Accreditation Council for Continuing Medical Education

Responses to Call-for-Comment

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

October 2008

ACCME

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

Limiting the Interactions between Accredited Providers and Commercial Interests over Commercial Support

For Comment

It is ACCME's position that the manner of interaction between potential commercial supporters, or their agents, and some Accredited Providers may need to be altered.

The ACCME takes the position that the following is the manner of interaction required in order for an Accredited Provider to maintain its compliance with SCS 1: Independence of the *ACCME Standards for Commercial Support*[SM],

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

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

In order to comment click here or go to https://accme.wufoo.com/forms/call-for-comment-1/.

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

RESPONSES TO ACCME Call-for-Comment

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

Response received	Organization Type
I completely agree and I appreciate the clarity of this process.	Accredited CME provider
I would like to comment on commercial support for cme events. My experience with chairing the cme committee of [redacted] for 16 years and being a member of the cme committee of [redacted] for 14 years and hosting both parmaceutically supported and non-supported faculty have led me to the following conclusions. The quality of cme programs is only dependent of the quality of the chosen faculty. Period. Good faculty with pharmaceutical connections are far better speakers, much better educators, and provide much better information for the benefit of children than "non-good" academic faculty without pharmaceutical connections. In fact, my "opinion" (since I have not kept accurate data), is that there are far more "better" educators in the pharmaceutical supported group than the non-pharmaceutical supported group. There is a potential bias from both sides. Since the ultimate goal is to provide pediatricians with the best, most recent, most accurate information available, please do not make it difficult for cme committees to invite the best educators. I would leave it up to the cme committees from each chapter to implement their own guidelines instead of applying a one guideline-fits-all situation. I do believe in full disclosure of any pharmaceutical support and use of only generic labeling (when appropriate). Sincerely, [redacted]	Accredited CME provider
I totally agree that there should be no guidance of any kind by a commercial interest forthe topics of CME events. We need total separation from any proprietary interests, nuanced or overt. Education should not be influenced by promotion. How else can the public trust the advice of doctors? The public trust is destroyed.	Accredited CME provider
I would support this stance in general, but the specifics of exactly what this means (give examples of what is ok and what is not) and how one might correct this situation, if it occurs so a program was not in breech of guidelines, I believe is necessary before implementing the standard.	Accredited CME provider
Identification by commercial supporters of therapeutic areas of interest does not pose a threat to the independence of education provided within that therapeutic area. It does greatly assist CME providers in targeting their funding efforts to organizations (commercial or non-commercial) with an interest in the therapeutic areas for which they are seeking funding. Likewise, knowledge of non-content-related internal criteria for evaluation of grant proposals would be useful in targeting funding efforts to organizations for which CME providers meet the criteria. Without knowledge of such internal criteria, organizations could waste inordinate amounts of time in seeking grants that will never be approved. With no feedback as to the reasons for denial, the system sets up an inherent inefficiency in grant-seeking that burdens both the CME provider and the funding source who spends time evaluating non-eligible grants. While restrictions in discussions with commerical supporters of actual content for CME activities is absolutely appropriate, allowing transfer of basic information regarding therapeutic areas of interest and non-content-related criteria for evaluation seems critical to efficient efforts on the part of CME providers in seeking grants and of funding sources in evaluating grants. We all want to maximize our efforts toward the ultimate goal--providing quality education that improves patient care. The more efficient we can make the administrative processes required to fund CME activities, the more effort that can be devoted to the development of quality educational initiatives.	Accredited CME provider

Taking the position that commercial support should continue, I do not understand how a provider is to apply for an educational grant when there are no generalities provided with regard to the content area. "Please send me $500,000 for the general support of my next symposium" or why should I go to all the trouble to prepare a proposal and submit it to dozens of companies when I would be looking for a needle in a haystack? The conentration of effort here should be on the content and the intended result of the content. If the end result of the activity should be the appropriate prescription of a new agent balanced with existing agents (specifically I am referring to the enormous advances made in AIDS care over the last 15 years primarily and almost solely due to the introduction of new drugs and the education of physicians who care for HIV patients). This example is one of "due" influence. On the other hand, the overuse of more costly products such as stents or bioengineered antibodies, HGH or erythropoeitin are issues for health care economists and are not always in the hands of CME practitioners. The process suggested will not only undermine the independence of CME but it will undermine its intelligence.	Accredited CME provider
You will have to be quite strict on this policy in order to work. Drug reps often have the drugs they detail on the back of their business cards. When a rep hands someone in CME a business card with the drugs they detail on the back, is that an expression of interest in a CME topic? It will be used that way.	Accredited CME provider
I have never had any pressure from the wide range of people from Commercial Support companies I have worked over an eight year period in regards to interference in the 'content of activity'.	Accredited CME provider
June 17, 2008 Murray Kopelow, MD Chief Executive Accreditation Council for Continuing Medical Education 515 N. State Street, Suite 2150 Chicago, IL 60610-4377 Dear Murray, Thank you and the ACCME for affording CME professionals the opportunity to comment on issues related to commercial support. I begin with a root cause analysis of the reasons, in my opinion, we find ourselves in the current environment. 1. The Senate Finance Committee Report iterates that CME providers who have infringed on or violated the Standards for Commercial Support, have not been sanctioned or punished immediately and severely for their actions. Such allegations have reinforced the media's suspicions and scrutiny. Examples include accredited providers involvement in HHS OIG investigations and legal actions. Does the ACCME ask an accredited provider or a provider seeking initial accreditation, whether they are currently or have been involved in an investigation or legal process regarding alleged violations of existing laws/regulations? If not, I recommend this be done proactively rather than the ACCME learning of these situations after the fact. 2. Mingling certified CME and non-certified CME has caused many, if not most, of the confusion in the media; US Congress, States Attorney's General, the Macy Report, etc., leading to inaccurate and misleading conclusions. Even [redacted]esearch paper does not separate certified and noncertified education in the research findings he cites. I suspect the reason is that there is no definitive research separating certified CME from non-certified. Without evidence-based data, conclusions are without merit and certainly should not be acted upon as factual. 3. Bias is an inherent human trait. We all have our biases as to what we believe is right and truthful unless proven otherwise. I agree fully that there is no place for commercial interest to promote entrepreneurial self-interest in certified CME. Since the HHS OIG Compliance Program Guidance was enacted, there has been a dramatic change in the conduct of commercial interest and their interactions with healthcare professionals. Over time, such interactions will continue to improve toward full compliance. Certainly the Updated Standards for Commercial Support have contributed greatly to compliance as well. Placing undue and unproven practices in place to eliminate bias will not work. Bias, with or without commercial support, is a reality in all types of education, not just medical. 4. CME providers collectively have been negligent in actively pursuing funding sources other than commercial support. Granted it is more difficult and time consuming. In my organization, we have a major goal to do so. Balancing, if not off setting commercial support as the major source of revenue, is essential to the future of CME. 5. Influential organizations (ie, AMA, AAMC, FSMB, ABMS, and national specialty societies, etc.), have not until very recently stepped up to actively take positions on the appropriateness of commercial support for CME. While the AMA's proposed position to prohibit commercial support was rejected, I think it did catalyze many organization to think seriously about commercial support and the formulate position statements. In my opinion, now is the time we need leadership to harmonize all these organizations to formulate a uniform position on commercial support. Having briefly described the root causes of our current environment, I wish to comment on the ACCME's position (current and proposed). I agree with the ACCME's current position regarding interaction with commercial interests. I recommend that the ACCME give serious consideration to the adverse outcomes of dictating that, "commercial interests must not send communications announcing or prescribing any specific content"…Other than make life more difficult for colleagues in professional education and educational grant offices, this restriction will have little or no impact. CME providers know the therapeutic areas and interests of commercial supporters. Even before the HHS OIG guidance, when there were no educational grant offices, CME providers knew what supporters were interested in funding and what type of activities. Currently most requests for proposals are mostly instructive	Accredited CME provider

and not prescriptive. Moreover, the interest in and willingness to fund CME is the decision of the supporter. Government and foundation grants establish their areas of interest and some are very prescriptive in their interests. A much better solution to this issue would be to communicate with leaders in educational grant offices to self-regulate the content of RFPs by eliminating any influence on the content of CME neither nuanced nor direct. In my opinion, the elimination of commercial support to CME will have absolutely no impact on the cost of healthcare. It will however, severely damage the medical education system in every respect. Those funds will be shifted to non-certified CME, detailing, and DTC advertising. Consequently, the cost to the consumer will not change. The accessibility of and cost to the healthcare professional will change. Paying more for their CME, they or their employer will pass their cost along to the patient. What have we gained and what have we lost? Needless to say, there will be many fewer accredited providers should this occur. As was stated many times in testimony this past weekend to the AMA Reference Committee on Constitution and Bylaws relative to the CEJA Report, the loss of funding from commercial supporters will adversely impact the accessibility, quality, and diversity of CME. To suggest that a mechanism to distribute commercial support delivered from industry-donated pooled funds is at best wishful thinking. Industry support to medical education, research and publications is not a charitable endeavor. Rather it is intended to education physicians in the safest and most effective use of medications. Requiring pooled funding is a euphemism for eliminating commercial support of medical education. It seems obvious to me that I do not see any concerted efforts to eliminate commercial funding for research, clinical trials, publications and support to the FDA. All of the endeavors share the same risks of commercial influence and bias. Why is it that CME must bear the burden, risk and dire consequences of eliminating commercial funding? In fact, the amount of commercial support to CME is dwarfed by the magnitude of support for research, clinical trials, publications and FDA support. Your consideration of my comments is appreciated. I stand ready to assist the ACCME in its efforts to advance the integrity and viability of the ACCME. All the best, [redacted]	
I fully understand and appreciate the approach being considered. I'm concerned however about an unintended consequence. I suggest that this policy will only serve to create a new group of middle companies that will facilitate CME. Thus the accredited provider will have no direct communication but that communication will still exist. At first it may seem simple to merely state that the accredited provider should have no direct or indirect communication, but there is no mechanism to monitor for indirect and in fact it would just be impossible to monitor private companies and what they do or don't do. Thus at present, the policy would not eliminate the behavior it is intended to eliminate and may actually serve to create a new artifical layer or a new business line for businesses already polluting the field.	Accredited CME provider
There probably would not be a problem within the CME offices of the accredited providers. The problem lies within many of the clinical areas that still interact with commercial support agents whether on campus or off. How can an accredited provider have control over that type of interaction? Some instates no longer allow commercial support reps on the premises, but many still do. What about the MECCS who provide funds from commercial sources and sometimes slides to presenters? I receive a litany of calls and e-mails from companies who wants to provide my institution with "ready" presentations for grand rounds, presenter and lunch provided. There seems to be a lot of influences on their part since most of these presenters have a relationship with the commercial companies funding their projects. These types of interactions need to stop.	Accredited CME provider
The intent of the requirements seems overall reasonable. My societies already adhere to such guidelines, so there would be no problem at all. I see some difficulty, however, in potentially fulfilling the verbatim of #1: "Accredited providers must not receive communications from commercial interests..." The word "must" is a harsh prohibition of passive communication, whether by phone, electronic, personal or mail means. In some cases one would have to open the communication before discovering its content, and the act of opening a "prohibited" communication would constitute receipt thereof, and a violation of Rule #1. The CME providers must not initiate the communications but they cannot bar receipt of the same. Same argument applies to #2. It is obvious what you are intending but the language explicitly would punish the innocent: the recipient, and not the transgressor, who is the sender. So, I propose altering the language to reflect reality. The reality: if one receives a prohibited communication two paths of action are reasonable and viable: 1. The information should not be allowed to influence program content. 2. The sender should be notified that such communications are prohibited and should cease.	Accredited CME provider

Having been on both sides of the fence (previously with an educational partner; now employed by a pharmaceutical company) it is important for all to understand the business needs. It order for CE grant departments to get funding from upper management they need to put together a detailed budget. How would ACCME propose those groups go about doing so without having general ideas? On the flip side it Providers were not at the very least told of the areas of therapeutic interest, they could be wasting precious time in submitting to pharmaceutical companies who may at that time have no interest in funding said area. The only place an RFP would be appropriate is for national meetings. More so that every one has an opportunity to put together a request and have it reviewed versus putting a request together for something that is already received funding.	Commercial supporter
The commercial supporter can use RFP's to address educational needs identified not being addressed by incoming grant requests. Under certain circumstances the commercial supporter can send out RFP's to address these educational gaps: •If the commercial supporter has a well defined and documented process around analyzing the educational needs by therapeutic area, including but not limited to: o Defining educational needs and translating these in educational objectives §\tSystematically identifying and collecting educational gaps §\tDefining educational needs for these gaps o By therapeutic area and or by physician type and or medium (grant round, vs teleconference, vs live, vs enduring) • And, in addition, if the commercial supporter has a system in place to match incoming grants' educational objectives with predefined educational needs • And, in addition, if the commercial supporter has a very well defined and objective process for contacting providers and distributing the RFP's, including o minimum requirements for the number of providers that need to be contacted o minimum information requirements and format of the information included o Appropriate independent review of the need, process and RFP • Then, submitting RFPs, can be conducted in a compliant manner without any undue influence from a commercial supporter, and benefit of the patient at large o Under certain, well documented and independently reviewed circumstances, applying objective guidelines, it is to the patient's benefit to have physicians educated on these identified gaps If through a rigorous needs assessment the incoming grants are not addressing educational needs, I would make the argument that the company has a responsibility of finding means to address these educational needs, as the company might have information that will benefit the treatment of patients. I have several clients (commercial supporters) who have documented a compliant and objective process, not giving preference any provider over the other. I have documented and mapped the process around sending RFPs. I would be more than happy to share the details, process maps, SOPs and tools developed by [redacted] and applied by several of our clients.	Other
Interactions between Providers and Commercial interests: In certain heavily technological subjects, ultrasound and pacemakers being prime examples, it is hard to imagine a lack of contact between the CME providers and manufacturers. Use of different names for similar prcesses (management of atrial fibrillation) and different processing algorithms (in color flow Doppler) are much, much easier to understand after discussion with manufacturers. CME sponsorship: I predict a marked reduction in CME offerings at smaller venues. What department is going to offer a course bearing the full financial risk if attendance is poor? Many of our best lecturers have come to expect remuneration that is beyond the reach of many smaller organizations. Thank you for reading my comments	Accredited CME provider
Point 1 is reasonable. We should not seek or accept communications from commercial interests, i.e. guidance on the content of activity. In regard to point 2, companies like Pfizer have their own Written Agreements which we have been obliged to sign in order to receive grants. These agreements outline Pfizer's policies with respect to CME. Would receiving and signing a Written Agreement for a grant be prohibited by the position noted in Point #2?	Accredited CME provider
The ACCME might consider limiting the amount an accredited organization may receive from any one commercial entity per year, both for a specific activity as well as for its overall program, similar to limited contributions politicians can receive. Also, there needs to be restrictions on those educational/marketing companies through which the commercial companies are channeling funds for and to CME providers. There needs to be guidelines by which they can interact with CME providers. They contact the departments within the University Hospital with an already planned and established activity without any acknowledgement of its CME office. Then they later want to know if the CME office wants to give the credits to the session that is, incidentally, already a part of an accredited regularly scheduled series.	Accredited CME provider

With the increased costs of travel, increasing office overhead expenses, and decreases in Medicare and other insurance reimbursements, any increase in costs of obtaining CME would be personally devastating to physicians. While I support the independence of content, I object to any motion or policy that would restrict the use of commercial funding of CME that is so essential to keeping CME costs reasonable to physicians.	Other
The [redacted] need to offer legitimate needs assessments and establish firewalls between commercial and educational activities at their meetings. It should be the function of a [redacted] to know what members want to learn about and this should be fully disclosed to those who are interested in offering satellite educational programs. The process of RFPs by drug companies should be eliminated as bias exist and many request these just to give to their favorite vendor or a company run by someone they used to work with... The amount spent for programs should also be audited as their are many excesses. Those reviewing grants should not have any conflicts of interest but if they do, should excuse themselves from reviewing a particular grant. MEC's should be chosen based on the quality of their work and fair pricing. We feel that it is not the role of MEC's to necessarily be accredited as that is a conflict in itself. Once we can focus on the educational gaps and needs, then a legitimate needs assessment can be presented for funding and it is fair competition. Multiple sponsorships should be the norm and not the exception. ACCME should make publicaly available those accreditors who are under disciplinary action and more adequately recognize those with exemplary status. There shoudl also be more standardization of fees. Those in attendance of programs should be alerted via AMA guidance that it is their responsibility to critique the program for balance and quality and evaluations for CME programs should also be more standardized. A centralized database for such forms would then "weed" out the overly commercial activity and distinquish the quality education from the pandering. Just a few ideas...	Non-accredited CME provider
While I understand the goals of the ACCME and commercial support, I feel this is cutting your nose off ... I am a member of the Education Committee [redacted]. We strive to meet all ACCME criteria and provide CME that is free from commercial bias. However, in order to provide quality CME ... and not by second, third, or fourth string presentations, we will use principal physicians, CMOs, etc. in companies or wound care consulting firms. Their presentations are free from commercial bias, as judged by our planning committees, the Education Committee, and by participants at the CME offerings. I'll give you an example. 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. According to your steps in SCS 1, 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.	Other
I agree with this statement and believe and practice independence in CME planning and development.	Accredited CME provider
I am in agreement with the intent of items 1 and 2. However, I find the language problematic in considering how an organization is to remain compliant with them. In particular the use of the word "receive" and "receiving" is a bit too ambiguous. If a commercial interest sends me a communication, I have "received" it regardless of whether I agree with the proposal or not. Organizations have no control over what is sent to them and, by implication, have no control over what they "receive". What they have control over is how they respond to these communications and what they include in their CME programs. I suggest that clearer language or guidelines be published that will describe how organizations can be compliant with these items. As written, it is silly to say they cannot "receive" these communications. What they cannot do is honor the requests or alter program content.	Accredited CME provider
These comments are provided on behalf of the [redacted] The [redacted] supports the ACCME's interpretation of the requirements for an Accredited Provider to maintain compliance with Standard 1: Independence. [redacted]	Accredited CME provider

Date: \tJuly 8, 2008 To: \tACCME \tMurray Kopelow, MD MS(Comm) FRCPC, Chief Executive, ACCME From: \[redacted]RE: \tResponse to ACCME's Call for Comment Dated 6/11/08 Call for Comment: ACCME will ensure current processes of attaining commercial support will not undermine the independence of continuing medical education. Regarding items one and two for comment: The [redacted] supports the restrictions on communications between accredited providers and industry. However, the Academy would like to stress the importance of communications that allow us to stay up-to-date on new and emerging trends, technology, literature, and data regarding products and services used by our member-physicians. The [redacted] expects that the ACCME will consider the issue fully and to the extent that this information is necessary to educate members and ensure patient safety, that they allow those interactions to occur.	Accredited CME provider
i agree.	---
I believe the ACCME has and is doing a great job in keeping CME "clean." I think the ACCME and the pharma companies should rely heavily on the independence and quality of accredited academic health centers. As a company who partners with leading academic health centers, we know that these academic health centers will maintain complete independence from commercial influence or bias and that our programs will be carefully reviewed to ensure they comply with ACCME and AMA guidelines for commercially suppported CME. However, if there are academic health centers or commercial CME companies that the ACCME has identified that have not played by the rules, these organizations should be posted on the ACCME web site and a letter should go to all pharma companies listing these non-compliant entitities (not unlike a neighborhood sex offender list). This will encourage the pharma companies to provide grants only to organizations (preferable only academic health centers) who have NOT violated the rules and therefore they can feel safe with funding CME programs. This whole climate of panic over industry-supported CME has to change as CME is greatly needed to improve patient care and CME cannot exist without industry funding - it's that simple. The ACCME must restore a climate of harmony between industry and accredied CME providers so that high-quality CME can continue to help America's physicians provide the best possible patient care. [redacted]	Non-accredited CME provider
I believe the ACCME has and is doing a great job in keeping CME "clean." I think the ACCME and the pharma companies should rely heavily on the independence and quality of accredited academic health centers. As a company who partners with leading academic health centers, we know that these academic health centers will maintain complete independence from commercial influence or bias and that our programs will be carefully reviewed to ensure they comply with ACCME and AMA guidelines for commercially suppported CME. However, if there are academic health centers or commercial CME companies that the ACCME has identified that have not played by the rules, these organizations should be posted on the ACCME web site and a letter should go to all pharma companies listing these non-compliant entitities (not unlike a neighborhood sex offender list). This will encourage the pharma companies to provide grants only to organizations (preferable only academic health centers) who have NOT violated the rules and therefore they can feel safe with funding CME programs. This whole climate of panic over industry-supported CME has to change as CME is greatly needed to improve patient care and CME cannot exist without industry funding - it's that simple. The ACCME must restore a climate of harmony between industry and accredied CME providers so that high-quality CME can continue to help America's physicians provide the best possible patient care. [redacted]	Non-accredited CME provider
I agree	Accredited CME provider
Commercial companies must develop priorities for using their CME support budgets. This includes the identification of therapeutic areas, scope of programs, etc. If these priorities include marketing strategies there is definitely a problem with interactions with CME providers. However, by not allowing commercial companies to reveal any information about funding priorities, a "guessing game" is created for CME providers, and very poor quality proposals are received by commercial companies. I believe that Pfizer is on the right track with this. They are transparent in publishing their priorities and types of projects they want to fund. They do not fund requests that appear to be marketing a Pfizer product and they have told me that the quality of the proposals they are receiving have greatly increased. It is probably worth conducting an evaluation study to determine whether their strategy has increased content bias or decreased the quality of CME that is associated with their funding initiatives. It seems to me that we can answer a number of questions related to ACCME's concern using an empirical method that can be held up to scrutiny and add to the evidence on this issue of commercial bias. I would actually recommend that the ACCME urge all commercial companies to be	Accredited CME provider

very transparent about their funding priorities and I would urge them to publish information about the projects that they fund. If there is any hidden marketing occurring, a "sunshine" policy would be more useful than to require all communications to go "underground."	
Question: If a pharmaceutical company has denied a request for a grant, Is it ok for a physician that would be hosting the CME event, to call the pharmaceutical rep to have them relook at the grant request?	Accredited CME provider
I think the answer is to make sure that all "commercial support" is blind. The idea of a fund into which commercial entities deposit money earmarked for education; and accredited providers can apply for through a grant process is the only way to go. It could be run a bit like public television, where people and corporations (commercial intersts) donate to the station and then film makers and producers (accredited cme providers) apply for the money for specific activities. There would be a list of "contributers" to the "Medical Education Fund" that would include all contributors. None would ever be singled out. The grant process would also need to be blind and standardized so there would be no bias - (think of orchestra auditions which are held behind a screen so the maistro can hear but not see who is auditioning.) It could be done on a state or national scale, and should be managed by both a representative from the medical world and from the pharma world to make sure there is balance. The money from commercial interests can be a great benefit to the CME world if we manage it in an intellegent, unbiases and balanced way.	Accredited CME provider
The proposed change in wording is reasonable and all providers should be able to meet the requirements. I think that in the process of trying to protect the providers and for profit companies that are primarily supported by commercial support, the ACCME is doing a disservice to those of us that have prohibited commercial supporters from influencing content and/or faculty selection, for years. I question the efficacy of the "firewalls" that companies have erected in order to maintain compliance. The ACCME is disingenious if it thinks the average person believes that separating the education component from the marketing component stops the flow of information and that there won't be any influence on activity development. Until the ACCME weeds out those providers that are in essence fully funded, by commercial supporters, the rest of us will continue to struggle to meet the never ending changes the ACCME enacts in order to mollify critiques. The interesting point is that the criticism and allegations of corruption seem to be growing louder.	Accredited CME provider
I agree wtih and support this clarification in keeping CME independent of commercial interests. The only problem that I foresee is enforcement and monitoring of this policy, similar to some of the other SCS policies. How will we know if providers are actually adhering to this policy? Providers should be proactively asked during the accreditation/reaccreditation process how they are in compliance with this, rather than it being a matter of investigating infractions only when they are brought to the ACCME's attention. I also think the ACCME should look at and make a decision regarding independent speakers' bureaus or networks that at times appear to be an agent of one or more commercial interests by making similar proclamations or announcements as is described in item 1. These are organizations that support the work of providers by located faculty and completing grant requests. Though not directly affiliated with any commercial interes, at times, these bureaus or networks send out emails or bulletins that advise providers that they are aware of or have received grants for certain topics or faculty, encouraging the providers to program along those lines. My understanding is that these independently owned and operated, for-profit speakers' networks or bureaus may profit by taking some of the commercial support funding that is used to pay honoraria. And, these same networks or bureaus charge providers and make money by completing grant requests for commercial support, either taking a portion of the grant or charging the provider who then probably turns over a portion of the grant. Thank you for this opportunity for comment.	Accredited CME provider
For those of us in the CME trenches where time is a valuable resource, knowing which topics or theraputic areas a company will support allows us to appropriately manage our resources. Our CME activities are initiated by the gaps seen in practice by our own hospital/medical school faculty and are not driven by outside funding. However, the additional funding allows us to reach a wider audience.	Accredited CME provider

