputation through our years of training and post-graduate education to be thrown away in this manner. We are professionals and should be treated as such. Many of us who work with the poor and underserved don't make huge sums of money. Taking away low cost CME would mean we would either have to stop caring for these populations to be able to afford the high prices charged for CME units or give up practice altogether. I am appalled that certain members of my profession think so little of me and my ability to think independently that they think they have to legislate any possible bias out of my educational activities. What about their biases? These actions would increase the cost of my continuing education, and likely limit the extent of my education. I am [redacted]. If Industry Support for CME activities at both of these Institutions were to disappear our [redacted] activities in [redacted] would be permanently crippled since our local Universities are totally dependent on research grants for support and there is little to no national support available for extramural community education of physicians. I think that the elimination of Industry support for CME approved medical conferences would be a disaster and would reap nothing but progressive deterioration in the quality of medical care in our country. Don't throw out the baby with the bath water! There is a limit to how much money from my under-reimbursed primary care practice I can spare for CME. Company-supported CME plays an important role in the education of residents and continuing education of private physicians. Without industry-supported CME, many of the CME activities I participate in, including Grand Rounds from a local major academic institution would not be present. I strongly encourage the AMA to not make a statement which would make industry-supported CME taboo. Many good CME events whose companies are regulated by the ACCME would be gone if this bill goes through. Right now we have a choice of many good and decent companies, yours included, which bring quality education to physicians like me. You make sure that my education stays up to par by providing the most recent updates and innovation. Once these meetings are gone and I have to choose from expensive meetings in my region or further away (think $$ airfare, $$hotel, $$rental car using $$ gas), if it's not in my budget I cannot afford it-- who suffers? My patients will as I am not up to date in knowledge like I can be now thanks to sponsored CME meetings. A physician with all his training and desire to help people MUST be able to distinguish between good and bad. Good CME is a valuable service provided by these companies. It's valuable to patients, and it's generally convenient so that you don't have to travel or take off time from your practice. If the AMA is afraid of bias, they can always sample the programs themselves if they don't trust the evaluations of the participants. I have been very pleased with pharmaceutical industry-sponsored CME courses/materials. There has been virtually no bias that I could detect. I cannot imagine being able to complete my 150 hours of required CME without the vast availability of current CME programs (largely pharmaceutical industry supported). If these CME programs were discontinued, who would be able to create that many CME programs across so many specialties? There are not enough non-pharmaceutical industry organizations that are interested or funded enough to make up the difference in lost CME activities. In the first years of practice, where the learning curve is steepest and money most limited, free CME is essential for continuous learning. Without it, I would have to use the money currently allocated for joining organizations to purchasing CME -- as State licensing requires CME and not professional organization membership. Unless the AMA plans to provide some alternative free CME, outlawing all pharma sponsored CME will likely lead to this unintended effect for many new physicians; with potential impact upon professional organization membership long-term. I think that it is very naive to think that sponsorship by a pharmaceutical company for CME has any significant impact on physicians' learning. Physicians are sufficiently intelligent and independent-minded to make their own treatment decisions. It is for that review and for any new potential therapeutic applications to a disease state that I attend industry sponsored CME. I personally am offended that the AMA people think that I do not have the intelligence and discernment to detect bias

Keep the Status Quo Surrounding Commercial Support for Continuing Medical Education Programs! To whom it may concern: We are writing in response to the request for comment by the Accreditation Council for Continuing Medical Education (ACCME) proposing the elimination of commercial support for continuing medical education programs. By way of full disclosure, we own a medical education company and have spent many years developing high quality, commercially supported, CME/CE programs that have always been conducted in accordance with ACCME guidelines. Over the years, the ACCME has instituted a wide range of rules designed to reduce bias in commercially supported programs—initiatives that we believe have worked well to ensure fair-balanced programming. Currently, commercial supporters can have no involvement with the educational topic, agenda, content, faculty, etc. of any CME/CE program. So, in effect, these supporters are already relying on the integrity of the accrediting body, the experience of the educational provider, and the expertise of the faculty to produce a high quality, non-biased educational program that is meaningful to healthcare professionals. In short, we believe that there is no need to change the current system because it isn't broken and there are enough checks and balances in the current system to ensure objectivity "across the educational continuum." If a decision were made to eliminate commercial support for continuing educational programming, we believe this would: •\tSeriously limit the options for today's busy healthcare professionals who are required to accrue continuing education credits to maintain certification or licensure •\tDelay dissemination of valuable, fair-balanced information that may be vitally important to improving patient care and optimizing outcomes •\tPut healthcare associations (and others who exist to educate their constituents about new developments in their field) at risk based on withdrawal of grants from industry The new paradigm scenarios under which commercial support would be allowed to continue are unrealistic, unnecessary, and highly bureaucratic— especially when it appears that government is being seen as the body that will: define the need, monitor and measure the outcomes, approve the content, and assess the program for bias. Who exactly will do this, how much will it cost, and how would one expect the government to know more than the professionals in a given healthcare area? In conclusion we recommend that you don't blow up the current system to start over again but, instead, continue scrupulous adherence to the current guidelines that have been years in the making and are working just fine. Sincerely, [redacted]	**Other**
Leave it alone, preserve the STATUS QUO!! We need all the support we can get, incl. commercial support! commercial support enhances my CME experience, suggesting it influences my medical decision making is an insult! KEEP the STATUS QUO!	**Other**
Monitoring and management of the content, quality, and objectivity of CME are certainly vitally important, and AACME's efforts have been helpful. However, I have several comments on the proposed extension of recommended restrictions on development of CME, specfically exclusion of writers who create promotional materials and lecturers who do promotional programs from doing any CME. 1) Everyone has conflicts of interest, and increasingly limiting the roles of medical professionals whose entire professional life involves balancing these dualities will not eliminate them. Instead, a likely consequence is that both promotional and CME programs will continue but performed by nonprofessionals who are salaried by various organizations and lack the internal ethical standards which underly professional activity. That is, the opposite of the desired result may occur if clinical professionals are replaced by surrogates salaried by a sponsor. 2) If CME is to continue, financial support will have to come from either the drug and device industry, the health management industry, including the highly profitably insurance industry, or governmental agencies, all of which have their own conflicts of interest. Manufacturers and distributors benefit from greater use of their products, while health management, insurance, and governmental sponsors all benefit from as much restriction of services and products as appears possible. Targeting only the drug and device industries creates an imbalance which is likely to reduce the extent and quality of health services. 3) Clinicians in academia, and indirecly their institutions, rely extensively on income from educational and research programs. Abruptly reducing access to this income by preventing academics from doing either CME or promotional programs at all is likely to have another unintended consequence: marked reduction in the numbers of clinicians on medical school faculties, unless, as seems unlikely, other funding to support them is provided immediately.	**Accredited CME provider**

My comments are to encourage commercial support of CME activities as occurs currently. When I go to a course, I am given information on who provides funding, which speaker receives funding from which pharm company, etc. I am required to take CME courses by various entities as well as my desire to stay current with information in my field (PCP). While I can take free on-line courses my preference is in person courses--because the other doctors seem to ask so many questions that I wished I had thought of asking, and really need to know, thus enhancing the educational value dramatically. Commercial support of CME activities also seems to provide for speakers that usually are quite expert--locally, regionally or even USA-wide (speakers whom I usually would not have access to). For PCP doctors, expenses always goes up but income goes down. I also need to take CME courses at hours that I don't work. The cost to me of having to pay for every CME hour, would just add another burden.	Other
necessary to have as much free access to CME. Particularly for people who are not connected with a hospital structure but working as free standing psychiatrist in the community.	Other
No commercial CME means less oppurtunities to keep up to date; means less than the latest and best patient care is delivered; means bad for patients and bad for doctors and bad for health care.	Commercial Supporter
No. I don´t accept the eliimination of commercial suport for CME Activities [redacted]	Commercial Supporter
Not being an economist, I am uncertain as to the future of CME with $1.2B removed from the funding stream. There are many factors which could be discussed here, such as where does most of the funding go (what type of provider, etc), but many educational grants are given to large professional organizations and are used to defray the costs of national meetings and other events. There is no provision in the current health care economy for physicians to increase prices to cover the cost for expenses that were previously absent. If medicine truly were a free market economy, then the price of a visit would just go up. Placing the funds in a "pool" or sending it to the deans of the medical schools (notice, no one said send it to the associate dean for CME) would simply result in more buildings being built during the dean's dynasty and would, I daresay, never 'trickle down' to there they are needed. It is unlikely that this scenario would fly with pharma, so the dollars now spent would result [in increasing the duration of the nation's erections-you know, I really don't want to say this, but I can't make myself delete it!] in more marketing, which is 100% biased and in the best interests of the bottom line. Who would pay for the academic detailing that would be necessary to counterbalance unfettered unbalanced marketing?	Accredited CME provider
Note, this is an addendum to the comments submitted by [redacted] The endnotes were mistakenly omitted. Please use the below references when reading our comments. Sorry for the confusion. Thank you, (1) 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 (2) Podolsky SH, Greene JA. A Historical Perspective of Pharmaceutical Promotion and Physician Education. JAMA, 2008;300:831-833. (3) 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. (4) 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. (5) 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. (6) Harris G. Stanford to Limit Drug Maker Financing. New York Times. August 25, 2008. http://www.nytimes.com/2008/08/26/business/26drug.html?_r=1&scp=2&sq=stanford%20medical&st=cse&oref=slogin. (7) Hager M, Fletcher S. Continuing Education in the Health Professions: Improving Healthcare Through Lifelong Learning. New York, NY: Josiah Macy, Jr Foundation; 2008. (8) Steinbrook R. Financial Support of Continuing Medical Education. JAMA, 2008; 299:1060-1062. (9) Relman AS. Industry Support of Medical Education. JAMA, 2008; 300:1071-1073. (10) Pharma-Free CME. http://www.pharmedout.org/pharmafree.htm. Accessed 11 September 2008. (11) Independent Experts. HealthNewsReview.org. http://www.healthnewsreview.org/independentexperts.php. Accessed 11 September 2008. (12) PharmFree Scorecard. www.amsascorecard.org. Accessed 11 September 2008. (13) Faculty Disclosure of Conflicts of Interest. http://med.stanford.edu/coi/. Accessed 11 September 2008. (14) Kovaleski D. No Pharma Funding. Medical Meetings Magazine. January 1, 2008. http://meetingsnet.com/cmepharma/cme/no_pharma_funding_012808/. Accessed 11 September 2008 (15) 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. (16) Zimmer Announces New Compliance Model [news release].Warsaw, IN. April 17,	Other

2008. http://www.zimmer.com/z/ctl/op/global/action/1/id/10082/template/CP. Accessed 11 September 2008. (17) Attorney General Consumer and Prescriber Education Grant Program http://www.fsmb.org/re/open/default.html. Accessed 11 September 2008. (18) 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. (19) 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). (20) 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. (21) 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. (22) 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. (23) 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. (24) 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.	
On behalf of the [redacted] a not-for-profit organization of [redacted] provide the highest quality of care possible for patients—thank you for the opportunity to comment on the Accreditation Council for Continuing Medical Education's (ACCME's) proposal to consider eliminating commercial support of continuing medical education (CME)activities. As ACCME framed the debate over commercial support in three scenarios, [redacted] will respond accordingly to each scenario. Scenario 1: The status quo with commercial support of CME as an acceptable funding mechanism. [redacted] supports maintaining the status quo with commercial support of CME an acceptable funding mechanism along with continued management of conflicts of interest. [redacted] understands the dilemmas associated with commercial support of CME; the Society makes every effort to ensure that industry support enhances, but never dictates, the programs it provides for its members. Rather than removing commercial support, [redacted] supports ensuring that there is a firewall to separate industry's monetary influence from the Society's CME-related decisions. At this time, [redacted] follows a four-step process to ensure a firewall exists between developing educational activities and fundraising: 1.\tThe [redacted] Education Committee, Program Committee, Postgraduate Education (PGE) Committee, [redacted]) editors are responsible for planning, producing, evaluating, and improving all of the [redacted] activities. 2.\t[redacted] currently contracts with a former employee (who was responsible for commercial support) to communicate with the biotechnology, medical device, and pharmaceutical industry. This individual is responsible for all industry communications on behalf of [redacted] and has no role in the development of educational content. 3.\tThis individual informs the appropriate [redacted] Education Director ([redacted]) if industry is interested in supporting one of the Society's live activities or an enduring material that is based on a live meeting. The [redacted] Web Editor or the [redacted] is contacted if industry is interested in supporting one of the Society's enduring materials. 4.\tThe [redacted] Education Committee, Program Committee, PGE Committee, [redacted] ensure that all of the faculty for [redacted]-sponsored meetings are treated exactly the same; the [redacted] follows the ACCME Standards for Commercial Support. [redacted] believes these important changes are effective in protecting CME from commercial bias without producing the negative effects elimination of all commercial support could potentially cause. Scenario 2: The complete elimination of commercial support. [redacted] is firmly opposed to eliminating commercial support for CME. Through its financial support, industry helps ensure that CME in the United States is of the highest quality in the world. Eliminating support would likely diminish the quality and quantity of CME, which would reduce physicians' knowledge of new technologies and practices. Such a draconian approach would negatively affect the quality of patient care in the United States. Scenario 3: A new paradigm. [redacted] is concerned about the proposed new paradigm. According to ACCME, commercial support would only be allowed if the CME content is identified by a governmental agency, addresses a professional practice gap corroborated by organizationally-determined performance measures, is created from a continuing education curriculum, and is verified to be free of commercial bias. This paradigm is so cumbersome and unproven that [redacted] questions what, if anything, would be eligible for commercial support. In addition to the seemingly over-restrictive nature of the proposal, [redacted] has other concerns about the new paradigm. [redacted] questions why ACCME plans to require governmental agencies to identify and verify educational needs for CME. Medicine has always been a self-regulating profession. From accreditation of medical schools and graduate medical education to certification of individual physicians, the profession is responsible for monitoring the quality of medical education and physician practice. Is it necessary to introduce the government into medical education? The community is already aware of the difficulties governmental agencies face in participating in medical oversight; for example, the government's attempt to assess and regulate quality of care, via the Agency for Healthcare Research and Quality, has been largely ineffectual due to limited budgets. In a time of budgetary constraint in the federal arena, why place additional burden on agencies already stretched thin? Members of professional societies like [redacted] represent the full spectrum of the medical community and offer exceptional	**Accredited CME provider**

insight into what constitutes an educational need. Rather than take the responsibility of identifying educational needs from those that lead the profession, [redacted] supports ensuring that members involved in creating CME remain free of industry influence. For example, [redacted] requires all members of Council, committees and advisory groups, and editorial boards to disclose any conflicts of interest they may have. Anyone with control over education content must also complete a conflict of interest disclosure form. Review of disclosure material identifies all financial relationships from the previous 12 months. Any changes in disclosure are consistently identified while refusal to disclose will lead to dismissal from the [redacted] activity. In addition, [redacted] plans its educational material based on feedback from participants in the Society's educational activities and the requirements for certification and maintenance of certification through the [redacted] believes that valuing the feedback from participants and following the blueprint of ABIM requirements, and therefore the needs of the Society's members, is the most effective method for creating CME. Straying from this model by embracing ACCME's new paradigm may negatively impact [redacted] members' success in obtaining and maintaining certification. ACCME also suggests that the proposed paradigm could "provide a basis for a mechanism to distribute commercial support derived from industry-donated, pooled funds." [redacted] opposes such a mechanism, largely because it creates an unnecessary infrastructure that will lead to inequities in providing CME. By creating an entity that doles out pooled funds, ACCME will create conflict where it does not currently exist. Currently, societies solicit their own funding for CME. If societies must apply for funding from commercial interests, smaller societies will be pitted against larger societies, while larger specialties (such as cardiology) will dominate smaller ones (such as geriatrics). Available funding will likely be stratified according to society size, specialty, and available resources. Again, thank you for the opportunity to comment on ACCME's proposal. [redacted] looks forward to working with ACCME and the rest of the community to continue to assess the best approach for protecting CME from commercial bias while also providing members of the renal community with high-quality, innovative educational programs. To discuss [redacted] comments, please contact [redacted]	
On behalf of [redacted], we appreciate the opportunity to provide the following comment: Costs for formal education - university, medical school and post-graduate medical training, are substantial and continue to grow. The same can be said for costs associated with designing and implementing effective continuing medical education. Meanwhile, well documented epidemics of obesity and diabetes grip the nation; substantial disparities exist in patient health outcomes and in physician knowledge, competence and performance. Commercial support provides a significant source of funding to address these genuine public health needs. Simply discontinuing commercial support may reduce bias or the perception of commercial bias, but it will also dramatically reduce the volume and quality of continuing medical education. CME is currently experiencing a "golden age" and great strides are being made in reinventing educational interventions; for example the implementation of performance improvement CME initiatives. These types of activities that tie self-assessment to performance measures and document outcomes in practice behavior hold tremendous promise, but they are also tremendously time consuming and expensive for CME providers. If commercial support is eliminated for these types of CME activities, then innovation will slow and education will rely on more traditional formats. If all of the costs of CME are to be the burden of the physician learners, they will undoubtedly participate in fewer activities. Traditional large meetings and journal CME will likely be the favored options for obtaining CME, despite the fact that a growing body of literature suggests that these are not very effective formats for educational interventions. The new framework proposed might be an interesting alternative however additional development is needed. For example, performance measurements have not been identified throughout all of medicine; "bona fide organizations" have not identified CME curricula; and there needs to be a clear definition of what is meant by "verified" as free of commercial bias – verified by whom? In the past two years there have been significant changes in the accreditation system, with the implementation of the new criteria specifically related to both the quality of education produced and the management of commercial support. The impact of these changes on the quality of accredited educational programs is just starting to be evaluated. Elimination of commercial support of CME accredited activities will have an immediate and potentially detrimental impact on both the quality and quantity of accredited education. The changes to the accreditation system need to be evaluated before such drastic action is imposed. The [redacted] and the [redacted] oppose the proposal to eliminate commercial support and recommends status quo while decisions regarding additional regulatory changes or the adoption of a new framework may be informed by data collected from the surveys current being performed under the new accreditation criteria.	**Accredited CME provider**

On Elimination of Commercial Support of Continuing Medical Education Activities [redacted]) believes the elimination of commercial support of continuing medical education (CME) activities would be highly detrimental to the interests of the U.S. healthcare system. With the continuing heavy burden of chronic diseases, the aging of the population, the quick pace of new developments in clinical medicine, and ever-increasing demands on the time of busy practitioners, our healthcare system depends on clinicians who are well informed on best current practices in diagnosis and management. The elimination of commercial support for CME will decrease the availability of fair-balanced information directed at identified needs and practice gaps, yet it will serve no useful purpose. The proposal on which the ACCME has requested comments, to ban commercial support, is based on the premise that independent medical education cannot be developed with funds derived from a commercial interest; and that the use of such funds inherently includes the introduction of commercial bias into the activity as well as influence from the commercial interest. Yet, there has been no evidence to date—even in the research commissioned by ACCME—to corroborate this notion. If the concern indeed is to address the perception of influence, [redacted] believes that better, less draconian measures can be employed. Adequate requirements established by ACCME are already in place. Providers must identify and manage any possible conflict of interest, disclose any relationships those in control of content may have with commercial interests, and adhere to the requirements of content validation. These provisions, which have been widely adopted by CME providers as the standard of practice, ensure activities are independent of commercial influence and bias. Indeed, practitioners give [redacted] CME activities that are supported with grants from industry extremely high approval ratings for fair balance, lack of commercial bias, and sound evidence base. For activities thus far in 2008, with more than 7,500 clinicians answering each question: •\t98% of 7,561 said activities present a balanced view of therapeutic options available for the applicable disease state(s). •\t95% of 7,925 said activities presented content that fairly represented, and was based on, a reasonable and valid interpretation of available information. •\t95% of 14,046 said activities did not appear to place an unreasonable emphasis on one product or service. Far from accomplishing any public good, the elimination of commercial support would significantly reduce the availability of this fair-balanced, evidence-based information. We are not aware of any serious suggestion as to what other sources would replace the $1.2 billion in CME support that came from the industry in 2007, according to ACCME data; such funding is highly unlikely to come from the Federal or state governments, managed care organizations, practitioners themselves, or any other source. As an alternative to outright elimination of commercial support for CME, the ACCME has put forward a “new paradigm” that it believes, if followed, would provide that commercial support “would be in the public interest and could continue to be allowed.” But this proposal is detrimental to the public as well. First, this “new paradigm” also would reduce the amount of education by requiring a complex system of working through multiple organizations with inefficiencies, duplication of effort, and the resulting higher costs. Second, the first three elements of this “new paradigm” would, for all intents and purposes, remove any element of initiative and creativity from the accredited provider—again, without any evidence that the end result would be better education. This would come at the same time that ACCME has taken two major steps to put CME and the accredited provider in the forefront addressing the needs of the practicing physician: •\tThe publication of “CME as a Bridge to Quality” outlines how CME can become a centerpoint of the education and continuing improvement of the practicing physician. •\tAll Providers are expected to have implemented the “new” criteria, first announced in 2006, requiring that educational activities be based on identified practice gaps of “their” physicians, and provide solutions that are evidence-based and in the best interest of patients. [redacted] believes that CME, as it is developed and delivered in 2008 under ACCME guidelines and with commercial support provided under ACCME-directed guidelines, serves the public interest well. The elimination of commercial support, or forcing commercial support into the specific channels outlined by the ACCME’s “new paradigm,” would reduce the amount and quality of education available to clinicians and, indeed, mandated for clinicians by medical societies and licensing bodies. If the ACCME wishes to address a problem of perception in CME fair balance, there are other, more constructive, actions it could take. For example: •\tProhibit Providers from certifying activities that are not supported by a minimum of two commercial interests, in cases where commercial support is a funding source. •\tRequire that participants pay for a certain percentage of activity funding. This could be based on a generally accepted standard; a percentage of the activity development cost; or, in the case of a live activity, the cost of non-educational aspects, such as a meal. •\tAssist in a public awareness program on the importance of CME and the need for support from non-traditional funding sources, such as large employers.	**Accredited CME provider**