1) re: "Accredited providers must not receive communications from commercial interests announcing or prescribing any specific content …" We believe that CME providers are certainly able to determine educational needs/practice gaps without the commercial supporter's Request for Proposal (RFP). We regard a commercial supporter's RFP as an administrative convenience. We expend resources in terms of staff, time, and budget in compiling needs assessment/practice gap data. Our efforts may include a scan of the literature on the topic, accessing data from resources such as the CDC, discussion with the relevant medical society's education department, clinical practice guidelines analysis, a survey of the target audience, and interviews with several faculty who keenly understand the everyday practitioner's practice environment. The RFP informs us that funding exists to support an educational initiative, thus saving us valuable internal resources expended in seeking educational grants. Recently we responded to the announcement that a commercial supporter wanted to fund a symposium at a society's annual meeting. There was no mention of the topic. Through discussion with the society's department of education, we were able to determine the topic and write a grant proposal using the aforementioned data resources, and the activity ultimately received grant funding. This is a good example of an RFP that contributes to independent education, and is merely an administrative assist to time-, budget-, and quality- conscious CME providers. The RFP allows us to spend our resources appropriately to create relevant educational activities rather than spend those same resources in merely issuing a quantity of grant requests. 2) "Receiving communications from commercial interests regarding a commercial interest's internal criteria for providing commercial support would also be considered the receipt of 'guidance, either nuanced or direct, on the content of the activity or on who should deliver that content.'" The Office of Inspector General and the Senate Finance Committee have expressed great interest over the years in how commercial interests determine educational grant awards. As a result, commercial interests have developed elaborate online grant submissions systems. These systems may include the use of templates, such as budget templates, for the correct submission of grant requests. Keep in mind that CME providers, in their efforts to reduce the perception of bias in activities, are more often approaching a number of commercial supporters for educational grants, and this involves that grant request submissions be made in a number of templates. Receiving communications from commercial interests regarding their internal criteria for providing commercial support is an administrative aid. For instance, the commercial supporter may indicate willingness to support a CME activity if the budget is reduced. This communication does not involve content of any sort, and we do not consider this guidance. Funder representatives speak at conferences, including the Alliance for CME, about the criteria for a grant request that can garner support. We do not consider this guidance, since it is general in nature and not specific to a topic. CME departments are understaffed and overworked. Ultimately, it serves all provider types in an administrative fashion for commercial supporters to publicly announce what general therapeutic areas they will support with educational grants, or to announce for which annual society meeting they are willing to support an educational activity during a meal (satellite symposium). If this information goes away, CME departments will continue to serve their learners, but under greater hardship.	Accredited CME provider
I agree with most of the recommended language. However, I think restricting CME providers from engaging in communication as simple as an indication of an are of "therapeutic area" of interest is unnecessarily restrictive.	Other
We have no problem with either of these requirements since we already follow them.	Accredited CME provider
"Receiving" this kind of communication should not ,per se, put a provider into non-compliance. If an email arrives, or a commercial interest rep announces that his company would fund some specific physicial to talk on a specific subject, and the provider accepts the offer.....that acceptance would put the provider into non-compliance. Accepting improper input from a commercial interest is the offense, not getting an email or having a rep stop you in the hall and make an inappropriate offer. In our office, inappropriate offers are logged, and our rejection (and any other actions) is documented. .....The rest of the text looks fine.	Accredited CME provider
While I think it is extremely important to separate commercial interests from CME, I am concerned that being too restrictive will result in loss of funding for many programs that do a very good job of separating interests. A "service line" approach should be acceptable, with an entity being funded for activities involving the service line, as long as the sponsor is responsible for arranging the speakers, etc.	Accredited CME provider

Since our Office of CME has never based its CME activities on any communications from or with commercial interests, I can't see where this will impact our operations at all. We develop our Agenda, objectives, and faculty and then and only then contact commercial interests about possible grant support. It is helpful to us to know the broad categories of interest for a given company so that when we are soliciting grant support we know which companies might have an interest-i.e. a company which produces baby nutrition products is hardly interested in a geriatrics conference.	Accredited CME provider
As currently stated in the ACCME position, CME providers "must not receive communications from commercial interests," as they may be construed as guiding or influencing the content or delivery of CME activities. Accredited CME providers develop CME activities independent from commercial interests, and the Standards for Commercial Support provide a basis for mutual understanding of these requirements from all those involved in the development or support of CME activities. CME providers establish protocols in accordance with the ACCME Standards for Commercial Support as to how they may interact effectively with commercial interests to ensure independence from any actual or implied influence on the content or delivery of individual CME activities. However, it may be challenging for CME providers to comply with the ACCME position, as it is currently written. CME provider staff can control the circumstances under which they may initiate communication with commercial interests about supporting a CME activity, and the organizational separation of educational departments and staff from development departments and staff, along with internal 'firewall' policies for assuring separation, is one way this may occur. Unless directed by the ACCME to notify commercial interest contacts that sending information about content or internal criteria may be construed as influencing providers' CME programs and in violation of the Standards for Commercial Support, it would be extremely difficult for CME providers to ensure full compliance with this position as written. CME providers are not able to control what information they receive from commercial interests, as this is initiated outside the scope and direction of the CME provider. On the other hand, CME providers can control what they do with any unsolicited information they receive. Therefore, it is suggested that the ACCME rewrite this position to better distinguish between communication that may be initiated either by commercial interests and/or CME providers as well as to clarify how this position may be implemented, as enforcement beyond a code of honor or attestations of compliance may be difficult to realize.	Accredited CME provider
Hello... 1) Is this really in the best interest of patients and the public? If there was a cure for cancer (or some other, less dramatic, benefit to the public) and a pharmaceutical company asked the CME community to help get the word out, the language being considered by ACCME would exclude very helpful communication from the drug company to the provider community about helping physicians learn about a new advance in medical practice. In this example, the ban on communication would HURT patients and NOT be in the pubic interest. 2) How could a CME unit of a medical school prevent a commercial interest from communicating to one of its faculty members? At the [redacted], we have over 1200 faculty members and 4000 staff members; there is no realistic way that I could police the interactions of all of these faculty and staff members. The issue that should be focused on is "passive" communication versus "active" communication by those in the position to control content. The language proposed does not address this issue. 3) The biggest issue to my organization is the opportunity cost related to writing proposals that have no chance of being funded. The lack of communication with the drug companies would lead to much wasted effort, drive up opportunity costs, and decrease the amount of edcuation being created and developed. It also would stifle creativity and partnering. The analogy at [redacted] would be for medical researchers to "guess" what the federal government was going to fund. Transparency is what we are loooking for, not a ban on communication. Further, I believe that if this language was adopted, the communication would not be stopped; rather, it would be driven underground. Thus, only a priviledged few would "know" what was going to be funded. Open RFPs help level the playing field. The proposed language will hurt CME providers who can't compete with groups who have (hidden) relationships with industry (perhaps using "middle men" disguised as business development consultants). 4) The internal criteria (used by the drug companies and told to providers) could be very general and thus not "be considered the receipt of guidance". For example, the criteria might simply be something like this: Proposals will need to include budgets, how educational formats were decided, and how educational outcomes will be measured. The proposed language related to "internal criteria" is too draconian. Some allowance for this should be allowed. Bottom line: the proposed statements are (1) not in the public's best interest, (2) will drive non-compliance processes underground, and (3) will lead to a lot of wasted effort. The proposed solution does not fit the problem!	Accredited CME provider

The proposal to limit interaction between accredited providers and commercial interests over commercial support totally contradicts the current requirement of collaboration and the ability to design CME actives that address professional practice gaps, match the learners' scope of practice, overcome barriers and improve professional practice. It appears the ACCME has taken a very narrow focus and categorized all accredited providers into one huge "Pharma" group. Many professional practice gaps involve helping the physician to integrate diagnostic technology such as ultrasound into clinical practice. In order to effectively learn how to use and accurately apply the skills, it is critical to have the specific equipment available for CME activities in order to improve physician competence and performance to integrate the skills learned into clinical practice. Ultrasound equipment is extremely expensive and new models or upgrades are made by the manufacturers on a yearly basis. This makes it cost prohibitive for providers to purchase systems for use in CME actives, thus in-kind support is imperative. It requires communication and relationship building to coordinate the appropriate equipment for use in a planned activity. Furthermore, commercial entities have a strong working relationship with their physician customers to ensure the technology developed is consistent with the physicians' current and projected clinical needs and scope of practice. This information is very valuable to an education provider to use in identifying professional practice gaps, and general needs assessment. In addition, it can help the provider to anticipate future needs for CME based on advancement in technology. Communication between an accredited provider and a commercial interest does not mean the commercial entity is involved with the planning or in any way influences the CME provider in speaker selection or program content. To disallow communication between commercial interests and CME providers negatively impacts the providers' ability to offer education that fully addresses the identified practice gaps and will allow the physician to overcome barriers to change in order to integrate new techniques into clinical practice. Although I have used diagnostic ultrasound as an example, this concept applies to many other diagnostic and/or interventional applications. To approve this proposal will impede providers' ability to offer CME activities consistent with the updated criteria and a true disservice to the physicians and patients they serve. The proposed policy change appears to be extreme. It would be more prudent to investigate those providers who have demonstrated non-compliance with the standards for commercial support or in which the ACCME has received complaints regarding compliance with the SCS.	Accredited CME provider
I agree with this statement: "CME providers can receive commercial support from industry. CME providers cannot receive guidance, either nuanced or direct, on the content of the activity or on who should deliver that content."	Accredited CME provider
We agree that it is necessary for accredited providers to maintain independence when developing accredited CME activities. We also agree that communications sent from commercial interests to accredited providers that announce preferred topics or grant approval criteria could impact the provider's decisions when developing a program and influence the content of the activity. We do, though, feel that it is helpful for providers to have some knowledge of what topics or therapeutic areas a commercial interest will consider when reviewing grant proposals. Because of the time required to develop and submit a grant request, and then wait for a response from the grantor, a substantial amount of time could pass before a provider learns that a grant request was declined and that provider may not then have time to pursue other funding alternatives. If the grant request is denied only because the activity addresses a therapeutic area that the grantor has chosen not to support, the grantor's inability to communicate this to the provider could prevent a needed educational activity from taking place. Information about therapeutic areas would not have to be sent directly to potential providers from the commercial interest, but could be made available as part of the grant submission process. At that time the provider, upon learning that the request has no chance of approval, could make the decision to find other funding sources with adequate time to identify alternatives. Posting guidance on the commercial interest's web site where grants are submitted is essential for the successful implementation of granting programs. This can and must be done in a manner to avoid undue influence and maintain the integrity of the proposed activity.	Accredited CME provider
The ACCME should ban commercial support from accredited CME. That is the only real way to ensure independence.	Accredited CME provider

In 2004 when the updated Standards for Commercial Suport were implemented, our CME Program made the decision to only provide display fees only, we setup a daily display table within each hospital of our CME Program where the Rep can pay $150.00 display fee, which goes directly into our CME fund for the privilege to stand there for two hours daily from 7:00 a.m. - 9:00 a.m. and we found it to help our CME fund to have a healthy balance which helps us to obtain our own speakers, and it helps pay our conference expenses as our CME fund is a general fund. At the time we started this process, we were not aware that this is not even identified as Commercial Support, however we still use the Standards for Commercial Support to be our guidelines with written agreements, policy and procedures to be followed and we found this to be a successful approach to help fund our CME Program, it is working well in Southern Oregon. We also allow Displays at our full-day conferences at $500.00 per table, located in the room where we keep the dietary and displays separate from our conference auditorium at all events with same policy and procedures followed. We found this to be a win-win for our CME Program. Our State Society complimented us on this unique process in our Survey.	Accredited CME provider
I agree with this statement, but subtopic #2 appears a bit confusing: 2. Receiving communications from commercial interests regarding a commercial interest's internal criteria for providing commercial support would also be considered the receipt of 'guidance, either nuanced or direct, on the content of the activity or on who should deliver that content." The words "internal criteria" could be construed to infer the specific details for submitting a grant into the on-line system of a commercial supporter, or other related communication. The guidance listed in subtopic #2 seems to indicate that there should never be any communication between the commercial supporter and the accredited provider, even on technical or procedural matters. I believe that this statement should be clarified to focus on what the spirit and intent of this guidance is, the prohibition of communication related to program content or faculty.	Accredited CME provider
I think the ACCME needs to decide what its ultimate goal is: to best educate the physician or to best educate the physician without commercial support. As an MD that has been intimately involved with CME activities on multiple levels for over 15 years, as a speaker on several pharmaceutical company panels, as a former consultant to a few pharmaceutical companies, as an MD that has done pharmaceutical research for almost 20 years, and as a full time practicing physician, I can say that at the present time the smartest people, the brightest scientists, the best speakers, and the best educators have pharmaceutical ties. This is not to say that pharmaceutical companies and all of their speakers are pure- far from it. But, do not throw out the baby with the bath water. If the goal is to prepare the physicians with the most recent, best medical knowledge, do not make it difficult for those of us involved in CME activities to do the very best in educating our fellow physicians. Full disclosure is important. Impartiality is important. Give enough leeway for the CME directors to do the rest. In addition, from a practical point of view, the pharmaceutical industries financial support of education (with no interference on education content) is needed to fund these educational activities. CME physicians as a general rule are devoted, unpaid, hard-working people. Have a little faith that we will do what is best to educate physicians. Do not over-regulate us or you will under-educate us. Thank you. [redacted] and dedicated to the very best education of pediatricians	Accredited CME provider
Response to ACCME's Call for Comment: Limiting the Interactions between Accredited Providers and Commercial Interests over Commercial Support Interpretation of guidelines and compliance requirements typically hinges on the question of intent. Guidelines are set up to promote or prevent a particular outcome that the healthcare system and society at-large deem important. In the case of ACCME's Standards for Commercial Support, the intent is to eliminate the potential for bias in the content of accredited educational activities that stems from influence by commercial interests on decisions made by the provider. The SCS appropriately limit potential vehicles of communication between providers and commercial supporters in which educational content for programs might be discussed and influenced. Of paramount concern is the need for fair-balanced, evidence-based CME that stems from gaps in physician knowledge and performance that are determined through an established process and verified by multiple sources. Given the above, it is reasonable to infer that RFPs, or "requests for proposals," from commercial interests to accredited providers can be seen as vehicles to influence or bias the provider-supporter relationship and the educational initiative. We believe that this interpretation is accurate and that eliminating the RFP process will result in more effective CME programming. Even though RFPs vary in depth and specificity, they typically include therapeutic area parameters, budget guidance, and timelines for educational delivery. It should be noted however, that compliant ACCME accredited providers, in adhering to the letter of the Standards for Commercial Support, and in the spirit of ethical educational development, will use these RFPs as a means to develop a more thorough and independent needs assessment and gap analysis, and will propose only those educational activities through a response to the RFP deemed appropriate to address the practice or performance gaps that have been independently verified. Acknowledging that the RFP process may lead to the potential for non-compliance and for the injection of bias, we concur that the parameters for any educational initiative should	Accredited CME provider

come from the needs assessment alone and determined solely by the ACCME-accredited provider. [redacted] believes that some appropriate, limited, and specific communication from commercial interests to providers is acceptable if, and only if, the ACCME strictly defines what may and may not be included in those communications and that accredited providers adhere to these definitions as they would other SCSs as a requirement of maintaining their accredited status. Keeping in mind that with ACCME accreditation, there is an inherent level of trust on the part of the ACCME and the CME industry that providers have a thorough understanding of what is, and is not, acceptable communication and will act accordingly in any response to communications from industry. This trust results from the broad, all-encompassing implementation of ACCME policies and standards, and the oversight and review of providers' activities and processes by the ACCME during the self study process.	
[redacted]: The [redacted] supports the clarification of the ACCME Standardsfor Commercial Support as in item 1 above. Background: [redacted] recognizes that a commercial interest provides commercial support for a CME activity that is often (although not always) within the scope of that commercial interest's business objectives. This is only logical. Even non-commercial interests (organizations that fall outside the definition of a commercial interest as defined by the ACCME) generally support activities that further the mission or the objectives of the supporter. For example, the prestigious [redacted] whose mission is "to enhance the quality of life of infants and young children in nutrition, care, and development" would most likely not support a CME program that addresses [redacted] in the older patient. SCS 1 rightly places the burden of documentation and truth upon the provider to ensure complete independence from commercial interest bias or control. Commercial interests in the pharmaceutical industry have recently changed their behavior to comply with regulation from the OIG, and in so doing, are avoiding communicating desired content areas for grants to be submitted for potential support. In this light, the proposed ACCME clarification would be consistent with current behaviors of commercial interests and CME providers, and of the intent of the ACCME Standards for Commercial Support. ACCME call for comment item 2: "Receiving communications from commercial interests regarding a commercial interest's internal criteria for providing commercial support would also be considered the receipt of 'guidance, either nuanced or direct, on the content of the activity or on who should deliver that content.'" [redacted] position: The [redacted] supports the clarification ofthe ACCME Standards for Commercial Support as in item 2 above. Background: The [redacted] member organizations invest significant resources, both human and capital, in addressing their missions to provide continuing professional development for their members. To address these missions demands that the organization look beyond the member's dues/CME registration fees to other sources of revenue. Corporate support is one such revenue alternative. Many, if not most, commercial interests have initiated a grant process that standardizes the application and levels the playing field for fair evaluation of requests. It appears reasonable for potential grantees to seek to understand the criteria for a grant request to comply with grant requirements. Such process communication between grantee and grantor is common practice with private philanthropies (such as the Robert Wood Johnson Foundation) and with the federal government (such as AHRQ), as well as with industry, and is considered standard operating procedure. However, it would be inappropriate for an accredited provider to request, or for a commercial interest to communicate content preferences, such as preferred topics (see ACCME 1 above), in discussions prior to submitting a grant. Again, SCS 1 rightly places the burden of documentation and truth upon the CME provider to ensure independence from commercial interest bias or control. In this light, the proposed ACCME clarification would be consistent with current behaviors of commercial interests and CME providers, and of the intent of the ACCME Standards for Commercial Support.	Other
The proposal to restrict interactions and communication with commercial interests, do little to address more fundamental issues relative to commercial support. Regardless of the funding path or mechanism, commercial support for CME undermines the integrity and professionalism of medical education. The objectives of commercial interests are inherently different from those of CME, healthcare providers, and healthcare systems. CME's continued reliance on commercial support fuels the appearance and concern, rightly or wrongly, that education is potentially biased.	Accredited CME provider
I completely agree with the position as stated.	Accredited CME provider