Paradigm 1 - continue industry support - This appears to be the only workable solution since the proposed ACCME "compromise" is unworkable (as described below) and withdrawing industry support would be an educational disaster, and relegate US continuing medical education to the dark ages (oblivion) since there is no other viable source of funding - the federal government wont do it - the professional societies are all intensely dependent on industry funding, and physicians won't pay for it out of their own pocket (given the considerable expense of putting on large-scale CME events) Paradigm 2 - withdraw all industry support of CME - It is almost impossible to express what an educational disaster this would be. We could not have national meetings. We would be unlikely to provide honoraria to outside speakers. Nobody could afford to put on a medium-to-large scale CME meeting. US continuing medical education would come to a screeching halt. And US medical care would suffer significantly. THIS IS A REALLY BAD IDEA. Paradigm 3 - Industry support allowed with the ACCME criteria This is an invitation to screwing up the sytem even more than it already is. Current ACCME requirement are draconian, and look to be headed in a direction making it impossible to document legitimate impact on clinical care. And now you want to insinuate some sort of "approved" neutral needs assessment and ask the government to tell us what the needs are? The same government that seems incapable aof doing anything without multiple layers of inefficiency, idiot regulations and incompetence? Gods forfend ... Other possibilites (considered and rejected) Allow industry sponsorship IF multiple sponsors are involved - this would require some threshold of involvement of a second party (beyond a token 1$ contribution) that would be really hard to agree on, and implement - not impossible, just really hard to do. Allow industry sponsorship with tighter enforcement of needs / fair balance assessment - the problem is - WHO will enforce this? Different rules for single lectures (grand rounds) versus multiple lectures (symposia) and bigger meetings - allow single industry sponsors for grand rounds and single day symposia, but anything bigger would have to involve multiple sponsors, with no single sponsor providing more than 40% of the funding - you still need to tighten up the oversight of single-vendor sponsored events And ... what are you going to do about CME enduring material, like monographs, web casts, and articles? All in all, it would seem prudent not to withdraw industy support until you have a viable alternative that has been tested and shown to be workable. You risk the equivalent of a bad artificial heart in a patient that may not need it. You take out a heart that is not perfect, but still functioning, and replacing it with something completely untested. What dies in the end - could be our entire ability to provide quality CME - and US continuing medical education becomes the laughingstock of the world as we regulate ourselves into oblivion.	**Other**
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. Rather than banning therapeutic area content experts who receive appropriate compensation from commercial interests to create or present promotional material from all continuing medical education endeavors, the [redacted] recommends that the ACCME consider establishing guidances or rules aimed at ensuring that these therapeutic area content experts respect the strictly non-promotional requirements of the independent continuing medical education endeavor. Guidelines that help ensure that such people bring no promotional intent to their independent continuing medical education work might be a reasonable alternative to a complete ban.	**Commercial Supporter**
Please allow commercial support to continue in medical education. 1. With proper supervision it can continue to provide a hedge against many inflationary costs for strapped academic institutions. 2. With proper guidelines, it can offer lowered costs for many strapped medical students, nursing students and para-professionals, in a world of escalating costs. 3. Education in all forms of society is part of the economic system of this country 4. Education in all forms has a way of generating counter points which stimulate greater learning.	**Accredited CME provider**
please continue CME funding. It is an excellent source of maintaining our expertise. We need it.	**Other**
PLEASE CONTINUE TO ALLOW COMMERCIAL SUPPORT FOR CME'S. THIS IS ONE OF THE VARIOUS WAYS MEDICAL PROFESSIONALS CAN OBTAIN CME'S. MY FEELING IS THAT THIS IS AN EXCELLENT INITIATIVE FOR A PROFESSIONAL TO OBTAIN CME.	**Accredited CME provider**
PLEASE continue your continuing CME activities	**Other**
Please do not change anything.	**Other**
please do not eliminate commercial support of continuing medical education activities	**Other**

Please do not eliminate commerical support of continuing medical education activities. Commercial support of continuing medical education (cme) provides excellent source for information regarding evaluation and possible inclusion of evidence based treatment in practice. No amount of commerical support of cme is going to adversely affect my practice. Never has and never will. Am greatful for not having to spend much needed funds for cme. Commerical support for cme is even more vital with increase of many expenditures for family care such as health care, food, transportation. Please leave the much needed commerical support of continuing medication education activities available.	Other
Please do not eliminate this source of funding. while I realize that there may be a bias at some time, it is a very important source to get medical information out to providers	Other
Please do not impede easy access to continuing medical education. Thank you, [redacted]	Other
Please eliminate ALL commercial support for CME--it is VITAL for our integrity. THANKS! [redacted]	Other
Please first submit evidence that commercial support, as it is regulated today, is associated with increased bias in educational activities. I believe that evidence should drive these decisions, and not other forces such as political pressure. It is unfair, as well, to single out certain provider types (eg, MECCs) when conflicts of interest have been shown to exist in various types of provider organizations.	Accredited CME provider
Please keep CME available. It is vital to patient care. [redacted]	Other
Please keep the status quo. Elimination of Commercial Support of CME with make CME costly and to some unavailable. Just price some of the "professional journals" sometime. I believe the decision will have a profound impact on patient health outcomes. Commercially supported programs do help "get the word of new changes in meds and healthcare" to the masses of providers in an affordable, time efficient manner. I encourage the ACCME to maintain the status quo, with commercial support of CME remaining an acceptable funding mechanism. Thank you, [redacted]	Other
Please protect our ability to continue with unbiased medical education. Thank you for your attention.	Other
Please see separate e-mail.	Accredited CME provider
present systom effective please do not change	Accredited CME provider
Presenters should always declare possible conflicts of interest. The education would disapear without comercial support in most places.	Non-Accredited CME provider
[redacted] that I have attended were of high quality. They do not show bias to the pharmaceutical company that funds the seminar. Materials presented were balanced and evidence based studies quoted. It is not possible for me to keep up with the changing challenges I face in medicine. The seminars help me keep up to date with new products . I do not prescribe new products immediately until it has been proven to be efficacious. To totally ban industry sponsored seminars will be a disservice. I believe physicians are basically eithical in their training and judgement. However the institution that I work in has done away with industry sponsored events. I have to take weekends and evenings to attend [redacted] seminars of my own choice. (If the topis is relvant and I feel I can learn new advances.)	Accredited CME provider
Recommend Initiative one. Elimination of Commercial Support is unnecessary, draconian, and will simply divert enormous sums of money to increased direct advertising to patients. More good derives from the present system with its current restraints than if its few problems are replaced by the proposed changes--there is a pragmagmatic limit to well-meant meddling with something that works reasonably well. "Beware of unintended consequences."	Accredited CME provider
Response to ACCME's Call for Comment: Due Consideration Given to Elimination of Commercial Support Of Continuing Medical Education Activities The foundation for certified CME activities is to improve clinical practice and patient care and outcomes. This principle often gets lost amid all the discussions surrounding CME regulations. The first and most important question is: does CME improve physician practice and ultimately patient care and outcomes? The proven answer, supported by documented and published evidence, is a resounding "yes." As with any industry, there will be those entities that choose to violate regulations and operate only in their best interests. No amount of regulation or oversight can ever hope to	Accredited CME provider

completely eliminate this. Instead of eliminating the current system, the focus should be on methods for identifying offenders and establishing and consistently applying appropriate subsequent actions. [redacted] is sensitive to the fact that the ACCME is receiving some external pressure from those outside of our industry who suggest that commercial support means "influence" over CME. However, it is our belief that the elimination of commercial support of continuing medical education activities is not the solution. [redacted]'s responses to ACCME's three possible scenarios follow. 1) [Preserve] the status quo with commercial support of CME an acceptable funding mechanism. No credible, recent (ie, 2006 – present) evidence has been cited to support the allegations that the current system is not working. Recent, credible evidence does exist to support the current system for the majority of cases. Evidence includes, but is not limited to: a) ACCME's commissioned report, "The Relationship between Commercial Support and Bias in Continuing Medical Education Activities: A Review of the Literature." This report provides evidence from physicians' opinions that the majority of physicians do not believe CME activities are biased by commercial support. Moreover, the majority of physicians believe they are capable of making clinical decisions that are in the best interests of the patient, and are not influenced by commercial interests. b)ACCME and state medical societies have conducted numerous surveys of accredited providers for assessment of adherence to guidelines and regulations. \t Since fewer than 10% of accredited providers have been put on probation, the other 90% (or more) of surveyed providers are deemed compliant with current standards as evidenced by their initial accreditation or reaccreditation awards. Numerous Self Study reports include CME activity participant evaluations attesting that the majority of certified activity participants did not perceive commercial bias in certified activities. Finally, the content of certified activities provides evidence of adherence to ACCME guidelines since compliance by providers signifies certified activities' content is based on evidence that is accepted within the profession of medicine and scientific research that conforms to the generally accepted standards of experimental design, data collection and analysis (per ACCME Validation of the Clinical Content of CME) and is documented in participant activity surveys and evaluations. c) A recent survey (June 10, 2008) of more than 20,000 physician participants of [redacted] sponsored programming was conducted to determine their opinions on the elimination of commercial support for CME. More than 1,000 physicians responded, with 88% of them indicating that they do not believe commercial support should be banned. Attached, please find a sample list of their comments. Evidence of effectiveness a) Agency for Healthcare Research and Quality report, Effectiveness of Continuing Medical Education, prepared by the Johns Hopkins University, Evidence-based Practice Center. (Available at: http://www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat1b.part.1) This is a systematic review of the medical literature was conducted to evaluate the effectiveness of CME in improving knowledge, attitudes, skills, physician behavior and clinical outcomes. Overall, despite the generally low quality of the evidence, most of the studies reviewed suggest that CME is effective, to some degree, in not only achieving, but also in maintaining the objectives studied. b) Numerous outcomes measurements (eg, Outcomes, Inc., academic institutions, individual provider outcome measurements) of certified activities demonstrating effectiveness of the educational intervention. c) Ongoing efforts by organizations external to ACCME are underway for monitoring of guideline adherence, transparency processes, and increased regulation. Among them: §\tFDA has tightened financial conflict of interest policies among committee members. §\tIncreased transparency by industry regarding educational grants, ie, Eli Lilly and Company, Pfizer Inc, is in effect. §\tNewly updated PhRMA code has been published to enforce compliance by industry. §\tCreation of a certification program for CME professionals by the NC-CME, which is supported by the Alliance for CME, designed to provide additional credibility of providers. §\tUpcoming audit conducted by NAAMECC of a statistically significant number of certified CME activities across multiple provider types to assess the prevalence of commercial bias in CME will provide additional information for compliance and improvement practices. §\tThe Joint Sponsor Attestation Form created in collaboration by NAAMECC/SACME is a demonstration of two types of providers working together to ensure compliance. §\tRegulations and policies of individual providers and industry uphold, and in many instances, are more restrictive than, ACCME's Essential Areas and Elements, Standards for Commercial Support, and FDA's Final Guidance on Industry-Supported Scientific and Educational Activities, have been implemented. Unfortunately, this information does not appear to be presented in defense of CME to recent allegations. Questions that have been repeatedly raised over the past several months have a common theme: do Congress, the media, and physicians really understand what is being done by many in the CME enterprise, including industry, to ensure that the CME offered by the quality accredited CME provider is based on the best evidence available and not unduly influenced by any special interest? The various forms of this question provide credence for initiatives to educate Congress, the media, physicians, and other relevant parties about the differences between promotional activities and certified CME, including the standards, regulations, and policies that already exist and are adhered to by the majority of providers. The Council for Medical Specialty Societies has gone on record saying, "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." The available evidence should be presented in defense of the current system instead of alluding to the failure of the system by proposing a new system that will lead to a decrease in quality and availability of valuable educational programs and ultimately result in suboptimal patient care. 2) The complete elimination of commercial support. Per ACCME's annual report, a minority of accredited providers receive the majority of commercial support. It is important to be aware and

understand that this minority of providers has been those who develop innovative activities based on adult learning principles that address the different learning styles of physicians. Also, creation of in-depth needs assessments, design and implementation of interactive educational platforms, and incorporation of evolving technology to better address the needs of certified activity participants have all been possible through commercial support. The majority of providers have not chosen this profession as a means to become wealthy from commercially supported educational grants, but for the purpose of improving healthcare and patient outcomes. A number of organizations have spoken against elimination of commercial support. The following is a representative sample: a) Representatives of the primary voting blocks of the AMA House of Delegates—primary care doctors, state medical societies, and specialty medical societies—referred the CEJA proposal to eliminate commercially supported CME back to the council. (June 16, 2008) b) The Council for Medical Specialty Societies has gone on record saying, "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 c) The North American Association of Medial Education Communication Companies (NAAMECC) has stated, "We do not believe that effective management requires elimination of the commercial support that enables nearly half of the certified CME that informs today's patient care." 3) A new paradigm. Since significant evidence points to the fact that the present system is working, it should not be dismantled, which could lead to potential chaos in the industry. Given the current economic state, and the debatable efficiency of government agencies, as well as lack of available funds for additional agencies, staff and resources necessary for implementing certified activities are scarce. Further reduction of funds will consequently lead to a decrease in the quality and availability of certified activities. It is always beneficial to assess current processes and possibilities for improvements. Due to the increased scrutiny by the government and media, many new initiatives and regulations have already occurred across the entire spectrum of the CME environment. Improvements are already underway but are still too new for accurate assessment of the CME environment. In spite of the evidence that the current system is effective, new paradigms for consideration have been requested from ACCME. While gathering ideas from numerous individual providers is a worthy goal, this approach appears to be "putting the cart before the horse." Logically, efforts for any new paradigm require organization and transparency to maintain credibility and accountability to appropriate stakeholders. Immediate questions that must be answered are: §\twho will review proposed ideas, §\twho will make decisions regarding each idea, and §\twhat will form the basis for further action of selected ideas? Forming a committee representing a cross section of various providers seems a logical step. Ideas from individual providers could be sent to the appropriate representative for processing. A ranking system would allow the submissions to be categorized for consideration. With regard to the specifics of ACCME's proposed new paradigm: 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) Response: It should be noted that many US Government agencies are not free of any financial relationships with industry. Government agencies usually require long time frames for conducting assessments, surveys, etc. Medicine changes quickly and these changes need to be communicated quickly. If educational needs must be identified and verified by such organizations, "just in time" certified education will become a thing of the past, ultimately resulting in reduced quality of patient care. 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 learner's own practice Response: Not all professional practice gaps can be verified by a bona fide performance measurement, yet still represent a legitimate and necessary educational need. 3) When the CME content is from a continuing medical education curriculum specified by a bona fide organization or entity (eg AMA, AHRQ, ABMS, FSMB) Response: a medical education curriculum by such organizations is often broad and does not capture educational needs at a detailed level. 4)\tWhen the CME is verified as free of commercial bias. Response: the structure for this already exists. Summary [redacted] bases our position on the fact that, as an ACCME-accredited provider, we are committed to the ACCME's 2004 Standards for Commercial Support. We are thoroughly committed at all levels of our organization to our mission, which is to deliver education that brings measurable change in healthcare professional competency with the goal of improving performance and patient health outcomes. Further, we contend that the 2004 Standards for Commercial Support, given time and the proper levels of oversight and enforcement by the ACCME, have the potential to address many of the concerns that currently face our industry. We believe that elimination of commercial support will not result in higher quality educational opportunities, but will limit the access to high-quality, sophisticated, independent, and timely continuing education that follows the principles of rigorous educational design to improve health outcomes. If the ACCME and others are concerned about the influence of commercial support on continuing medical education, the focus should be at the individual ACCME accredited provider level. Eliminating commercial support based on little or no data supporting the premise of bias compromises educational access, diversity, and quality in the future. The result will have a discernable negative impact on patient care in the US healthcare system.	
See complete comment in letter to Dr. Murray Kopelow dated September 12, 2008	**Other**

Accredited CME provider

September 12, 2008 R. Russell Thomas, Jr., DO, MPH Chair, Board of Directors Accreditation Council of Continuing Medical Education 515 North State Street Suite 1801 Chicago, IL 60654 Proposal: Commercial support of continuing medical education be eliminated. Dear Dr. Thomas: [redacted] welcomes the opportunity to provide comments concerning the ACCME June 2008 "Call-for-Comment: Proposed Policy to Support Independence in Accredited CME." [redacted] strongly believes that the proposal to eliminate commercial support of Continuing Medical Education (CME), as well as the proposed "new paradigm", would have severe consequences for ongoing medical education of [redacted] practitioners, and would hinder our organization's ability to support the membership through [redacted]-specific content. The [redacted] is a non-profit organization dedicated to fostering and advancing the [redacted]. The core of the [redacted] mission is to define and promote lifelong training and education in the rapidly evolving field [redacted]. The large majority of [redacted] members are board-certified surgeons with advanced training [redacted] and a record of publication in peer-reviewed journals and books. Due to this focused expertise, the opportunity for practice-based learning that will promote competence, performance and patient outcomes is limited outside of specialty societies such as [redacted]. [redacted] has a well-established record of providing valuable learning interventions through its annual [redacted] Both CME events engage multidisciplinary education planned for and by the entire [redacted] team and are designed to address performance-based gaps in learning with a commitment to quality improvement. The majority of small professional societies that serve narrowly defined subspecialties depend on commercial support to advance their mission; [redacted] is no exception. The funds [redacted] receives from companies are combined and are not specifically dedicated to support of any one speaker or activity relating to continuing medical education. The companies have no involvement whatsoever in the planning and implementation of the program. The ACCME proposal to eliminate commercial support of CME activities would prohibit [redacted], and other similar organizations, from planning and implementing CME activities that benefit members and the patients whom they serve and instead convert the same critical activities to Non-CME educational activities. [redacted] strongly urges the ACCME not to adopt the proposal to eliminate commercial support from accredited CME activities. [redacted] is also concerned that the proposed "new paradigm" sets forth the following conditions that must all be met in order to allow commercial support of individual CME activities: 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). As noted above, [redacted] believes there are limited resources aside from focused professional societies that could adequately and efficiently evaluate specific practice gaps and create relevant educational activities for a subspecialty such as [redacted]. Requiring educational needs related to [redacted] be identified by an entity other than [redacted], or similar organization, is unrealistic and will result in content that is inappropriate to the learners' current or potential scope of professional activities. [redacted] would be forced to meet its members' specific educational needs through Non-CME meetings and activities, with the result [redacted] would need to meet their CME requirements through non [redacted], unfocused educational activities. The ultimate effect would be severe impediment to the standardization and dissemination of state of the art knowledge and practice in our field. 2. If the CME addresses a professional practice gap of a particular group of learners that is corroborated by bona fide performance measures (e.g. National Quality Forum) of the learners' own practice. [redacted] has a long history of tracking outcomes through the [redacted] and is supportive of approaches to track and improve outcomes and measure performance. However, Condition #2 seems like a narrow approach to CME. Tying CME activity to a select number of predetermined performance measures is limiting and stifling. CME should be dynamic and permit for a more robust and timely approach to address educational needs and learning gaps. 3. When the CME content is from a continuing education curriculum specified by a bona fide organization or entity (e.g. AMA, AHRQ, ABMS, FSMB). As a bona fide organization that accredits [redacted] fellowship training within the United States, [redacted] is fortunate to meet Condition #3. In fact, [redacted] accredited training programs serve as the primary pathway for [redacted] and associated privileges. [redacted] has developed the [redacted]. As members navigate MOC it would preferable for [redacted] to be able provide [redacted]-specific CME. 4. When the CME is verified as free of commercial bias. ACCME currently has rigorous standards in place to ensure the independence of CME activities. [redacted] strongly supports the current standards and advocates that Condition #4 be the guiding principle for CME activities. The ACCME has a reported 10% non-compliance rate for the current standards. [redacted] joins other organizations in encouraging the ACCME to focus on helping the non-compliant groups take corrective actions through remediation. [redacted] applauds ACCME's effort to improve the standards for CME activity. However, the proposal to eliminate commercial support of CME activities and the proposed "new paradigm" will have unintended consequences for surgeons and physicians that have completed additional training and practice within subspecialties. If approved, these proposals will be a dead end for practice-based learning instead of the intended bridge to quality. [redacted] appreciates the opportunity to submit comments on this important issue. As described above, the proposed changes will have an enormous impact on the future of CME activity and should be carefully evaluated to ensure the needs of all physicians are met through CME

activities specific to area of practice. Additionally, it is unclear what alternative sources of revenue ACCME is recommending to replace commercial support. [redacted] would be pleased to assist in any efforts to refine a new paradigm. If you have any questions, please contact [redacted]	
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."(1) 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.(2) 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,(3) 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 (4-6) and the medical profession,(7-9) a trend toward developing CME that is free from commercial support is gaining momentum.(10,11) 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.(12,13) Memorial Sloan Kettering Cancer Center bans any commercial support for CME.(14) 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);(15) Zimmer, a major manufacturer of orthopedic medical devices, announced it would use only independent, third parties to support CME.(16) 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.(17) 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%).(18) 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.(19,20) 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.(21) 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.(22) 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 years(18,23) 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.(24) The most far-reaching (and the one we favor), legal restrictions would	Other

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, [redacted]	
September 12, 2008 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: [redacted] is pleased to submit this letter in response to the Call-for-Comments on the proposals recently announced by the Accreditation Council for Continuing Medical Education (ACCME) related to commercial funding of continuing medical education (CME). Proposal that Due Consideration be Given to the Elimination of Commercial Support of Continuing Medical Education Activities [redacted] believes that commercial support of independent medical education is extremely important to the health care community and should continue. [redacted] has no objection to the implementation of additional reasonable safeguards in respect of commercially-supported activities to further ensure that there is no fact or perception of influence. [redacted] also agrees that Providers must independently verify the need for education in a certain area and should not rely solely on the Supporter's identification of health care competency gaps. However, [redacted] does not agree that commercial support of an individual continuing medical education can occur only if the first three conditions set forth in this Call-for-Comment are satisfied. Independent medical education has long provided a forum for discussing things such as cutting edge medical advances and late-breaking research in a vast array of therapeutic areas such as cardiovascular disease, oncology, infectious disease, etc. As a practical matter, it may take years for a particular educational need be recognized and incorporated by entities such as the AMA, and to prohibit or severely restrict commercial support of CME in these areas in the interim may ultimately be detrimental to patient care. The fourth condition specified in the Call-for-Comments - "CME is verified as free of commercial bias" - appears to go to the crux of the concerns expressed by ACCME. [redacted] believes that this condition can be addressed to ACCME's satisfaction through measures such as expanding the scope of the Provider review/auditing process to include more focus on review of the content of activities for commercial bias. As a result, the imposition of the other three conditions may not be necessary. We appreciate the opportunity to comment and encourage the ACCME to publish all of the responses to these Calls for Comment to ensure an appropriate and balanced decision procedure. Best regards, [redacted]	**Commercial Supporter**

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 [redacted] 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? 2 I. Public Policy, Process and Procedural Issues The [redacted] for Healthcare Communication ([redacted]) 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 reregistration. 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. 3 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. 4 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	Other