I am concerned that the well intentioned attempts to keep commercial interests from influencing physicians' decision making are overly broad and counter-productive. Barring the physicians who are experts and sought after by drug companies/manufacturers/developers and paid for legitimate work in development from later participation in CME activities may end up excluding the very people who are most involved and respected in their fields. Are physicians to be barred from teaching once the research and development have concluded?? If no longer on retainer is that really necessary or appropriate??? Full disclosure seems more appropriate---perhaps with barring physicians from CME on directly related content while the physician is employed by the commercial venture. The proposed wording is too vague and needs to cone down onto the specifics--and then be open to comment once again. The present proposal is clearly unrealistic and counter-productive.	Accredited CME provider
Comment on Elimination of Commercial Support It appears that this proposal although perhaps well intentioned is literally planning to "throw out the baby with the dirty bath water." Not every CME provider organization or every company or commercial interest is incapable of complying with the ACCME SCS. This proposal assumes the contrary, that any communication is bad and that everyone is beyond temptation to be self-serving. The sole purpose of our organization is to provide the highest standard of training for physicians in the area of diagnostic ultrasound. We try to do so based upon identified professional practice gaps and to provide training to enhance the physicians' scope of practice. This is in compliance with the AMA's recommendation to expand the utilization of diagnostic ultrasound to other specialty practice groups such as emergency medicine, anesthesiologists, family practice, urologists, Intensivists, internal medicine practitioners and the list goes on for pages. It is also our goal to do this in accordance with guidelines set forth from the ACCME to overcome learning barriers and ultimately to improve the physician's knowledge, competence and performance to provide safe and effective care for their patients. Elimination of any commercial support especially the "In-Kind" that gives both the provider and the learner access to the equipment to provide this training would jeopardize patient care and would make the training cost prohibitive and impractical where no actual "practice or 'hands-on' training" would be able to be included within the scope of the activity. Although our business model is based upon ultrasound training there are many other CME activities that focus on skills training for implementation of devices or surgical techniques etc which would be eliminated or compromised if this plan is approved. This would definitely create barriers to potential life saving implementation of these procedures and restrict the style of learning to just theoretical and abstract learning. No actual skills would be achieved and thus no professional practice gaps would be narrowed. Although the interest may be to ensure no bias or commercial arm twisting is being employed in providing ANY commercial support, it makes a terrible assumption that there are no ethics among either the commercial interests or the providers. It is lumping everyone into the "Pharma" model of delivering CME which is unfair and absolutely incorrect. Our organization has been involved with "In-Kind" commercial support for nearly 24 years and we have been an accredited provider since [redacted]. We could not have survived without the "In-Kind" commercial support or at least not without charging the participant learners a small fortune for their training. The cost and dynamics of maintaining "state of the art" equipment for the variety and scope of training would be impossible for any CME organization. By working with most of the manufacturers and providing a wide range and scope of equipment to use for the training we create a very user friendly and non-biased environment to acquire the skills necessary to safely implement into practice. If we had to purchase the equipment we would have to select from a single vendor which would in turn create a very biased appearance to the participants attending the program and which would also limit the access by the participants to develop the necessary skills. Instead of actually getting to practice the skills several times they would have to share access to the equipment with many other participants and only get a limited opportunity to work with the equipment. From a practical stand, point how will companies be able to evaluate the benefit of improvement of technology without interaction with luminary facilities and faculty to perform their clinical trials. How then will that information get disseminated to the medical practitioner who wishes to provide safe, effective treatment options for their patients? This technique of bringing developments to the medical market place has been working successfully in many areas for years, pharmaceutical delivery aside. Besides the ACCME and the FDA which strictly control and limit a company's influence and claims of effectiveness the manufacturers have [redacted] to help regulate their ethical business practices and relationships with each other and their customers. Many companies have purposely outsourced many of their educational activities to ensure non-biased faculty and to eliminate the appearance of any conflict of interest to be in compliance with both [redacted] and to assist their customers through effective education options. The scope of this proposal is widespread but is based upon a very limited model of delivery of CME and although that "Pharma" model has a poor track record of compliance other models have successfully integrated limited, ethical commercial support. Instead of "throwing out the baby with the bath water" perhaps a better design of measuring compliance and restricting non-compliant providers should be considered. Restricting the ability of an organization to provide the necessary skills training for physicians by eliminating any communication with a commercial interest or any "In Kind" commercial support goes directly against your own mission statement to ensure that CME activities provide improvements in competence,	Accredited CME provider

knowledge and performance to enable physicians to implement them into practice and thus provide improvements in patient outcomes. Please reconsider your position on this proposal and examine the wider context and delivery of CME outside the limited "Pharma" model that this proposal seems to be in reaction to. Otherwise, I fear you will be limiting a physician's opportunity to attend affordable effective training that meets their need for acquiring specific skills and which will ultimately be putting patient outcomes at risk.	
The ACCME Standards for Commercial Support, when adhered to by accredited providers of CME, are an effective means to mitigate the potential for bias in the content of independent medical education activities. The [redacted] believes in and supports the ACCME Standards for Commercial Support. Since the inception of the SCS in 2004 the ACCME has made significant progress at clarifying definitions and specifying expectations regarding provider compliance and practices. The result has been strict limitations on supporter/provider communications, clarification of provider responsibilities for content development and faculty relationships, clarity of policies and practices, and documentation requirements. Current practices for disclosure of potential conflicts of interest ultimately ensure transparency by informing learners appropriately at the beginning of each activity. In order to ensure the independence of accredited education the provider must be in control of all elements of planning and implementing activities including assessing learner needs; defining learning objectives and content; selection of all faculty, planners and authors; determination of educational methods and materials; evaluation and outcomes assessment. We support the ACCME Board of Directors statement that, "CME providers can receive commercial support from industry. CME providers cannot receive guidance, either nuanced or direct, on the content of the activity or on who should deliver that content." Specifically, we believe it is not appropriate for accredited providers to have communication with commercial supporters about topics, content, faculty or planners for a CME activity. Any such involvement would be reasonably construed as directing or influencing the content of an activity and therefore would be in non-compliance with the Standards for Commercial Support. However, we believe it is reasonable and important for accredited providers to receive from commercial supporter's general information about their interest in offering funding for independent medical education in therapeutic areas of interest to the commercial supporter. Further, as a practical matter, we believe it is appropriate for commercial supporters to identify the level or amount of funds available. In current practice this information is offered by some companies without any communication, direct or nuanced, about the content or faculty of an activity. Such information is appropriately communicated by a Request for Proposal or a web site. It may be accessible to a sub-set or the universe of accredited providers. Among the consequences of limiting communication between providers and commercial supporters about the availability of funding as suggested are: •\tDiscourages commercial supporters from providing funding for CME activities •\tWastes providers time and resources guessing at supporters' interests and funding levels •\tDiscourages innovation and creativity in CME by eliminating the ability of providers to develop novel instructional design and delivery approaches. In order to ensure the transparency of their review processes, and the inability to influence content and faculty selection, it is necessary for commercial supporters to define the criteria by which grant requests are evaluated so long as the criteria relate to the quality of the application and not the content or speakers. This practice is standard operating procedure for government contracts which publish the evaluation criteria in the RFP. The lack of published criteria, and obligation to provide feedback, exposes the system to greater suspicion and concern that grant requests were selected based on prior relationships or sidebar conversations about content of faculty.	Accredited CME provider
August 28, 2008 Murray Kopelow, MD, MS, FRCPC Chief Executive Officer Accreditation Council for Continuing Medical Education 515 North State Street, Suite 1801 Chicago, IL 60654 Dear Dr. Kopelow: The [redacted] appreciates the opportunity to comment on the vital issues brought forth in the "Call for Comment", any resolution of which will have a significant impact on the future of medical education and the practice of medicine in this country and abroad. The [redacted] recognizes the urgent need to examine the relationship between providers of physician education and the commercial interests/companies/entities and supports the ACCME in its efforts to ensure that such education not be unduly influenced by private interests. Call for Comment: ACCME will ensure current processes of attaining commercial support will not undermine the independence of continuing medical education: limiting the Interactions between Accredited Providers and Commercial Interests over Commercial Support…" "Accredited providers must not receive communications from commercial interests regarding a commercial interest's internal criteria for providing commercial support would also be considered the receipt of guidance……" The [redacted] understands and supports the necessity to separate industry from Continuing Medical Education and through its rigorous accreditation process, demands independence from commercial support be documented in all accredited activities. The [redacted] supports this statement and feels it offers further clarification of the ACCME Standards for Commercial Support. The pharmaceutical industry has instituted a more stringent grant application process which ensures compliance through the entire process: application to reporting. It is the CME accredited provider's responsibility to determine the need for an educational activity, outline the content, write the objectives, choose the faculty –	Accredited CME provider

all of which are based on the determined needs. This is not industry's responsibility, but through the posting of available funds, the provider can make a decision on whether [redacted] and industry have a parallel need. With separation of industry and providers, we would support the stance that industry must not influence the direction of the program, but supply providers with the knowledge of available funds for general disease states and then, based on clinical needs, the provider could determine whether to submit an application to secure funding. Call for Comment: The ACCME believes that due consideration be given to the elimination of commercial support of continuing medical education activities: The [redacted] does not support this ACCME proposal. In 2004 the ACCME released the updated Standards for Commercial Support (SCS). As an accredited provider, the [redacted] embraced this change and accepted these standards as strict guidelines to eliminate bias within CME activities. The ACCME requires that providers comply with these standards and must offer proof of adherence during the very stringent self-study reaccreditation process. Through this process the ACCME has the right to impose regulatory standards by which a provider can lose their accreditation if not in compliance. Policies are clearly stated and measures must be enacted to resolve conflicts if identified. The SCS demand that commercial interests not have any control over the content of the CME or influence in speaker or delivery of said content. Through the disclosure process learners are informed what relationships exist from any person who could possibly influence the content of an activity and result in a conflict. Also, the ACCME has required that thorough content review processes be followed to evaluate CME content for any bias which might exist. These measures truly protect the integrity of medical education. By following these regulatory measures, the [redacted] has taken the necessary steps to ensure that quality educational opportunities are presented to the learners and was recently awarded "Accreditation with Commendation" status by the ACCME at their July 2008 reaccreditation. Pharmaceutical and device companies have supported [redacted] medical education opportunities for many years which have allowed us to offer quality education to physicians and allied health professionals at a cost affordable to all. It is the responsibility of the accredited provider to ensure that all educational activities are free from commercial bias and are evidence based. The [redacted] mission is to provide quality educational opportunities which will enhance physician performance, or competence or will result in better patient outcomes as stated in our mission statement and we have proven through your stringent reaccreditation process that we have adhered to the essentials and criteria that the ACCME has established. We feel that the elimination of commercial support would have a detrimental effect on quality education for our members and, therefore, even larger professional practice gaps would exist. Also, the elimination of commercial support would have a negative impact on patient outcomes and would not promote better patient care. It is important that ACCME accredited continuing medical education providers be in control of providing the latest education on standards of care, procedures, and devices that are presented in an unbiased setting. If CME providers were no longer in control there would be free reign for pharmaceutical and device companies to convey the information in promotional settings which would definitely facilitate venues for biased education. As an accredited provider it is our job to ensure that we adhere to the policies and essentials set forth by the ACCME. It is also the provider's responsibility to ensure that we offer not only our members, but any medical professional, the opportunity to participate in quality evidence-based educational opportunities. Without this funding or in-kind support it would be next to impossible to provide the quality of education we have produced in the past which outcomes measurement has validated the fact that this education has resulted in better patient outcomes. No published study has produced statistical data that supports the premise that corporate supported CME programs produce biased activities. Several studies exist which state that most physicians do not believe that commercially supported CME is biased or creates bias in their prescribing behaviors. One point the [redacted] would also ask that you review is that some providers have yet to be reviewed under the new Standards for Commercial Support. When all accredited providers have been reviewed and if a large number of providers are found to be non-compliant, then, you could propose additional measures to prevent commercial bias. As an accredited provide who has successfully undergone your reaccreditation process and received a 6 year "Accreditation with Commendation" status, we ask that you reconsider your proposal and ensure through your accreditation process that all providers have been evaluated under the updated "Standards for Commercial Support" criteria and if shown to be negligent, disciplinary measure are instituted. Call for Comment: "ACCME proposes a new paradigm where ACCME accreditation will continue to reflect only what is in the best interests of the public. The ACCME proposes that if the following conditions were all met, then the commercial support of individual activities would be in the public interest and could continue to be allowed:" Before we comment on the specifics of the new paradigm, it is important to note several aspects of the current system. First, we strongly support the continuation of the ACCME's critical role in oversight of medical education. Second, we believe that ACCME's current system has substantial mechanisms in place to ensure that medical education is properly provided. The current guidelines of the ACCME provide clear and effective direction for avoidance of undue commercial influence in medical education. Third, the [redacted], and other accredited organizations not only enforce strict conformance to the ACCME processes, but also have their own mechanisms to further strengthen the current policies. For example, the [redacted] has a robust Content Review Committee composed of physicians who scrutinize activities for conflict of interest, and ensure its content is fair and balanced, as well as scientifically sound and relevant. But because there is disagreement about

whether the current system works, we understand the need to revisit, revise and add new provisions. 1)\t"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), and" We do not understand how the federal government or a comparable organization would be able to identify and verify the specific and intricate clinical educational needs of our physicians. It is difficult to envision both conceptually and operationally. Associations have the means to separate commercially designed needs assessment and focus their educational efforts on the needs expressed by their individual members. The federal government and/or the private sector are the likely candidates to assume responsibility for the provision of the depth, breadth and scope of medical education currently supported by joint efforts between industry and a variety of medical associations. There is no indication whatsoever that the federal government is willing or able to take ownership of the medical education agenda. Indeed, the federal government has long recognized the unique contribution to the healthcare system that is made by health professional organizations, and depends upon them heavily for the expertise represented by their members. And in instances where the government has ventured into this realm, it has been unsuccessful for a variety of reasons. The more promising candidate for entry into this market is the private sector. We believe that there are serious drawbacks to this alternative. First and foremost, it would result in the dominance of promotional education, which causes the perception of bias among course participants, and indeed, runs a much higher risk of true bias, both deliberate and unintentional through subtle or blatant means. And because there is no independent oversight body to police industry promotional education and activities, such bias would not be exposed or addressed. 2)\t"If CME addresses a professional practice gap of a particular group of learners that is corroborated by bona fide performance measurement of the learner's own practice, and …." While this is desirable, it is premature. It takes years and tremendous research resources to identify bona fide practice gaps. The NQF and other national bodies are making headway, but to assume that they have made sufficient headway in this relatively new area that would be able to guide associations' selection of relevant topics makes no sense. Of course, in those limited instances where the NQF has in fact identified such practice gaps, the [redacted] and other medical associations will gladly incorporate such priorities into its curriculum. But these known practice gaps are so few compared to the body of knowledge that must be mastered and reinforced with physician groups that it would not encompass most of what the membership needs the healthcare demands. Once again, the medical specialty society is best equipped to address the performance practice gaps that each member has clearly identified. 3)\t"When the CME content is from a continuing education curriculum specified by a bona fide organization, or entity, and."… We are in support of the third provision which recognizes the need for a bona fide entity to sponsor such education. The [redacted], who is charged with developing the educational curriculum based on practice gaps, is working closely with the [redacted], who certifies the physicians, to develop its core curriculum and tie it to MOC. The design of educational opportunities for physicians should not be removed from the specialty societies. 4)\t"When the CME is verified as free of commercial bias." We support and have always supported this provision. The ACCME enacted the Standards for Commercial Support which clearly was designed to eliminate bias from CME. Each accredited provider must show adherence to this policy and have checks and measures in place to make sure this policy is followed. We, the accredited provider, have the responsibility to ensure that our educational programs are free from bias and constructed without any commercial influence. Call for Comment: 1.\tShould those who write promotional materials be excluded from having any role in writing CME content? 2.\tShould those who teach in promotional activities be excluded from teaching in independent CME activities? The AUA does not support the two questions above. Those who write promotional materials should not be excluded from having any role in writing CME content nor should those who teach in a promotional activity be excluded from teaching in an independent CME activity. Industry seeks the most renowned physicians and researchers to construct the content of promotional activities. This is no different than an accredited provider selecting the best and most renowned physician or researcher in a specific field to deliver a lecture on a specific topic. The ACCME requires measures to eliminate bias: Content Review Committees through their very careful analysis can provide the watch guard measures necessary to eliminate bias in accredited activities. If bias or commercial influence is determined there are other measures to resolve conflict: peer review, modify the content of the lecture, include a pro/con panel to debate the issue, or provide on-site monitoring. Our learners must also be advised of any participant's disclosures prior to an activity taking place. Medical education which follows the already required essentials and standards set forth by the ACCME ensures the independence of accredited CME from promotional interests. Sincerely, [redacted]

We passed along the Call for Comment to our CME Committee and following are the responses "What I have noticed about a few, not many, CME presentations is not so much what is said, as most have some caliber of evidence to back their claims for a certain pharmaceutical agent or treatment, but more importantly what is NOT SAID. An example that was highly evident at the [redacted] this year was that the 'bent' of the industry-sponsored sympsium was to point to the efficacy of their product and not mention in equal importance the evidence for other products. As well, everyone pretty much knows that only PIs and physicians who have worked on that company's studies of the particular product are asked to give the symposia and lectures. They have a conflict of interest in that they have devoted much time in getting the pharmaceutical study at their institution- which provides the institution with an income, part of the salary of the physician and protected time for that physician. Of course, they have a conflict of interest because not only do they know that product because their reputation is improved if the product is successful, but they have spent a disproportionate amount of time with the product to the exclusion of other products. I would feel more confident in a talk that was given by a physician who did not work on the industry-sponsored studies for that product." "I feel strongly that the education of physicians should not be contaminated by industry. As a rule we do not have speakers sponsored by industry. The [redacted] is discussing this at the present ." "This is most reasonable." "the language seems consistent with the general "trend" in this area and thus I suspect it will be adopted." "ACCME makes it challenging to invite providers to meetings who have alot to offer physicians and their patients. With our foot course, I think we lost a little by NOT allowing the orthotists to speak and dsiplay their knowledge. I think disclosure should suffice for them as well as the physicians. The interpretation could easily apply to MD's or other health care personnel that want to provide education that it is promoting utilization of THEIR products i.e. services, office facilities. You get the idea." "I support reining in the power of these companies, especially sponsored lunches for the housestaffeven tho these are not CME). I often speak for the [redacted]: these CME courses pay me through [redacted] and sponsor the meal for the providers, with no promotional materials or review of the talk allowed. May I suggest that you pay attention to the PA and NP educational materials as well-- several of these mid- level providers have indicated to me that they speak frequently directly for companies because they need the extra money."	Accredited CME provider
Comment from the [redacted] on Proposed Criteria for the Commercial Support of CME Activities The conditions suggested by the ACCME for a CME activity to receive commercial support would eliminate the possibility of the [redacted] and we believe a number of narrowly defined medical specialties seeking and receiving commercial support for its CME activities. In smaller professional societies these conditions could have the chilling effect of limiting access to quality evidence based CME activities for members of the profession. For example, few local CME providers offer approved CME activities focused on the specific practice gaps and learning needs of the small group of transplant specialists in their service areas. It is not “profitable” for these organizations to do this. Yet these same professionals must accumulate CME credits for licensure, credentialing and other important purposes. Transplant specialists must turn to groups like the [redacted] to find CME activities that address their specific professional concerns in transplant patient care. This usually requires significant registration fees and travel related expenses to appropriate meetings. These costs, of course, must be passed on to the patients we care for. Commercial support for these activities makes it possible for transplant care providers to attend specialty focused CME at an affordable price. Commercial support for these activities makes it possible for the [redacted] to offer specialty focused CME at an affordable price to the transplant physician community. Without this support [redacted] would not be able to serve the profession in this way. The result is that individual health care provider would suffer, the profession would suffer and, we believe, ultimately patient care would suffer. We say this for the following reasons. First, [redacted] is unaware of any organization, other than itself, consistently identifying and verifying educational needs and identifying practice gaps of practitioners in the field of transplant medicine. Requiring that the practice gaps and educational needs of physicians in the field of solid organ transplantation be identified by an organization other than [redacted] is irrational and unrealistic. Second, it is the [redacted] not organizations like the AMA, AHQR, etc, that is developing and specifying content and curricula for transplant medicine. The field of transplant medicine has not been addressed by groups like those suggested by the ACCME. Requiring groups external to the specialty establish curricula without expertise in the field as a condition of commercial support is a disservice to the field. These organizations have no expertise to do this work without significant input from the very specialists who are in the membership of [redacted]. Meeting this condition is impossible at this time. Finally, the fourth condition is not necessary for the majority of accredited CME providers. With only a 10% reported non compliance rate the current Standards for Commercial support SM appear to be effective. ACCME attention should be focused on helping the ten percent non-compliant groups take corrective actions by moving beyond an inspection only model of accreditation to an improvement model of accreditation. The [redacted], like many ACCME accredited providers, has rigorous policies and processes to assure that all of its CME activities are free of commercial bias. Recently the Society passed a “transparency” policy requiring that both the source of commercial funds for its CME activities as well as the amount of support received be disclosed. In addition, any person who can affect the content of an [redacted] CME must not only disclose those relationships as required by the ACCME Standards for Commercial Support SM but must also	Accredited CME provider

disclose the amount of support received. These disclosures and the potential for bias that might result [redacted] CME activities are taken very seriously by the leadership of the Society. Any person not meeting the [redacted] polices for disclosure or deemed to be in a position where a conflict cannot be resolved are not permitted to participate in any way in [redacted] CME activities. The conditions proposed by the ACCME for commercial support would have absolutely no impact on how [redacted] meets it obligation to assure its educational activities are free of commercial bias. The conditions could however, make to impossible for the [redacted] to meet its obligation to provide professional development opportunities to the physician transplant community that have a positive impact on the delivery of care to the transplant patient. We urge the ACCME not to adopt these conditions and focus its efforts on addressing the non-compliant practices of a minority of CME providers.	
The [redacted] is a not-for-profit medical specialty society representing more than [redacted] worldwide who provide [redacted] and other surgical procedures of the [redacted]. Founded in [redacted] is to enhance the ability of [redacted] to provide the highest quality patient care through education, research, and advocacy. [redacted] is providing comment to the ACCME clarification of acceptable interaction between an Accredited Provider and a commercial supporter. The first clarification states, "Accredited providers must not receive communications from commercial interests announcing or prescribing any specific content that would be a preferred, or sought-after, topic for commercially supported CME (e.g. therapeutic area, product-line, patho-physiology) – as such communication would be considered 'direct guidance on the content of the activity' and would result in Non Compliance with Standard 1 of the ACCME Standards for Commercial Support℠." [redacted] supports this clarification. We concur that by identifying that content for which industry is interested in seeing certified continuing medical education offered, they are potentially influencing the content of an educational activity. It should be noted that we believe this to be true within the purview of clinical education but may not be as likely to be an issue in other areas such as patient safety and practice management. This said, [redacted] supports a standardized approach that calls for a consistent ban on industry announcing or prescribing specific content that would be preferred or sought after by the company. With this stance, we are compelled to point out that regardless of this clarification, Accredited Providers who abide by the ACCME Essentials, Elements, Standards and Policies should, by default, be providing education that is devoid of bias and based upon the best available evidence as accepted by the profession. We believe that the clarification above adds an additional layer to protect our highly respected educational initiatives from being perceived as even marginally influenced by commercial supporters. The second clarification states, "Receiving communications from commercial interests regarding a commercial interest's internal criteria for providing commercial support would also be considered the receipt of 'guidance, either nuanced or direct, on the content of the activity or on who should deliver that content." We believe ACCME needs to clarify what it means by the term "internal criteria." If the internal criterion includes non-content based information such as budget and demonstrated ability to produce successful educational activities, we have no problem with the commercial supporter disclosing its "internal criteria." If, on the other hand, the criteria are directly linked to educational initiatives they have identified, then our response would default to that of the first clarification which is that this information should not be made available to providers of certified continuing medical education. It should be noted, however, that when seeking sponsorship support, providers are well aware of the specific disease states and product lines in which individual companies are involved. This is why [redacted] strives to have multiple sponsors for any one event – to avoid even the appearance of bias toward or against any commercial supporter.	Accredited CME provider
When pharma posts on their website information on therapeutic areas in which they are interested and guidelines to follow, this in no way "controls the content of a CME certified program". It is a tremendous help to us and saves many long hours uploading proposals that have no chance of funding.	Accredited CME provider
We certainly agree with the intent of the statement in this call for comment, however I wish to address specifically the concept of communication between the commercial supporter and the accredited provider. It appears that the ACCME is trying to eliminate communication between commercial supporters and accredited providers. I have a different perspective on this as in addition to working in CME for the last 18 years, I also do humanitarian work where I seek out donors to support humanitarian projects. Our organization ([redacted]) works in some 70 countries in the poorest regions of the world. Our grantors support our work because they have specific interests, perhaps in a certain region of the world, or perhaps in a certain type of project ([redacted]), etc. In order for them to support our work, they require knowledge of exactly what their money will be spent on. This requires communication between the organization and the supporter. Further, they want to follow-up on the projects to see that the money was well spent and in accord with their wishes as a requirement to further support. Now what I am speaking of does not relate to a "commercial" interest, but yet the grantor still requires this level of specificity, communication, and follow-up. I can't help but compare this to	Non-accredited CME provider

the CME world. If supporters and grantors are not provided information about where their funds would be spent, or have accountability, or relationship and communication with accredited providers, the amount of support for CME will go down dramatically.....to the detriment of patient care in my opinion. One only needs to look outside the world of CME to foresee the consequences that would result.	
Regarding communication between potential or actual commercial supporters and accredited providers, we agree providers should be independent from such supporters when developing accredited continuing medical education (CME) activities. We further agree that communication from a commercial supporter – whether direct or indirect – that requests a particular topic be addressed conflicts directly with the ACCME Standards for Commercial SupportSM. We do, however, feel that certain communications from commercial supporters regarding internal criteria for providing support can be beneficial to the accredited provider in terms of understanding certain requirements, deadlines, supported therapeutic areas, etc. Prior to submitting a grant request to a commercial supporter, it is important for the accredited provider to be aware of basic information such as what therapeutic areas are supported and how far in advance of the educational activity that the request needs to be submitted for the provider to be able to make decisions from where to obtain support. It is our position that "internal criteria" needs to be defined in a manner that reflects exactly what the ACCME is proposing. It is also the opinion of the [redacted] that there is an important partnership between academia and industry which needs to be strengthened and improved upon in order to maintain stable and manageable working relationships rather than completely severing those partnerships. Further, participation by members of industry on Boards of Directors of non-profit organizations and academic committees typically enhances the scope and work of these organizations and is not detrimental to their adherence to the ACCME Standards for Commercial SupportSM. For example, members of industry serve admirably on [redacted] study sections and have affiliate appointments at academic institutions.	Accredited CME provider
[redacted] RESPONSE: The [redacted] agrees with the goal of not influencing specific program content. We strongly disagree with the prohibition of any communication on therapeutic areas or pathophysiology. Limiting discussions about therapeutic areas or pathophysiology would result in wasted time and effort on grant requests for both providers and commercial interests. We believe that these discussions can occur at an appropriately general level to avoid biasing program or content. The [redacted] agrees that there should not be specific guidance issued on preferred content or who should deliver content. It is appropriate to define broad, internal criteria (cost, target audience, pedagogical approach, appropriate venues, etc.). For instance, the proposed standard would not make it possible for commercial interests to communicate how they will interpret and apply the new PhRMA Code.	Accredited CME provider
With proper guidelines there is still a place for RFP's and/or other communication between commercial supporters and providers. A commercial supporter should be allowed to say that it funds continuing medical education in specific therapeutic areas. An appropriate communication mechanism for dissemination of RFP's would be to post the RFP in a public portion of the pharmaceutical companies' website. This leaves no doubt about transparency since the posting is in the open. This type of posting would not be deemed 'direct guidance' since all providers will have equal access the RFP info. In the end, accredited providers' must still abide by the Standards for Commercial which ultimately enforce the independence of continuing medical education.	Accredited CME provider
The [redacted] is pleased to offer a response to the proposed policy changes to the Accreditation Council for Continuing Medical Education (ACCME) Standards for Commercial Support. In this response we will reflect three perspectives — that of [redacted]. who seek quality, unbiased continuing medical education (CME); that of a professional medical specialty society; and that of an ACCME-accredited provider of CME. First, [redacted] affirms that ACCME is now, and should remain, the leading national multi-specialty entity that develops and disseminates CME rules and regulations. A strong ACCME is in the best interest of both physicians and the patients they serve. We also assert that the [redacted] carefully monitors our adherence to the ACCME's 2004 Standards for Commercial Support, as well as other pertinent laws, regulations, ethical codes, guidelines and considerations that inform our ability to ensure the identification, disclosure, and resolution of real or perceived conflicts of interest and/or bias, and are proud to have earned the designation of "Accreditation with Commendation" from the ACCME in 2001 and again in 2007. However, the [redacted] disagrees with several premises or solutions set forth by ACCME in its June and August 2008 calls for comment. Call for Comment Item 1 appears below, and Items 2 and 3 will be submitted separately online. ACCME proposes that "Accredited providers must not receive communications from commercial interests announcing or prescribing any specific content that would be a preferred, or sought-after, topic for commercially supported CME … deliver that content." [redacted] agrees with ACCME that independence of CME must be assured; but [redacted] objects to further restrictions in communications between accredited providers and	Accredited CME provider

commercial interests regarding various practical topics for consideration that pertain to the financial support but not the educational content of CME. [redacted] believes that the current ACCME guidelines for interactions between accredited providers and commercial interest are sufficiently effective in assuring independence, and that further restrictions on communication could jeopardize best practices in patient care by restricting or slowing the translation of medical research into education and practice. As an ACCME-accredited provider and the country's [redacted], [redacted] appreciates the fact that ACCME will update its criteria and expectations on a regular basis to support continuous improvement in the provision of CME. In fact, [redacted] has adopted ACCME's criteria for [redacted], and we require that [redacted] seeking [redacted] likewise comply with ACCME policies and standards for commercial support. We agree on the importance of rigorously applied safeguards to assure CME independence, such as the identification, disclosure, and resolution of real or potential conflicts of interest. We remain committed to ensuring that [redacted]-provided CME and [redacted]-accredited CME is objective and relevant; not influenced inappropriately by external support or other factors that would introduce bias in a manner that could jeopardize the appropriate translation of science into research, education, and practice. We regularly and rigorously verify that [redacted] CME is designed and conducted in a manner that supports improvements in professional competence, practice performance, and ultimately, patient outcomes. [redacted] disagrees, however, with ACCME's proposed additional restrictions in interactions between accredited providers of CME and industry; they are both unnecessary and operationally impractical. Professional medical specialty societies seeking funding must be allowed to communicate, directly when appropriate, with industry about matters of mutual interest which may at times include discussion of broad therapeutic topics for educational content, or scientific evidence for the incidence and burden of various diseases and conditions. Likewise, external supporters, whether commercial, private foundations, government agencies, or other entities, must be allowed to convey in broad terms what activities they are willing to fund. No evidence has been disseminated by ACCME or others to show that such broad conversations lead to '… guidance, either nuanced or direct …' in a manner that inappropriately influences CME.	
The [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 concern about adoption of the proposed policy to ban persons paid to create or present promotional material for commercial interests form controlling content of CME on that same content. The proposal may have some merit as it relates to those who write promotional materials, but barring anyone who has presented promotional material from speaking at CME activities on that content could severely restrict CME programs from using the speakers who are most knowledgeable about the topic, including those who are on company speakers' bureaus and whose research is funded by commercial interests. Who is better at presenting research results than those who have conducted the research? If providers are diligent about identifying and resolving conflicts of interest, disclosing financial relationships to the audience, and monitoring whether presentations are objective and free of commercial bias, there should not be a problem having these persons speak at CME activities. Also, under the Updated Criteria, the CME program, not the speaker, decides on needs and objectives before selecting a speaker. There is the added challenge of how providers would identify whether a potential speaker has done promotion. Speaker selection could become much more difficult and time-consuming. Submitted on behalf of the [redacted]	Accredited CME provider
COMMENT FROM [redacted] Members of a focus group for the [redacted] agreed that the position ACCME has proposed would 1) be difficult to police; 2) appear to make the process of attaining commercial support even less transparent; and 3) heighten the sense of impropriety between accredited providers and commercial interests. Accredited providers in the focus group agreed that Commercial Support is a value-added asset to continuing medical education. Increased transparency would encourage thorough public disclosure of grants available, amounts available for specific therapeutic areas, and the clear identification of criteria to be used to assess the grant applications – similar to the process used for government grants. With all information made public, concerned parties would then have the means to assess on their own the propriety of the grant process, and participants in the process would feel an even greater sense of accountability in the submission and selection of grants. Inability to know about internal criteria for approval of grant support results in a heavier administrative burden to the provider at a time when they should to be spending time planning and implementing quality programs.	Other

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. By following the current ACCME Standards this is already covered . By identifying and resolving conflict and having grants be unrestricted it seems the interactions are removed. Proposals one and three are redundant and we do an excellent job of screening for and eliminating commercial bias. If the ACCME has concern that some programs don't; it should be addressed individually in the reaccreditation process.	Accredited CME provider
[redacted] appreciates the opportunity to comment on the recent calls for comments by the ACCME related to commercial support. Let me begin by explaining who we are. [redacted] is a [redacted] pharmaceutical company who is strongly committed to enhancing the health and well being of people everywhere. One dimension of our commitment is supporting independent medical education because we believe that it can enhance patient care by providing health care professionals with the most current information on disease states, treatment options and effective doctor-patient interactions. In early 2005, [redacted] set up a separate grant-making department, known as the [redacted]. Using objective criteria and a rigorous review and decision process, the [redacted] is responsible for ensuring that [redacted] funds bona fide independent educational activities. Our processes are based on policies at [redacted] that are consistent with the FDA Guidance on Industry-Supported Scientific and Educational Activities, the PhRMA Code on Interactions with Healthcare Professionals, the OIG Compliance Program Guidance and the ACCME Standards for Commercial Support. Our decisions to provide support are also based on available budgets and the quality of the grant application submitted by educational providers. These applications propose activities that address identified educational needs of health care professionals in their efforts to enhance patient care. We believe that a number of changes announced recently by PhRMA and the ACCME will address some of the continuing concerns related to industry's CME contributions. The recently revised PhRMA Code on Interactions with Healthcare Professionals that will take effect on January 2009 includes a number of new provisions that reflect guidance provided by the OIG and ACCME since the first PhRMA Code was released in 2002. The revised PhRMA Code reinforces the principles of independence in medical education activities conducted by educational providers. PhRMA has strengthened the section on Adherence to the Code with the inclusion of companies publicly stating their commitment to abide by the Revised PhRMA Code and to self-certify annually that they have policies and procedures in place to foster compliance with the encouragement to have an external verification of this. You also recently announced plans to enhance the ACCME's focus on monitoring and surveillance of the CME system. These steps to strengthen the ACCME's oversight are encouraging. We also find encouraging your intent to be transparent and disclose compliance information on your website. The information you obtain about a provider's compliance will be valuable to industry in evaluating applications. Currently, it is difficult to obtain information about providers who are non-compliant, except through our own, necessarily limited monitoring efforts. As a commercial supporter, [redacted] wants to make informed decisions when awarding grants so that grants are given to ACCME-compliant educational providers. We also applaud the recent changes made by the ACCME to the Essentials and Elements and Accreditation policies. These changes will continue to raise the bar in CME by focusing on the important connection between the educational provider developing and evaluating quality educational programs and the adoption by health care professionals of best practices based on best evidence and available data. These criteria are only now being implemented and used as a measure for accreditation by the ACCME. Time is needed to fully implement all of these recent changes on top of the changes since 2003 and to assess their impact before considering further changes relating to commercial support. In response to ACCME's specific Call for Comments: 1)\tEnsuring that the Current Processes of Attaining Commercial Support Will Not Undermine the Independence of Continuing Medical Education – Limiting the Interactions between Accredited Providers and Commercial Interests over Commercial Support [redacted] receives over [redacted] applications per year from a wide range of educational providers. We seek to provide an efficient and effective grant review process that enables organizations to request commercial support for quality independent education that addresses the unmet educational needs of health care professionals and also aligns with areas of interest within [redacted]. It is the responsibility of the educational provider to conduct needs assessments and to design educational activities that address those identified gaps by providing valuable information designed to assist health care professionals in their efforts to enhance patient care. We see our role as deciding whether or not we will be a commercial supporter of a particular educational activity after careful review of the grant application received. Our position is that Industry should be able to provide information on their grant application process as many do on their websites currently or through formal calls for grant applications. The desire is to be as transparent as possible about the grant process. At [redacted] we provide grants to support medical education that address the unmet education needs of health care professionals but they must also align with educational areas of interest within [redacted]. Completing applications for grants is time consuming and so educational providers need to know if their	Commercial supporter

planned educational activities will be considered by a commercial interest when seeking commercial supporters. Information provided by the commercial interest, including therapeutic areas of interest or budget availability, can assist the educational provider in determining whether or not they want to submit a grant application to a commercial interest. Our position is that posting information on our website or requests for educational grant applications with general requirements identified is a similar approach taken by other grant making entities such as the National Institutes of Health (NIH) and should not be considered "inappropriate guidance" by the ACCME with the understanding that accredited providers have the responsibility to conduct needs assessments and to have full control of their developed educational activities. We request that ACCME clarify their intent with the statement on "internal criteria". It should be appropriate for companies to identify areas of educational interest and broad categories of information needed by the commercial interest to evaluate grant applications such as needs assessment, learning objectives, audience and budget details. Requesting certain information may be necessary in order to assure compliance with applicable law and guidances from the OIG and FDA as well as compliance to the ACCME Standards for Commercial Support and the PhRMA Code. Communicating on logistical matters is also necessary at times. It should also be appropriate to communicate with the grant requester on general reasons for denial. These types of communications bolster transparency in our processes and should not be misinterpreted as direct guidance from the commercial interest or controlling content and creating commercial bias. [redacted] appreciates your consideration of our comments. If you have any questions, please contact me [redacted]	
The [redacted] was started as healthcare professionals started to realize that [redacted] ought to be the standard of care, and that [redacted] 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 [redacted] 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] 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] 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. RESPONSE: Point #1 and 2: We agree that it is necessary for accredited providers to maintain independence when developing accredited CME activities. Regarding developing firewalls to reduce undue influence, many grantors have responded appropriately by investing significant resources to develop comprehensive websites for online grant submission and review processes. We commend those who have built those firewalls between accredited CME grants and promotional support. The new Phrma Guidelines should also strengthen those efforts. We are also in agreement that communications sent from commercial interests to accredited providers that announce preferred topics or grant approval criteria could impact the provider's decisions when developing a program and influence the content of the activity. We do, though, feel that it is helpful for providers to have some knowledge of what topics or educational areas a commercial interest will be considered when reviewing grant proposals. It is very time consuming to develop a grant, seek a partner and wait for a response. If the likelihood that the grant will not even receive due consideration because it is not in a company's focus area, both the grantor and the grantee have wasted valuable resources and lost valuable time in the granting process. We do believe in an open RFP process that should be posted on grantors websites. This process would allow for an open and fair process for all relevant educational partners to submit proposals to intervene and potentially partner on an educational intervention. We also support open conversation with supporters about areas of interest. We believe that there are times that conversation is the best mode of communication. This can and must be done in a manner to avoid undue influence and maintain the integrity of the proposed activity. Our leadership is confident that these discussions and or inquires can be made without undue influence or future CME program development bias. It is not uncommon in the philanthropic community for grantors to identify their key areas of interest, types of organizations that they support, average amount of grants, deadlines, submission guidelines, etc. There is nothing unethical or inappropriate about this national directory. Verbal communication is also a common practice. This is just a wise use of very valuable and limited resources for all parties involved. We acknowledge that there are differing objectives involved, but we also believe that the entire enterprise should not be punished for the actions of a small percentage. . The Board of Directors of [redacted] takes its role in providing quality, unbiased continuing medical education seriously. Therefore, [redacted] has established its own set of policies and procedures	Non-accredited CME provider

for dealing with conflict of interest and conflict resolution that are in accordance with the ACCME Standards. We also believe very strongly in the integrity of our organizers and speakers and trust the feedback from our attendees to identify any potential or perceived bias. If bias is reported the [redacted] leadership has processes in place to deal with those individuals.	
We believe further clarification is needed. For instance, it seems reasonable for a commercial interest to include a list of disease sites or therapeutic areas they are willing to support within an on-line application for funding. Likewise, if a company has an RFP pertaining to a specific topic and providers have to go on-line to access the proposal, this seems reasonable. This enhances the efficiency of providers so they do not spend time working on grants that won't be funded. Does this refer to a brochure about the grant application process? On the other hand, if you are referring to direct communication in the form of a letter or conversation, it would help if this was more clearly stated.	Accredited CME provider
REVISION...Please disregard previous submission 1.Accredited providers must not receive communications from commercial interests announcing or prescribing any specific content that would be preferred, or sought-after, topic for commercially supported CME (eg, therapeutic area, product-line, patho-physiology)—as such communication would be considered 'direct guidance on the content of the activity' and would result in Non Compliance with Standard 1 of the ACCME Standards for Commercial Support. We believe further clarification is needed. For instance, it seems reasonable for a commercial interest to include a list of disease sites or therapeutic areas they are willing to support within an on-line application for funding. This enhances the efficiency of providers so they do not spend time working on grants that won't be funded. Does this refer to a brochure about the grant application process? On the other hand, if you are referring to direct communication in the form of a letter or conversation, it would help if this was more clearly stated. 2. Receiving communications from commercial interests regarding a commercial interest's internal criteria for providing commercial support would also be considered the receipt of 'guidance, either nuanced or direct, on the content of the activity or on who should deliver that content.' We believe further clarification is needed. The terms guidance and direct are easily discerned. However, the term 'nuanced' continues to be open to interpretation. Does this include information included in on-line grant applications or the brochure describing the grant process that is publicly available, or are you referring to information provided from a commercial interest to a provider on an individual basis? One could argue that information provided about what they \twant in answer to specific questions constitutes 'guidance.' It seems entirely appropriate that if we are requesting funds from a company, they should have the right to document their requirements. This enhances transparency and will save time for providers and grantors.	Accredited CME provider
The proposal would provide only a minor inconvenience for commercial interests. The interests of specific companies in specific topic areas are obvious. A CME activity that trumpets the prevalence, under diagnosis, and severity of a specific condition will atract funding from companies that market -or plan to market - treatments for that condition. A CME activity that covers treatments for a disease will interest pharmaceutical companies that market the best-selling drugs for that disease. The ACCME proposal will foster the prosperity of CME providers that correctly identify industry-friendly topics, and the failure of CME providers that create industry-independent programs. "Independent" industry-funded CME is a chimera.	Other
Comments by [redacted] It is our perception that, other than the topic area, there is currently no communication from commercial interests regarding specific content of CME activities. It is the accredited CME provider's responsibility to identify a practice gap and corresponding educational need and then determine if grant money is available in the identified topic area. CME professionals and physician CME leaders have the ability to plan activities in this order. §\tFrom a practical standpoint, unnecessary work is created for CME providers when there is no knowledge of the topic area for which funds are available. •\tProposed Policy: Receiving communications from commercial interests regarding a commercial interest's internal criteria for providing commercial support would also be considered the receipt of 'guidance, either nuanced or direct, on the content of the activity or on who should deliver that content.' o\tComments by [redacted]: CME providers, through newer grant processes, do not receive information from the commercial interest about the reasons for awarding a grant or not awarding a grant. [redacted] agrees that CME providers should not receive specific direction regarding the content of a CME activity from commercial interests; however, guidance on process is often helpful. For example, a recent grant application submitted by [redacted] and one of its joint sponsors was rejected because the budget was presented in percentages rather than actual numbers. Knowledge of this process detail was important for the success of future grant applications. As long as communications are written, transparency is documented and providers' independence of developing CME activities is preserved.	Accredited CME provider

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 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]	Other