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 [redacted] 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 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. 5 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 [redacted] raises the litigation possibility not because it has an intention to file a legal action. Instead, it raises it because the [redacted] 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). 6 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. 7 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 [redacted] agrees to organize an effort to enable this at no cost to ACCME. Meanwhile, the [redacted] 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. 8 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 [redacted] 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 datadriven, 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. 9 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. [redacted] Position: The [redacted] 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 peerreviewed 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 cannot readily be said for the myriad other largely unaudited sources of information encountered and managed by physicians each day. 10 The [redacted] 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 [redacted] 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 [redacted] 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 evidencebased 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. [redacted] in a recent conference call with members of [redacted] indicated that based on [redacted] 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, 11 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 [redacted] 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 [redacted] 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 12 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 [redacted] 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 13 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. 14 [redacted] Position: The [redacted] 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 [redacted] 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 15 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

September 4, 2008 The undersigned members of the [redacted], an organization composed of [redacted], wish to provide feedback to the Accreditation Council for Continuing Medical Education in response to its June 2008 request for comment on the proposal "that the commercial support of continuing medical education end." We believe that commercial support of certified CME by pharmaceutical and medical device companies is appropriate, and should remain an option. Our [redacted] support the many efforts made over the past several years by the FDA, HHS-OIG, and ACCME to clarify appropriate relationships between CME providers, their physician faculty and commercial supporters. All of these oversight organizations, as well as CME providers themselves, have strengthened policies and procedures to identify and manage conflicts of interest among faculty and education activity planners in order to reduce or exclude commercial bias from certified CME. ACCME's updated Standards for Commercial Support (2004), updated accreditation criteria (2006), and the more recent definitions of commercial entities (2007) have also contributed to the attempt to assure physicians and the public of the validity, currency, objectivity and fair balance of CME content by the CME enterprise. To quote the American Association of Medical Society Executives in its recent letter to the American Medical Association regarding this topic, "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." Eliminating all commercial support of CME might cause more problems in our current health care and economic climate without any indication of how this change in the funding of medical education would improve either CME or patient care. ACCME's own statement to the Institute of Medicine Committee on Conflict of Interest in Medical Research, Education and Practice (2008) declares that "although it has been speculated that commercial support produces bias in CME programs, no published studies have examined this question. Therefore, there is no evidence to support or refute this assertion." The only support for the existence of such a relationship is in opinion pieces in the lay press and the medical literature. On the basis of these realities, the undersigned medical society executives support the development and execution of rigorous scientific studies to look at the relationship between commercial support and bias, including an assessment of the physician's ability to recognize bias and industry influence, as well as the impact of the physician's ability to recognize bias on patient care. We support continued implementation of more effective mechanisms to identify and manage individual and organizational conflicts of interest and enhancement of more balanced portfolios of CME funding sources that include, but go beyond, pharmaceutical and medical device companies. Thank you for your serious consideration of these comments, as well as those submitted by many of our respective [redacted]. We stand ready to discuss this important matter at greater length with Dr. Kopelow and other ACCME representatives. Sincerely, [redacted]	**Other**
Since reading the proposal about banning those who give a promotional lecture from CME I have reviewed several "promotional" slide kits. All of them contain information that is taken from the FDA approved drug label, including details of side effects and results from clinical trials that had FDA oversight. Is it ACCME's assumption that the FDA has not done due diligence in its drug labelling procedures? The assumption that the materials for different programs can be entirerly different is somewhat naive. Also, if the promotional material is left out of CME lectures, what is left? Are speakers then going to "cook up" material to make slides? Will they imagine side effects that are not recognized as such by the FDA? Rather than an outright ban on such dual activities, I would suggest that certain limits be placed on both the content (eg allow only FDA approved material) and the amount of promotional activity done by a speaker (eg it may be appropriate to not allow someone who speaks every week for a company, but should that apply to someone who did an occasional promotional lecture - perhaps a non CME grand rounds at an institution)?	**Accredited CME provider**
Status Quo [redacted] strongly recommends that the ACCME continue allowing the use of commercial support of CME as an acceptable funding mechanism. It seems reasonable to allow he newly developed ACCME compliance and improvement processes to have sufficient opportunity to demonstrate their effectiveness. The partners and stakeholders in the CME enterprise are all banning together to strengthen their policies and procedures to create even more transparency and systems to deal with inappropriateness. [redacted] would ask that we be given due time to govern, manage, and monitor ourselves. As doctors, we are educated and trained to study, diagnose, treat and prescribe using evidence and ethics. We can and do use these same principles to guide us in developing and presenting CME activities even when funded by commercial support. Complete Elimination of all Industry Support [redacted] rejects this scenario. This scenario would significantly interfere with the quality and quantity of CME programs that [redacted] would be able to provide. It would limit the scope of specialized educational interventions, because we cannot pass the additional cost of the educational activities onto the learners as they are already having their travel and professional development budgets cut. As a subspecialty organization that is multidisciplinary, it is critical that cross-professional training and education continue to be provided. We are always seeking additional funding sources to support our ongoing activities, including the personal investment from our members and educational attendees, government agencies, and the private sector. We feel to consider excluding industry from the responsibility of funding medical education when they are clearly an important stakeholder is unreasonable. While we do not	**Non-Accredited CME provider**

want those who are providing funding to have any influence over the content, we accept that they are in a position to benefit from advances in medicine just by the nature of the business they are in. New Paradigm: In response to Condition number one, we would ask that the ACCME consider that bias can exist whenever there is an opinion on an issue and that no entity is exempt from bias because no entity is independent of funding; lobbying funds can weigh heavily in the decisions of government agencies, even those who receive NIH funding can be influenced. [redacted] respectfully submits that as a subspecialty organization, it is uniquely positioned to address the educational needs and objectives of its learners and to identify the specific needs in the field of biological therapy of cancer working in concert with all stakeholders from academic, industry and regulatory settings. In response to Condition two and three, [redacted] is committed to providing high quality educational interventions to facilitate educational exchange among learners who come from various professional practice settings. As there are few approved biological therapies for cancer, there is little opportunity for change in clinical practice. For organizations like [redacted] who are basic and translational focused, these conditions regarding performance measures and curricula are difficult if not impossible to meet. [redacted] would ask the ACCME to consider the [redacted] and other basic and translational organizations when setting standards and guidelines to ensure that they are relative to all who must adhere to them. In response to Condition number four, please see our response to Point 1 and 2 regarding the definition of commercial interest.	
Strongly disagree with changing current status	**Other**
Such Elimination of support will essentially deprive the medical community from most of the currently available CME activities as most institutions including Universities have little funding to fill such void.It would be disastrous and most unwise thing to do.	**Accredited CME provider**
testing	**Accredited CME provider**
Thank you for allowing public comment on the consideration to eliminate commercial support of CME activities. It is my opinion that commercial support for CME activities should be eliminated. Numerous avenues for obtaining industry-free CME exist. These may be internal (e.g. within a hospital that is an accredited CME provider) or external (e.g. Prescriber's Letter, Medical Letter). Physicians are prfessionals and as such need not be "enticed" to an educational event with the promise of fine cuisine or other gifts. If commercial support of CME activities is eliminated, there will quickly be a number of new avenues for obtaining CME that will be developed to fill any void. I am a member of the CME committee at the facility where I work. All of our sponsored CME activites are funded internally and are free from outside influence.	**Accredited CME provider**
The "pooled funds" idea sounds very good. If real CME, then the needs from gaps are established and the organization is free of financial relationships and the content is bona fide and the activity is certified free of commercial bias. Otherwise we only have promotion of someone's interests. If we do our job and are sincere in providing the best education, true education, then we eschew commercial promotion. We need to 'get the hook' and get the offenders off the podium. Enforcement is necessary to demonstrate that the accreditation council means business. Pooled funds may be a little cumbersome, but it is guaranteed if we are establishing real CME, not make believe. If we meet the criteria, then we will be supported. We are not guaranteed anything from commercial interests, only what they want to promote. We are looking to protect the public and promote the best health care for our patients.	**Other**
The [redacted] feels that implementation of Proposal #2 would have the consequence of decreasing access of physicians to CME. The financial consequence of this proposal is to transfer the burden to the physician. In the current situation the physician seeking to attend a CME course must pay a registration fee plus transportation and lodging. In many cases this fee is reduced based on unrestricted educational grants from companies. Without this support, professional associations such as the [redacted] would need to transfer this cost to the physician. This comes at a time when medical reimbursements are being reduced and physician expenses are increasing. Raising the fee would have the effect of reducing the ability of physicians to obtain CME. This should be counter to the goals of the ACCME. Industry support of CME benefits both the company and the patient, by providing physicians with more information on which treatment decisions can be based. Reducing the amount of information available benefits no one. One significant problem with the proposed mechanism for allowing industry funding in Proposal #2 is that it imposes a rigid, top-down definition of useful educational topics that will surely be cumbersome and slowly responsive. If a cure for cancer were developed today and adequately documented in the scientific literature, it would probably take a decade before CME events would be allowed to include a discussion of it. The scope of a government bureaucracy required to define a curriculum for all medical specialties and keep it updated would be staggering in cost and personnel. In addition, there is no guarantee that government regulations prevent bias. The rules already in place require that all CME events address “practice gaps,” but at present these practice gaps can be defined by a variety of mechanisms. The [redacted] has recently begun work with the [redacted]	**Accredited CME provider**

[redacted] are slowly leading to a small number of practice guidelines. However, it will be years before we have an assessment of performance on this small number of measures. Should we abandon all discussion of circadian rhythm sleep disorders because there is no P4P measure available? Item #3 fails to define what constitutes a "bona fide" organization. Is the [redacted] bona fide? What are the criteria? Finally, Item #4 proposes an ideal that can never be achieved. What are the limits of acceptable commercial bias? Who does the verifying? If the speaker can't sleep and sees a Lunesta advertisement on late night television does he or she become commercially biased for a talk the following morning? This pathway requires that all four of these criteria be met – a completely impractical solution. Implementation of the final suggestion in this proposal difficult to imagine ("Alternatively, these conditions could provide a basis for a mechanism to distribute commercial support derived from industry-donated, pooled funds."). What industry would voluntarily donate to a fund that would result in no direct benefit to the company? And if they do, who has the job of deciding where the pooled funds go? The [redacted] supports a continuation of the status quo regarding industry funding for CME. We feel that the current standards for commercial support are sufficient to insulate learners from undue bias, while allowing providers to reduce the cost of CME events and open the learning process to additional physicians.	
The [redacted]. is responding to the ACCME's request that due consideration be given to the elimination of commercial support of continuing medical education activities. The [redacted] would like to comment on each of the three scenarios posed by the ACCME. (1) The status quo, with commercial support continuing to serve an acceptable funding mechanism. - [redacted] believes that commercial support can continue to serve as an acceptable funding mechanism for CME, as there has not been an evidence-based study demonstrating that industry funding causes bias within certified CME. This funding mechanism has been in place for years, with specific measures in place directing providers to handle any perceived attendee bias promptly and thoroughly. Perhaps the ACCME should consider an increased role in measuring perceived bias at commercially-supported programs and intervening when unacceptable levels of bias are reported. (2) The complete elimination of commercial support. - [redacted] believes that complete elimination of commercial support would have a detrimental effect on patient care worldwide. Without commercial support, there will not be adequate funds dedicated to developing and implementing timely, high-quality CME, which would lead to a significant increase in treatment gaps. The intent of CME is to address treatment gaps proactively, thoroughly, and without bias, and in the absence of commercial support, physicians will not have access to the information needed to reduce these gaps. (3) A new paradigm where needs would be identified by organizations that are free of financial relationships with industry (eg, US Government agencies) and content would be developed by such bona fide organizations as the AMA, AHRQ, ABMS, and FSMB. - [redacted] has utilized information from bona fide organizations in the past and continues to do so in supporting needs assessment research and the identification treatment gaps. However, because these organizations do not always maintain current data, do not have the resources to generate new data quickly in the face of rapidly evolving patient management options, do not have the staff to assess information and determine needs, and often do, in fact, have relationships with industry, we do not feel that it is appropriate to designate the determination of needs to these organizations. While [redacted], Inc. does understand and support the need for greater monitoring of all providers, we do not accept that MECCs should be singled out for any assumed propensity towards bias in activities, nor do we believe that commercial support should be believed to predispose a program to bias, in the absence of any data proving either of these assertions to be true.	**Accredited CME provider**
[redacted] appreciates the concerns about industry support and the importance of nonbiased nonbiased continuing medical education (CME). The [redacted] believes that the ACCME's new standards should be given an opportunity to be evaluated and that commercial support should not be completely eliminated. The [redacted] works hard to assure that commercial support does not influence our educational events. For example, all CME sessions at the [redacted] are planned and faculty selected by committees for each event – Workshop Committee for workshops, Course Committee for courses, etc 1 year in advance.. These committees utilize post-activity evaluation data as well as assessing the needs of physicians based on their professional expertise to create these sessions. All sessions and faculty are determined before commercial support in the form of unrestricted grants is sought. Commercial support can therefore in no way influence the sessions. This method assures nonbiased physician education. An example of this is the series of neuromuscular medicine update courses offered at the 2007 [redacted] meeting. These sessions were recommended by the Board to meet the need for education for physicians who would be sitting for the new neuromuscular medicine board specialty examination. Long after these sessions were developed and faculty chosen, the [redacted] was given an unrestricted educational grant to support these sessions. In order to evaluate whether attendees found the sessions relevant to their educational needs, and whether or not the sessions increased physician knowledge in the area of neuromuscular medicine, attendees were surveyed after the sessions and again 3 months after the meeting. Survey data showed that 87% of respondents stated that attendance at the session improved their knowledge of neuromuscular medicine. When attendees were asked what influenced their decision to attend the meeting, 40% responded that the neuromuscular update courses were the most important factor in their decision to attend,	**Accredited CME provider**

while 55% stated the overall educational sessions were of greatest importance. Overall, 80% of respondents stated they had some increase in knowledge in neuromuscular and electrodiagnostic medicine following their attendance at the 2007 [redacted] annual meeting, and 46% stated they definitely had changed the way they care for patients by incorporating new practice tools learned from attending the meeting, while 42% stated they were in the process of changing their care. All these results occurred even though the [redacted] did receive funding for some session at the meeting. If a decision is made to ban pharmaceutical support of educational activities, there would be a disparate impact on small associations. The [redacted] has a staff of 15 and approximately 5000 members. The organization historically has had very little pharmaceutical support for its educational events. The organization has relied almost entirely on its membership for revenue. The organization expanded its scope in 2004 to include neuromuscular medicine. As a result of this expansion, the [redacted] has been able to receive some commercial support. In 2007, the [redacted] received approximately $230K including all forms of commercial funding (bags, lanyards, unrestricted grants, etc) for the meeting. This support has been invaluable to allow the [redacted] to continue to offer other educational benefits to the membership. Podcasts, web-based case studies, a CD lecture series, teleconferences, and other educational events have all been added to the [redacted]'s programming. Many of these offerings are free to physicians. The cost of creating technologically advanced educational products continues to grow making it difficult for small associations to provide these member benefits. We recently received an estimate of $21,000 to create a educational CD ROM that would assist member in studying for our certification examination. This is cost prohibitive. The sales of the product will not cover the cost of the product. We are hopeful that we can get a grant to fund this project. Again, the project has been 100% planned prior to seeking pharmaceutical support. The plan to eliminate all support by pharmaceutical companies will hamper the [redacted]'s ability to continue to create educational products and services. At the [redacted], we have implemented several mechanisms to handle conflict to comply with ACCME's new standards. For example, if a speaker states they have a conflict, the manuscript and PowerPoint presentations are submitted for outside review to assure that there is no bias present and that all products are equally discussed. Additionally, a committee member attends and observes the session. If bias is noted, the speaker is notified, and may be banned from speaking at future [redacted] meetings. The last step, is asking participants if bias was perceived. All of these methods are in place to assure that commercial influences are not introduced in educational sessions. These new mechanisms should have an opportunity to be assessed prior to banning all support by pharmaceutical companies. The [redacted] strongly believes that CME should be independent and free from commercial bias. We have implemented processes to assure that in our own CME offerings. It is clear that the [redacted] takes the needs of the physician, the evaluation of educational activities by the learner, as well as the relevance of activities seriously when planning educational sessions for learners. Commercial support should not be eliminated. Sincerely, [redacted]	
The [redacted] strongly opposes the ACCME's suggestion that commercial support for CME activities be eliminated. [redacted] has delivered quality, unbiased education to head and neck surgeons since 1952. Our reputation as a pillar of excellence and quality is firmly cemented in the field of otolaryngology. Our educational activities are planned and presented by tens to hundreds of surgeons connected by their passion for the field of head and neck surgery. Without commercial support, our small specialty-specific Society would fail to provide continued educational activities at the same quality and spectrum as we do today, thus removing a small but vital educational entity from the medical education umbrella. Already the numbers of head and neck surgeons are diminishing as fewer residents commit to this subspecialty. Without appropriate CME, these numbers will likely continue to decline. Additionally, without our raison d'être (medical education), the role our Society plays in other areas such as cancer and quality of life outcomes research, will be greatly diminished. [redacted] applauds the ACCME for attempting to address concerns about bias and undue influence in CME activities. The new Standards for Commercial Support, enhanced by the policy recently enacted by the ACCME Board of Directors, are appropriate. If there are organizations that do not uphold the Standards, we fully support the ACCME in the removal of accreditation from these entities. Most troubling to members of our society is the "new paradigm" suggested by the ACCME. It seems as though the ACCME is asking us to abdicate our education to a governmental entity (or other body). These alternate organizations will not necessarily consist of experts in the multidisciplinary field of head and neck oncology and therefore will not, in our opinion, have the critical insight needed to plan timely, thorough and effective educational experiences as [redacted]. Essentially, out of the fear of bias, we are looking at an option that will add layers of cost, time and bureaucracy and will remove the experts from the design of educational activities. Additionally, as the ACCME states in the response to the US Senate Special Committee on Aging, "No data demonstrating commercial content bias is found in the medical education or regulatory literature." We do not support radically changing medical education just to appease those who "think" there is bias. As stated in the ACCME response to the Josiah Macy, Jr. Foundation, "The United States has an excellent and admirable continuing education system." [redacted] is resolute about providing the highest quality education at the lowest cost to our target audience. Appropriately managed commercial support is essential to reaching this goal. Sincerely, [redacted]	**Accredited CME provider**

The [redacted] to the ACCME's call to end commercial support of continuing education. This letter is the [redacted] response to the ACCME's recommendation to end commercial support of CME and that, as explained herein, the [redacted] does not support that recommendation. The [redacted] The [redacted] is a voluntary health agency supported by public contributions and the donated time of millions of volunteers dedicated to reducing disability and death from heart disease and stroke. The [redacted] is a nationwide organization consisting of 8 affiliates and [redacted]. The mission of the Association is Building healthier lives, free of cardiovascular diseases and stroke. The Association is committed to supporting research, educating physicians, nurses, other healthcare professionals and the public about risk factors and providing educational programs for the community to help reduce disability and death from cardiovascular diseases and stroke. The Association's impact goal is, by 2010, to reduce coronary heart disease, stroke and risk by 25 percent. The Association has already met its goal related to coronary heart disease, and preliminary data shows that the stroke goal has been achieved as well. We recognize that much work is yet to be done especially as it relates to disparities of care. The Association's primary areas of emphasis are: Cardiovascular Disease Risk Factors: •\tHigh blood pressure •\tHigh cholesterol •\tTobacco •\tPhysical inactivity •\tPoor nutrition •\tDiabetes •\tOverweight/obesity Science topics: •\tAcute event •\tCardiac and respiratory arrest •\tStroke •\tAtrial Fibrillation •\tAcute Myocardial Infarction (AMI) •\tPeripheral arterial disease •\tNovel risk factors •\tCongenital disease •\tGlobal risk approach •\tHeart failure •\tArrhythmias •\tSubclinical atherosclerosis The Continuing Professional Education Expectation/Promise [redacted] Continuing Professional Education Program passionately strives to be the most trusted learning and change agent for translating emerging science to best practice through continuous quality improvement. Mission Statement (Purpose) To focus the [redacted] Continuing Professional Education Program on emerging research and the improvement of clinical competence, performance and enhanced patient outcomes for the prevention, diagnosis and management of cardiovascular disease and stroke. Continuing Medical Education and the [redacted] The [redacted] takes its role as an accredited provider of continuing medical education very seriously. As such, we closely follow the accreditation requirements set forth by the ACCME. We realize the importance of CME credits for helping to meet relicensure requirements as well as the opportunity we have to affect clinician competence, performance and, ultimately, patient outcomes with each of our educational activities. Our activities provide ample opportunities for learners to engage with content in their preferred learning environment or format, including live conferences, grand rounds, journals, online activities, satellite broadcasts, webcasts, and podcasts. Our educational activities are managed through our Professional Education Center, in which we have over 177,000 registered users/learners. We are in alignment with the ACCME in that our ultimate goal is to improve patient care. We are dedicated to providing valid, evidence-based content, and to upholding the essential requirements of managing conflicts of interest and remaining independent of commercial influence in all the educational activities we provide. Our policies, procedures, and internal processes support the achievement of these elements in our CME enterprise. Furthermore, our philosophy supports the practice of continuous quality improvement in all we do. CME as a Bridge to Quality We believe the ACCME publication: Leadership, Learning, and Change within the ACCME System – CME as a Bridge to Quality1 is a giant step on the continuous quality improvement continuum and a large commitment by the ACCME. As you note on page 13 regarding maintaining independence between CME providers and commercial interests, both the CME community and the commercial interests share a concern for improving the public's health. You further state, "The ACCME is resolute in its efforts to ensure that CME is provided through a valid and credible accreditation system…independent of commercial bias in all CME topic selection, planning decision, and presentation content."2,3 We continue to maintain that the ACCME is positioned to ensure that commercial bias is absent from CME through the development, measurement, monitoring, enforcement, review, and improvement of their policies and procedures. We applaud your call for transparency and for further monitoring of the CME enterprise, including "enforcement" as needed, to ensure these goals are met. We feel such heightened measures are necessary to ensure independence of CME activities. [redacted]'s Response to the ACCME's Recommendation The [redacted] does not support the ACCME's recommendation that Commercial Support of continuing medical education end until there are further studies of the issues that might diminish quality patient care. Further, we question whether an abrupt, immediate change is contradictory to the tenets of the ACCME. In the Statement from the Accreditation Council for Continuing Medical Education to the Institute of Medicine Committee on Conflict of Interest in Medical Research, Education and Practice, your appropriate and increasingly successful efforts related to maintaining independence of CME and commercial support are acknowledged. You have effectively assumed the role of "custodian" of the Standards for Commercial Support. It would therefore seem best to heed the call to action as described in the "…CME as a Bridge to Quality" Initiative and to continue to work toward the continuous quality improvement of the process. The proposed curtailment of commercial support for CME would appear to disrupt that process and perhaps set things further back before moving forward. Current State of the CME Enterprise The findings from the April 2007 Committee Staff Report to the Chairman and Ranking Member of the Senate Finance Committee titled, Use of Educational Grants by Pharmaceutical Manufacturers identified elements in the process that have provided for the good of both the health care community and patient care. A major re-invention of the process was not the focus of this report and modification and refinement appear to	**Accredited CME provider**