In the Call, ACCME takes the position that Accredited Providers must not receive communications from commercial interests that would provide information related to areas that the commercial interest may have reason to fund. ACCME feels this would be considered "direct guidance on the content of the activity." [redacted] does not agree with this position. Grant-giving entities often provide detailed information related to the areas in which they are interested in providing financial assistance. This minimizes unnecessary work for those who pursue grants, as well as those who award grants, particularly when there is no funding available or little interest or support of concept. CME Providers must identify an education need for a CME activity based on a recognized practice gap in the physician population. Should there not be a gap, or should the physician population not have a need to close that gap, there will be no participants in the activity. When a commercial interest makes it known it has funds to support activities in a particular therapeutic area, it is not dictating the content of the activity, but rather making it easier for hard-pressed providers to become aware of potential resources. [redacted] does not believe that provision of this general information can in any way be construed as receiving "direct guidance on the content of the activity." The content is determined by the Provider and is dependent on the manner in which the practice gap will be addressed. The comment also states that "receiving communications from commercial interests regarding a commercial interest's internal criteria for providing commercial support would also be considered the receipt of 'guidance … on the content … or who should deliver the content.' " [redacted] fails to see the logic in this statement. "Internal criteria" have nothing to do with content, but rather establish the rules related to the application for support. This is a common practice of most, if not all, organizations that provide grants to others. How can one construe steps in process to be "direct guidance on the content"? Any grant-giving organization, including the Federal Government, must have a "process" for individuals to follow. What sense does it make for that "process" to remain secret?	Accredited CME provider
We, the [redacted] support the proposed change to the Accreditation Council on Continuing Medical Education's Standards for Commercial Interactions as a step in the right direction for CME. Furthermore, all commercial support for CME should be banned because it creates inherent and irremediable conflicts of interest. Conflicts of interest are deleterious to the medical profession. The ACCME recognizes conflicts of interest by prohibiting commercial interests from controlling CME activities. It is appropriate to extend the ACCME policy to prohibit control of CME content by persons who are conflicted by their role in promotion of a product. While further insulating professional activities from promotional activities is a step in the right direction, any solution that maintains a role for commercial support of education cannot remove the influence of commercial interests. The piecemeal approach toward managing conflicts of interest continues to fail and for this reason, we urge the ACCME to take another step forward and prohibit commercial interests from participating in CME activities at any level. Sincerely, [redacted]	Other
The [redacted] understands and strongly agrees with the ACCME that CME programs must present a balanced, fair representation of scientific and clinical data without undue influence by commercial interests. Nevertheless, industry is a vital member of the medical community. According to 2007 statistics, 47% ($58.8 billion) of total medical research conducted in the United States takes place in an industry setting. For physicians to be up to date on medical advances, the ACCME must seek a mechanism to provide a balanced presentation of the important work performed by scientists and clinicians working in industry. If the goal of CME were to merely educate clinicians about FDA approved treatments then some of the requirements being put forth by the AACME might be valid. Unfortunately, for many diseases there is no FDA approved therapy. In many other disorders, such as cancer, FDA approved treatments can be toxic and provide only amelioration of symptoms without hope of cure. The AACME has stated "The content of CME is that body of knowledge and skills generally recognized and accepted by the profession as within the basic medical sciences, the discipline of clinical medicine, and provision of health care to the public." (Quoted from the ACCME's "Essentials, Guidelines and Standards") Exclusion of industry from CME activities will prevent the timely dissemination of information in basic sciences and clinical trials that are key to moving medical advances from bench to beside. Ultimately, excluding industry from being part of the medical education process will negatively impact clinical research, medical education, and patient care. Members of [redacted] are keenly aware of the important contribution industry-based researchers can make to medical education. Gene therapy is a novel treatment approach that is being evaluated for a wide variety of diseases. Currently there is no FDA approved gene therapy product in the United States, but there are over 1000 approved clinical trials worldwide seeking to treat disease through the transfer of genetic material. Clinical success of will require combined expertise in basic science, clinical trials, and the special regulatory and compliance issues unique to genetic therapies. Moreover, while academics are often at the forefront of discovery, require industry involvement if novel therapies are to move from the bench to a licensed product. Members of [redacted] are keenly aware of this interface that speaks to the heart of translational research. The National Institutes of Health has realized this important interaction and has actively encouraged academic-industry partnerships. Since 50% of medical research is industry based, removing these industry-based researchers prevents CME programs	Accredited CME provider

from providing a balanced view of ongoing clinical trials and basic science advances. The proposals put forth by ACCME would lead to serious gaps in learners' knowledge base. We encourage ACCME to find a means to manage bias rather than eliminate important factual information from an educational program. Bias in science and medicine is not a new concern, nor will it be solved by any one solution. Academicians, patient advocacy groups and industry all put forth information that others may consider biased. By removing industry-based researchers from medical education because of potential bias ignores important advances in basic research and clinical trials, while doing nothing to manage bias from others involved with CME programs. Physicians and scientists have developed systems to manage bias when communicating medical advances. Specifically, the peer review system has provided a rigorous method for assessing print publications for scientific accuracy and commercial bias. [redacted] and most other professional organizations utilize a similar system for developing CME programs. Speakers, whether from industry or elsewhere, are chosen for the quality of their peer-reviewed research. Those involved with marketing are excluded from speaking and industry support for the meeting is only accepted as unrestricted educational grants. Why is it important for industry-based scientists to be part of medical education? First, there are world-class researchers in industry and excluding these highly talented individuals from the educational process does a disservice to learners. Furthermore, physicians conducting research must keep current on advances in basic science if they are to maintain the quality of their own research. Clinicians must also be up-to-date on advances in clinical research if they are to give a balanced opinion to patients seeking counseling on clinical trial options for diseases where no effective or approved treatment exists. For academicians, it is critical to hear, and critique, the most current advances in basic and clinical research as they prepare their lectures to medical students and other learners. We hope in the following letter to illustrate how the proposed ACCME guidelines will negatively impact medical education and patient care. We also offer some potential solutions to prevent undue influence in CME programs. RESPONSE: Limit the Interactions between Accredited Providers and Commercial Interests. The [redacted] agrees with the underlying premise that commercial support for CME activities needs to be provided as unrestricted education grants. We also agree that the commercial interest should have no part in setting the content or speakers for CME programs. Nevertheless, item #2 in the ACCME proposal regarding communication of the commercial interest's internal criteria for funding grants is ill defined and impractical. Granting organizations must be able to communicate some guidelines as to the topics they wish to fund. Without such guidance the potential grantee could expend significant resources in preparing an application only to have the request denied because the activity addresses an area that the grantor has chosen not to support. By the time the decision is communicated to the grantee, it may be too late to seek additional funds resulting in cancellation of a needed CME program. As an alternative, we encourage the ACCME to work with CME providers to develop guidelines for granting policies that are compatible with unrestricted educational grants. This should be required of both commercial and non-commercial entities, since the latter organizations may also be biased as to therapeutic options. Furthermore, the ACCME should support the publication of these policies on company websites. This increases rather than decreases transparency and will allow CME organizations to review the policies when deciding whether to accredited a proposed CME activity. The philanthropic community has begun to provide this type of transparency, specifically the Foundation Directory provides a grantor list with their areas of interest, types of organizations that they support, average amount of grants, deadlines, and submission guidelines. There is nothing unethical or inappropriate about this national directory. Such interactions are a practical necessity for any grant process. What the ACCME could require is that granting organizations limit their communications to the scope and process for grant submissions; they may not communicate specific topics, speakers, or venues. Furthermore, organizations seeking funding should be limited to communicating the general topics and objectives of the meeting and speaker lists and lecture titles should be withheld from the grantor until after a funding decision is reached.	
The [redacted] disagrees with the position that accredited providers must not receive Request for Proposal (RFP) communications from a commercial interest because it could be considered that they are in receipt of 'guidance, either nuanced or direct, on the content of the activity.' The [redacted] considers this type of RFP communication to be (appropriate) top-level guidance used to assist the [redacted] in the selection of commercial interests which may have the potential funding resources to support education in an area where the [redacted] has identified an existing gap in physician knowledge and/or performance. However, the [redacted] proposes that this top-level communication be limited to the following criteria: quality educational process requirements, topical area of interest, provider type (e.g. 6-year ACCME accreditation) and amount of support available in the identified area of interest. Specific topics, product lines, pathophysiology, etc. should not be included in the RFP.	---

Comment #2 The [redacted] strongly disagrees with this proposal for 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.	Accredited CME provider
The [redacted] appreciates the concerns about industry support and the processes used to create nonbiased continuing medical education (CME). The [redacted] believes that the ACCME's new standards will assure that CME is not undermined by commercial support. We believe that the new standards set by the ACCME should be given time to work and that no further standards need to be developed at this time. 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 profession 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 that attaining commercial support does not undermine the independence of CME. There is a role for commercial support and it should not all be seen as inappropriate. There are good programs like the [redacted] that receive commercial support in a nonbiased way. This should be allowed to continue. Sincerely, [redacted]	Accredited CME provider
As an ACCME-accredited provider, [redacted] supports the ACCME's efforts to improve the quality and independence of CME within a self-regulated environment and to strengthen standards and policies designed to enhance the credibility of the CME certification system. [redacted] is one of the most utilized sources of medical information by physicians. The importance and value of [redacted] professional network is evidenced by the fact that there are more [redacted] CME activities that were completed by physicians and other health professionals, [redacted] to the [redacted]. [redacted] commitment to physician education is evidenced in the fact that the majority of the CME developed by [redacted] is not funded by external commercial supporters, which has permitted us to provide a broad range of educational information to physicians, in topics as diverse as communicating with terminal patients and their families and detecting evidence of domestic violence. 1.\tConsideration of the Elimination of Commercial Support of CME 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: (1) 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	Accredited CME provider

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. In conclusion, [redacted] strongly recommends that the ACCME reconsider any proposal to eliminate commercial support for continuing medical education activities or to implement the proposed "new paradigm."	
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). Proposals to Limit the Interactions Between Accredited Providers and Commercial Interests Over Commercial Support [redacted] first wishes to comment on the ACCME proposal that "[a]ccredited providers must not receive communications from commercial interests announcing or prescribing any specific content that would be a preferred, or sought after, topic for commercially supported CME (e.g., therapeutic area, product-line, patho-physiology) . . . . Receiving communications from commercial interests regarding a commercial interest's internal criteria for providing commercial support would also be considered the receipt of 'guidance, either nuanced or direct, on the content of the activity or on who should deliver that content.'" [redacted] believes that it is indeed appropriate for a commercial entity (hereinafter "Supporter") to succinctly communicate to Accredited Providers (hereinafter "Providers") broad and substantiated gaps in health care provider competencies for which support of continuing medical education is warranted. Identifying such competency gaps is an efficient means for Providers to become aware of the areas of greatest need for continuing medical education. The mere identification of a potential competency gap should have no impact on the educational content of the ultimate program, because it is solely the Provider's responsibility to independently verify the types of educational needs that exist, and to develop the activity independent of the influence of the Supporter. [redacted] believes that communicating an interest in supporting continuing medical education about a therapeutic area or the pathophysiology of a disease/condition is appropriate because it is	Commercial supporter

sufficiently broad. We further agree that identifying a specific product line would be too narrow and could be construed as introducing Supporter influence into the content of a program – something that is strongly opposed by [redacted]. [redacted] believes that it is appropriate for a Supporter to inform Providers of the Supporter's guidelines for submitting a grant request, provided that such guidelines are procedural only and provide only information about the process for the submission of such a request. Any such guidelines should not provide any information or guidance regarding the proposed content or faculty for the activity. In this regard, the mechanism that [redacted] uses to communicate potential competency gaps and grant submission guidelines to Providers is a request for an independent education grant proposal (RFIEGP). Through this process, [redacted] asks Providers to include in their grant proposals information about the needs assessment that the Provider has conducted, the proposed educational objectives and methods of the program, participant recruitment mechanisms, and plans for outcomes assessment in respect of the program. [redacted] believes that because Providers are already required, per ACCME guidelines, to consider this information when planning their activities, that seeking this information does not in any way provide any guidance about, or exercise influence over, the program content or faculty of the activity. In addition to [redacted] position set forth above, we would like to use this opportunity to seek clarification on the following two points: (1)\t[redacted] medical and education personnel frequently present at industry meetings where the topic of independent medical education is addressed. These presentations may include information about [redacted] grant process and compliance expectations. We request ACCME's guidance on whether these types of presentations to constitute the provision of "internal criteria." (2)[redacted] asks that ACCME clarify its position on the propriety of interactions between Supporters and Providers about purely logistical aspects of already funded activities such as the timing of the activity, the venue of the activity, and the Provider's plans for awareness mechanisms. 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]	
September 12, 2008 Murray Kopelow, MD Chief Executive Accreditation Council for Continuing Medical Education 515 North State Street, Suite 1801 Chicago, IL 60610 Re: ACCME Calls for Comments We have been asked to review the Accreditation Council for Continuing Medical Education's ("ACCME") "Call for Comments" on ACCME's recent proposal to end commercial support for continuing medical education (the "Proposed Changes"). We understand that the ACCME seeks comments on three scenarios in particular, including: (1) the status quo; (2) the complete elimination of commercial support; and (3) a new paradigm, whereby all commercial support would be banned except when four specific conditions are met.(footnote 1) For the reasons discussed below, it is our opinion that, if adopted, the Proposed Changes would raise serious questions under the antitrust laws. Since the Supreme Court held two trade associations (or their members) liable under Section 1 of the Sherman Act in the 1980s, courts have closely scrutinized standard-setting and certification programs like the ACCME to determine whether they constitute a concerted refusal to deal in violation of the antitrust laws. See Allied Tube & Conduit Corp. v. Indian Head, Inc., 486 U.S. 492 (1988); American Society of Mechanical Eng'rs v. Hydrolevel Corp., 456 U.S. 556 (1982). Indeed, in Hydrolevel, the Court observed that "a standard-setting organization . . . can be rife with opportunities for anticompetitive activity." 456 U.S. at 571. Courts recognize, however, that standard setting may be an objective of an association and understand that the organizations involved in standard setting may include competitors in the decision making process. As a result, unless the promulgation of standards is simply a pretext for price fixing, market allocation, a group boycott, or some other per se unlawful agreement, standard setting is evaluated under the "rule of reason," which weighs the procompetitive purposes of the collective actions against any anticompetitive effects. Under the rule of reason, courts typically first inquire whether collective action is justified to accomplish a legitimate procompetitive objective. If so, courts then consider a number of factors in assessing whether the action is, on balance, procompetitive and therefore permitted, or anticompetitive and therefore in violation of the antitrust laws. In circumstances likes these in which a standard excludes certain competitors from the market, or, at a minimum, significantly disadvantages them, such factors include: •\twhether the standard (as written and applied) is reasonably related to the stated goals in enacting the standard; •\twhether the restrictions imposed by the standard are narrowly tailored to achieve the objective or unnecessarily overbroad; •\twhether those who enacted the standard are economic competitors of the excluded or disadvantaged competitor; •\twhether the standards are objective; •\twhether the standards are arbitrary; •\twhether the standards are enforced by the same entity that promulgated the standards, or whether enforcement is left to governmental regulatory bodies or other interested parties (such as customers); and •\twhether the standard-setting organization has implemented procedural safeguards to ensure that competitors are not excluded unnecessarily or unfairly. When evaluated against these factors, the Proposed Changes appear more like a concerted refusal to deal than a legitimate exercise of the ACCME's standard-setting authority. Several key facts support this conclusion. First, the members of the ACCME Board of Directors, who have proposed the Proposed Changes and will ultimately decide whether or not to implement them, have been nominated by organizations whose members currently compete with companies that will be, at a minimum, competitively disadvantaged, or in most cases, completely excluded, from providing accredited	Other

CME programs. Should the Proposed Changes be approved, ACCME will also be responsible for enforcing the Standards as modified. As a result, we believe that a court would likely view the ACCME certification process as an agreement among competitors. This makes the conduct subject to closer scrutiny under the antitrust laws. Second, and on a related note, the ACCME Board is comprised largely of representatives from academic teaching hospitals who are less reliant on commercial support to develop and publish CME content than are other accredited CME providers. As noted above, CME providers who receive commercial support will be competitively disadvantaged, and risk outright exclusion from the market, if the Proposed Changes are implemented. It is clear, therefore, that the Proposed Changes will benefit certain CME providers, including those that proposed and ultimately will enforce the Proposed Changes, at the expense of those who may have little ability to comply with them. This problem is compounded where, as here, there is no objective evidence justifying the more rigid standard. We cite, among other things, the report recently commissioned by the ACCME, "The Relationship between Commercial Support and Bias in Continuing Education Activities: A Review of the Literature." That exhaustive report failed to find any empirical evidence to support or refute the position that commercial support produces bias in CME programs. The conclusions from this report seriously call into question the need for implementing such drastic measures as contemplated by the Proposed Changes, and courts have not hesitated to find the standard-setting process to be anticompetitive in nature in circumstances where there is no demonstrated evidence to support to a more restrictive standard. (footnote 2) Third, ACCME accreditation without question is essential to companies hoping to compete in the market for the post-graduate continuing education of physicians. Notwithstanding their genuine desire to stay current with the latest developments in their fields, medical professionals simply will not attend non-CME-certified educational programs in sufficient numbers to sustain a non-accredited entity. As a result, entities whose programs lose CME-certification as a result of the Proposed Changes will be essentially foreclosed from competing in the market. The loss of these competitors in the end will reduce the availability of vital educational programs for physicians, limit choices, reduce competition, and ultimately raise prices. Fourth, the Proposed Changes are not narrowly tailored to achieve their intended objective that the delivery of CME be independent from the influence of commercial interests. Rather than exclude any program from ACCME certification where the provider receives commercial support, ACCME can and should explore alternative, less restrictive, means to achieve its objectives, such as by requiring firewalls that separate those individuals who interact with commercial supporters, and those individuals of the provider who are responsible for developing CME content, or through better enforcement of existing guidelines. As described above, overbroad standards are more likely to be found anticompetitive than standards that are narrowly tailored to meet legitimate objectives, particularly where competitors of the excluded companies determine and enforce the standards. Finally, the bright line approach contained in the Proposed Changes provides absolutely no procedural safeguards to ensure that competitors are not unnecessarily or unfairly excluded from the market. To be sure, the Proposed Changes do not take into account that a commercially supported CME provider in compliance with existing rules may have been providing outstanding service for years, and not allowed itself to be influenced by commercial interests. In light of such exceptional performance, there is no justification for excluding such providers without some formal review to determine if commercial support has somehow tainted their CME offerings. Simply put, these considerations illustrate how the Proposed Changes, if adopted, will disproportionately impact certain CME providers and potentially expose the ACCME (and possibly the CME providers represented on its Board of Directors) to liability and significant legal expense under the antitrust laws. We believe, therefore, that despite the ACCME's laudable goals, the Proposed Changes are not in the best interests of physicians, accredited CME providers, or the ACCME. Very truly yours,

[redacted]

footnote 1 - According to the "Call for Comments," those conditions are as follows: "(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." Since we believe that all four of those conditions will rarely, if ever, be met, we see no real distinction between scenarios two and three described above. Accordingly, these comments treat scenarios two and three as if they were same, and the concerns raised herein apply with equal force to both.

footnote 2 - According to the "Call for Comments," those conditions are as follows: "(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." Since we believe that all four of those conditions will rarely, if ever, be met, we see no real distinction between scenarios two and three

described above. Accordingly, these comments treat scenarios two and three as if they were same, and the concerns raised herein apply with equal force to both.	
Comments of [redacted] on the ACCME Proposal: "The ACCME Will Ensure Current Processes of Attaining Commercial Support Will Not Undermine the Independence of Continuing Medical Education" [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. As the nation's largest medical device manufacturer, [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. ACCME has proposed two new standards to maintain compliance with its existing policy SCS1: Independence of the ACCME Standards for Commercial Support. [redacted] generally supports the underlying principles of the new standards, but is concerned that as drafted they will impede appropriate communications among industry and CME providers. The first proposal states that: Accredited providers must not receive communications from commercial interests announcing or prescribing any specific content that would be a preferred, or sought-after, topic for commercially supported CME (e.g., therapeutic area, product-line, patho-physiology) – as such communication would be considered 'direct guidance on the content of the activity' and would result in Non Compliance with Standard 1 of the ACCME Standards for Commercial Support. [redacted] agrees that commercial interests should not prescribe content or topics for independent CME programs, even ones that they support financially. However, the broad language of this proposal would prohibit virtually all communications by manufacturers regarding new areas of study. For example, it is common for manufacturers to issue white papers or similar communications about the research they have conducted or sponsored, or about new products they have brought to market. These documents typically end by calling for further study, discussion or education. Arguably, one could read this as "announcing" content that would be a "preferred, or sought-after, topic" for commercially supported CME. Such a broad reading would not serve the purposes of the ACCME, nor would it in any way improve the quality or objectivity of continuing medical education programs. Moreover, the proposal fails to distinguish between broad communications about education generally, and statements that could direct content in an inappropriate way. For example, a general statement by a manufacturer that it would like to see more CME programs related to women's health issues, or on minority subpopulations in disease states, is substantially different than a request for a grant proposal on a particular product-line, drug class or type of surgical procedure. There is also value in a manufacturer noting that there has been a shortage of CME programs for certain practitioner specialties. Again, this is a far cry from prescribing, or even recommending, program content, but is of practical use to CME providers in evaluating the need for programming. [redacted] recommends that ACCME revise the language of the proposal, to be less absolute, and to clarify that "direct guidance" resulting in non-compliance must be specific to CME, and not just a general announcement about the need for training and education. Accredited providers must not seek out or accept communications from commercial interests recommending or prescribing any specific content that would be a preferred, or sought-after, topic for commercially supported CME (e.g., product-line, drug class or surgical procedure) – as such communication would be considered 'direct guidance on the content of the activity' and would result in Non Compliance with Standard 1 of the ACCME Standards for Commercial Support. This revised language focuses the prohibition on the conduct that is inappropriate – "direct guidance on the content of the activity" – without inadvertently restricting communications that would not influence content but are beneficial to the CME process. The second proposal states that: Receiving communications from commercial interests regarding a commercial interest's internal criteria for providing commercial support would also be considered the receipt of 'guidance, either nuanced or direct, on the content of the activity or on who should deliver that content.' Again, this language sweeps too broadly. While [redacted] understands the purpose behind the proposal – to prevent commercial interests from influencing CME providers with regard to content – that is already addressed by the first proposal above. This second standard adds little to the basic principle already laid out that manufacturers may not seek to prescribe or recommend specific content for CME. However, its broad language prohibits many interactions that would not influence content but are key to efficient interaction between commercial interests and CME providers. The most basic example would be that most manufacturers have requirements for how CME grant proposals must be submitted, e.g., that they must include an agenda, budget and justification of the educational need. Providing these criteria will in no way influence CME content, but will enable providers to prepare their grant requests in a way that will allow manufacturers to process them efficiently. Similarly, it is common for manufacturers to limit CME grants to entities that are accredited, and that comply with the FDA Guidance on Industry Supported Scientific Education. Disclosing these criteria	Other

certainly would not influence scientific content of CME programs, but would improve understanding among CME providers of regulatory compliance expectations. Moreover, when denying grant requests, manufacturers often inform the CME provider of the reason for the denial, e.g., the need for physician education in that area is not clear, or the proposal did not meet the company's own criteria for regulatory compliance. Again, this would not impact the content of CME, and there is clear value in providing this feedback to grant requesters. Speaking more broadly, if a CME topic is not of interest to a potential sponsor, no one is served by requiring the sponsor to conceal that fact. Prohibiting a sponsor from telling a CME provider that a topic is not of interest will simply result in repeated drafting of unwanted grant requests, and increased frustration for all concerns. At the same time, it will not improve the quality or objectivity of CME. ACCME's goal should be to restrict communications that could actually influence CME content, without blocking appropriate discussion between commercial sponsors and CME providers about the process of actually seeking commercial support. It should drop the second proposal with regard to internal criteria, and instead provide clear guidance through its first proposal that communications seeking to recommend or prescribe specific CME content are prohibited.	
September 12, 2008 Murray Kopelow, MD, MSC, FRCPC Chief Executive Accreditation Council for Continuing Medical Education (ACCME) 515 N. State Street, Suite 1801 Chicago, IL 60654 Re: Request for Comments regarding Independence of and Commercial Support for Continuing Medical Education (CME) Dear Dr. Kopelow: The [redacted] appreciates the opportunity to comment on the commercial support issues raised by the ACCME in your June 11 and August 6, 2008 calls for comments. [redacted] represents more than 1,200 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. [redacted] members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology technologies, thereby expanding the boundaries of science to benefit humanity by providing better healthcare, enhanced agriculture, and a cleaner and safer environment. As an organization whose biopharmaceutical company members are committed to supporting quality CME, [redacted] appreciates ACCME's role in developing standards for conducting CME programs to benefit physicians, other health care providers, and their patients. We encourage the continuing dialogue on what factors and characteristics create CME that is unbiased, independent and contributes to advancing medical care. Specifically, [redacted] submits these comments to fulfill the ACCME's request for comments by: (1) discussing why the current processes of attaining commercial support will not undermine the independence of CME; (2) addressing the proposal to consider the elimination of commercial support of continuing medical education activities; and (3) providing practical feedback on how to define "commercial interest" to assure that CME content provided by particular individuals does not compromise independence. These issues are addressed below. I.\tEnsuring That the Current Processes of Attaining Commercial Support Will Not Undermine the Independence of Continuing Medical Education ACCME's Standards for Commercial Support (SCS), Standard # 1, Independence, states that a CME provider must ensure that decisions regarding the identification of CME needs, determination of educational objectives, selection and presentation of content, selection of persons/organizations in control of content, selection of educational methods, and evaluation of the activity are "free of the control of a commercial interest." In the context of this standard, ACCME seeks comment on the interpretation that: •\tAccredited providers may not receive communications from commercial entities announcing or prescribing any specific content that would be a topic for CME; and •\tAccredited providers may not receive communications from commercial interests regarding internal criteria for providing commercial support. [redacted] has concerns regarding the potential impact of such an interpretation on the ability of both providers and prospective commercial supporters to efficiently communicate areas of potential support. Without such identification, prospective providers stand to "shoot in the dark", resulting in wasted resources that properly should focus on real educational needs. [redacted] seeks clarity from the ACCME regarding exactly what interactions between CME providers and commercial interests would be permissible. Is ACCME seeking to disallow all transparent communications from a commercial interest to multiple CME providers regarding general areas of interest, or only one-on-one communications regarding potential topics, or both? If such communications are permissible, is ACCME seeking to limit the format or content of such communications, or both? For example, a commercial entity may wish to post proposed general topics of interest on its website for potential providers to access as they wish, and to enable interested providers to respond. Such proposed topics may be very broad in nature, e.g. "Company X would be interested in supporting CME on depression" or may communicate interest in supporting CME in a subset of a broad therapeutic area, e.g., "Company Y is interested in providing support for CME addressing treatment options for patients with advanced breast cancer." This is similar to the posting of calls for grant applications from various entities, and, as is the case here, it is not a matter of introducing bias, but rather of creating an efficient and effective system. Is it ACCME's intent to disallow a CME provider from accessing a general communication by a commercial entity stating that it is interested in supporting CME in a general topic area? Is it ACCME's intent to disallow a communication such as this in a website posting, or in a general letter to a group of CME providers, or both? Additionally, a potential CME provider may wish to obtain information regarding a commercial entity's interest	Other

in or application requirements for providing commercial support. Is it ACCME's intent to prohibit a CME provider from seeking to obtain such information by requesting it from one or more potential commercial supporters? In another example, a commercial entity may wish to conduct a vetting process of CME providers to determine what their compliance records and capabilities are, and to ensure high educational value, in the interest of supporting CME that is independent and fully compliant. The commercial entity may subsequently wish to send a call for grant applications or a request for proposal (RFP) to a subgroup of these CME providers, who meet its predefined criteria, identifying a general topic area of interest which they would be interested in supporting. In follow-up, a commercial entity may then wish to communicate a grant evaluation decision to an applicant, including information about the reasons for a denial, such as budgetary reasons or failure to provide an adequate needs-assessment. A commercial entity may also wish to post information regarding approved CME grants, in an effort to be more transparent. Would communications to identify compliant/capable CME providers be permissible? Would distribution of an RFP be permissible? Would communications regarding a grant decision, or to identify grant recipients, be acceptable to the ACCME? [redacted] is concerned that that without guidance from potential commercial supporters regarding information to be submitted by a CME provider seeking a grant, the process of submitting and evaluating the grants would be less efficient, and educational provider requests could potentially be denied because of failure to provide adequate information, even where the request did not lack merit. If it is ACCME's interpretation/intent to disallow these exchanges, [redacted] is concerned that such limitations on information dissemination would adversely impact realization of the value and purpose of CME programming. Such prohibitions would effectively banish an efficient method of matching accredited CME providers with potential CME supporters, and matching independently-identified educational needs with appropriate and compliant sources of funding. This would likely result in the inefficient use of resources by providers and commercial interests, as well as missed opportunities to positively impact patient care. [redacted] believes that general communications announcing interest in a general topic/area, without any suggestion of specific content, presenters, or products are appropriate and acceptable. Such communications do not interfere with the independence of CME, as the mere suggestion of a general topic or criteria for support or application need not influence the outcome and educational value of a program or activity. There are numerous other controls in place to assure that CME activities remain independent, objective and educational. For example, SCS Standard #5, "Content and Format without Commercial Bias", requires that CME programs promote improvements or quality in healthcare by providing education on a full range of treatment options, rather than focusing on a particular medicine. Also, pursuant to SCS Standard#1, "Independence", it is the responsibility of CME providers to identify CME needs and education objectives, and select the content for a CME program, without control of a commercial interest. What concerns does the ACCME have regarding general communications from potential commercial supporters to CME providers? [redacted] believes that a limitation on general communications intended to identify potential sponsors would serve only as an impediment while adding no real benefit to the quality or independence of CME. We further note that the newly issued PhRMA Code on Interactions with Healthcare Professionals (http://www.phrma.org/code_on_interactions_with_healthcare_professionals/) states that "a company may communicate to multiple CME providers or the public a general topic for a CME program that might be of interest to physicians." (See PhRMA code, Q. 21) [redacted] agrees that such communications are appropriate and useful, and can contribute to the development of CME that can meet the needs of the medical community and benefit patients. Finally, [redacted] also seeks clarification on whether ACCME's interpretation of SCS #1 would impact logistical discussions between commercial supporters and CME providers. Logistical discussions may include communications about potential types of educational design (e.g., live activity versus web-based activity), timing of educational initiatives, budget for educational initiatives, geographical location, status updates regarding a grant budget, and other matters unrelated to the content of or audience or faculty for the activity. Given that such discussions do not involve the content of a CME program, or the selection of faculty/presenters, does ACCME agree that such logistical communications are acceptable and do not interfere with the independence of a CME activity? II.\tConsideration of the Proposal To Eliminate Commercial Support of Continuing Medical Education Activities ACCME seeks comment on whether commercial support of CME activities should continue or should be eliminated, and requests that stakeholders, including the medical community, education community, and the public weigh in on and debate the subject. ACCME further seeks comment on whether a new paradigm should be created as an alternative to the current structure of commercial support for CME. If such changes to the current model of CME are being considered, a broad gathering of input and information and full debate is warranted. This is a very complex and significant issue for stakeholders, including [redacted] members. Creating a new paradigm would have a major impact on how CME is conducted and how opportunities for medical education are created. In turn, [redacted] is concerned that if health care providers have less access to quality CME, this could have a negative impact on patient outcomes. Without any evidence that commercial support for CME results in programming that is inherently biased, a change in the current ACCME standards may be unwarranted. In fact, a report commissioned by the ACCME concludes that there is no empirical scientific evidence that industry support of CME results in bias : "With the widespread concern about the impact of industry support on medical

research, practice, and education, the question of whether this support produces bias in accredited CME activities is critically important. The ACCME Standards for Commercial Support are designed to assure that CME activities are not biased toward the commercial interest supporting the activity. However, to date, there is no empirical evidence to support or refute the hypothesis that CME activities are biased." Further, as noted previously, there are numerous other controls in place to assure that CME activities remain independent, objective and educational. In addition to the PhRMA Code, FDA's 1997 "Guidance for Industry: Industry Supported Scientific and Educational Activities" addresses company funding, disclosure of relationships, and other aspects of CME programs to ensure that commercially supported CME is not considered promotional. Given the significance of such a major potential policy change, [redacted] recommends that ACCME should proceed deliberatively. It would be premature to reach a conclusion regarding support for CME without further assessment of the need for a change, evidence that there is, indeed a concern to be addressed, and what the impact of specific changes is likely to be. In assessing commercial support for CME, there are a number of questions to be considered, including: •\twhether commercial support for CME compromises the independence and scientific quality of CME programs; •\twhether the existence of commercially supported CME has a detrimental impact on medical education and patient care; •\twhether the process of CME sponsorship will be consistent for all types of CME providers, including for profit-providers, university and hospital providers, and professional medical societies; •\twhether existing controls and standards, such as disclosure of commercial support and financial relationships, are sufficient to achieve the goals of independence, non-bias, and educational quality; and •\twhether elimination of commercial support would impact the quality and availability of CME activities. [redacted] recommends that these and other data points should be studied and assessed before any major change is proposed or implemented. A paradigm shift such as this should not be undertaken without evidence of potential benefits to medical education and public health. Given that there have been a number of recent developments in this area, including issuance of the revised PhRMA Code, and that governmental and commercial entities are currently assessing and re-assessing these issues, ACCME should also take these other efforts into consideration prior to reaching any conclusions. If, following such an assessment, ACCME determines that an alternative paradigm would be beneficial, it would then be appropriate to launch a pilot project, to test the impact of any new program prior to it adopting it more broadly. III.\tHow to Define "Commercial Interest" To Assure That CME Content Provided by Particular Individuals Does Not Compromise Independence ACCME's Standards for Commercial Support, Standard #1, Independence, states that a CME provider must ensure that decisions regarding selection of CME presentation and content, and the persons in a position to control the content must be free of the control of a commercial interest. In this context, the ACCME seeks comment on whether individuals who are not employees of a commercial interest, but who are involved in the promotion of that company's products and services, should be excluded from controlling CME content. For example, the ACCME asks whether physicians who are paid by commercial entities to deliver promotional content to other physicians may also teach in independent CME activities. ACCME seeks comment on the following policy: •\tPersons paid to create, or present, promotional materials on behalf of commercial interests cannot control the content of accredited continuing medical education on the same content. The ACCME expands on this proposal, stating that not every financial relationship between an individual and industry would implicate this policy.—e.g., persons conducting research funded by industry, or reporting on the results of industry-funded research, would not be affected unless they also participate in promotional activities on the same content. BIO appreciates the ACCME's efforts to define the appropriate methods of assuring that education is separate from promotional activities, and that CME programs are conducted independently. However, [redacted] is concerned that a policy excluding certain persons from CME participation may only address a perception of bias, and would not serve the primary goal of providing high quality independent CME. Physicians involved in research and clinical trials on innovative therapies are generally the most knowledgeable about important advances in science and treatments, by virtue of both their background in a therapeutic area and participation in the research. Biopharmaceutical companies engage these experts to participate in research because of their specific expertise, and, following that research may also determine that these experts are the most informed and proficient to conduct training or educational sessions on the therapy for their colleagues, as consultants to a company. And again, when a CME provider is seeking experts to present at a CME program, these same physician experts may be the most qualified, particularly in a niche therapeutic area, where the number of experts or specialists may be very limited. [redacted] believes that such experts should not be prohibited from presenting CME content, solely because of a consulting relationship with a commercial interest in that content area. Exclusion of such experts could deprive CME program attendees of hearing from and learning from the best and the brightest in particular therapeutic areas. As stated previously, the existing ACCME Standards, including the requirements for disclosure of all relevant financial relationships with any commercial interest, and the provision of a balanced view of therapeutic options, are sufficient to produce CME programs that are independent and unbiased. The ACCME's proposal appears to assume that physicians with recognized expertise in an area would not be capable of presenting unbiased scientific/medical information, an assumption that we do not accept. Further, physicians who would attend such CME programs are sufficiently educated and sophisticated to assess the nature of the information presented and the relevant

disclosures. [redacted] appreciates your consideration of these comments and looks forward to ACCME's clarifications on the issues we have raised. If you have any questions, please contact me [redacted]. Sincerely, [redacted]	
[redacted] believes further clarification and definition of what communications are acceptable or not acceptable is required. Companies regularly send out blast emails regarding their products, recent research etc. Are accredited providers to insist on being opted out of such communications? [redacted] would like further clarification/definition regarding commercial interests' "internal criteria." What information will commercial interests be able to provide regarding the grant submission process? What information will commercial interests be able to provide regarding reasons for rejection should a grant be rejected. As currently written the policy leaves too much to interpretation could lead to inconsistent adoption.	Accredited CME provider
This action would eliminate the "request for proposal" process currently used by many commercial supporters. The following outlines the rationale as to why this process should not be eliminated: •\tBased on feedback from participants at the recent [redacted] meeting, this vehicle for generating grant requests for review from accredited providers does not hurt the integrity of the CME enterprise (see Almanac, Alliance for CME, Volume 30, No. 6, June 2008); we agree with this assessment. In our experience, RFPs contain information regarding only a therapeutic area and the therapeutic area is so broad (eg, oncology) that it negates any consideration of perceived guidance on content. •\tRFPs are now generated by the medical education department within a given company, rather than the marketing department as was common in the past. •\tWhere it may be perceived that the RFP process crosses the line is when a specific educational tactic is identified along with a therapeutic area; yet, many RFPs are for satellite symposia with time-sensitive application dates and slots that are tied to commercial support funding of the society—so perhaps working with societies on the manner in which they assign/award satellite symposia would be an important first step. •\tPer the ACCME guidelines, even if a general topic is identified, providers are still required to go through the process of identifying the practice gap that exists through the needs assessment process, thus eliminating any perceived direction from commercial support •\tThe RFP system is most useful for a number of items: o\tTime-sensitive CME activities such as satellite symposia at national society meetings; rather than timing all application due dates for a congress and waiting for the traditional 60-day grant review period o\tHelps prevent accredited providers from submitting extensive grants with large budgets to companies who do not have the funds to support the activity (whether solely- or multiply-supported)---see blinded submissions/futile process comment below •\tWith recent updates to the Standards for Commercial Support and ACCME Essential Areas and Elements, providers of CME are struggling to keep pace with the resultant increase in workload and time commitment. Eliminating the RFP process will only serve to add to this load by: 1) forcing providers to do more research into the therapeutic areas of interest for potential grantors and; 2) necessitating an increase in blinded submissions, which, because of the lower success rate, will increase the overall amount of grant submissions, and the work it entails, by 2-3 times. •\tThe ACCME has charged CME providers with maintaining the independence of their CME programs. It is now time to step back and allow these providers an opportunity to prove they can do so. Rather than invoke more regulations and guidelines that will cut out the RFP process, be confident that providers are adapting to the newly revised accreditation system and using CME as a "bridge to quality." Ultimately, if the system is working, CME providers will not respond to RFPs they deem are suspect.	Accredited CME provider
ACCME Call for Comment 1 – Response from [redacted]. 1. Accredited Providers must not receive communications from commercial interests announcing or prescribing any specific content that would be a preferred, or sought-after, topic for commercially supported CME (eg. therapeutic area, product line, pathophysiology) as such communication would be considered 'direct guidance' on the content of the activity" and would result in non-compliance with Standard 1 of the ACCME Standards of Commercial SupportSM. 2. Receiving communications from commercial interests regarding a commercial interests internal criteria for providing commercial support would also be considered receipt of 'guidance, either nuanced or direct, on the content of the activity or on who should deliver that content'. Introduction [redacted] appreciates the opportunity to respond to the ACCME's Call for Comment as stated above. [redacted] believes that certain circumstances and types of communications between a commercial supporter and an accredited provider are essential, and when such communications are appropriately focused and managed they do not compromise the independence of an activity or compliance with the ACCME Standards of Commercial SupportSM. [redacted] has developed and implemented comprehensive policies and processes for managing all aspects of the entire process of providing support for certified CME, including management of communications, with the fundamental goal to preserve independence of all activities we support. Without these communications, it would be impossible to conduct business and it is likely that funding for CME would be entirely withdrawn. Our companies active participation in the [redacted], leads us to believe the [redacted] approach to managing grant processes (implemented 5 years ago) is similar to a large majority of	Commercial supporter

commercial supporters, and is consistent with the recommendations in the new PhRMA Code. Instead of imposing new changes now, in the wake of many other recent changes imposed by both the ACCME and Pharmaceutical Companies, we recommend in depth evaluation of activities and programming resulting under the current system; particularly in the absence of any current evidence to support or refute the claim that industry supported CME is in fact commercially biased The [redacted] processes for managing educational grants are described below and a number of examples of communications between [redacted] and grant applicants are provided. [redacted] Commitment to Independent Education: [redacted] is committed to supporting continuing medical education activities that are designed to address important educational needs aimed at closing healthcare gaps and improving patient care in areas in which the company has significant medical and scientific expertise. Indeed, all of our drug development and research efforts are aimed at addressing recognized healthcare gaps and improving the health of patients and the public; our independent medical education supports this mission as well. We receive approximately 5,000 grant applications annually and we support about 35-40% of these requests. [redacted] Procedures for Ensuring Independence: We take very seriously the importance of managing conflict of interest and preventing commercial bias in the educational activities we support. To that end, we have detailed policies and procedures in place to ensure the independence of these grant funded activities and compliance with all external regulations and guidances (OIG, PhRMA Code, ACCME Standard for Commercial Support, etc.). Our granting function is managed by a centralized group within [redacted] entitled the [redacted], and marketing and sales play no role in the grants process. The [redacted] is staffed professionals with strong scientific and clinical background (e.g. PharmD's, PhDs, MDs, Nurse Practitioners, etc.) and is headed by an individual with a Ph.D. in [redacted]. All [redacted]) within the [redacted] group receive training in educational design and outcomes assessment to enable meaningful evaluation of the educational methods of grant proposals in relation to the educational needs, the learning objectives, proposed outcomes methods etc. and to assess alignment with the Updated ACCME criteria. All grant applications are submitted via a website ([redacted]). Every grant application is reviewed by a [redacted] consisting of three core voting members: a Medical Director (MD or PhD) who assesses the scientific/medical quality of the application; an Education Manager who assesses the validity of the educational need as well as the education design/quality of the grant application; and a lawyer who assesses compliance with all laws, policies and regulations. A unanimous vote is required to approve a grant, and grants over $500,000 or that span multiple years require a secondary review. Our policies specifically prohibit sales professionals from having any involvement what-so-ever in a grant application – and any hint of such would result in a decline of the grant regardless of its merits.. In addition an investigation of the circumstances would be undertaken and appropriate disciplinary action applied as necessary.,. Grants may only be awarded as part of a written grant agreement that requires adherence to ACCME Standards of Commercial Support. We believe that accredited providers who achieve the ACCME's updated Criteria for Compliance will generate the highest quality education programming and will accomplish the essential goal of improving patient care and closing healthcare gaps. Communications with Applicants: Our policies govern the nature of communications that are considered appropriate between the company and a grant applicant. More specifically, communications with providers are aimed at ensuring that : 1) the applicant understands the independently defined health care needs and gaps that we have identified as the focus for funding (i.e. so they don't have to guess or waste time with applications that are not aligned); 2) applicants have the opportunity to provide clarification and/or additional information necessary for the complete evaluation of a request; and 3) applicants understand the reason(s) why a grant was declined. We believe our approach to managing these communications is appropriate and does not compromise the independence of the activity in any way. In fact, the restrictions we have placed on communications with potential and actual applicants continues to result in confusion and inefficiencies and we are seeking new ways to communicate without compromising the independence of education. Described below is [redacted] current approach and the limitations on each of these forms of communication. Communication about Topics, Gaps and Needs: Providers need to understand the independently defined health care needs and gaps that we have identified as the focus for funding so they don't have to guess or waste time submitting applications that will be declined as a result of a poor guess. Our National Education Managers are responsible for undertaking comprehensive analysis of independently defined healthcare gaps and unmet educational needs related to the therapeutic areas and drug classes in which the company has expertise and interest. They accomplish this through ongoing review of health quality indicators, health priorities defined by government, societies, academic centers, healthcare organizations, insurance companies, review of peer-reviewed literature etc. We select a subset of these independently defined needs and gaps as the focus for funding in a given period of time. To assist applicants in understanding these educational priorities, we currently have two different mechanisms. The first is a listing of broad therapeutic areas posted on our website. (e.g Cardiovascular, Oncology, Diabetes, Metabolism, Bone, Respiratory, etc.) These reflect the areas in which our company has scientific and medical expertise. Within each broad area, we provide greater specificity by listing areas of interest (e.g. [redacted].). Feedback from applicants is that this is still

not adequately focused, and we continue to decline a significant number of grants based on poor understanding of the healthcare educational priorities we have selected to support. The second way we communicate our educational priorities is through Requests for Proposals (RFPs) which are sent to a minimum of three qualified applicants. These requests for proposals provide information on the independently defined healthcare gaps that we have selected to support through educational activities. In these RFPs, we site literature on the magnitude of the health care need/gap, and include references to the independent source(s). The RPF also provides information on the categories of information that must be included in the application. The [redacted] template for RFPs is attached along with an example of a completed RFP in the area of Prevention and Treatment of Venous Thromboembolism. We believe that this level of information is appropriate and does not constitute 'guidance, either nuanced or direct, on the content of the activity or on who should deliver that content'. In fact, we are currently proposing a new model in which we would post information provided in RFPs on our website as an added level of specificity, and with an aim for transparency, under each Therapeutic Category and Area of Interest. Posting these independently defined needs/gaps on our website would provide complete transparency in our educational priorities and enable all applicants to submit appropriately focused applications. In every case, an applicant is expected to independently validate the health care need as appropriate. Communication of Internal Criteria for Deciding Grants: As mentioned above, every grant is evaluated on multiple dimensions including scientific merit, articulation of educational need, educational design, quality of the evaluation plan, process for assuring scientific accuracy, faculty development, ability of the applicant to execute the program as described, budget, compliance with ACCME etc. The organization and information on the grant application contains these categories and our RFP provides a comprehensive explanation of what is expected in each of these categories. When a grant application does not provide sufficient detail or is unclear, we communicate with the applicant in writing to seek additional information or clarification. Virtually all communication regarding the application occurs electronically with the exception of budget discussions which may take place on the phone between an applicant and our purchasing department. We maintain complete documentation of the communication for our records. Examples of the types of questions that might be requested as follow-up on an application include: •\tPlease explain how you plan to ensure that your program faculty are well trained to execute the methodology you have proposed? •\tPlease explain the expected qualifications of your program faculty and how you intend to recruit this faculty? •\tYour learning objectives are not aligned with the agenda or the instructional design that you are proposing. Please clarify. •\t[redacted] is interested in supporting this activity at a lower level of $X. If you are interested in this level of support, please update your budget and resubmit. •\tPlease explain your process for ensuring scientific accuracy of the activity. [redacted] has developed standard language for the most common requests for more information. We believe that these communications do not directly or indirectly influence either the content or who delivers the content; in contrast, these communications ensure that members of the grant committees have all the information necessary to appropriately and fairly evaluate the merits of a grant request. Communication of Reasons for Why a Grant is Declined: As mentioned earlier, [redacted] receives approximately 5,000 requests for funding and we are able to support only about 35-40% of these. One of the most frustrating experiences for applicants is receiving a decline without a reason. So in 2005, [redacted] implemented a set of standardized decline reasons to provide some very basic information on why a grant was declined (attached). When a grant is declined, the Therapeutic Area Grant Committee selects the one best reason for the decline and this is conveyed to the applicant in an automated, standardized email message. We do not believe that these communications in any way compromise the independence of any subsequent grant application activity. Applicants whose grants are declined continue to complain that the reasons we provide are too vague, however, we believe that we must limit our communications to ensure that we do not influence content, methods, faculty, outcomes plans, recruitment methods, or any other material aspect of potential subsequent applications. Concluding Comments: In sum, [redacted] believes that elimination of the types of communications described above would be very detrimental to the quality and efficiency of our grant application process. We believe that the approach we have taken to focus and manage these communications is completely consistent with the ACCME Standards of Commercial SupportSM and the goal to preserve independence of the proposals we receive and the activities we support. Further restrictions on communications would exacerbate existing inefficiencies, and would likely result in [redacted] withdrawal of all support for CME activities. We have great confidence in the safeguards we have established to ensure independence and we invite the ACCME to visit our grant website at www.[redacted] to further understand our process. In lieu of further changes at this time, we recommend and support in depth evaluation of the certified activities supported through the current processes and systems since these involve many recent changes both by the ACCME and Pharmaceutical Company practices. New changes at this time would be pre-mature, particularly in the absence of any evidence to support or refute the claim that industry-supported CME is in fact commercially biased (Cervero et al, ACCME website, 2008) We look forward to working closely with the ACCME to ensure that our procedures are consistent with the goal to support high quality education that has the potential to close important healthcare gaps.