be the intended direction, not radical change. End of Commercial Support: The Effects We believe a sweeping decision to end commercial support before establishing other credible pathways of support would have a significantly negative effect. We suggest the ACCME consider this position carefully. Commercial support for CME is evident in major academic medical centers (although with a few high profile exceptions), large hospital systems, major regional and national medical meetings and major on-line CME efforts. Without industry support, many high-quality CME activities, the content and delivery of which are independent of the supporter, will no longer occur. The impact will be felt by both large scientific conferences and smaller grand rounds occurring at the local hospital level. The cost for CME would be shifted to the learner. These costs are not trivial and would in our opinion represent a major disincentive for CME. We believe the immediate result would be fewer attendees at medical conferences, less dissemination of valuable practice guidelines and latest research results, and reduced application of new information at the bedside, possibly resulting in worse patient outcomes. These negative outcomes would be experienced not only by physicians, but also by nurse professionals, pharmacists, and other health care clinicians who depend on CME activities. To be clear, not every program that carries the "CME' label merits such. But the better approach is to identify and eliminate programs (and supporters) that fail to meet the high standards of the ACCME rather than to undermine all efforts-- the majority of which are appropriate and compliant. Commercially Supported CME and Bias The ACCME is obviously expressing a heightened concern surrounding the relationship between commercially supported continuing medical education and bias. We absolutely share that concern. However, even the literature review conducted by ACCME and posted on their website on 6/11/08 (www.accme.org) entitled: The Relationship between Commercial Support and Bias in Continuing Medical Education Activities: A Review of the Literature5 showed at best inconclusive results and ended with a call to initiate rigorous scientific studies on the following: §\tCommercial support and bias in CME activities §\tHow is bias produced? §\tAre the accreditation guidelines put forth by the ACCME effective in preventing bias? §\tDoes commercial support contribute to a physician's increased use of the commercial supporter's product? §\tDoes adoption of the commercial supporter's product actually lead to better patient care? Until those data are forthcoming, the rationale for a radical change at present is based more on perception rather than principle. As custodians of this very necessary and effective educational tool, we should all heed our own standard and make our decisions evidence-based. Our Recommendation We recommend that the ACCME not call for an end to commercial support for educational activities before further analysis. Rather we encourage you to continue to support research efforts designed to determine the questions posed above. Furthermore, we especially recommend that educational activities draw support from multiple supporters to reduce the possibility or appearance of bias in the case of sole support from a single commercial entity. Further information is necessary to assess the effectiveness and validity of the improved monitoring system ACCME has activated, so that continuous quality improvement methods can be implemented. A measured and thoughtful review of the impact of such a program is far preferable to the call for elimination of all commercial support for valuable, unbiased educational activities that impact care and patient outcomes. References 1.\tLeadership, Learning, and Change within the ACCME System – CME as a Bridge to Quality, retrieved June 15, 2008 from http://www.accme.org/dir_docs/doc_upload/e2843247-7cae-40fe-a0eb-27a982b8fcc0_uploaddocument.pdf 2.\tExecutive Summary of the November 2007 Meeting of the ACCME Board of Directors, retrieved June 15, 2008 http://www.accme.org/dir_docs/whats_new/aa64ed0e-fbbc-44fd-abad-550a6da7edef_uploadfile.pdf 3.\tACCME Letter to the Committee on Finance, United States Senate, August 3, 2007, retrieved June 15, 2008, http://www.accme.org/dir_docs/doc_upload/ff745720-2080-496a-bece-2c50b09d4c7c_uploaddocument.pdf 4.\tApril 2007 Committee Staff Report to the Chairman and Ranking Member of the Senate Finance Committee, Use of Educational Grants by Pharmaceutical Manufacturers, retrieved June 15, 2008, http://www.finance.senate.gov/press/Bpress/2007press/prb042507a.pdf 5.\tThe Relationship between Commercial Support and Bias in Continuing Medical Education Activities: A Review of the Literature Ronald M.Cervero and Jiang He June, 2008. Respectfully submitted, [redacted]	
The [redacted] is a national specialty association whose mission is "[redacted]." Eliminating commercial support of continuing medical education activities would make it virtually impossible for [redacted] to fulfill its mission and would hinder the development of educational programs that are vital for our members and enable them to provide quality patient care. [redacted] encourages the dissemination and investigation of scientific and clinical information relevant to the field of clinical immunology. Our members are the physicians whose research pioneers advances in the prevention, diagnosis and treatment of diseases of the immune system. We firmly support and agree that all continuing medical education activities be free of commercial bias. However, the proposed requirements and conditions that commercially supported activities would have to adhere to would make supporting the society's mission unachievable and ultimately damage the association and impede the education of our members.	**Accredited CME provider**

The CME courses are helpful in keeping up the up to date information. Eliminating it would be a travesty.	Accredited CME provider
The [redacted] appreciates the opportunity to comment on the Accreditation Council For Continuing Medical Education's (ACCME) recent proposals and efforts to ensure that commercial support does not undermine the independence of continuing medical education (CME). The College represents more than 17,000 pathologists who practice medicine in community hospitals, academic medical centers, independent laboratories, and other health care facilities. The mission of the College is to represent the interests of patients, the public, and health care providers by fostering quality and safety in health care delivery and laboratory medicine worldwide. In 2008, the [redacted] received the designation of Accreditation with Commendation as a provider of continuing medical education for physicians by the ACCME. The [redacted] offers education in anatomic pathology, clinical pathology, practice management, and laboratory procedures, focusing on practical, take-home education for pathologists and laboratorians. [redacted] education is offered in a wide variety of formats, including online training, audioconferences, podcasts and live events. [redacted] praises the efforts of the ACCME and others who ensure that CME is an asset for all stakeholders who seek to improve the quality and safety of health care delivered in the United States. However, [redacted] urges ACCME to assess the impact and effectiveness of the current oversight mechanisms, including existing accreditation standards, before changes are undertaken. Additional research and evaluation is required before a decision can be made about significantly altering the guidelines that address commercial support for continuing medical education. The [redacted] is in favor of the current paradigm and in retaining commercial support of CME and believes that the following principles should guide any alteration of the current system: ·Medical societies, medical schools, teaching hospitals and specialty organizations have a proven track record of offering educational content free of bias and conflict-of-interest while managing the support of non-accredited partners. ·The peer review process, as well as transparency and a commitment to fulfilling education objectives, ensures that practitioners are equipped and tested on the best available science and evidence. ·The ACCME should not limit a physician's ability to participate in CME activities; any new standards or policies should not diminish the supply of such educational offerings. ·The ACCME should not adopt policies that could limit the availability of courses needed to comply with the requirements of Maintenance of Certification and Maintenance of Licensure. ·Periodic review of commercial support is warranted and suggestions for new models for offering continuing medical education should be based on evidence of bias and change would be required to ensure independence. ·Since ACCME Standards on Commercial Support were adopted in 2004, there has been insufficient time for these standards to be fully implemented. ·Consideration must be given to the consequences of any changes in support for continuing education and to identify how new paradigms would be supported if commercial support is prohibited. · Excluding those who write promotional materials from participating in independent CME activities could lead to prohibitions of nationally recognized experts who participate on medical advisory boards or who belong to speakers' bureaus from sharing their expertise with their field. ·Excluding those who teach or write promotional items for commercial interests would discourage many leading experts, and those with the most experience, from participating in CME programs and sharing their expertise with their field. The [redacted] supports the objectives of ACCME in ensuring that CME activities are transparent, independent and of high quality; however, changes should not be undertaken unless there is evidence that the current system requires modification. Additional study and discussion, with input from leading national medical organizations, is required. Questions about these comments can be addressed to the [redacted] Thank you for your consideration of these comments.	Accredited CME provider
The Commercial Support of CME has been invaluable to me since the costs of either attending meetings or purchasing the required CME credits for maintaining needed education not only in my own specialty area of multiple sclerosis and pain management, but all other areas of medicine as well, would be prohibitive. While I realize the concerns from the outside have been that there is bias and undue influence exerted by such commercial support, this is both insulting to the participating physicians, as well as to the sponsoring organizations. Physicians have a moral, ethical and directly personal obligation to their patients to make the best judgments, irrespective of how or who supports their continued medical education. Following the flawed argument encouraging elimination of commercial support is no different than arguing against the use of funds obtained from earnings through the care of the very patients for whom we are trying to learn more in order to support paying for their care, since that may influence the courses we take, thus potentially limiting our knowledge base. After all is said and done, if Commercial Support of CME is banned, the cost of CME, like the cost of malpractice insurance, will be passed on to the consumer as a higher cost of doing business. Who in the end will be influenced. When patients learn of the chain of events that caused their healthcare costs to go yet higher, and at the hand of those legislators who profess to have the interest of providing them with affordable healthcare, they will act accordingly. They will not stop seeing their doctors, but they will stop voting for those people who raised their taxes. I am totally and unabashadly in favor of continued Commercial Support for CME.	Other

The consequences of altering the manner in which CME activities are presently funded would have a negative effect on learners like me. Limiting providers' abilities to develop effective CME activities will mean that fewer options for learning will be available. Further, the major portion of available education would then be primarily of a promotional nature from pharmaceutical and device companies. Lastly, the decision could also limit the availability of activities to address the requirements of Maintenance of Certification and Maintenance of Licensure. I believe this decision could also have a deleterious impact on patient health outcomes. With more limited CME activities to choose from, it will be more difficult to apprehend evidence-based treatment options in disease states where cutting-edge interventions involve off-label usages, or the science behind novel therapies that may soon fit into our treatment armamentarium. In short, the decision to eliminate commercial support could have a negative mpact both on the quality and quantity of CME available to practicing healthcare professionals, as well as on patients. The same can be said for the new paradigm scenarios under which commercial support would be allowed to continue. While I recognize that the current system can be improved, I encourage the ACCME to maintain the status quo, with commercial support of CME remaining an acceptable funding mechanism.	**Other**
The consequences of altering the manner in which CME activities are presently funded would have a profound effect on learners like myself. Limiting providers' ability to develop effective CME activities will mean that fewer options for learning will be available. Further, the major portion of available education would be only of a promotional nature from the pharmaceutical and device companies. Lastly, the decision could also limit the availability of activities to address the requirements of Maintenance of Certification and Maintenance of Licensure. In the end, however, I believe this decision will have an even more profound impact on patient health outcomes. With limited CME activities to choose from, learners like myself will be hard-pressed to understand evidence-based treatment options in disease states where cutting-edge interventions involve off-label usages, or the science behind novel therapies that may soon fit into our treatment armamentarium. In short, the decision to eliminate commercial support could have a great impact both on the quality and quantity of CME available to practicing healthcare professionals, and also on patients. The same can be said for the new paradigm scenarios under which commercial support would be allowed to continue. While I recognize that the current system can be improved through minor adjustments, I encourage the ACCME to maintain the status quo, with commercial support of CME remaining an acceptable funding mechanism.	**Other**
The consequences of altering the manner in which CME activities are presently funded would have a profound effect on our learners. Limiting providers' ability to develop effective CME activities will mean that fewer options for learning will be available. Further, the major portion of available education would be only of a promotional nature from the pharmaceutical and device companies. Lastly, the decision could also limit the availability of activities to address the requirements of Maintenance of Certification and Maintenance of Licensure. In the end, however, this decision will have an even more profound impact on patient health outcomes. With limited CME activities to choose from, learners will be hard-pressed to understand evidence-based treatment options in disease states where cutting-edge interventions involve off-label usages, or the science behind novel therapies that may soon fit into their treatment armamentarium. In short, the decision to eliminate commercial support could have a great impact both on the quality and quantity of CME available to practicing healthcare professionals, and also on patients. The same can be said for the new paradigm scenarios under which commercial support would be allowed to continue. The current system can be improved through minor adjustment. I encourage the ACCME to allow for the commercial support of CME to remain as an acceptable funding mechanism.	**Accredited CME provider**
The consequences of altering the manner in which CME activities are presently funded would have a profound effect on physicians like myself. Limiting providers' ability to develop effective CME activities will mean that fewer options for learning will be available. Further, the major portion of available education would be only of a promotional nature from the pharmaceutical and device companies. Lastly, the decision could also limit the availability of activities to address the requirements of Maintenance of Certification and Maintenance of Licensure. In the end, however, I believe this decision will have an even more profound impact on patient health outcomes. With limited CME activities to choose from, physicians like myself will be hard-pressed to understand evidence-based treatment options in disease states where cutting-edge interventions involve off-label usages, or the science behind novel therapies that may soon fit into our treatment armamentarium. In short, the decision to eliminate commercial support could have a great impact both on the quality and quantity of CME available to practicing healthcare professionals, and also on patients. The same can be said for the new paradigm scenarios under which commercial support would be allowed to continue. While I recognize that the current system can be improved through minor adjustments, I encourage the ACCME to maintain the status quo, with commercial support of CME remaining an acceptable funding mechanism. I also find it insulting that the ACCME believes that physician's prescribing habits can be bought with a dinner or web tutorial. Yours truly,	**Other**

The continuation of fair-balanced CME is an essential part of medical education. As a frequent CME speaker I am well aware for the potential of bias in programming sponsored under the guise of CME. Organizations that are receiving funding from multiple sources should unquestionably be allowed without restriction. Single source sponsored programs remain essential, but content should be developed independently by educators/speakers and should not be generated by the CME vendor. Without the ability of CME to be funded by pharma, we put ourselves at even greater risk of an increase in unregulated promotional programs to compensate for this proposed restriction of CME.	**Other**
The convoluted language of ACCME itself may require a course to understand. It seems to me that ACCME's dictatorial approach is losing track of the essence of CME: continuing medical education. This education is becoming compartmentalized into filling "gaps" in one's knowledge. What happened to the concept of reinforcement of knowledge? Is that irrelevant? Is the act of providing a program that is intellectually satisfying and enriching to the attendees alien? ACCME's constantly expanding slew of constraints and procedural requirements taxes the abilities of meeting organizers, many of whom are physician volunteers receiving absolutely no compensation for the regulatory and data-recording grief imposed by the ACCME. What will the elimination of commercial support moneys do to dermatology CME conferences? As program chair of a state society meeting and program director for a national society meeting I tell you that it would devastate the meetings. Without commercial support the registration fee for my state meeting would have to triple to quadruple in order to balance the meeting budget. Furthermore, the commercial exhibitor section of the meeting would be shut down, as there would be no commercial support allowed. The exhibits serve a valuable function in exposing the meeting attendees to a variety of products relating to dermatology. The "hands-on" evaluation and contrasting of products between exhibitors is a learning experience that enhances one's dermatologic expertise. It is not measured in any "gap" evaluations, but it serves an educational purpose, as do the booksellers that exhibit and sell medical textbooks to attendees at a discount. They would be gone, too, under your proposal. Your concept is that industry is a disease needing complete eradication. Well, that sounds noble, but economic reality reveals that in the case of dermatology many excellent educational meetings would become financially impossible to continue without industry support. Be assured that "support" means just that: unencumbered, unrestricted financial support without any input or influence on any of the meeting structure or content. The system of ethically managed commercial support works very well now for dermatology. It needs to be preserved for the educational sake of dermatologists. Keep it as it is.	**Accredited CME provider**
The [redacted] believes that the ACCME Standards for Commercial Support, along with the PhRMA Code and oversight from the HHS Office of Inspector General, are sufficient to ensure that CME content is not influenced by industry. To date no data has been published on the implementation of the updated Standards for Commercial Support. [redacted] suggests a study be conducted by an independent organization (outside of the ACCME) to identify compliance issues. [redacted] believes that eliminating commercial support would likely result in a dramatic increase in promotional “education” by the pharmaceutical and device industry. Moreover, providing certified CME without industry support would create a significant financial burden on the learner. Commercial support allows accredited providers of CME to be innovative in addressing knowledge and practice gaps, which ultimately enhances patient outcomes. Lack of commercial support may contribute to the demise of educational activities and initiatives that truly represents the basic purpose of CME, that of positively affecting the health of the American populace. Regarding the new paradigm proposed by ACCME, the conditions to be met are somewhat vague, in particular the definition of a bona fide organization. [redacted] believes the intent of the conditions could be more clearly articulated. The new paradigm also suggests a mechanism to distribute commercial support derived from industry-donated, pooled funds. Individual pharmaceutical firms tend to focus their research on and ultimately create products for specific disease states. Asking them to donate to a pool that may result in CME that has no relationship to their research and product efforts could actually result in decreased support for quality educational activities.	**Accredited CME provider**
The [redacted] administers the CME programs developed for their membership through the [redacted] We are an accredited provider by the [redacted] The council supports and endorses independence of CME from commercial interests. CME is driven by needs—the needs of learners, not the needs of companies. We adamantly oppose this policy. Such a policy will undoubtedly eliminate smaller cme providers like us leaving only very large organizations and care systems (who are commercial for their purposes). If the program is free of influence it shouldn’t matter that there was commercial support.	**Accredited CME provider**
The elimination of commercial support will severely limit the availability of free CME on the internet, which is the only way I can afford to do as much as I wish to. Please give me the courtesy and respect of being able to recognize bias in a presentation when I see it.	**Other**

The [redacted] has been extremely disappointed by the reactions of continuing medical education industry leaders to accusations of certain parties relating to the perceived negligence of our work in educating health professionals. The ACCME's Standards for Commercial Support, as currently formulated, adequately address concerns about bias occasioned by commercial support. The frenetic reaction and discussions of complete industry overhaul and elimination give the perception to the public and our lawmakers that continuing medical education professionals are guilty of negligence and wrong-doing, when, in fact, we provide a critical, high-quality service to this nation's healthcare providers. In short, we support the status quo with commercial support of continuing medical education. [redacted] also supports the recent establishment of increased ACCME oversight, monitoring, and compliance (Steve Singer) of ACCME Standards for Commercial Support and believes an entire agency should be devoted to such work. The complete elimination of commercial support would be devastating to the professional development of healthcare providers. Decisions for change should not be made quickly and in haste. We have spent many years building a system that provides much more benefit than harm to both healthcare providers and patients. The proposed "new paradigm" is ambiguous and seems beyond the ACCME's authority to implement. Our lack of understanding of the new paradigm makes it difficult to provide specific response commentary. We urge the ACCME in this tumultuous regulatory environment to please stand up for the principles and values of continuing medical education and our role in health professional development. The standards you have established and set forth are important and valid. Don't let misguided and inaccurate perception destroy the mission of our work.	**Non-Accredited CME provider**
the many choices of cme's with pharm support have been extremely beneficial	**Other**
The medical providers need to be educated related to medications, changes in indications, black box warnings, results of research in use. New medications are advertised patients come in and providers know nothing about the drug. Elimination of commercial support for CME activities would limit access to information for providers. Medications with indications for use to alleviate or improve conditions would not be prescribed appropriately creating a loss in treatment for the medical community and a suoptimal response for patients. Pleas give this due consideration and continue to allow Commercial Support of CME Activities. Thank you.	**Other**
[redacted] which administers the CME and intrastate accreditation programs of the [redacted], supports and endorses independence of CME from commercial interests. CME is driven by needs—the needs of learners, not the needs of companies. [redacted] expresses serious concerns about adoption of a policy to consider elimination of commercial support. Because of limited resources, many CME programs could not operate without commercial support. The committee does not oppose providers' use of commercial support. By complying strictly with the ACCME Standards for Commercial SupportSM, providers would keep CME independent from the influence of commercial interests. An acceptable method would be to accept only unrestricted educational grants that would be pooled in a general fund and distributed for activities chosen by the planners. Commercial support could improve a provider's ability to have national speakers at CME activities. The Updated Criteria goal of linking CME to outcomes is very resource intensive. Commercial support of a CME program could help fund this effort. Submitted on behalf of the [redacted]	**Accredited CME provider**
The Necessity of Commercial Support for Continuing Medical Education [redacted] We file this comment to state our support of ACCME's current rules governing commercially sponsored CME. We oppose the suggestions of prohibiting commercial support or establishing a new paradigm that is very complex and probably unworkable. We believe that the loss of commercial support would greatly diminish the quality of CME and ultimately have a detrimental impact on patient welfare. Physicians have ever-increasing demands on their time. Trends are toward more specialization of practice. Simply keeping up with new innovations in medicine is becoming unmanageable. The effective use of medical device technologies requires on-going education. Physicians considering therapies involving new medical device technologies clearly have the ethical directive to learn about the application which is appropriate to their practice and their patients. [redacted] Medical truly believes that patient care is of the utmost importance. Timely physician education of new technologies, independent of commercial bias, can only happen when commercial interests and medical practitioners work together to common ends. Appropriate controls for fair balance and independent review can and already do serve their functions well, and as a result, provide quality CMEs to physicians seeking to learn about new medical device therapies. More than 50% of sponsorship for CMEs is derived from commercial sources. We believe it would not be in the best interest of patients to dramatically change the current rules or to eliminate the system in its entirety. [redacted] is grateful for the opportunity to submit these comments and would welcome the opportunity to further assist in this endeavor.	**Commercial Supporter**