These comments will be sent by letter as well since formating useful to you is lost in this web submission September 11, 2008 Accreditation Council for Continuing Medical Education 515 N. State Street, Suite 1801 Chicago, IL 60654 Dear Dr. Kopelow, In response to both of the recent requests for comments, [redacted] is pleased to provide the following commentary. June 2008 Policy Announcement and Request for Comments Issue 1: Accredited providers must not receive communications from commercial interests announcing or prescribing any specific content that would be a preferred, or sought-after, topic for commercially supported CME (eg, therapeutic area, product-line, patho-physiology) - as such communication would be considered 'direct guidance on the content of the activity' and would result in Non Compliance with Standard 1 of the ACCME Standards for Commercial SupportSM . Response: If the intent of ACCME's proposal is that no form of communication will be allowed by commercial supporters that identifies where funding may be available, then we disagree with this proposal. We do, however; support any policy revisions intended to ensure specific content is not communicated or controlled by commercial interests either directly or by proxy. It is appropriate for commercial interests to clearly communicate areas of available funding in order to benefit providers' search for a balance of available funding support resources. If efficient mechanisms are not available for providers, a great deal of operational efficiency is lost by both the provider and commercial supporter community. In addition, providers are much more likely to become overly dependent on fewer sources of commercial support funding if these efficient transparent mechanisms are not encouraged. A lack of transparency also contributes to a culture where "business development" models of engaging industry gain a strong advantage over "educational support" models of communication. Any policy that discourages transparency will have the unintended adverse consequence of encouraging practices that are more highly dependent on personal interactions between provider business development personnel and commercial supporters. These business development practices, which may employ financial incentive systems that potentially overshadow patient health concerns, pose a much greater risk to content validity and issues around independence than transparent communications. Finally, it remains important to honor provider independence by recognizing they have a choice about whether to pursue funding, and to optimize their ability to seek balanced funding for programs. There is a spectrum of risk in terms of what is being defined by terms like "topic", and a great deal of heterogeneity around the use of this term. The spectrum as we define it is outlined in the table below. Ultimately, what is appropriate should be defined by what is in the best interests of patients. The table is intended to be a general guide where the accurate decision can only be determined by the patient-centric facts and circumstances of the situation. In general we view the first three levels as consistent with ACCME standards and therefore appropriate in descending order of preference while those that follow are almost universally inappropriate. Funding Area Statement Type\tExample\tRisk of Content Control\tProvider Benefit (Efficiency)\tComment 1. Performance gap based on publicly available measures\tPatient non-adherence to treatment plan as measured by HA1c\tLow\tHigh\t Program level communications where commercial interests identify evidence based gaps in healthcare performance around which mutual patient-centric interests might align represent the optimal balance between risk and efficiency. This does not focus on content at all but encourages providers to seek funding for PI CME initiatives much more efficiently. We believe that commercial supporters using this framework can most effectively function within the spirit of Standard 1 of the SCS. 2. Clinical area\tDiabetes\tLow\tModerate\tAppropriate to efficiently communicate budget support areas for providers but still leaves them "guessing" about specific areas of diabetes support. This in turn wastes grant application resources. 3. General Topic\tCurrent update on treatment options for diabetes\tModerate\tHigh\tAppropriate in most cases if they are not specific to a method of treatments, but can blur the line if not carefully delineated 4. Prescribed Topic\tUpdate on specific therapeutic option (compound specific) or an exclusive focus on a single content focused learning objective that is associated with a new drug launch (ex: mechanism of action)\tHigh\tHigh\tInappropriate in most cases when topics prescribe specific content in a manner that does not reflect what is new, true and/or important to patients or where there is not an opportunity for a broad fair balanced discussion of all available options 5. Prescribed Content\tAnything specific from learning objectives to content elements \t\t\tUnless externally mandated by government agencies to address public safety concerns, we can not envision a scenario where this would be appropriate 6. None Allowed\t No information available\t Low at the activity level, but potential for high at organizational COI level\t Low\t Undermines transparency and favors providers who expend greater resources to determine funding areas through business development rather than educational development practices. Issue 2: Receiving communications from commercial interests regarding a commercial interest's internal criteria for providing commercial support would also be considered the receipt of 'guidance, either nuanced or direct, on the content of the activity or on who should deliver that content.' Response: This proposal raises two issues. The first is the nature of the commercial supporter's criteria being referenced here. The second is the transparency of the actions of commercial supporters in this regard. Certainly criteria established by commercial supporters that attempt to influence content in any way are inconsistent with the spirit of the Standards. Beyond these kinds of attempts to influence providers, we believe that commercial supporters can and should set out precepts that embody their philosophy about quality CME; [redacted] is currently doing this. We also think that full transparency is central to avoiding the traps that internal, opaque criteria can create. To that end, we support the principle of transparency wherever it can	Commercial supporter

be practically implemented. In our view, commercial interests have internal criteria whether they are public or not. Without transparency, there is no opportunity to understand if the criteria are appropriate. In addition, today's system creates an un-level playing field that disenfranchises many "duty of care" providers who simply do not have the administrative resources to understand the basics of such "black box" systems. The lack of transparency is part of the culture that has contributed to the creation of a "business development" rather than "educational model" of interaction. It rewards those providers who invest in business development personnel who spend time developing relationships with commercial supporters. In our view, this approach has more universally succeeded in understanding what is in the "black box" of criteria in a manner that creates an unfair advantage for these providers. This in turn contributes to an issue we believe still remains at the core of the more serious conflict of interest issues currently facing the CME community where provider financial incentives can potentially overshadow public health concerns. We would suggest that providers should only be allowed to seek support from commercial supporters who are publicly transparent about their criteria for decision-making coupled with transparency about the decisions they have made. With respect to the specific issue of Requests for Proposals or Calls for Grant Applications, we also feel this is an effective mechanism to more efficiently align resources with public health needs in a manner that is transparent. In an ideal future state, CGAs should not be necessary when there is a clear emergence of robust national needs and corresponding proposals, but that is not today's reality. Prior to the use of CGAs, it was extraordinarily rare to receive a grant request for performance improvement CME. Almost universally, the only grants received have been "one and done" didactic lectures of limited benefit to patients. We do think CGAs need to be based on some very clear principles. •\tLimited to defining the evidence based performance gap where funding is available. Anything beyond this infringes on provider independence with respect to all of the other areas of educational planning. •\tUniversally available to all providers. The prior selection of which providers will receive these creates its own set of potential bias issues. We would also encourage ACCME consideration of endorsing acceptable independent review standards for CGA responses. The CGA mechanism modeled after NIH type RFP's is an efficient vehicle to more clearly communicate the availability of resources and encourage performance improvement approaches. The only criticism we have heard of this practice has been the perception that the recipients may be pre-determined. That could be handled by requiring that CGAs are sent out broadly. We would like to address that by transparently posting all responses in the future, but the provider community has not been universally supportive of that to date. Short of a future independent review mechanism, ACCME might consider this transparent disclosure a mandatory requirement for any provider responding to an RFP or CGA. Under separate cover, we are sending examples of two Calls for Grant Applications along with all responses received.. One is for the area of smoking cessation and the other is for improving patient adherence to treatment plans. We hope you find them useful in your review. Issue 3: The ACCME Believes that Due Consideration be Given to the Elimination of Commercial Support of Continuing Medical Education Activities The ACCME proposes that if the following conditions were all met, then the commercial support of individual activities would be in the public interest and could continue to be allowed. 1)\t 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)\t 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)\t 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)\t When the CME is verified as free of commercial bias. Alternatively, these conditions could provide a basis for a mechanism to distribute commercial support derived from industry donated, pooled funds. General Statement: Fundamentally, we believe that using commercial support as a resource to improve performance around professional practice gaps, is clearly in the public's interest and we have enthusiastically aligned our processes and procedures behind those standards. This transformational approach to viewing industry support in the context of performance improvement initiatives holds great promise to more effectively manage current issues related to commercial support. We do not believe that either the status quo or the complete elimination of industry support is in the best interests of patients. If; however, the profession determines that commercial support does not contribute to patient care, then industry should respond with reallocating these funds to other areas as rapidly as possible. Response to Specific Conditions: Condition 1: We do not feel that needs assessments need to be free of commercial support. The issue is management of conflict of interest. There are limitations to an approach where all educational needs are identified and verified by organizations that do not receive commercial support and are free of financial relationships with industry. Needs assessments conducted by NGOs rarely address the multiple levels of data needed by the CME community in order to devise strategies for planned change. Most do little to address domains of learning that include the various attributes contributing to the learner's motivation. Often, NGO type needs assessments may be based only on an epidemiologic view. They can also contribute to the lag in translating new evidence based research into practice if not conducted on a very timely basis. To this end, we feel that one of the more important contributions commercial support can make is to provide funding for needs assessments that are more tailored to the needs of the professional CME community. These kinds of assessments must span the horizon

from traditional epidemiological data to barriers and facilitators of care. They need to take into account the availability of public domain resources that may be of help to CME planners. Realistically any nationally based needs assessment must be viewed as but one cell in a complex matrix of assessments that includes regional and local inquiries that align to form a framework for educational intervention design. A typical example of this may be statewide quality improvement initiatives where commercial support is sought. We are attaching a Call For Grant applications in the area of adherence along with the responses we received to illustrate one such approach. We do believe that better mechanisms need to be found to avail the CME community of this type of support in order to avoid both real and perceived risks of bias. One option might be to include an external independent review board; another is to solicit an existing organization like SACME to take on this role. To that end, we would enthusiastically endorse any approach that could set up an independent review mechanism for aligning commercial support resources with the development of needs assessments. A foundational principle to industry support of needs assessment work is that the same standards applied to clinical research should apply here. For example, it should be mandated "a priori" that any needs assessments funded in this manner are to be part of the public domain. Anything less is unacceptable and represents a clear risk to introduce bias into the provision of needs assessment data. Condition 2: Completely concur with number 2 where those measures exist. In areas where they do not exist, the principle remains the same that commercial support should be restricted to areas that can improve professional competence. Condition 3: We agree that CME content is ideally established from a continuing education curriculum established by a bona fide organization. The major potential gap in the above approach relates to the clarity of defining what level of curriculum is being referred to. If the level is defined too low in the structural hierarchy, then delays in incorporating new science into formal curricula could result. As long the level of detail being referred to in the curricula relates to objectives found higher in the hierarchy that define professional practice gaps, then this approach would not erect barriers to translating new science into practice. If however, the understanding was that the curriculum was explicit in all of its content without regard to the latest evidence, then the subsequent delays of incorporating new science into education would not be in the public interest. We also take a broader view of the CME content development process. We believe the content element goes well beyond the construct of a curriculum. We envision that content development takes into account all the elements referred to in the competencies of the ACGME for instance. In addition, practice will be influenced by external expectations of governmental bodies and others considered stakeholders in the quality of healthcare. In our view of this element great care should be taken to be inclusive of both multiple stakeholders and multiple sources of information so that the most robust and dynamic product emerges. . . Condition 4: It is important that all CME is managed for conflict of interest. If supplemental mechanisms can be developed like the ones proposed, it would have the additional benefit of streamlining grant review, where monitoring for COI has been a necessary and major focus. The elements that need to be incorporated into such a mechanism need to move beyond the process -driven current system: one in which the activity files may be entirely in order-- yet the risk for real bias existed within the actual framework of planning. From a commercial supporter perspective, we have experienced what we considered bias from providers whose paperwork was apparently exemplary. Therefore, an important element of any new system that may emerge is to ensure that commercial support does not go to organizations that have a CME structure that potentially puts financial considerations ahead of public health concerns. Additional issues: In addition to the issues outlined by ACCME, balanced funding is an important principle for the profession and the public. We believe that balanced funding is a strong surrogate for proposals to pool funds. Further we assert that additional mechanisms are needed to ensure appropriate utilization of commercial support both at the organizational and activity level. It is our view that support from any one commercial entity should not exceed 50% for a major activity (non-RSS) and that any organization that relies on too high a percentage of commercial support for its overall activities should also not be eligible to receive this support. In addition, we believe that commercial support should increasingly be understood as inappropriate for supporting non-educational expenses that are not directly beneficial to learning. Today, no standards exist upon which we can develop informed policies for balanced funding requirements. August 2008 Additional Request for Comments Should those who write promotional materials be excluded from having any role in writing CME content? Yes. We currently expect firewall provisions to include this separation, but it is hard to evaluate and monitor from a commercial supporter perspective. Should those who teach in promotional activities be excluded from teaching in independent CME activities? Our definition of promotional activities is all of those where faculty involvement is governed under FDA regulatory requirements and therefore directly controlled by commercial interests. We believe this is a discussion where views will continue to evolve over time on the basis of additional experience and discussion, and that ultimately it is a question for the medical profession to decide. We do feel that the confusion between independent continuing medical education and FDA regulated promotional programs has been a large contributor to the continuing confusion and subsequent criticism of industry's role in support of CME. We offer the following three suggestions that if implemented soon would largely ameliorate the concerns being addressed while the larger debate around this issue continues within the medical profession: 1)\tMinimally, strengthen disclosure requirements by requiring more specificity with respect to participation in promotional programs. While current disclosure requirements help

the learner understand the general nature of potential conflicts of interest, they do not currently illuminate the issue of greatest concern relative to ensuring that the learner realizes the faculty may have given a promotional talk on a related topic within the same trip as the current activity is occurring. More specific disclosure of these elements would add clarity to the confusion between education and promotion and more fully inform the learner of potential bias issues. 2)\t Institute a mandatory separation in time and place between promotional programs and independent activity involvement. The most frequent example of a practice we would encourage ending occurs where a promotional speaker gives the same content area talk in the context of independent education within the same geographic area on the same trip. Even when commercial supporters have policies prohibiting this, faculty continue to occasionally encourage it through their own direct contact with providers. Many providers find this acceptable because they save on travel expenses. We think it contributes to the confusion between independent education and promotion. 3)\tRecognize educational efforts as exemplary conflict of interest management practices for elements related to this standard. Continuing professional development efforts for faculty who participate in both independent education and company sponsored speaker's bureaus in order to insure they demonstrate a competent understanding of the difference offer enormous potential to manage this issue more effectively. For example, the effort that will be launched by the [redacted] CME later in 2008 to address this gap in CME practice may serve as a useful mechanism for providers to manage this potential conflict of interest. Finally, we would like to express our appreciation for your proactively encouraging responses from all stakeholders to include commercial supporters. Respectfully, [redacted]	
1) Accredited providers must not receive communications from commercial interests announcing or prescribing any specific content that would be a preferred, or sought-after, topic for commercially supported CME (eg, therapeutic area, product-line, patho-physiology) – as such communication would be considered 'direct guidance on the content of the activity' and would result in Non Compliance with Standard 1 of the ACCME Standards for Commercial Supportsm [redacted] takes pride in supporting independent medical education that provides timely, accurate, fair and balanced education to healthcare professionals so that patient outcomes can be improved. While we understand the goal of limiting communication between commercial interests and accredited providers, we have found the unsolicited educational grant requests received do not always meet the educational needs identified by the [redacted] There are internal requirements, such as government required risk management programs, for example, that need to be met. Communicating those topics and even broad therapeutic areas of interest helps to fill those gaps. Providing a framework for Providers to work within is similar to the ACCME's Essential Areas and Elements. While the ACCME provides the Essential Areas and Elements, ACCME does not tell the Providers how they must be implemented. Allowing Grantors the opportunity to occasionally, generically, and publicly communicate areas of educational need through a request for funding does not translate into having control over the educational content. Providers are keenly interested in maintaining their accredited status and Grantors are equally interested in supporting compliant independent medical education. [redacted] encourages ACCME to consider this point of view. 2) Receiving communications from commercial interests regarding a commercial interest's internal criteria for providing commercial support would also be considered the receipt of 'guidance, either nuanced or direct, on the content of the activity or on who should deliver that content.' Educational grant requests are essentially developed in a similar fashion regardless of the Provider. They each contain the expected information: who, what, where, when, how, how much, and why. Providing online submission portals, with accompanying templates, does not mean that internal criteria are shared. It is merely a mechanism used to standardize the volume of educational grant requests. This standardization allows the individual grant committees to evaluate the merits of each educational grant request in an efficient manner. [redacted] makes the following information available to Providers: •\tInternal compliance guidelines •\tTherapeutic areas of interest •\tGeneral budget information •\tTiming associated with educational grant request review It is the [redacted]' view that none of the aforementioned criteria is intended to be 'guidance, either nuanced or direct, on the content of the activity or on who should deliver that content.' This general information is shared in the spirit of efficiency and transparency for both parties. 3) 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, [redacted] recommends that the ACCME consider establishing guidances or rules aimed at ensuring that these people 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

On behalf of The [redacted] we appreciate the opportunity to provide the following comments: Point 1: "Accredited providers must not receive communications from commercial interests announcing or prescribing any specific content that would be preferred..." Comment: The proposed regulation is addressing an important concern with Requests for Proposals (RFP). Commercial supporters can bias educational grant proposals and subsequent activities via excessive direction in an RFP or subsequent Requests for More Information (RMIs). However, it should be noted that the proposed regulation may drive RFPs away from accredited providers and into the hands of unaccredited providers. This proposed change will necessitate a role for non-accredited providers as middle men between commercial supporters and accredited providers. The industry will suffer as non-accredited and therefore unregulated providers will be inextricably relied upon to respond to commercial supporters and thus be placed in a position to influence content. Additionally, the current RFP process allows accredited providers to quickly determine if their identified needs are in line with the focus of a potential commercial supporter. This allows time to be spent on developing quality education activity proposals that will receive due consideration and minimizes the time spent by providers developing proposals that will not be considered because they are outside of the focus area. [redacted] oppose the proposed restriction on the receipt of RFPs from commercial supporters. Point 2: "Receiving communications from commercial interests regarding a commercial interest's internal criteria for providing commercial support..." Comment: Simple procedural information is crucial in assuring timely consideration of complete grant submissions. Developing and submitting quality educational activity proposals require significant time and effort. Understanding the criteria that will be used to evaluate a proposal allows effort to be spent providing the components required for consideration. If accredited providers are not able to receive this information, then non-accredited providers will be at a competitive advantage in the grant process. This proposed change will help to ensure a niche for non-accredited providers as middle men between commercial supporters and accredited providers. What benefit will there be for the CME industry if non-accredited, unregulated providers are inextricably relied upon to respond to commercial interests and thus be placed in a position to influence content? [redacted] oppose the proposed restriction on communication of a commercial interest's internal criteria for providing commercial support.	Accredited CME provider
Page 4 for Comment •\[redacted] strongly disagrees with this position. It is impossible for any provider to prevent anyone from receiving news releases, postcards, emails and other forms of communications from commercial interests. Receiving unsolicited communications from commercial interests must be excluded. It is unreasonable to expect providers have control of what is received. •\tCME programs could be developed or in development long before commercial interests set their criteria for sponsorship – How does ACCME determine compliance? •\tProviders seek sponsorship from commercial interests that are relevant to the activity being offered – How does a provider prove that communication was not received or that the provider was not developing the program just to meet the criteria set by commercial interests? Why would a commercial interest want to support any educational programs that are not relevant to their services or products? •\tWith such stringent conditions, CME programs will not be eligible for funding from commercial interests. Commercial interests consequently would NOT support any CME activities in fear of scrutiny. For Comment on Page 6 •\[redacted] agrees with scenario #1. Before drastic changes are made to the NEW current criteria set by the ACCME, providers must be given a chance for full implementation and evaluation to determine if change is needed. •\[redacted] STRONGLY DISAGREES with Scenario #2 - to eliminate commercial support of CME would greatly reduce not only the availability of CME programs but their quality as well. o\tACCME must consider the alternatives if key providers drop accreditation and offer only non-CME programs. What will this mean to physicians, patients or the CME community? o\tCost of CME programs will increase dramatically making it difficult for physicians to participate. o\tAlternatives, such as webcasts, are still costly and do not create an environment where there is personal interactions with colleagues, peers and faculty! o\tWithout CME, physicians will not receive the latest information in their field. •\tScenerio #3 – New Paradigm. [redacted] believes this is just a way for ACCME to eliminate commercial funding as providers CANNOT possibly meet all the conditions listed. o\tIt is nearly impossible for providers to meet ALL conditions set by the ACCME as currently stated. There needs to be clarification on all the conditions. o\tCondition #1 is conflicting as Government agencies also receive funding from commercial interests. Will the ACCME list all agencies that are free of financial relationships with industry on their website? o\tCondition #2 – Please define bona fide! Who qualifies as bona fide and who determines the qualifications? o\tCondition #3 – Again, who determines when an organization is bona fide? This is vague and needs to be further defined. o\tCondition #4 – How will CME be verified as free of bias? Is this done by ACCME or other institutions? Please clarify.	Accredited CME provider