The overwhelming majority of online CME courses that I have taken over the past 5 years have been remarkably free of commercial bias. This includes many courses funded by the pharmaceutical industry. Those who argue that subliminal influences might be present and overlooked apparently have little faith in the ability of physicians to tell the difference. Yes, the research literature has been shown to be biased in favor of recommending those drugs from companies funding said research. And physicians and now patients are repeatedly exposed to biased propaganda from drug makers, undeniably affecting medication selection among some providers. It is admirable that some in our profession are working to reduce the effect of bias. But I enjoy online CME, compare information and data presented to other sources, and keep my antenna in its awareness and critique mode when studying a CME program presented through industry funding. For you to deny me that opportunity says that you consider me incapable of determining validity of data when an online activity has commercial support. Why not take a far more logical approach? Require that commercially supported CME be reviewed by the ACCME before it is placed online, and bill that entity providing commercial support for such review. Grade such activity on a 1-5 scale in which 1 means no bias detected, and 5 means extremely biased. Then have that online activity have a box warning clearly visable at the beginning of the program where the ACCME grade and its meaning are given. Please do not take away the choice many of us make by learning and reviewing some very good material via commercially funded CME. Even if the program is brought to us by an entity seeking for itself and its products to be viewed by us with favor.	**Other**
The [redacted] supports the ACCME Standard for Commercial Support as the effective and appropriate mechanism to manage the potential for bias in industry supported CME and to ensure the independence of CME from industry influence. The conditions governing the receipt of industry support for CME and restrictions on communication or interaction about the content or selection of faculty are clear and effective. There is no evidence or even well supported inference that commercial support of CME leads to education that is biased or potentially deleterious to patient care. There is no reason to consider the elimination of commercial support for accredited CME. In fact, the only existing evidence suggests that bias in commercially supported CME does not exist and the impact on supporting changes in clinical practice and patient care are positive. Continued commercial support of CME is desirable and necessary. It represents a large percent of overall CME funding. There are no sources of money are available to fill the gap should commercial support be reduced or eliminated. Commercially supported CME is valued by physicians as a source of new and relevant information about advances in medical science and clinical practice. Industry support for physician education is currently promotional education and independent accredited education. Should the requirements for commercial support of CME become overly restrictive, resources will shift to promotion, thus compromising the quality and objectivity of information provided to physicians. The ACCME proposed four conditions to determine the appropriateness of commercial support are overreaching, impractical, arbitrary and too restrictive. Condition Number 1: A comprehensive needs assessment provides insights to the specific educational needs of a target audience and should consider several and varied sources of information including government reports and data when available. However, such information does not usually provide the depth and insights necessary to identify the nuanced points. Many organizations receiving commercial support provide valuable sources of information which are needs assessment essentials. These include academic medical centers and professional associations which publish practice guidelines, research, professional journals, surveys and other data sources offering useful insights to gaps in knowledge and educational needs. Patient registries, a valued source of practice information for needs assessments, are often supported by industry. Surveys and focus groups conducted by [redacted] associations and [redacted] are important sources of information to set priorities for education. All accredited CME providers regularly conduct evaluations of their activities and outcomes assessments to define practice changes. Feedback from learners provides guidance on additional educational gaps and needs which help to translate knowledge into clinical practice changes. Therefore, it would be a setback for the practice of CME and the ability to finely pinpoint the educational needs of physician learners to handicap providers by limiting the sources of needs assessment data to organizations not receiving commercial support. Again, the source of funding an organization receives does not in itself create a bias. Condition Number 2: The availability of 'bona fide performance measurements' is spotty and limited to select therapeutic areas with large patient populations. These data and reports are valuable as general sources of needs assessment data but without complimentary or alternative sources of data they lack the depth necessary to focus the level and scope of the learning objectives. Also, such performance measures are a retrospective view of practice patterns and are not useful for CME which is designed to impart information on new developments and therapeutic options. Condition Number 3: When the ACCME Standards for Commercial Support are followed the content of a CME program is not influenced by the supporter and thus, is unrelated to the funding. The content of a CME activity, be it a curriculum, research from recent studies, opinions of thought leaders, peer to peer case presentations, etc. is determined by the planners and faculty based upon the learning objectives. A well constructed CME program should draw upon multiple sources of information from which content is derived. Limiting content to existing continuing education curricula is too restrictive. Curricula are not available for all specialties, sub specialties and disease states. Curricula may not reflect the most current information as they are only updated periodically. Reliance upon curricula would slow communication of new	**Accredited CME provider**

information and the uptake of new practices. Curricula follow actual clinical practice; they do not drive innovations in practice. Condition Number 4: The requirement to warrant CME content as free of commercial bias prior to receiving funding is impractical as well as undesirable. In the lifecycle of a CME activity the source of funding (tuition, grant from industry, institutional operating budget, association dues) is defined in the early stages of planning after the needs assessment and learning objectives have been defined. The review of content for a live meeting, internet program or publication as a precondition for commercial support might encourage the company (supporter) to make funding decisions based upon the content, rather than the need for education.	
The practice of medicine requires constant decision making about the value of treatments we bestow on our patients. Learning to decipher the studies presented to us as evidenced based or even clinical anecdotes are critical to the process of selecting agents that may be useful or harmful to a patient. CME should and cannot be held to some lofty status that appears beyond the scope of questioning the veritas of the data presented. By cutting out sponsored CME do we hope to relieve the possibility of tainted material so we no longer need to question the truthfulness of a presentation? This would only serve to make physicians more complacent and devalue the process of critical thinking that it takes to make everyday determinations about healthcare in the 21st century. Why would we cut out the educational responsibility of the industry that we rely on to produce pharmaceutical products that have become essentially the practice of western style medicine that our patients demand? Develop standards for disclosure and transparency in CME presentations. Allow physicians to discern the subtleties of commercialism and interact with the industry in a manner that promotes mutual respect. Eliminating commercial support for CME is contrary to the autonomy that each physician sought as they entered a field of technical training that required a vast army of teachers and mentors that contribute to the process of becoming a critical thinker. Allow us the autonomy of rejecting or embracing the cutting edge of free enterprise's contributions to the wizardry of healing. Allow us to make our own decisions and not blindly adopt the ethics dejour of the ruling academics and vocal theoreticians that dictate where we are to get our information from.	**Other**
The present is extremely helpful,I would be at a loss if it were to change. Thank you, [redacted]	**Non-Accredited CME provider**
The proposal to ban commercial support of CME activities, and the alternate proposals to severely restrict the conditions under which commercial support of individual activities would continue to be allowed fundamentally assume that commercial support equals introduction of bias into educational content, a premise that has not been proven, and that is strongly guarded against via the 2006 Updated Standards for Commercial Support and more recent policy updates. The commercial supporters with whom we work have been quite willing to abide by the updated standards, a testament to their commitment to support of unbiased, fair balanced CME. Additionally, the proposal assumes that US government agencies are free of potential influence because they do not receive commercial support. However, government agency agendas are notoriously driven by political agendas. A prime example is the extensive federal funding (over $1.3 billion) of abstinence-only education despite myriad calls for comprehensive sex education from "bona fide" organizations such as [redacted] As Senator Henry Waxman pointed out in a recent (April 23, 2008) congressional hearing on abstinence-only programs, the Bush Administration itself in 2007 released the result of a longitudinal, randomized, controlled study of 4 federally funded programs that showed that compared to the control group, the abstinence-only programs had no impact on whether or not participants abstained from sex, on the age teens started having sex, on the number of partners, or on the rates of pregnancy or sexually transmitted diseases. In addition, Waxman has continued to expose overt attempts to censor information regarding the failure of abstinence-only education (see Waxman letter to congress May 9, 2006 highlighting last-minute interventions of the Department of Health and Human Services to alter the content of a CDC-sponsored 2006 National STD Prevention Conference to minimize criticism of abstinence-only educational initiatives. Last minute changes were made to the agenda and to panelists speaking, without allowing for the review process required for all other content presented at the meeting.) Waxman has also continued to unearth misinformation contained in abstinence-only education initiatives funded by the federal government. To quote Waxman, "this triumph of ideology over science is bad economics and even worse health policy." Add to these ideological concerns, the overarching government focus on healthcare cost containment, and one can clearly see that the provision of quality healthcare is not and will not be the primary focus of government agencies. To the extent that government agencies do identify educational needs, the focus is on the most common chronic illnesses that cost the government the most	**Accredited CME provider**

money through Medicare and Medicaid. These are valid areas of focus, which are being addressed through a combination of government and privately funded efforts. In fact, government information is routinely incorporated into the needs assessments that CME providers conduct for their CME programs. However, there are many sources of information outside of government agencies that identify educational needs for less common, less mainstream illnesses. Given that 1 in 10 US citizens suffer from rare diseases that affect less than 200,000 people annually, the CME community is at risk of leaving a substantial portion of the patient population underserved if we restrict our educational efforts to only the more common diseases that have gotten the attention of government agencies. Are the constituent organizations represented by the ACCME willing to accept a scenario in which attention and focus by the medical community on a given disease requires it to rise through the bureaucracy of government agencies to the point that it is identified as an area of focus? As a US citizen and consumer of healthcare, independent of my role as a CME provider, I would be gravely concerned about allowing the US government to mandate not only what treatments are subsidized by federal funding, but at a fundamental level, what information can be provided to practicing physicians via education. This is an invitation to government censorship rather than a call for higher quality education or healthcare. CME professionals should be allowed the autonomy to respond nimbly and quickly to emerging needs in the medical profession and to provide cutting edge information to the physicians charged with our healthcare. Allowing the US government to drive the educational agenda for the entire US medical profession is likely to subjugate scientific and medical advances to the political and economic agendas of the reigning political party. The result will be less well-informed healthcare professionals and slowed uptake of improved techniques and emerging therapies, which are the lifeblood of the continuing professional development of physicians and critical to our ability to provide patients premium health care. Tying CME to professional practice gaps identified through “bona fide” performance measures will restrict education to those areas that have those performance measures in place. Again, there are many areas of medicine for which these do not exist, but for which there are “best practices” established by experts, which need to be disseminated to less well informed physicians. Again, the approach suggested in the call for comments will limit the CME profession to discussion of mainstream agenda topics to the detriment of those unfortunate enough to be suffering from a less common ailment. Our objection is not that the mainstream diseases are unimportant, but that they are not the only diseases that are important. This proposed restriction will not necessarily increase the amount of education being provided for mainstream illnesses, but will certainly decrease the ability to provide CME in other areas, to no beneficial effect for physicians or their patients. Who determines what organizations or entities are “bona fide” for setting educational curricula, and what makes these entities less subject to industry influence than any other group dedicated to the education of physicians? Again, to the extent that such organizations are addressing needs, CME providers already incorporate those into their needs assessments. Restricting those who are allowed to identify areas of need channels whatever funds that are available to those entities (which is essentially a restriction of trade), but it does not change the fundamental equation. All of the efforts of the CME profession require money. The money has to come from government or from private sources. Given that the US government is currently at war and facing an estimated $410 billion dollar budget deficit for fiscal year 2008, it is unrealistic to expect that funding of needs assessment research and practice gap analysis, much less CME activities, is going to be a high government priority over the next 10 years, except in areas of high political consequence. If the pharmaceutical industry is willing to be socially responsible and step in to assist in funding the identification of educational needs and practice gaps and education to fill those gaps, then why not let them, particularly given all the safeguards currently in place to assure fair balance? And if the funding source for needs assessments is the same for “bona fide” organizations as for the presumed “non-bona fide” CME providers, is not the potential for bias the same? So what is gained by narrowly restricting who is eligible to identify needs? In my view, nothing is gained, and much is lost by restricting the free exchange of information regarding physician educational needs. The ACCME standards already establish that CME must contribute to patient safety and practice improvement, be based on valid content, and be independent of commercial bias. This proposal will result in a reduction of the quantity and quality of the needs assessment data generated, which will in turn negatively impact the quality of the education available to physicians. And who ultimately loses will be the patients, the very persons we are all trying to protect. My recommendation is that before you move to these extreme measures, which are fraught with unfair assumptions about bias and the lack thereof, you give the updated standards and the increased monitoring steps a chance to prove what seems to be me to be the reality--that the current system is working to provide good medical education and to protect the interests of the healthcare consumer. To shackle the medical education of physicians to the behemoth of government bureaucracy and to restrict the educational dialogue to topics of interest to a select few “bona fide” organizations, not only restricts freedom of speech and freedom of trade, but also restricts the intellectual milieu in which physicians exist as they seek to improve their clinical skills. I commend the ACCME’s efforts to effectively respond to criticisms launched by the Senate Finance Committee, but I would caution that you not over-respond. The current rules are doing a fine job of regulating the CME enterprise to the benefit of physicians and of patients alike, and we are likely to continue to see improvements in educational offerings and in ultimate outcomes as we embrace the tenets of the Bridge to Quality outlined by the ACCME. The updated Standards for Commercial Support and protocols for content validation and conflict of resolution all guard against the potential for bias, commercial or otherwise. If freedom from commercial bias is the ultimate

intent of all 4 of these propositions, then I contend that you have achieved your goal through the implementation of these recent policy changes and that no further regulation is necessary.	
The proposal to eliminate commercial support of CME activities is completely ludicrous. It is inconsistent with the goals of the updated criteria and jeopardizes physicians ability to do the following: •\tparticipate in a CME activity that requires one to apply skills learned to integrate new techniques (using diagnostic or surgical devices) into clinical practice •\tProvides potential harm to the public as a result of limiting physician participation in activities that bridge a professional practice gap between education and technology. If there is substantial evidence documenting widespread abuse of commercial support guidelines, a new paradigm may be necessary, but the one proposed is unfair and clearly suggests the future elimination of select organizations (Medical education companies and/or for-profit organizations) from being eligible to become or continue to be an accredited provider. It would appear the most prudent and logical approach is to evaluate those organizations that are in clear non-compliance with commercial support guidelines; provide an opportunity to correct the problem within a realistic time-frame, and make a decision whether to retain or revoke their accreditation status. If there is significant paranoia about the competence of first time applicants, perhaps the new applicant could be required to attend an ACCME workshop and successfully pass a test to demonstrate full understanding of the accreditation criteria before being eligible to submit their accreditation application for review. The new proposed paradigm is unfair by making the four requirements all-inclusive by using the verbiage “and”. It also clearly excludes medical education and/or for profit organizations, potentially involving restraint of trade. Any new paradigm should be developed to require providers to meet one of several categories of applicants. It should not exclude any organization that has proven their ability to comply with the ACCME Essential Areas and their Elements. As an accredited provider since 1996, we have consistently proven a for-profit organization is fully capable of providing CME activities that include commercial support (mostly in-kind) that effectively addresses improvements in physician competence, performance, and/or patient outcomes including accreditation status with commendation. The new paradigm suggests CME activities should only be made available by professional societies, governmental agencies, or medical colleges (excluding medical education companies). Again, many medical education companies are designed to fully comply with all ACCME Essential areas including commercial support guidelines. Many have greater flexibility to meet their CME mission as compared to other organizations due to less bureaucracy. All of the proposals made for comment appear to be extreme “knee-jerk” reactions to the Macy Foundation report. Once again, categorizing all CME providers into a “pharma” group and assuming widespread abuse of commercial support is narrow minded. It will only serve to impede providers ability to offer CME activities consistent with the updated criteria. More importantly, it limits physician access and choice to attend CME activities that fill their specific professional practice gap resulting with the potential to negatively impact patient outcomes and/or patient safety. In my opinion, the ACCME has not fully thought through this proposed requirement, its impact on the physicians you serve or the medical public. Rather, it is an extreme reaction to quickly avoid further confrontation with those involved with the Macy Foundation who clearly do not have a clue about what goes on in the real world.	**Accredited CME provider**
The provision of certain devices and teaching aids by manufacturers, at no charge, to CME providers for hands-on workshops and skills training represents an ethical and economically responsible means of delivering high-quality medical education. Outcomes achieved with a certain product may differ between individuals, practices, departments and hospitals. This may relate to skills, patient mix or environmental factors and may be beyond the control of the operator. Direct experience may safely inform a decision whether or not to acquire new products. The opportunity to evaluate products before commiting a hospital's precious resources to their purchase represents sensible stewardship of scarce resources, facilitates direct and experiential training and serves patients' interests.	**Commercial Supporter**

The quaility of CME available to physicians like myself, is great! Commercial support can be vital to the planning and disemination of information and content of these various programs, whether in person or on the internet or in written form. This allows for multiple viewpoints from which physicians can determine the correct plan of treatment of a patient, or the future direction medical concerns and planned development of solutions is taking. To eliminate all commercial funding and input would be to strip medicine of one of its present day pillars. [redacted]	**Other**
The [redacted] as started as healthcare professionals started to realize that [redacted] ought to be the standard of care, and that blood transfusion should be viewed as the alternative. [redacted] is dedicated to improving patient outcomes through optimal blood management; which includes the appropriate provision and use of blood, its components and derivatives, and strategies to reduce or avoid the need for a blood transfusion. [redacted] is recognized as the key educational resource for [redacted] in the United States. [redacted] is grounded in scientific validation, evidence-based practices, and focused on promoting the patients' best interest through effective and optimal blood management. We promote education and training to achieve change through a multidisciplinary approach to [redacted] and utilization. This is done by creating a source of knowledge for all types of [redacted]t strategies. Our goal is to work toward incorporating blood management modalities into clinical practice, and in helping the public and medical communities to embrace the benefits of simple, safe and effective blood management practices. As there are currently no existing guidelines for [redacted], [redacted]M has expertise to develop evidence-based guidelines, creating a platform for the conception of standards or best practices in blood management. While we are not an accredited provider, we do provide accredited CME at our annual and regional educational meetings as a joint sponsor. We use CME as a tool to disseminate the knowledge of this new field to clinical practitioners. We hope that you will give our response equal weight and consideration as to those entities who are accredited. Scenario #1: Status Quo [redacted] strongly recommends that the ACCME continue allowing the use of commercial support of CME as an acceptable funding mechanism. It seems logical and prudent to allow the newly developed ACCME compliance and improvement processes to have sufficient opportunity to demonstrate its effectiveness. The partnership between all relevant stakeholders in the CME enterprise are all banning together to strengthen their policies and procedures to create even more transparency and systems to deal with inappropriateness. We would ask that we be given due time to govern and monitor ourselves. We are educated and trained to study, diagnose, treat and prescribe using evidence and ethics. We can and do use these same principles to guide us in developing and presenting CME activities even when funded by commercial support. Scenario #2: Complete Elimination of all Industry Support Commercial support is critical to ongoing medical education efforts. Unrestricted educational grants are critical to professional societies, most of which are not-for-profit organizations with a large number of academicians. These organizations would not be able to provide a comprehensive CME program without grant support from commercial sources. [redacted] acknowledges that abuses have occurred in some CME programs, especially when medical communication companies have controlled the content, but believes firmly that the vast majority of CME programs, including those co-sponsored by professional organizations, have presented fair, accurate information. As a subspecialty organization that is multidisciplinary, it is critical that cross-professional training and education continue to be provided. We are always seeking additional funding sources to support our ongoing activities, including the personal investment from our members and educational attendees, government agencies, and the private sector. In general, [redacted] believes that the entire medical profession should not be penalized for the actions of few. Scenario #3 New Paradigm: In response to Condition number one, we would ask that the ACCME consider that bias can exist whenever there is an opinion on an issue and that no entity is exempt from bias because no entity is independent of funding, lobbying funds can weigh heavily in the decisions of government agencies. Even NIH funding can have bias. [redacted] respectfully submits that as a subspecialty organization it is uniquely positioned to address the educational needs and objectives of its learners and to identify the specific needs in the field of [redacted] working in concert with all stakeholders from academic, industry and regulatory settings, across disciplines. In response to Condition number two and three, [redacted] is committed to providing high quality educational interventions to facilitate educational exchange among learners who come from various professional practice settings. As there are no approved [redacted] standards or best practices, the opportunity to corroborate professional practice gaps or educational curriculum by another bona fide performance measure or organization would be difficult if not impossible to meet. This is one of the educational objectives for [redacted]. We are currently working with The Joint Commission to develop [redacted] and our Education Committee is working toward the development of [redacted] Standards. Once developed we hope to be able to educate healthcare professionals and change the standard of practice in regard to transfusions to improve patient outcomes. In response to Condition number four, [redacted] agrees that CME should always be verified as free of commercial bias, as stated, because it is in the best interest of the learners and the patient (public).	**Non-Accredited CME provider**

The [redacted] welcomes the opportunity to respond to the ACCME's proposal to eliminate commercial support for CME activities. [redacted] is comprised of over 6,000 surgeons and allied health professionals and is the primary surgical society in North America for minimally invasive and gastrointestinal surgery. As an organization dedicated to providing our members and surgeons throughout the world with high quality educational programs, we would like to express our strong and vigorous opposition to the ACCME proposal under consideration. [redacted] has delivered high quality, unbiased education to our growing membership for over 20 years. The Society has consistently followed the ACCME Essentials and Standards and received full accreditation four times. Our annual meeting attendance continues to grow, the scope of our educational outreach continues to expand, and the impact on our profession is increasingly seen at the national and international level. [redacted] applauds the ACCME for attempting to address concerns about bias and undue influence in CME activities and, as an organization, we fully support the ACCME's position that accredited providers should not receive any communication or direction in any form from commercial interests regarding topics or contact for CME activities; we also support the ACCME in the removal of accreditation from entities who violate these policies. The new Standards for Commercial Support, enhanced by the policy recently enacted by the ACCME Board of Directors, has led [redacted] to institute one of the most comprehensive set of policies of any surgical organization to ensure that our CME programs remain unbiased and free of any influence by commercial interests. While we understand that those who seek to completely ban commercial support of CME events have good intentions, we believe this approach is misguided and does not fully take into account the diverse educational needs and demands of surgical organizations like our own. Specifically, we would like to express the following concerns about the proposal under consideration: 1. A ban on commercial support would be a serious threat to the high quality CME programs that have been a hallmark of our organization. Without such support, it is unlikely that we would be able to train and educate as many medical professionals as we do today. Our registration fees would increase significantly, making our annual meeting unaffordable to many surgeons as well as international delegates, several hundred of whom regularly attend our annual meeting. In addition, we would be less able to produce enduring materials and other innovative surgical educational tools that reach many surgeons beyond our annual meeting events. The ACCME has suggested as a possible alternative an undefined "mechanism" to distribute commercial support from industry derived pool funds but it is highly unlikely that such a pool would fund surgical societies like our own at a level that would sustain our current level of educational programs. 2. Without commercial support (both financial and in-kind) our Society would be unable to sponsor and hold hands-on laboratory courses taught by world-renown faculty, which have provided invaluable learning opportunities for surgeons. Without such in-kind support, who would provide the high quality imaging systems, endoscopes and other specialty surgical devices that allow surgeons to develop and refine their surgical skills and learn new techniques under the guidance of [redacted] leaders in the field? 3. Most troubling to members of our society is the "new paradigm" suggested by the ACCME that the direction for our CME activities be determined or verified by other "bona fide" organizations. Who are such bona fide entities and who would they represent? The [redacted] and other alternate organizations including US government agencies have not been well represented by surgeons and the unique surgical education and training needs have not always been given due consideration by such groups. Furthermore, the absence of representation by surgeons with experience in gastrointestinal and endoscopic surgery will not, in our opinion, be as likely to result in comparable cutting edge, innovative and effective educational programs as those put forth by [redacted]. Finally, practice gaps as defined by bona fide performance measures with current levels of quality data remain relatively crude measures of surgical outcomes and performance. It is highly unlikely that such measures as they currently exist are valid for the diversity and rapidly evolving educational needs of surgical organizations like ours that are on the leading edge of surgical practice and innovation. As the ACCME states in the response to the US Senate Special Committee on Aging, "No data demonstrating commercial content bias is found in the medical education or regulatory literature." We feel that the radical change in continuing medical education being proposed is a classic case of "throwing the baby out with the bathwater" and is totally without foundation for surgical organizations like our own. As stated in the ACCME response to the Josiah Macy, Jr. Foundation, "The United States has an excellent and admirable continuing education system." We feel that these steps proposed by the ACCME will add layers of cost, time, and bureaucracy, will delay development of educational programs for rapidly evolving techniques, and will remove the experts from the design of educational activities. [redacted] is resolute about providing the highest quality education at the lowest cost to our target audience and appropriately managed commercial support is essential to accomplishing this goal. Sincerely, [redacted]	**Accredited CME provider**
The [redacted] is a not-for-profit medical specialty society representing more than 5,600 surgeons and allied health care workers worldwide who provide heart, lung, esophageal, and other surgical procedures of the chest. Founded in [redacted], the mission of the Society is to enhance the ability of cardiothoracic surgeons to provide the highest quality patient care through education, research, and advocacy. [redacted] is providing comment to the ACCME proposal that commercial support of continuing medical education end. We strongly disagree with the contention that commercial support should be banned for certified continuing medical education. [redacted] surgery is a data driven, evidence based specialty. As such, we seek to	**Accredited CME provider**

better understand the data the leads the ACCME to make this recommendation. We are concerned that "firmly held beliefs" without empirical evidence is driving this proposal. In its 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 states, "ACCME has commissioned an independent review of the literature looking for the evidence base to support the conjecture that accredited commercially supported CME is commercially biased. Although it has been speculated that commercial support produces bias in CME programs, no published studies have examined this question. Therefore, there is no evidence to support or refute this assertion. In addition, the impact of the 2004 ACCME Standards for Commercial Support℠ on commercial bias has yet to be assessed. No studies have been reported using data derived from CME planned and presented under the supervision of the 2004 ACCME Standards for Commercial Support℠." Lacking clear evidence that a problem exists, we are concerned with the ACCME's interest in changing the status quo of commercial support. This is tantamount to developing an educational program without the use of a needs assessment. [redacted] educational activities evolve through purposeful evidence-based data and we encourage the ACCME to use similar data driven processes rather than opinions proffered in the lay and medical literature. Further, we believe that steps that ACCME has taken in the past few years, including providing the updated accreditation criteria and a clarification of the definition of "commercial support" have reinforced the importance Accredited Providers must place on ensuring that their certified educational programs are independent of commercial bias and based upon the best available evidence as recognized by the medical community. To eliminate commercial support without assessing the impact of ACCME's advances in the past few years gives short shrift to the work of ACCME and to the Accredited Providers who have worked diligently to comply with these advances. In addition to ACCME efforts, [redacted] is aware of the efforts made over the past several years by the FDA, HHS-OIG, PhRMA, and AdvaMed to clarify appropriate relationships between CME providers, their physician faculty and commercial supporters. As a result of these many initiatives, [redacted] has strengthened policies and procedures to identify and manage conflicts of interest of faculty and education activity planners in order to reduce or exclude commercial bias from certified CME. We believe it is important for the ACCME to understand that our Workforce on Clinical Education has worked diligently in the past several years to guide the Society in the direction of developing and providing continuing medical education utilizing innovative instructional methodologies. We have worked to enhance our educational activities by increasing interaction and where possible, hands-on education utilizing resource intensive medical devices and supplies required to provide safe procedural education. Without industry support, [redacted] must reconsider these dynamic components of our educational activities – pushing us backward to the didactic "talking head" CME of the past and quite possibly jeopardizing the safe adoption of innovative and life-saving medical technologies. We are confident that this is not the goal of ACCME but must reinforce that this is a likely outcome not just for [redacted] but for most organizations offering procedurally oriented continuing medical education. With the above said, we believe the CME enterprise would be well served by a robust, scientifically sound research study designed to investigate the impact, if any, that commercial support has on bias in certified CME. Further, we believe a parallel study ought to be conducted that assesses the ability of physicians to identify bias and/or industry influence in certified CME and the impact this ability has on actual patient care. We support the concept that a broader array of funding options needs to be explored to support CME. We would welcome the opportunity to work collaboratively with other Accredited Providers in exploring feasible funding resources. Finally, in its call for comments, ACCME has asked for feedback with regard to "a new paradigm" for commercial support that requires the Accredited Provider to meet four distinct criteria: 1.\tWhen 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), and 2.\tIf 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.\tWhen the CME content is from a continuing education curriculum specified by a bona fide organization, or entity, (e.g. AMA, AHRQ, ABMS, FSMB), and 4.\tWhen the CME is verified as free of commercial bias. We believe these criteria are excessive and will preclude most Accredited Providers from being eligible for commercial support. For instance, at what point would ACCME accept that "CME is verified as free of commercial bias?" Would this verification be based on proposed content to be presented or would an Accredited Provider not be able to accept commercial support until after the program had concluded and the verification of the actual content takes place? What would ACCME require as documentation that "verifies" that an activity is "free of commercial bias?" In closing, we strongly support the need to maintain independence of certified CME from commercial influence. We urge the ACCME to focus on assisting Accredited Providers with identifying ways to improve the quality of the activities currently offered to physicians and less time on reflexive responses to opinions not supported by empirical evidence. ACCME is right to be concerned with the quality of the CME offered and STS stands ready to work with the continuing medical education community to this end.	
THE STATUS MUST BE MAINTAINED: COMMERCIAL SUPPORT SHOULD REMAIN AN ACCEPTABLE FUNDING MECHANISM. THANKS	**Accredited CME provider**

The [redacted] fully respects the ACCME's consideration to the Elimination of Commercial Support of Continuing Medical Education Activities; however, this action would absolutely hinder our department's ability to provide Continuing Medical Education Programs. Majority of the funding for our programs are requested tirelessly from commercial support, which greatly suppresses program costs. Without commercial support, our department would not be able to support the costs of providing a CME activity based on our budget alone. Although CME attendees are required to pay to attend the event, we will not be able to receive attendee fees until closer to the activity. We hope you will take our concern to the elimination of Commercial support in consideration so that our CME programs can continue to operate successfully with the support of Commercial vendors. [redacted]	**Non-Accredited CME provider**
There is a significant distinction between elimination of commercial support and elimination of commercial bias. The later is what the Senate Committees on Finance and Aging are concerned about. Much attention is being paid by Sen. Grassley to incomplete disclosure from academic faculty/consultants to their respective institutions. Issues at Harvard and Minnesota recently have created an image of distrust when large sums of money are being paid to consultants for non-CME projects are suspected to influence their comments if/when they speak in a CME activity. Situations like this reflect negatively on all faculty, when in fact, most faculty are honest and allow data to drive their decisions. Is it a conflict when data, supported by a research grant from industry results in a finding that happens to benefit the study drug or device? Who is to say that the investigator who received grant support found in favor of the supporter just because a grant paid for the work. Of course it happens at times, but do we really think that all research is subject to conflict of interest even when the protocol calls for a double blind randomized trial and the results still favor the supporter's drug? Just because a CME activity is supported by a commercial interest does not mean that the content of the education is biased. The proof of bias comes from the evidence presented and the perception of the participants who determine whether the speaker presents the data in a fair balanced and supports conclusions with evidence. Eliminating commercial support to solve the bias problem is like amputating a leg to solve a soft tissue infection that could become life threatening. Better prevention and monitoring of activities would minimize the risk of bias as would adherence by faculty to ethics of reporting conflicts of interest and in the best interest of the learner, presenting all pros and cons of recommendations he/she might make. As a CME provider, it is our responsibility to provide the best available evidence in a fair balanced and scientifically rigorous activity. The fact is that sometimes drugs/devices are clearly superior to others. When the evidence supports that fact, the program should not be deemed bias unless evidence to the contrary was suppressed. There are others ways to monitor bias and conflict without eliminating commercial support. Holding providers accountable is one.	**Accredited CME provider**
there should be no commmercial contact.	**Other**
These comments are provided on behalf of the [redacted]). The [redacted] does not support the elimination of commercial support for continuing medical education. It does endorse the concept of a new ACCME CME funding paradigm, but believes the "conditions" as expressed in the proposed new paradigm need to be broadened. Although it is assumed that commercial support of CME leads to bias, there is little evidence found in the medical education or regulatory literature. As recently expressed by the ACCME in its June 2008 statement to the IOM, since the implementation of the 2004 Standards there has been no empiric evidence that CME providers that accept commercial support and follow the ACCME Standards are presenting commercially biased content. Until there are such data, the ACCME should continue to monitor its accredited providers, but allow them to accept commercial support and require them to be accountable for their performances. The association does strongly support: 1) the monitoring and enforcement of the ACCME 2004 Standards for Commercial Support: Standards to Ensure the Independence of Continuing Medical Education, and 2) the ACCME's new accreditation criteria which provide clear direction for planning and conducting CME activities that meet the goal of improving patient care through the presentation of clinically relevant, validated content that is independent of commercial bias. In response to the "conditions" of the proposed new paradigm: 1) Needs Assessment Data – Educational needs assessment data should be gathered from more than one source to support the need for the development of clinical content. The ACCME should not change its policy to require that such data be obtained solely from organizations that have no financial relationships with industry (e.g., government agencies). 2) Professional Practice Gap – Various sources of data, related to performance measurement, should be used in the identification of a professional practice gap. Corroboration of these data by performance measurements from the learners' own practices should be included if available, but should not be a limiting requirement. 3) CME Content – Curricula developed by the AMA, AHRQ, ABMS, and FSMB ("bona fide organizations") should be used as a component in the determination of CME content. However to accommodate education related to new clinical issues that may arise, development of content should not be limited to the curricula of these organizations. 4) CME Verified Free of Commercial Bias – ADA fully supports that all CME activities should be free of commercial bias, and that the ACCME should make verification of this the responsibility of the ACCME	**Accredited CME provider**

accredited provider. [redacted]	
These four combined conditions are too restrictive and will have significant unintended consequences for many quality small "specialty medicine" CME providers. The recommendations should not be accepted. Many areas of medicine will not have the information available from this additive series of recommendations to even "qualify" for commercial support. To suggest that CME offered from these entities is not worthy of commercial support is not rational. Any suggestion of establishing a pool from which to fund CME activities should summarily be dismissed. Such a system would be filled with so many problems that it is not worth the time to continue consideration. This mechanism would simply shift the axis of potential bias from commercial interests to another entity.	**Other**
This ACCME is a vital entitity for many, many people seeking CME hours which are relevant, affordable and current. The convenience of CME via ACCME is unmatched.	**Other**
This bites. Every other industry in the US is allowed conduct business free of the strangleholds that have been imposed on drug companies. I think they should be allowed to continue to support educational activities.	**Other**
This does not make sense. Though problems exist with the behavior of some commercial supporters and their "agents", it is not enough to ban all commercial support of CME. Commercial interests do not always run counter to the best interests of our patients. Clearly, sometimes they do but many times this is not the case. I appreciate and applaud efforts to make the process of delivering CME to become less tainted by commercial influence. However, in no way shape form or fashion can I in good conscience support a ban of all commercial support of CME. It would be a disaster.	**Accredited CME provider**
This is a classic refelx response to throwing the baby out with the bathwater the concept of reducing Pharm manipulation is a vital one However using an Evidence Based Approach to CME standards and assessment of medical information and vetting this influence can be achieved Guidlines need to be strict not elimiated without this funding source many wortwhile methods of assuring continued growth in a time of exponenetial generation of knowledge and change would be lost	**Other**
This is all symantics. Four years ago most of our income came from exhibit fees, not commercial support then we went to the on-line grant process now we will be back to the exhibit fees. If we no longer had to apply for the on-line grants it would make life a lot easier. Applying for on-line grants takes up a tremendous amount of time, sending out exhibit letters and providing exhibit space is a much easier process.	**Accredited CME provider**
This is crazy. Commercial support of CME's allow me to continue my education. We are hopefully intelligent enought to extract any commercial bias for ourselves.	**Other**
This is in response to the “Call for Comment” by ACCME proposing the elimination of commercial support for CME activities. I am a [redacted], age 77, and in active practice. Our Medical Society recently discontinued CME activities because of lack of funds. In any event, many of the sessions were not related to what I do (similar for many CME activities you have to travel to and are costly and time consuming). I rely a lot on the Internet to learn about novel therapies, disease mechanisms, etc. Many of these are excellent and have commercial support. I am well aware of the concern of “commercial bias”, but any that occurs is easy enough to spot. I believe that commercial support is essential for better learning in today's times. Minor adjustments can be made in your proposals, but I DO NOT favor the elimination of commercial support. Please don’t throw out the baby with the bath water! [redacted]	**Other**
This is in support of [redacted] and similar organisations engaged in CME programs that benefit practicing physians greatly.	**Other**
This support for ACCME is a necessary and valuable teaching tool for physicians . I feel strongly this is done without pressure from the companies to physicians to buy their products. In the days of constricition of all help to doctors this is one necessary help for us to maintain a high level of academics. Personally, I have attended numerous medical talks sponsored by pharmaceutical companies, both CME and not, and have found it extremely helpful to my practice ,treating patients, and keeping up with the latest drugs and information. I hope you will support and not make more difficult these conferences that help us to treat our patients with the latest most up to date therapies.	**Accredited CME provider**

This would be a grievous mistake. The gradual erosion of commercial support over the years has impaired Continuing Medical Education already. The ability of commercial support to make CME accessible and convenient far outweighs any perceived manipulation of the medical profession. Physicians in the private sector, who make up the vasy majority of doctors, need every possible opportunity to gain CME for their own improvement, not just to satisfy licensure requirements. Comercially supported CME makes this all possible. Absolutely no change should be made to current guidelines.	Other
TO THE ACCME: Dear Sirs; For over fifty years, I have, and will continue to attend CME courses where the topics are pertinent to my specialty, or general medical interests. As the cost of presenting a first rate CME course can be prohibitive without "pharma" support,the support is needed to provide appropriate CME courses. The courses i Attend, although supported by "pharma" are carefully constructed so the contents avoid any direct marketing and are not mainly a presention of the sponsors product(s). It may surprise you that there are other physicians, other than myself, who can attend a scientific presentation without feeling obligated to prescribe any medication that is not appropriate for our patients. Please carefully consider any drastic and perhaps inzppropriate restriction of commercial support of post-graduate CME. Transparent supervision by appropriate agents should be in use to assure that the contents of the material is apprpriate with no undeclared conflict of interest among the presenters. Respectfully, [redacted]	Other
To the Docket Regarding ACCME Rules for Funding Professional CE August 25, 2008 I would like to voice my support for a CE process that continues to allow funding by commercial sources but places the delivery and content responsibilities for such programs within the direct control of accredited health professional schools and colleges and recognized health profession organizations. It is essential that costs for continuing education for all health care professionals be underwritten. Given economic realities for individual professionals as well as the institutions that they work and practice in loss of the ability for underwriting would severely compromise the ability for professionals to obtain necessary ongoing education and training, particularly in-person education. Lack access to such programming would adversely impact the ability to provide appropriate levels of care and thus serve the public interests poorly. Over the past few decades several approaches have been tried to maintain an important firewall between funders and content providers. Some have worked most of the time and some have not worked at all. It is my belief that content and management of professional education is the primary responsibility of health profession educators in accredited schools and colleges of these professions and of licensed professionals of recognized professional associations. Placing autonomous responsibility for the overall direction of continuing education under the immediate control of professional schools and colleges and recognized health professional associations is the most pragmatic approach to resolving the dilemmas faced in CE funding and delivery. I trust that ACCME, and related professional bodies that certify contusing professional education, take a reasoned and pragmatic approach to serving the needs of the public and the professions. This can best be done by: a)\tcontinue to allow appropriate and reasonable funding of continuing education by commercial sponsors; b)\treaffirming existing guidelines for funding by commercial sponsors that are already in place; c)\tplacing the sole responsibility for structuring, directing, managing and assessing professional continuing education with accredited health professional schools and colleges and recognized professional associations; d)\tproviding realistic and reviewable guidelines for process and accountability of academic and association based providers to use in their responsibilities. Sincerely [redacted]	Other
To whom it may concern, I understand proposals have been made which consider eliminating commercial support of continuing medical education activities.The consequences of altering the manner in which CME activities are presently funded would have a profound effect on learners like myself. Limiting providers' ability to develop effective CME activities will mean that fewer options for learning will be available. Further, the major portion of available education would be only of a promotional nature from the pharmaceutical and device companies. Lastly, the decision could also limit the availability of activities to address the requirements of Maintenance of Certification and Maintenance of Licensure. Currently, my employer allows an educational allowance of only $300 per year which would not come close to the cost of covering the 15 CEU I need annually to maintain my AADE license. In the end, however, I believe this decision will have an even more profound impact on patient health outcomes. With limited CME activities to choose from, learners like myself will be hard-pressed to understand evidence-based treatment options in disease states where cutting-edge interventions involve off-label usages, or the science behind novel therapies that may soon fit into our treatment armamentarium. In short, the decision to eliminate commercial support could have a great impact both on the quality and quantity of CME available to practicing healthcare professionals, and also on patients. The same can be said for the new paradigm scenarios under which commercial support would be allowed to continue. While I recognize that the current system can be improved through minor adjustments, I encourage the ACCME to maintain the status quo, with commercial support of CME remaining an acceptable funding mechanism. Yours truly, [redacted]	Other

To Whom it May Concern, If physicians, surgeons and dentists would band together with their voice -this would not be an issue. The reality is each speciality is having a continuing increase in overhead and a decrease in their own salaries to support their communities. CME that is sponsored by educational grants has strict guidelines to present non-bias presentations....it allows the healthcare professional to use their best judgement. Since the inception of the pharmaceutical industry no longer marketing with tickets....golf, and spa days unlike the oil and gas industry.....healthcare professionals use their "time away from families and their office" for continuing education....this helps the healthcare professional recieve their "required" CME or CE and in addition save a few 100 dollars. If we are too abandon live CME then we healthcare professionals should have alternatives to the continuing socialism that "society's" such as the ACCME deem necessary to the best and brightest to change careers as so many have done so already..... The next study should be "how many healthcare professionals have alternative professions" --most of us have turned to commericial, residential real estate so that we have the privlege to practice "old fashioned relationship building healthcare"...without the concerns of not only who is going to change the rules again but how many years will it effect the current healthcare system of our community.....We choose our community, our family of patients over any beauracracy and we hope other healthcare professionals will to!	**Other**
To whom it may concern, I've recently learned that the Accreditation Council for Continuing Medical Education (ACCME) is considering changing the "ground rules" regarding the funding of Continuing Medical Education (CME) programs. This strikes me as odd given the great success we've had in getting CME to practitioners, and ultimately to the benefit of their patients. There are a large number of clinicians who prefer to get their CME through venues which are commercially supported. I firmly believe that there are adequate safeguard built into the production of these programs so that they are fair and balanced and not commercially biased, regardless of the sponsoring organization. To deprive learners of a significant source of high quality CME would be a disservice to them, and could, quite possibly, be detrimental to the health of their patients. Thank you for your consideration. If you have any questions regarding my stance on these issue, please feel free to contact me. [redacted]	**Other**
To Whom it may concern: I believe that "all Continuing Medical Education activities" are the most important part of my proffessional life. I am attending this meetings for several years,and thre are just excellent media for delivering medical education. I didn't find ,negative aspect in these conferences, with commercial support. Also ,I believe that the ACCME, will re-consider this proposal, for the positive results in medical educatio and patient care. Sincerely, [redacted]	**Other**
To Whom it May Concern: I strongly applaud the concept that commercial support for continuing medical education activities be eliminated. To quote Marcia Angell, MD in her book The Truth About the Drug Companies: How They Deceive Us and What to Do About It: "We need to end the fiction that big pharma provides medical education. Drug companies are in business to sell drugs. Period. They are exactly the wrong people to evaluate the products they sell...drug companies pour money into medical schools and teaching hospitals, support most continuing medical education, and...subsidize profressional meetings.....There is no question that it influences educational content. The result is that doctors not only receive biased information but learn a very drug-intensive style of medicine. Once and for all, we should clairfy a simple fact: Drug companies are not providers of education and they cannot be. No laws, regulation or guidelines should be based on the idea that they are." Please consider eliminating entirely drug company sponsorship of continuing medical education programs. Thank you, [redacted]	**Accredited CME provider**

To Whom It May Concern: We, the [redacted], strongly support the ACCME proposal that "commercial support of continuing medical education end." We believe that this proposal is the most appropriate method to provide important, objective, evidence-based education to the medical profession for three main reasons 1) Commercial support inherently provides education designed to increase the sales of their products, 2) CME does not absolutely require funding from commercial entities and 3) The quality of CME would improve without commercial support. Commercial support of CME creates inherent and irremediable conflicts of interest. The Accreditation Counsel for Continuing Medical Education (ACCME), in fact, already recognizes these conflicts of interest by prohibiting commercial interests from controlling CME activities. But by maintaining a role for commercial support, commercial interests are still able to exert influence in CME. For example, commercial interests pay physicians through speaker bureaus to present information that is naturally favorable to their products. While the speaker may claim to present objective material, a litany of research in the last decade has shown even small gifts to physicians influences their opinions of drugs and their prescribing behavior. Even if communication about topic and content are eliminated between provider and sponsor, the presence of support continues to influence CME in several ways. According to the ACCME, "through their implicit or explicit control of, or influence on, CME content that commercial interests could create commercial bias in CME (ie, favoritism) that will result in a learner's inclination towards, or actual, use of a product or service that is more than is necessary". Moreover, commercially supported CME frames disease management within paradigms that emphasize the use of products created by commercial interests. The unfortunate reality is that CME has become highly dependent upon commercial support—entities with a fundamentally conflicting purpose. CME requirements were created to ensure physician competence. However, when CME was required for physicians, commercial interests eagerly exploited funding shortages that allowed them the opportunity to intertwine themselves into the fabric of CME. Now, with roughly fifty percent of funding provided from commercial interests, the medical profession is working out how to ensure CME is providing education rather than promotion. While fifty percent of CME funding is from commercial interests, a policy that eliminates commercial support of CME would not cause physicians to stop receiving CME. State medical boards have mandated CME for licensure and thus CME would necessarily exist. Moreover, there would be still be a important role for companies that choose to participate in system designed to genuinely educate physicians about important products instead of the current biased, marketing practices. The ACCME should also develop a policy that eliminates commercial support of CME given the result of past policy regulation within the medical profession. Past experience has shown that, despite regulation designed to control the influence of commercial interests by almost every major physician organization, commercial bias still permeates medical science. Just as squeezing an inflated balloon causes another part to bulge, policies designed to maintain a role for commercial interests have inevitably led to more creative approaches to influencing physicians. For example, the shortcomings of product representatives were overcome by physician speaker's bureaus; the initial barring of commercial interests from providing CME coincided with the explosion of for-profit education companies. The impact of influencing doctors is too powerful a financial incentive to be left to solutions that create loopholes for potential commercial interests; no matter how well scripted, a complex set of compromises will not succeed. The medical profession must assume responsibility for this vital component of physician competence. Changes to CME, such as shifting the burden of continuing medical education toward physicians, moving away from expensive, lecture-dominated destination meetings toward cheaper forms of CME (mail-in, online), and decreasing the largesse at meetings would be ease the gap created by loss of commercial support. For the sake of the medical profession, commercial support must be eliminated. Sincerely, [redacted] to call upon physicians and physicians-in-training to disavow marketing gifts from pharmaceutical companies. We have been advocating for stricter regulations of pharmaceutical marketing practices since the initiation of our PharmFree campaign in 2002.	**Other**
We are a small subspecialty hospital and have depended on commercial support to sustain our CME program. Without it, we will most probably have to curtail our activity considerably, unless we can convince our Development Department to create some fundraising initiatives that support the CME program. This may be difficult when they are being asked to find grantors for bricks and mortar initiatives. Another problem for us is that doctors have become so accustomed to free or discounted CME, that they just do not want or expect to have to pay much, if anything, to get it. I do think the idea of pooled funds is a good one and seems to be the most doable from the perspective our our small program. The 4 conditions the ACCME is proposing for continuing commercial support of individual activities will just create more hoops for accredited providers to jump through. Many of us in CME were not trained as educators, so we have had to learn our jobs from the ground up and keep our fingers crossed in the hope that we could accommodate the ACCME's constantly changing demands and keep our jobs. It is getting to the point where I do think the ACCME might have to send out word to accredited providers that they must hire M.Ed.'s and Ed.D.'s to run their CME Programs from this point forward, because the field is becoming specialized to the point of potentially putting many of us out of business.	**Accredited CME provider**

We are certain that the ACCME will be receiving many comments in regard to their calls for comment, thus we will be brief here in our responses. We disagree with the elimination of commercial support of continuing medical education activities for many reasons. First, commercial support of CME has many positive benefits, as has been proven on countless occasions in outcomes studies demonstrating favorable patient outcomes as the result of commercially supported CME. Second, as the ACCME has conceded, there is no evidence to support the belief that commercial support for accredited CME produces commercial bias, per the ACCME Report "The Relationship Between Commercial Support and Bias in Continuing Medical Education Activities: A Review of the Literature." So if there is no evidence to indicate commercial bias as the result of commercial support, why eliminate the support? Third, elimination of commercial support is not the result that the Senate Finance Committee is looking for (just ask them). Their interest is in reducing commercial bias. Fourth, the effect on patient care of eliminating commercial support has not been studied, and there is no adequate replacement for commercial support of any equivalency. Fifth, the possibility of bias can come from many sources outside of commercial support (managed care, insurers, government payers, physicians that have bias toward certain products or commrcial companies regardless of commercial support, etc.). Eliminating commercial support would not eliminate these other sources of bias. With the quality of patient care hanging in the balance, we urge the ACCME not to eliminate commercial support of CME, when there is no evidence supporting such a decision and the results of such a decision are unknown and potentially harmful to patient care.	**Non-Accredited CME provider**
We are in an odd place in organized medical CME. Many splinter groups have decided that is unethical to receive CME support from PHARMAs, that individual physicians are either too obtuse or too corrupt to filter out bias. As a privite Family physician for the last 24 years, let me assure you these judgements are incorrect! With the aid of the current system requiring speakers to report ties to PHARMAs, any bias (in my experience uncommon) is easily identified. I am concerned that current unsponsored CME can cost $150-300 an hour, too expensive for PAs/NPs, or for my shrinking income. Eliminating sponsored CME will lead to fewer CME hours. Is less training really a good solution? Academic physicians, who are often crying "unethical", have CME paid for or provided by their institutions, and the time off to travel to these meeting. I suggest these physicians simple choose not to attend industry-sponsored CME; those of use in the trenches, seeing 30 patients aday do not need their value judgement. I am professionally and ethically certain that the current system, with monor adjustments, is working for the practicing physician.	**Other**
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, [redacted] 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. [redacted]’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	**Commercial Supporter**

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. [redacted] appreciates your consideration of our comments. If you have any questions, please contact me. [redacted]	
We can always try a new paradigm and see how it works. However, I believe that the second scenario is the best proposal, the complete elimination of commercial support. As long as commercial support continues to exist, it will always be under scrutiny. If it does remain in existence the monitoring would be so intense that those who utilize commercial support would not continue to do so. That has already begun, with many of the pharmaceutical companies requiring more data when physicians apply for grants. Many have chosen to no longer apply. I think that is all for the better, because physicians must then use alternative solutions which do not require grant support.	**Accredited CME provider**
We commend the ACCME for continuing to strengthen and improve continuing medical education (CME). However, we believe that the elimination of commercial support will ultimately have a negative impact on patients and the quality of their health care. We propose that the CME industry maintain the status quo with regard to commercial support while increasing the ACCME's oversight of accredited providers to monitor compliance of all Standards for Commercial Support. Violations should be met with severe penalties. By removing the estimated $1.2 billion in commercial support from the system or changing how it is awarded, the quality and quantity of CME offered to physicians will certainly decline. And, at the end of the day, it is the patients who will suffer. It would be too unwieldy and unmanageable to create a system that will replace the current one and still respond in a timely manner to the needs of physicians, especially those in remote areas. For many diseases, time is of the essence, and physicians need to quickly learn of evidence-based treatment options, including off-label use and upcoming novel therapies. For example, over 400 cancer drugs are currently in the developmental pipeline, and new indications are emerging with increasing frequency. It is likely that new diagnostics and therapeutics will continue to grow in number and complexity. Concordantly, physicians' clinical loads and administrative burdens will increase, reinforcing the need for innovative and efficient creation and delivery of CME that is readily available soon after the initial release of information. With fewer educational opportunities due to reduced funding, we see the victims being: •\tPatients who: - Will have fewer treatment options as a result of less information and education that is available to their physicians (nowhere more true than in oncology) -Ultimately bear the costs in the health care system and will see those costs increase as a result of less education about more viable treatment options •\tPhysicians, who will have fewer CME options •\tInsurance companies, who will pay for potentially suboptimal treatments because of limited or slow dissemination of new information through CME The ACCME is rightly focused on ensuring that CME is independent of commercial interests and free of commercial bias. However, physicians are intelligent consumers, and if in fact CME providers put on biased programs, physicians would stop attending them. Commercial supporters would then discontinue funding, and this alone is a strong incentive for CME providers to create balanced programs. In addition, no empirical data showing that industry funding causes a bias within certified CME activities have been presented. In fact,	**Accredited CME provider**

industry funding allows programs to include topics that are not necessarily of specific interest to industry itself, such as patient communication skills and survivorship issues. Likewise, there is no evidence that eliminating commercial support would improve the quality of CME. However, there is proof of a minimal rate of noncompliance to the Standards for Commercial Support by accredited providers. We encourage the ACCME to disclose the issues contributing to noncompliance so that it is transparent to the public and so that others can learn from them. It is also important for the ACCME to educate the public about the current mechanisms in place to prevent potential bias due to commercial support, including separation of education content planning from commercial interests, disclosure of financial relationships, and firewalls within companies. By proposing a new paradigm, the ACCME is listening to the few and not hearing the majority. It is also not allowing the Standards or the reaccreditation process to work as it should. The proposed new paradigm is of concern because it would affect the timeliness of education and further slow the dissemination of knowledge and the adoption of promising technologies and interventions, thereby negatively impacting patient care. Our specific concerns are as follows: •\tGiven the rapid pace of change in medicine, the proposal to develop and vet educational needs by governmental or other agencies would slow the identification of needs based on important new discoveries and improvements in patient care. •\tRequiring that all practice gaps be corroborated by measures set forth by national agencies or individual practices would be cost prohibitive on a national scale. Feasibility studies have been conducted to attempt to identify quality indicators and measures in cancer care. These studies have been both lengthy and costly and have resulted in very few new measures. •\tAlthough many specialty societies and boards have educational curricula that form the basis of the specialty, the process for reviewing and revising core curricula to add new information can be lengthy. Because many such organizations do not update their curricula frequently, rapidly developing technology is often not addressed, thereby leaving key gaps in recently approved or recommended diagnostic and therapeutic areas. Changing the system through either the elimination of commercial support or a new paradigm will result in a decrease in educational offerings around the country that will ultimately have a negative effect on patient care.	
We doctors need commercial support to keep learnig at a decent cost.	**Commercial Supporter**
We have several concerns about these requirements: 1. We do a needs assessment and determine gaps 2x per year. If we receive commercial support for non-CME activities (lunches, receptions, tote bags, etc) it seems like another layer of bureaucracy to have to use an outside group to determine gaps. In addition to the ACCME increase in fees, are we now going to have to add another expense by paying a government or other agency to do our needs assessments? Soon only large organizations are going to be able to afford to provide CME. 2. Who will determine what bona fide performance measurements are when some have not been clearly identified for some specialties by the National Quality Forum? Who will "judge" that the learner has a practice gap? We are in agreement with #3 & 4. If we are allowed to continue to receive commercial support for activities associated with CME events (exhibit halls, tote bags, name badges, receptions, etc) , then we are in agreement that commercial support of CME courses end. If we are required to discontinue the associated activities, our attendees could not afford the cost of the conferences at which we offer CME and we are not in support of commercial support ending.	**Accredited CME provider**
We should all definitely 'consider' this proposal, since it was indeed deliberated by CEJA and the AMA. However, a rational consideration of all the implications such a move should lead to a prompt rejection. 1. If ACCME rejects pharma funding, CME as we know it will disappear. There are no other organizations with the resources to fund such efforts. It would appear that this would be a suicidal move by the ACCME. 2. If CME disappears, or if it is dramatically shrunken in its scope, the unintended consequence will be a lack of balance to promotional 'education.' CME currently provides a very important counterbalance to the promotional (in addition to efforts by professional societies, journals, etc., of course.) Many physicians would, as a result, only 'learn' from pharma's sales force (maybe that is what pharma wants?) How can that be a good thing? 3. The way to address any problems with CME is to deal with the problems directly and skillfull. Alot has already been done over the past 3-4 years, much to the credit of ACCME and the diligence of it's many provider members. Duality disclosures, for example, are important and place the edcuational messages in the proper context. Independent CME review is another major advance in this process. Also, realize that the physician recipient of CME tends to be very insightful about what is promotional and what is evidence-based medicine. I have participated both as a teacher and learner in CME. As a teacher, I see it as my duty to provide as bias-free a presentation as possible. When I feel that my view may be biased, I say so - and let the audience decide. My professional reputation and that of my university are at stake. I have never been approached by a funder in an effort to influence my messages. In fact, very often I am completely unaware as to who is funding the program. As a learner, 80-90% of CME presentations I've attended are similarly bias-free. Certainly, some programs smack a little of commercialism - there is no perfect world. But the audience usually picks up on this quickly and, if anything, this would tend to have a negative impact on the drug products being discussed. Accordingly, my recommendation is that you quickly reject this short-sighted and politically correct proposal, and continue to advocate for bias-free CME, funded in an unrestricted fashion by whomever has the resources to do so. Basically, I think the system works - but may need to be	**Accredited CME provider**

tweaked a little. The ACCME should focus its efforts on getting rid of the few bad eggs, and helping providers evolve the most rigorous systems to ensure the proper identification, disclosure, and management of all conflicts, be they financial, professional or intellectual. Thank-you.	
We the physicians at [redacted] do value all the continuing medical education programs made availbale to us.This is vital to us who practice in the rural communities and hope that continuing support by commercial agencies be allowed to us in the future.	**Other**
What is to be the source of replacement support to provide CME education? Why not ask for industry support for your program as a unrestricted grant rather than increase fees to the providers. The end result of this process wil be fewer opportunities for CME and/or increasing amounts of tution requests both of which are not intended I hope	**Accredited CME provider**
While I recognize that the current system can be improved through minor adjustments, i encourage the ACCME to maintain the status quo, with ciommercial support of CME remaining an acceptable funding mechanism.	**Other**
While I understand the goals of the ACCME and commercial support, I feel this is cutting your nose off ... and, in fact, eliminating commercial support will do away with effective CME. Some of the best breakthroughs in science and early presentations to cause change in practice patterns are supported commercially, but clearly stated by the presenters. Yet their presentations are free of commercial bias. Example #1, The CMO of Intellicure is one of the top researchers in hyperbaric and wound care medicine. Due to her software, she is in a unique position in order to assess outcomes, interventions, and best practice models based on analysis of the databases of multiple institutions that use her software. Her lectures can change the practice of wound care and hyperbaric medicine in order to improve care given by physicians to these patients. In fact, her lectures are sought after for that very reason. By reading these steps for allowed presentations, she would not be able to lecture at any of our meetings. Her knowledge of these trends "could be viewed" as 'direct guidance on the content of the activity.' Therefore, we have no way to broadcast plainly evident ways to improve care until all of this data is cleared by government organizations, such as AMA, AHRQ, etc ... some YEARS after it could have been changed. All this in order to meet the letter of your standard, yet undermine your directly stated philosophy of "assessing gaps in physician competence, performance, and patient outcomes." In summary, this iniative steps too far in erecting a wall between commercial entities and the purpose of CME. Example #2, the SIDESTEP study for diabetic foot infection management is critical for limb salvage in patients with severe diabetic foot infections. The principal investigator happens to have support from a drug company. He would be barred from presenting at these meetings. What a travesty to the medical community and moreso, the patients with limb-threatening diabetic foot infections! Surely, someone on your committee can see the injustice that these rules, with no use of common sense and firewalls, will engender. CME will be emasculated and crippled ... When I was getting a Masters degree in Curriculum and Instruction, I was a professor at the [redacted], specifically working with the Dean of Medical Education. There were, and there still are, NO quality studies that clearly demonstrate changes in physician competence and patient outcomes to CME. In fact, the studies clearly show that physicians who desire to provide the best care to their patients get the most out of CME. The average physician attending CME is doing so for the hours required for state licensure, nothing more. Your rules and initiatives do nothing for the average physicians, and they certainly harm those who are leaders in patient care. In summary, these rules will be ineffective while ruining CME for those who are leaders in patient care.	**Other**
why does ACCME have this paternalistic impression that pjysicians who have had a minimum of 9 years of post high school education are unable to judge commercially supported CME activities on its merits? I do not adopt new practices or new therapies just because I have participated in a CME activity whether or not it was commercially or non-commercially supported. I wait until I have read subsequent published consensus recommendations and guidelines from high level professional societies. In the interim I find it stimulating to know what is being discussed or looked at as new disease concepts or therapies. As a practitioner,I am not in a position to replicate studies on my own time and funding so this is what I depend on. At the same time,I wasn't born yesterday nor am I devoid of knowledge of medical history so I know the problems that a few early adopters get into. I do not believe that my approach is a minority approach among physicians.	**Other**
Why does the ACCME want to eliminate commercial support of CME activities? Do they believe doctors are so weak mentally that they can not evaluate any commercialism that is expressed? I think those companies that present CME programs empower us to think and access our knowledge. Keep our free CME programs alive.	**Other**

Why would we want to eliminate commercial support. If you think as a physician I am going to make bad decisions for my patients that would now be in their best interest because some commercial company helped fund a study or research...you greatly underestimate me and my colleagues. Enough damage has been done by jumping on this ridiculous band wagon. Let commercial funding continue, encourage pharmaceutical companies to continue research and development and learn to work together as a medical community. They are already under enough scrutiny without us making it more difficult for them to be a valuable resource. They are alread so closely governing themselves it is ridiculous. Be grateful for their support and let us as physicians do our job without micromanaging our decision making process!! [redacted]	**Other**
Will second it 100%.	**Accredited CME provider**
With many academic centers across the country minimizing and, in some institutions, eliminating interactions between the pharmaceutical industry and academia, no further support should be solicited from pharmaceutical companies to support CME activities. This would constitute, in my opinion, a "having your cake and eating it too." If academic medicine truly wants to create an arms length distance between the pharmaceutical industry and academia, then cut the ties completely and don't request funding from pharmaceutical sources.	**Commercial Supporter**
Without commercial support, the rural primary care provider would not receive the CME, CE that he/she needs to fill the practice gaps. [redacted] serves the rural healthcare provider - if Govt took over the gap analysis, these providers would fall through the cracks. They would never have their needs addressed. This would only contribute to the shortage of primary care providers in rural areas - how can that help patients? The CME events also gives them the opportunity to network with other rural primary care prividers helping them to overcome the isolation - another barrier to getting new physicians out to rural areas. We do not need more government interferance telling rural primary care providers what their practice gaps are and what the content of the activity should be. We ask every attendee is there was any commercial influence or bias and in three years, there has mot been one report to the positive. We already go to great lengths to insure balance and content validity - why put more roadblocks in our way?	**Accredited CME provider**
Without funding, there will be no way that I will be able to obtain the required [redacted] continuing education required by my State. I practice in a very rural area and it is impossible to travel to enough meetings during the year to obtain required CE. In my 20+ years of practicing as a pharmacist, I can only think of one or two programs that had an unrealistic slant towards the sponsoring pharmaceutical company. Who will provide [redacted] credit without commercial support? I feel a reasonable alternative had better be thought out before any unreasonable decisions are made. Thank You.	**Other**
Without question, continuing medical education in this country will suffer. This will mean that patients will suffer. We agree that all CME should be free of commercial bias, and that all discussions of products should be balanced between companies so that the learners will not be able to tell from the lecture and discussion what company/product might have sponsored the learning activity. But to say that all MUST be eliminated will ultimately work in the dis-interest of patients. Their providers will not be aware of the latest medications, they will not be aware of the latest drug interactions, they will not be aware of the best comparisons because the US system of educating physicians and nurses that is now in place has no mechanism to do this. I have been trying to learn how to do this myself now that the [redacted] has eliminated drug reps from the center. I have gone to the FDA website, have requested their automatic updates and problems by email but this does not inform me of the latest. I have discussed with our drug information pharmacist to alert us to these items. I also subscribe to roughly 15 journals in an effort to remain up to date. Besides that, I direct the Division, have 8 other faculty with me, have 5 fellow learners, and residents and students all around. Still being up to date with absolutely no Big Pharma influence is a problem. It is my passion that patients do not suffer as the pendulum swings from some of the abuses of the past which we all know went on. We policed the situation here even without mandates to do so. But I applaude your efforts to continue to purify the system. But let's not toss out some of the good things we now have. One of those is financial support by use of the unrestricted educational grants that allow us to have speakers, often including those who do not even discuss drugs. Finally, I believe in Free Speech, and give speeches without honorarium myself, even doing so last month. But like many others, I could not go out of town because of the time contraints without financial support to be able to do. But I resist and resent any company from telling me what to say, what to talk about, etc. I say, what is said must be evidence based, must be FDA approved, or ACIP approved and if there are differences, those differences should be pointed out. I hope this helps. Let me know if we can help here at [redacted]	**Accredited CME provider**

Yes I completely agree. Commercial support should not be involved in physician education in any way, shape or form, no free gifts, no nothing. Commercial support is still trying to give recommendations to my physicians regarding speakers and content. If an activity is planned in accordance with the new ACCME recommendations, commercial support should not be needed. We are an accredited CME provider. Your form would not let me enter the information in organization type.	**Other**
YES! The ACCME should eliminate commercial support of CME activities.	**Accredited CME provider**
Yes.	**Non-Accredited CME provider**
You recently issued a "Call for Comment" regarding the elimination of commercial support for continuing medical education (CME) activities. I have read that 3 scenarios have been proposed, continued acceptance of commercial support for CME, complete elimination of commercial support for CME, and an alternative system that requires meeting certain criteria prior to allowing commercial support of CME. First of all, I would like to say that this is a strange proposal, which I believe is seeking to fix a system that is not broken. Altering the CME paradigm would seriously affect physician access to CME programs for many, including for me. It would mean fewer options for learning, any remaining programs from pharmaceutical and device companies would be 100% promotional, and I would have fewer options of CME available that are required for maintaining my licensure. Furthermore, there is nothing wrong with pharmaceutical companies having a forum in which to present physicians with new treatment options. This is an important means for physicians to obtain information about the latest treatment strategies for diseases. Patients will be impacted by having their physicians knowledge base limited. Maybe there are certain things that need fixing, although I think that this is being totally overblown. I encourage the ACCME to permit the current rules to remain, allowing commercial support of CME.	**Other**
As an ACCME-accredited provider, [redacted] 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 ofCME 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 confmn 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	
The ACCME has proposed for discussion three (3) possible scenarios: (a) maintaining the current system of commercial support; (b) completely eliminating commercial support; and (c) a new paradigm that provides for commercial support if all of the following four (4) conditions are met: (l) educational needs are identified and verified by organizations that do not receive commercial support and are free of financial relationships with industry; (2) if the CME addresses a professional practice gap of a particular group of learners that is corroborated by bona fide performance measurements of the learners' own practice; (3) the CME content is from a continuing education curriculum specified by a bona fide organization or entity; and (4) the CME is verified as free of commercial bias. Alternatively, the preceding conditions could serve as the basis for a mechanism to distribute commercial support derived from industry-donated, pooled funds. The rationale and motivation for the published proposal on the part of the ACCME is unclear to us from the limited information made available to accredited providers through the ACCME's "Call for Comments." If the perceived concern is to foster the independence of CME content [redacted] fully supports the ACCME in initiating research that would look for evidence of bias and develop any necessary additional policies aimed at eliminating conflicts of interest that have the potential of affecting content developed by any accredited provider. We notice that the report recently commissioned by the ACCME, "The Relationship between Commercial Support and Bias in Continuing Education Activities: A Review of the Literature," failed to find evidence to support or refute the position that commercial support produces bias in CME activities. In	

addition, even as recently as July 11, 2008, when the ACCME responded to Senator Kohl's letter of June 20,2008, the ACCME admitted that it did not have any data to support or refute the prevalence or incidence of commercial bias in CME. In the absence of such evidence, we do not believe that there is any reason to consider any proposal that would eliminate or substantially modify current methods of commercial support. We believe that the measures taken by the ACCME during the previous 12 to 18 months, which were specifically intended to further assure the independence of CME content, are an appropriate means to achieve the objective of independent CME content. So, for example, under the ACCME policies recently adopted, accredited CME providers, as a requirement to accreditation, must demonstrate that structural and organizational safeguards are in place to assure independence. We believe that the compliance with current ACCME standards clearly demonstrates that an organization can produce CME content that is free from bias. We also fully support the future plans identified by the ACCME in its letter to Senator Kohl regarding developing new capabilities for maintaining a CME activity database that will provide a new source of information for ACCME's oversight process. We agree with the ACCME that requiring accredited providers to measure for commercial bias and content validity and to report their results will contribute to compliance with ACCME criteria. In that regard, [redacted] agrees with the ACCME that ACCME accreditation should only reflect what is in the best interest of the public's health. However, the elimination of a significant source of funding for CME, or the creation of unnecessary barriers to the delivery of continuing professional education, will ultimately limit the dissemination of vital information about advances in medicine that can benefit the public's health. The state of rapid change in medicine and treatment necessitates more sources of education for physicians, not less. In addition, one of the most important constituent groups in this debate, the practicing physicians themselves, also are overwhelmingly against any proposal to end commercial support of CME. This has been validated through the [redacted] poll, as well as surveys that [redacted] has conducted. In connection with the ACCME's proposal for a "new paradigm," we also strongly believe that any attempt to limit providers of CME content (or those who can approve a continuing education curriculum) to "bona fide" organizations is an artificial definition that also fails to ensure independence of CME content. There are many relationships and interests that have the potential for influencing activities and the CME content produced by those organizations, and these influences are no less if the organization is characterized as a non-profit, medical society or academic institution. Attempting to define which organizations are more likely to have conflicts of interest than others is not a meaningful exercise or a means to achieve the ACCME's objective. Developing policies that foster independent CME content, as opposed to policies that focus on potential conflicts of interest, would be a more productive means to ensure that CME content is independently developed.

Similarly, distinguishing between types of providers does not ensure compliance with guidelines that ensure CME content is independently developed. For example, the accreditation data released by the ACCME for 2006, as well as extensive data collected by third parties, overwhelmingly confirms that publishing/education companies that are accredited CME providers perform their function competently, and as well as, if not better than, other types of providers, including government agencies and non-profit organizations, including physician membership organizations, medical societies, and hospitals. The ACCME's 2006 Accreditation and Compliance Report concluded that commercial providers achieved the highest ratings for compliance, higher than any other group within the survey. In addition, it should be noted that in the same ACCME report, 84.6% of providers receiving probationary accreditation status (ie, failed to meet ACCME Standards), were non-profit physician member organizations, schools of medicine or hospital/health care delivery systems. In addition, that same report discloses that 37% of the 273 physician membership organizations and 30% of the 94 hospital/healthcare delivery systems were not in compliance with Standard 3.3A (disclosure of required information and relationships). The ACCME's own data further demonstrates that commercial providers are properly staffed, adequately funded and fully qualified to meet the needs of patient care, as well as to meet compliance functions. These data clearly demonstrate that the focus should appropriately be on policies that assure compliance. Simply stated, the evidence does not support the need for either the 2nd or 3rd alternative proposed by the ACCME for consideration. [redacted] continues to believe that the debate about independence in CME content is important, and we strongly believe that the objective of assuring unbiased CME content can be achieved in an effective manner by assuring compliance with the updated guidelines recently implemented by the ACCME. We are also supportive of proposals to augment the ACCME's resources to increase its ability to review CME providers' compliance with its guidelines.

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 decliae 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.	
To Whom It May Concern: I suggest that the ACCME maintain the status quo, with commercial support of CME remaining an acceptable funding mechanism. I feel that the current system will continue to make available to us healthcare professionals who need to have current updates in the diagnosis and treatment of problems that we often encounter in our daily practice of medicine.	Other
To whom it may concern, I am writing in response to the recently issued "Call for Comment" by the Accreditation Council for Continuing Medical Education (ACCME) proposing the elimination of commercial support for continuing medical education (CME) activities. In the document, the ACCME includes three scenarios: · the status quo with commercial support of CME an acceptable funding mechanism; · the complete elimination of commercial support; · a new paradigm that puts forth four criteria that must be met in order for commercial support to continue to be allowed. The consequences of altering the manner in which CME activities are presently funded would have a profound effect on learners like myself. Limiting providers' ability to develop effective CME activities will mean that fewer options for learning will be available. Further, the major portion of available education would be only of a promotional nature from the pharmaceutical and device companies. Lastly, the decision could also limit the availability of activities to address the requirements of Maintenance of Certification and Maintenance of Licensure. In the end, however, I believe this decision will have an even more profound impact on patient health outcomes. With limited CME activities to choose from, learners like myself will be hard-pressed to understand evidence-based treatment options in disease states where cutting-edge interventions involve off-label usages, or the science behind novel therapies that may soon fit into our treatment armamentarium. In short, the decision to eliminate commercial support could have a great impact both on the quality and quantity of CME available to practicing healthcare professionals, and also on patients. The same can be said for the new paradigm scenarios under which commercial support would be allowed to continue. While I recognize that the current system can be improved through minor adjustments, I encourage the ACCME to maintain the status quo, with commercial support of CME remaining an acceptable funding mechanism. Yours truly, [redacted]	Other
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8/21/08 To whom it may concern, I am writing in response to the recently issued "Call for Comment" by the Accreditation Council for Continuing Medical Education (ACCME) proposing the elimination of commercial support for continuing medical education (CME) activities. In the document, the ACCME includes three scenarios: •\tthe status quo with commercial support of CME an acceptable funding mechanism; •\tthe complete elimination of commercial support; •\ta new paradigm that puts forth four criteria that must be met in order for commercial support to continue to be allowed. The consequences of altering the manner in which CME activities are presently funded would have a profound effect on learners like myself. Limiting providers' ability to develop effective CME activities will mean that fewer options for learning will be available. Further, the major portion of available education would be only of a promotional nature from the pharmaceutical and device companies. Lastly, the decision could also limit the availability of activities to address the requirements of Maintenance of Certification and Maintenance of Licensure. In the end, however, I believe this decision will have an even more profound impact on patient health outcomes. With limited CME activities to choose from, learners like myself will be hard-pressed to understand evidence-based treatment options in disease states where cutting-edge interventions involve off-label usages, or the science behind novel therapies that may soon fit into our treatment armamentarium. In short, the decision to eliminate commercial support could have a great impact both on the quality and quantity of CME available to practicing healthcare professionals, and also on patients. The same can be said for the new paradigm scenarios under which commercial support would be allowed to continue. While I recognize that the current system can be improved through minor adjustments, I encourage the ACCME to maintain the status quo, with commercial support of CME remaining an acceptable funding mechanism. Yours truly, [redacted]	Other
August 19, 2008 To whom it may concern, I am writing in response to the recently issued "Call for Comment" by the Accreditation Council for Continuing Medical Education (ACCME) proposing the elimination of commercial support for continuing medical education (CME) activities. In the document, the ACCME includes three scenarios: •\tthe status quo with commercial support of CME an acceptable funding mechanism; •\tthe complete elimination of commercial support; •\ta new paradigm that puts forth four criteria that must be met in order for commercial support to continue to be allowed. The consequences of altering the manner in which CME activities are presently funded would have a profound effect on learners like myself. Limiting providers' ability to develop effective CME activities will mean that fewer options for learning will be available. Further, the major portion of available education would be only of a promotional nature from the pharmaceutical and device companies. Lastly, the decision could also limit the availability of activities to address the requirements of Maintenance of Certification and Maintenance of Licensure. In the end, however, I believe this decision will have an even more profound impact on patient health outcomes. With limited CME activities to choose from, learners like myself will be hard-pressed to understand evidence-based treatment options in disease states where cutting-edge interventions involve off-label usages, or the science behind novel therapies that may soon fit into our treatment armamentarium. In short, the decision to eliminate commercial support could have a great impact both on the quality and quantity of CME available to practicing healthcare professionals, and also on patients. The same can be said for the new paradigm scenarios under which commercial support would be allowed to continue. While I recognize that the current system can be improved through minor adjustments, I encourage the ACCME to maintain the status quo, with commercial support of CME remaining an acceptable funding mechanism. \t\t\t\t\tYours truly, [redacted]	Accredited CME provider
26 August 2008 Dear Sir/Madam I am writing in response to the recent "Call for Comment" by the Accreditation Council for Continuing Medical Education (ACCME) in which the elimination of commercial support for continuing medical education (CME) activities is proposed. The consequences of altering the manner in which CME activities are presently funded, through largely 'unrestricted' educational grants, would have a profound effect on professionals like myself who undetale continuing professional education as part of my personal development and training. Limiting CME providers' ability to develop effective CME activities will mean that fewer options for learning will be available. Furthermore, the major portion of available education would be promotional in nature. The ACCME proposal includes three scenarios: •\tThat the status quo prevails, with commercial support of CME continuing as an acceptable funding mechanism; •\tThat commercial support is eliminated; •\tThat CME is supported under a new paradigm in which four criteria must be met in order for commercial support to continue to be allowed. Ultimately, any decision not to retain the status quo is likely to impact on patient health outcomes as, with limited CME activities to choose from, healthcare professionals (like myself) who seek to maintain current awareness and recent advances in patient treatment and public health measures will be hard-pressed to be able to undertake adequate, timely and evidence-based continuing education. While I recognize that the current approach to industry support can be improved through minor adjustments, the very restrictive 'four points' paradigm proposed by ACCME would be counter-productive, and I encourage ACCME to maintain the status quo, with commercial support of CME, mainly through 'unrestricted' educational grants, remaining an acceptable and appropriate (but not sole) funding mechanism. The success of CME currently is testament to its importance in professional training and current users report little evidence of commercial bias in surveys. Yours sincerely, [redacted]	Accredited CME provider

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The same can be said for the new paradigm scenarios under which commercial support would be allowed to continue. While I recognize that the current system can be improved through minor adjustments, I encourage the ACCME to maintain the status quo, with commercial support of CME remaining an acceptable funding mechanism. My own position is that of a Senior Scientist working in the area of Diabetes and Endocrinology. I am for a better description a Doctor's Doctor. I am also outside the US, like many other Doctors and related professionals.This gives gives the existing CME provision an international dimension. I do not prescribe drugs and I am not therefore susceptible to either overt or Clandestine marketing in the Existing CME provision. However I have never seen any evidence of such marketing strategy. I greatly value what I am getting at the moment. In my long experience the quality of advice is inversely proportional to the notice that is taken of it. If it isn't broke don't fix it!!!! Yours truly, [redacted]	
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To whom It May Concern, I am writing in response to the "Call for Comment" by the ACCME proposing the elimination of commercial support for CME activities. In these busy times with limited economic resources available for CME activities, the consequences of altering the manner in which CME activities are presently funded would have a profound impact on learners like myself. I rely heavily on just the type of CME learning activities you are hoping to eliminate to provide current, easily accessable information necessary to provide excellent care to my patients. Further, it would negatively impact my ability to address the requirements of Maintenance of Certification and Maintenance of Licensure. I urge the ACCME to maintain the status quo in regard to commercial support of CME. To do otherwise would serve as a major injustice to both providors and patients.	Accredited CME provider
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To whom it may concern, I am writing in response to the recently issued "Call for Comment" by the Accreditation Council for Continuing Medical Education (ACCME) proposing the elimination of commercial support for continuing medical education (CME) activities. I feel this would be detrimental to continuing educational activities for our healthcare providers. In the document, the ACCME includes three scenarios: ·\tthe status quo with commercial support of CME an acceptable funding mechanism; ·\tthe complete elimination of commercial support; ·\ta new paradigm that puts forth four criteria that must be met in order for commercial support to continue to be allowed. The consequences of altering the manner in which CME activities are presently funded would have a profound effect on learners like myself. Limiting providers' ability to develop effective CME activities will mean that fewer options for learning will be available. Further, the major portion of available education would be only of a promotional nature from the pharmaceutical and device companies. Lastly, the decision could also limit the availability of activities to address the requirements of Maintenance of Certification and Maintenance of Licensure as well as increased knowledge base for our practitioners. In the end, however, I believe this decision will have an even more profound impact on patient health outcomes. With limited CME activities to choose from, learners like myself will be hard-pressed to understand evidence-based treatment options in disease states where cutting-edge interventions involve off-label usages, or the science behind novel therapies that may soon fit into our treatment armamentarium. In short, the decision to eliminate commercial support could have a great impact both on the quality and quantity of CME available to practicing healthcare professionals, and also on patients. The same can be said for the new paradigm scenarios under which commercial support would be allowed to continue. While I recognize that the current system can be improved through minor adjustments, I encourage the ACCME to maintain the status quo, with commercial support of CME remaining an acceptable funding mechanism. Yours truly, [redacted]	Other
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Dear Sirs; In response to the recently issued "Call for Comment" by the Accreditation Council for Continuing Medical Education (ACCME) proposing the elimination of commercial support for continuing medical education (CME) activities, I'd like to offer the following thoughts: 1. There is a disgusting case of bias demonstrated by organizations such as [redacted] in this issue, and it's being disregarded. If industry does not support CME programs, where will doctors like myself go? Ah, yes- [redacted], and other organizations offer their own CME program for which they charge money to self-perpetuate their organizations. While there may be a risk of bias in industry-sponsored CME programs, to make a decision influenced by such hypocritical organizations is naive and foolish. 2. The consequences of altering the manner in which CME activities are presently funded would have a profound effect on learners like myself. Limiting providers' ability to develop effective CME activities will mean that fewer options for learning will be available in general. 3. Industry would therefore seek to increase educational programs of only of a promotional nature, undermining not just their own credibility, but the credibility of the medical profession as a whole as physicians attend these programs instead of the far more infrequent CME events. To summarize, the decision to eliminate commercial support could have a great impact both on the quality and quantity of CME available to practicing healthcare professionals, and also on patients. The same can be said for the new paradigm scenarios under which commercial support would be allowed to continue. There will always be bias in any presentation of material. As long as there is a statement in CME programs of who is sponsoring the program and what those biases might be, CME programs sponsored by industry should continue as they are currently. I urge the ACGME to not be misled by the biases of the self-serving [redacted] and other organizations who compete for attendance at their own CME programs. Sincerely,	Other
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are better informed because of the range of CME available to them now. Cutting back on CME will lead to more poorly informed physcicians, is this the goal? In short, the decision to eliminate commercial support could have a great impact both on the quality and quantity of CME available to practicing healthcare professionals, and also on patients. The same can be said for the new paradigm scenarios under which commercial support would be allowed to continue. While I recognize that the current system can be improved through minor adjustments, I encourage the ACCME to maintain the status quo, with commercial support of CME remaining an acceptable funding mechanism. Yours truly, [redacted]	
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8/24/08 To whom it may concern at ACCME, Do you really believe that competent professionals are swayed by information provided in these CME's, without evidence base support? How stupid do you think we are? Are you saying that all the CME's you have participated in, which had funding, have lead you as individual's to provide care that is biased or incorrect vs. not completing the CME? Or did completing the CME's provide stimulus for you to ask more questions and seek more information. Please do not insult us by presuming that we cannot make up our own minds or that we cannot spot holes in the non-evidence supported material. I do agree that some published material both CME and other's have holes big enough, in the evidence, to drive an MRI through. Take for example Steve Nissan's report on Avandia, published in the NEJM. They would not include a study in the meta analysis unless a patient had died while in the study. I have yet to find one endocrinologist who supports that information. In the document, the ACCME includes three scenarios: •\tthe status quo with commercial support of CME an acceptable funding mechanism; •\tthe complete elimination of commercial support; •\ta new paradigm that puts forth four criteria that must be met in order for commercial support to continue to be allowed. I am an avid reader. Who will provide the CME's for Medscape, AMA, AACE, and ACP? The consequences of altering the manner in which CME activities are presently funded would have a profound effect on learners like myself. Limiting providers' ability to develop effective CME activities will mean that fewer options for learning will be available. Further, the major portion of available education would be only of a promotional nature from the pharmaceutical and device companies. Lastly, the decision could also limit the availability of activities to address the requirements of Maintenance of Certification and Maintenance of Licensure. In the end, however, I believe this decision will have an even more profound impact on patient health outcomes. With limited CME activities to choose from, learners like myself will be hard-pressed to understand evidence-based treatment options in disease states where cutting-edge interventions involve off-label usages, or the science behind novel therapies that may soon fit into our treatment armamentarium. In short, the decision to eliminate commercial support could have a great impact both on the quality and quantity of CME available to practicing healthcare professionals, and also on patients. The same can be said for the new paradigm scenarios under which commercial support would be allowed to continue. While I recognize that the current system can be improved through minor adjustments, I encourage the ACCME to maintain the status quo, with commercial support of CME remaining an acceptable funding mechanism. Yours truly, [redacted]	Other
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I strongly disagree with the elimination of commercial support of Continuing Medical Education Activities. Every year, hospital budgets are being slashed due to decreasing Medicare reimbursement. It is becoming increasingly more difficult to find funding for Continuing Medical Education. If the hospitals cannot afford to fund CME and ACCME eliminates commercial support of CME, where do you expect to get the funding for these programs?	Accredited CME provider
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Eliminating commercial support of CME would be devastating to solo/small practices in regards to affording quality CME. I am a solo practitioner with very limited resources and I depend on free CME on the internet, newsletters and conferences to help me keep up. I have not been able to afford the member fees for the AAFP since 2003- that would be immediate access to the monthly journals etc. I have not encountered comercial sponsored CME activities that are overly biased towards a certain product etc. I also choose very carefully which activities I participate in based on the track record of the sponsoring organization to reduce/eliminate such bias. My favorite web sites are the ones sponsored by [redacted] and [redacted]. The live CME lectures at [redacted] always disclose any speaker association with a particular company, etc. Physicians already have Medicare guidelines, formularies, etc that govern how we practice. We should be trusted to use our knowledge, experience and wisdom to discenr when a certain medication, etc is being marketed inappropriately. I provide care to the unisured at reasonalbe rates and I need samples, educational materials, coupons etc to help my patients become more healthy.	Other
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August 25, 2008 RE: Elimination of commercial support for CME The consequences of altering the manner in which CME activities are presently funded would have a profound effect on learners like myself. Limiting providers' ability to develop effective CME activities will mean that fewer options for learning will be available. Further, the major portion of available education would be only of a promotional nature from the pharmaceutical and device companies. Lastly, the decision could also limit the availability of activities to address the requirements of Maintenance of Certification and Maintenance of Licensure. While I recognize that the current system can be improved through minor adjustments, I encourage the ACCME to maintain the status quo, with commercial support of CME remaining an acceptable funding mechanism. Yours truly, [redacted]	Other
As a rural health provider who works with under insured and indigent patients I do not make a salary commensurate with other providers in this area. I depend greatly on the underwriting of medical education programs by pharma companies. Diabetes is my area of focus. I depend on the pharm companies to assist with patient education materials as well. If restrictions are placed on the ability of pharm companies to assist in providing reasonably priced continuing education programs it will place an undue burdon upon me and my abilities to continue practice. I will no longer be able to see patients gratis, thereby assuring that the people who need care the most will not recieve it; I do not believe I am alone in this position. In the name of "ethics" some of the most unethical results are to fall upon the neediest.	Other
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To Whom it May Concern; In my role as Nurse Manager and Educator for a large oncology practice, I am aware of the continuing need for nurses to remain updated on the most current therapies. One way that this is made possible is by the support of pharmaceutical companies through third party vendors for these activities. Elimination of support in this way will make it very difficult to impossible to remain updated on current and emerging therapies for many nurses. This will then impact not just the nurses but out patient and family population as well. A major source of patient and family centered education is provided by nurses who are able to speak to these populations in a language that they are able to understand and do so in a manner that enhances a give and take. This is not always possible in the patient-physician relationship where the patient/family unit may feel intimidated or afraid to ask questions because they fear appearing "stupid" or do not want to appear as questioning the physician judgement. It has been my observation that third party vendors are able to provide up to date, suitable, and appropriate education for the medical community in a fair and balanced method. In doing so, it provides a means to educate those medical professionals who will then provide an important service to the patient/family unit	Other
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education from world renowned experts. When I have been the speaker I have been given carte blanche to lecture on a topic without any interference from the sponsor. Frequently the quality of medical education events that are industry sponsored is higher than that provided by university courses. I believe that industry sponsored education gives us an additional source of quality education that complements other CME opportunities. In short, the decision to eliminate commercial support could have a great impact both on the quality and quantity of CME available to practicing healthcare professionals, and also on patients. The same can be said for the new paradigm scenarios under which commercial support would be allowed to continue. While I recognize that the current system can be improved through minor adjustments, I encourage the ACCME to maintain the status quo, with commercial support of CME remaining an acceptable funding mechanism. Yours truly, [redacted]	
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To whom it may concern, I am writing in response to the recently issued "Call for comment" by the Accreditation Council for Continuing Medical Education (ACCME) proposing the elimination of commercial support for continuing medical education (CME) activities. In the document, the ACCME includes three scenarios: ° the status quo with commercial support of CME an acceptable funding mechanism; ° the complete elimination of commercial support; ° a new paradigm that puts forth four criteria that must be met in order for commercial support to continue to be allowed. The consequences of altering the manner in which CME acivities are presently funded would have profound effect on learners like myself. Limiting providers' ability to develop effective CME activities will mean that fewer options for learning will be available. Further, the major portion of available education would be only of a promotional nature from the pharmaceutical and device companies. Lastly, the decision could also limit the availavility of activities to address the requirements of Maintenance of Certification and Maintenance of Licensure. In the end, howevwe, I believe this decision will have an even more profound impact on patient health outcomes. With limited CME activities to choose from, learners like myself will be hard-pressed to understand evidence-based treatment options in disease states where cutting-edge interventios involve off-label usages, or the science behind novel therapies that may soon fit into our treatment armamentarium. In short, the decision to eliminate commercial support could have a great impact both on the quality and quantity of CME available to practicing healthcare professionals, and also on patients. The same can be said for the new paradigm scenarios under which commercial support would be allowed to continue. While I recognize that the current system can be improved through minor adjustments, I encourage the ACCME to mantain the status quo, with commercial support of CME remaining an acceptable funding mechanism. Yours truly,	Other
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