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: [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 [redacted] and its education members have long noted the public policy and public health importance of the ACCME. [redacted] 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	Other

for Drug Evaluation and Research;4 (3) state medical licensing boards recognize ACCME decisions in meeting annual educational requirements to retain medical licenses; and (4) two officials of the federal government serve of the 18-member board of the ACCME.5 Even in the unlikely event that a court would decide that the ACCME is a private organization to which the substantive due process provisions of the U.S. and state constitutions do not directly apply, the [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 [redacted], 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 Coalition firmly believes that proposals to end half the funding of certified CME without offering plausible substitutes for that funding have no place in a serious public policy discussion on how to improve patient care. While some believe that government programs can replace commercial support, this is not realistic. Consider, for example, the current debate in Congress around adequate funding for FDA, clearly a critical priority. While most agree that the FDA has a current budget shortfall of at least a billion dollars a year, in 2008 Congress could only find one fourth of that for fiscal year 2009 and has not developed a consensus plan for fully funding this shortfall in subsequent years. If adequate funds cannot be found for a billion dollar shortfall at FDA, it is clearly unrealistic to expect that a similar amount could be found to substitute for commercial support for CME. Even if adequate government funding were available, it may not be optimal. Government funded CME often introduces a dangerous bias in favor of adoption of the immediately-least-expensive therapeutic or diagnostic practice. This bias is not always consistent with either the long term best interest of patients or even the government. Similarly, it is unrealistic to expect physicians, facing increasing financial pressure on their income from reduced Medicare fees and lower managed care reimbursement, to pay for their own CME. With 663,900 physicians in practice in the United States, the absence of commercial support would create a shortfall of $1,807 per year for each physician. Today it is clear to objective observers that clinicians participate in commercially funded activities to learn about new and better ways to diagnose and manage disease, and then return to their practices better prepared to treat their patients. While these activities are supported by industry, patients are the primary beneficiaries. At the same time, commercial supporters and providers have been leaders in studies and research on the value of CME to patient care in America. The [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 Coalition applauds ACCME's effort to present a new paradigm for the commercial funding of CME, it sees several issues with the recommendations. For example, point number three recommends CME content from curriculum specified by "bona fide organizations." Unfortunately, this approach will inhibit the delivery of cutting edge education addressing the latest

developments in medicine. In many instances, innovative education leads rather than follows these organizations in the development of new curricula and clinical guidelines. This is even more pronounced for government guidelines, which often are subject to several additional layers of review and regulatory process before adoption. Limiting CME programs to practice gaps “corroborated by bona fide performance measurements (e.g., National Quality Forum)” could well negate the value of the ACCME recognized advances in the current “needs assessment” processes. To only subject commercially funded CME to this criterion would, superficially, seem like a reasonable approach, but in practice would only delay and inhibit the transfer of knowledge about new treatments and breakthroughs. The CME community recognizes that conflict of interest is a legitimate concern for all in medical education. However, the elimination of commercial funding -- to address the issue of bias -- in the absence of collaborating evidence supporting such a move, is counterproductive. In fact, such a decision would cause a massive reduction in the amount of 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 [redacted] with [redacted]. The most important element of that agreement is the [redacted] agreement to comply with the ACCME standards of commercial support in its CME grant making process, and the additional promise by [redacted] to require employees and contractors to fully disclose that relationship in all educational programs, promotional and certified. It further binds [redacted] 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, n

On behalf of the [redacted]—a not-for-profit organization of 11,000 physicians and scientists dedicated to helping [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 limit the interactions between accredited providers and commercial interests over commercial support (Proposal 1). [redacted] appreciates ACCME's dedication to ensuring that continuing medical education (CME) remains free of conflict and influence; the Society generally supports the changes articulated under Proposal 1. The core of the proposed changes are alterations that [redacted] has already made to its committees responsible for creating content for the Society's educational programs, including [redacted]. For example, [redacted] has separated the role of developing educational material from the role of marketing and soliciting funding for the Society's educational programs and products. The clear distinction between the two tasks protects programmatic development from commercial bias. [redacted] has independently made these changes for the same reasons ACCME supports limited communication—to ensure that "processes of attaining commercial support will not undermine the independence of CME." While [redacted] is not opposed to the new restrictions that limit communication between accredited providers and commercial interests, the Society encourages ACCME to make every effort to ensure transparency. Societies like [redacted] are dedicated to managing conflicts of interest. However, given the current interactions between commercial interests and academic societies in the pursuit of providing high-quality CME, both sides need to clearly understand 1) how to appropriately solicit funding for educational programs and 2) what can and cannot be communicated between the two groups. In addition, [redacted] questions how the Society should interact with pharmaceutical, biotechnology, and medical device companies that require societies to request funding via a grants submission process. The grants submission process by its nature requires commercial interests to provide communications "regarding a commercial interest's internal criteria for providing commercial support." Again, thank you for the opportunity to comment on ACCME's proposal. To discuss [redacted] comments, please contact [redacted]	Accredited CME provider
Without question, accredited providers must be required to develop and conduct their activities independent of commercial supporters. Without that independence, the CME industry risks its role as a driving force to the quality improvement of the overall US healthcare system, relegating itself simply to being an extension of the marketing efforts of the pharmaceutical and device manufacturing industries. Public trust of the overall healthcare system is also jeopardized in the process. Of course, the issue of independence arises from the fact that commercial interests are allowed to provide financial support to continuing medical education in the first place (the merits of which are the subject of a separate call for comment and are not discussed here). Given that construct, however, steps the parties take to ensure independence of CME from commercial influence varies, but practically all stakeholders have increased their levels of transparent communications to help demonstrate the legitimacy of the commercial support offered and received. Commercial interests, for one, have a valid interest in knowing exactly what their financial backing supports; they are under greater scrutiny than accredited providers and bear an even greater burden from government regulators to ensure that the financial support they offer to the CME community is not conditioned on satisfying certain internal metrics or tied to their marketing efforts. Accredited providers also desire to engage in increased and transparent communications with commercial supporters to demonstrate that their activities are, in fact, independent of the commercial interests from whom they receive support, which also helps them to ensure they are in compliance with the overall restrictions placed on the commercial support of CME. Currently, the ACCME delineates the decisions that accredited providers must ensure are made free of the control of a commercial interest. The manner in which providers demonstrate compliance with this standard varies, and improved means of demonstrating compliance in this area might be explored. Generally limiting communications between accredited providers and commercial supporters, however, seems to make the overall environment less transparent, which worsens the appearance of impropriety and further erodes public trust in the system. It would make more sense if things instead were made more transparent through public disclosure of available grants, including amounts available for which therapeutic areas and the criteria to be used to assess the grant applications, similar to the process employed for the awarding of government grants. This would allow all involved, including the public at large, to judge the propriety of grants awarded to the various CME programs in the marketplace. Here, the ACCME suggests that no communications occur between accredited providers and commercial supporters regarding the topics to be supported or the internal criteria used to evaluate a grant request. Such a requirement would have little, if any, effect on the actual independence of the activities from the influence of commercial interests. Further, eliminating communications between the two parties involved does not itself prove or rebut the independence of the content of an activity, and accredited providers would still be required to demonstrate that decisions regarding their activities were made independent of the commercial interest. Eliminating these communications could, in fact, make that more difficult. Instead, greater and more transparent communications between all parties seems to be the right approach. Practically speaking, given the elimination of communications regarding topics of interest and internal award criteria, accredited providers would face greater burdens to seeking support of its activities from a commercial interest. To obtain a grant from a commercial supporter, accredited	Accredited CME provider

providers would be relegated to submitting applications to multiple commercial supporters in hopes that one of them might be interested in supporting the CME activity at hand. Alternatively, an accredited provider, before submitting multiple blind applications, and in an attempt to manage their time more effectively, might be forced to research the products and services of the various commercial supporters to determine indirectly which entity might be interested in supporting the topic at hand. All of this would contribute to an even greater appearance of impropriety and public mistrust of the system at large, particularly for those accredited providers actually receiving a grant of commercial support, given the lack of publically-available means to assess the criteria used to award a grant. More specific concerns with the suggested policies exist as well. What constitutes a "communication," what is considered "specific content," and what is considered "internal criteria?" The prescription of specific patho-physiology by a commercial interest would seem, on its face, to violate the independence standard as it currently exists. Topics themselves, however, do not seem to fall within the realm of specific content for that topic, and as mentioned before, product-lines can be mined through publically-available resources and increased amounts of research. Regarding topic identification and product-lines, the real problem seems to be with providers who do not meet the educational planning criteria the ACCME has fashioned (the identification of knowledge and performance gaps, the development of needs assessment, and the construction of educational interventions designed to improve those gaps in hopes of improving patient care) as a precondition to seeking commercial support. If internal criteria cannot be communicated, presumably, that would limit if not altogether eliminate the information a commercial supporter could even ask in a grant application, including specific financial budgets and information demonstrating the things on which the commercial support will actually be spent. This alone could cause wasteful financial practices among accredited providers, causing less dollars to be available to support greater amounts of education. In addition, if left to not being able to even request information from the accredited provider about the activity to be supported, a commercial supporter would have no basis for determination of which programs to support, forcing them to rely solely on external information about an accredited provider, such as the provider's level of accreditation through the ACCME, in order to make a grant determination. If commercial supporters are forced to rely solely on the accreditation level awarded by the ACCME to an accredited provider, the ACCME would bear an even greater burden and would be subject to increased scrutiny regarding its accreditation decisions, not only from accredited providers but also from the public at large, government entities and officials, and the overall healthcare community. At that point, the ACCME must ensure fair and equitable determination of accreditation levels for all providers, likely requiring a more balanced representation of provider types on the ACCME's board of directors and in its surveyor ranks, and further requiring independent audits of their decisions regarding accreditation levels awarded to its accredited providers. Instead, the ACCME should explore ways it can make the process even more transparent to the public at large, including government regulators and other watchdog groups. Possible solutions might include independent third-party public websites housing all available grants, including amounts, topics and criteria, and independent third-party audits to assess whether proposals that were granted support met the publically-disclosed criteria. Other solutions might include the accreditation of specific activities instead of entities and their processes, so that outside third-parties have the ability to control what CME activities actually make it out into the marketplace.	
Commercial support and relationships with commercial interests benefit the CME process if handled appropriately. We believe that an accredited provider can maintain its compliance with SCS 1: Independence while still receiving limited communications from commercial interests on non-content related areas, such as therapeutic area of interest, grant cycles and criteria for approval of grant support. Communications should be transparent and made through public announcements, similar to the process for government grants. Knowledge of available grants and grant cycles will allow accredited providers to use their resources wisely and only submit grant proposals to companies and organizations that are able to support an activity. Accredited providers must focus their often scarce resources on developing quality CME based on needs assessments and on seeking funding support only from appropriate sources	Accredited CME provider
The [redacted] is a 501 (c)(3) non-profit society of medical professionals. [redacted] was established in [redacted] with a mission to facilitate the exchange and promotion of scientific information about the use of [redacted]. [redacted] has a balance of members from academia, government, industry who represent clinical and basic scientists, all interested in taking the new biotherapies from the bench to the bedside. The goals of [redacted] are directed towards the rapid dissemination of information in these areas to expedite the safe transfer of both basic and applied research to the clinical setting. [redacted] To improve cancer patient outcomes by advancing the science, development and application of [redacted] [redacted] Interaction/Integration - exchange of information and education among basic and translational researchers, clinicians, and young investigators; societies and groups sharing the vision and core values of [redacted] Innovation - challenge the thinking and seek the best research in the development of [redacted] – promote the application and understanding of [redacted] - define what is	Non-accredited CME provider

new and important and effectively communicate it to all relevant stakeholders The Definition of Commercial Interest: The [redacted] respectfully requests that the ACCME place a call for comment to reconsider its definition of commercial interest to exclude those individuals who are scientific medical professionals working in industry, critical to the transfer of scientific information. We completely agree with prohibiting the promotion of products at accredited CME programs and activities and would never support marketing personnel presenting at accredited programs. But industry based PhDs, MD, or MD/PhDs advancing science and are publishing peer reviewed research. Preventing these physicians and scientists from presenting their work will leave significant gaps in learner's knowledge-base. According to 2007 statistics, 47% ($58.8 billion) of total medical research conducted in the United States took place in an industry setting. Patient outcomes would be negatively affected if the research conducted within industry (pharmaceutical and biotech) settings was not allowed to be shared in a scientific setting to allow for translation into the clinical setting. It is important to bring basic, translational and clinical practitioners from all venues into a learning environment in order to translate research to medicine, and medicine to patients and providing accredited CME is an enhancement mechanism used to achieve that objective. At this time there are few approved and marketed cancer biological therapy drugs. These agents are in the development stages and in clinical trials. That being said, it does not negate the need to bring all investigators together to share their research both positive and negative into one forum for exchange. Once a drug is approved it will be equally critical for the scientist that developed these agents to be allowed to present their findings in a scientific setting to their peers and for that scientific exchange to continue. To remove the CME component would create a situation where the translation from bench to bedside might be jeopardized. In [redacted] was founded on the tenets that through their joint research, development and collaboration, academia, government and industry scientists would find a cure for [redacted] using biologics (the bodies own immune system). These are the same guiding principles that led to the enactment of the 1980 Bayh-Dole Act that encourages academics, government and industry to partner to advance science from bench to bedside. [redacted] and we believe the field of medicine, is committed to the belief that these people are scientist first regardless who employees them. The consequences of the ACCME's new definition of commercial interest can and will be devastating to the advancement of finding a cure for cancer using biologics as well as all medical advances. [redacted] is one of many basic science/translational medicine organizations who feel the change in terminology and ideology is necessary and we plead with the ACCME to put a call for comment on the definition of commercial interest. RESPONSE: Point #1 and 2: As a joint sponsor, [redacted] agrees that it is necessary for accredited providers to maintain independence when developing accredited CME activities. We find the best way to achieve these results is to establish firewalls to increase transparency and reduce undue influence and bias. In our experience many grantors have responded appropriately by investing significant resources in the development of comprehensive websites for online grant submission and review processes. We commend those who have built firewalls between accredited CME grants and promotional support. We also commend the ACCME for its efforts to ensure transparency and reduce bias. The new PhRMA Guidelines should also strengthen efforts. As an extension of the websites, and to address the ACCME's concern regarding direct communication, we would suggest that industry post on their websites any RFPs that they are seeking. This process would allow for an open and fair process for all relevant educational partners to submit proposals to intervene and potentially partner on an educational intervention. It is not uncommon in the philanthropic community for grantors to identify their key areas of interest, types of organizations that they support, average amount of grants, deadlines, submission guidelines, etc. There is nothing unethical or inappropriate about this national directory. Verbal communication is also a common practice. This is just a wise use of very valuable and limited resources for all parties involved. We acknowledge that there are differing objectives involved, but we also believe that the entire CME enterprise should not be punished for the actions of a small percentage. This can and must be done in a manner to avoid undue influence and maintain the integrity of the proposed activity. Our leadership is confident that these discussions and or inquires can be made without undue influence or future CME program development bias. The Board of Directors of [redacted] takes its role in providing quality, unbiased continuing medical education seriously. Therefore, [redacted] has established its own set of policies and procedures for dealing with conflict of interest and conflict resolution that are in accordance with the ACCME Standards. We also believe very strongly in the integrity of our organizers and speakers and trust the feedback from our attendees to identify any potential or perceived bias. If bias is reported Society leadership has management processes in place to deal with those individuals.	

The [redacted], as a non-accredited joint sponsor of CME in compliance with the ACCME's Standards for Commercial SupportSM, fully supports independent medical education that is free of commercial bias in topic selection, planning decisions, and presentation content (ACCME Call for Comments, June 2008). [redacted] recognizes the importance of independent medical education that is objective, fair-balanced, scientifically accurate and rigorous, and not subject to a commercial supporter's influence or control[redacted] does not support a blanket position that providers must not receive any communications from commercial interests announcing or prescribing any specific content that would be a preferred or sought-after topic for commercially supported CME. Over the past year, [redacted] has substantially changed our approach to receiving funding for our educational initiatives. We independently assess the educational needs of the professionals we serve via investigator advisory boards and expert opinions, surveys of our target audience, and knowledge level of our audience based on audience response system data. Approximately 95% of the grants we submit are spontaneous and are not a response to a request for proposals. Additionally, over the past year, most of our grants have been submitted with the request for multi-company support, typically from between four to six pharmaceutical companies. The process for multi-company support is laborious and challenging because of the unknowns associated with how much funding, if any, is available for the therapeutic topic and target audience. It is a rarity for [redacted] to receive multi-company support as we intend in the initial grant. Specifically, one company may give no or partial support and another company give 100% of the amount requested, which results in partial funding of a program. With partial funding, the scope of the project and the associated offerings must inherently change. These changes must be re-submitted to and re-reviewed by the company providing partial support. Quality programs are sacrificed and delayed when providers have to waste time and energy going after unavailable funds. If funding opportunities by therapeutic category and target audience are communicated, providers and joint sponsors can budget grants more realistically and grant funding could be awarded more efficiently. However, [redacted] believes that the extent of what is communicated should be limited. A qualified CME provider does not need a pharmaceutical supporter to provide a detailed needs assessment. We believe a provider's needs assessment should help a pharmaceutical company's grant review committee determine the quality of the program for which funding is requested. In summary, [redacted] believes it would be appropriate and beneficial for supporters to have the opportunity to communicate to providers and joint sponsors funding capabilities for specific therapeutic areas and target audiences. We have yet to understand how such information jeopardizes the integrity of CME programs and the ACCME process.	Non-accredited CME provider
Call for Comment 1: The ACCME will ensure current processes of attaining commercial support will not undermine the independence of continuing medical education. 1.\tAccredited providers must not receive communications from commercial interests announcing or prescribing any specific content that would be a preferred, or sought-after, topic for commercially supported CME (eg, therapeutic area, product-line, patho-physiology) as such communication would be considered 'direct guidance on the content of the activity' and would result in Non Compliance with Standard 1 of the ACCME Standards for Commercial Support. 2.\tReceiving communications from commercial interests regarding a commercial interest's internal criteria for providing commercial support would be considered the receipt of "guidance, either nuanced or direct, on the content of the activity or on who should deliver that content.' [redacted]'s comments: The [redacted] is committed to ensuring that all CME activities that are certified for AMA PRA Category 1 Credit™ are planned and implemented independent of commercial interests at all stages. The Council does not believe that commercial entities should have any influence over the content of certified CME activities, as stated in our relevant [redacted] opinions. However, it is unclear what value the proposed policies add to the current process. The Council is unsure what ACCME means by "internal criteria." The grant application process for accredited CME providers to solicit funds from commercial entities should be a transparent one. The fact that a commercial interest lets providers, or the public in general, know what general areas it is willing to support and the process it uses in awarding grants does not necessarily interject commercial bias. In a time of fewer resources for accredited CME providers it is important they don't spend time applying for grants for which they would not qualify. Accredited CME providers have no control over how commercial entities disseminate their policies and procedures in legitimate ways for legitimate purposes. It also appears that these policies as currently written would be difficult to assess and monitor.	Accredited CME provider
[redacted] supports ACCME's efforts to prevent the introduction of commercial bias in CME activities, and agrees that interactions between providers and commercial interests regarding commercial support should be minimal. However, we strongly encourage ACCME not to prohibit providers from obtaining information from commercial interests regarding general subject matter and venues in which the commercial interest may consider funding CME activities. Such a prohibitive policy would again make the process for providers to obtain commercial support very difficult. We encourage a more reasonable approach involving general guidance to providers on what type of interactions between provider and commercial supporters are appropriate.	Accredited CME provider

Issue 1: Limiting the Interactions Between Accredited Providers and Commercial Interests Over Commercial Support "The ACCME takes the position that communication with commercial supporters should be strictly limited in order for providers to comply with independence as outlined in the Standards for Commercial Support." Below is [redacted] response to the ACCME position. Ø\ [redacted] feels it is our responsibility to comment on the ACCME position. Last year alone, [redacted] educated over [redacted] visits. In 2009, we anticipate similar if not greater participation in our educational activities and similar if not greater impact on patient care. 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. We are able to consistently demonstrate how we listen and respond to the needs of health care professionals to deliver education whenever, however, and on whatever topics will make for the best learning experience. Sharing these insights, barriers, and challenges with commercial supporters on topics of mutual clinical interest is critical to our ensuring that validated identified clinical care gaps and corresponding clinician educational needs of primary care physicians, cardiologists, pharmacists, oncologists, orthopedics, and allied health professionals are being met. Interactions with commercial interests over commercial support allows for this while not compromising or negatively impacting the independence requirements to which providers are obligated. Regarding demonstrable and measurable clinical gaps and educational needs, it is the accredited provider's responsibility to ensure that the communications are held only in that context. o\tAs a provider who already has highly structured communications with commercial interests, we agree that independence is a fundamental and pivotal responsibility of all providers regardless of whether there is commercial support or not. Commercial support makes the ability to adhere to and demonstrate compliance with the independence criteria that much more critical. It is essential that this independence be supported, enabled, and maintained. However, we do not support the ACCME position detailed in the "Call for Comments." o\ [redacted] feels that the outcome of this position would result in an environment whereby communication between commercial interest and providers would be so limited by rule and regulation that it would result in no communication around validated educational gaps and needs. We do not agree that by definition 'independence' and 'communication' are mutually exclusive. Appropriately managed communications between different stakeholders in the CME process is essential in order to achieve the goals, responsibilities, and deliverables of CME endeavors, particularly in identifying knowledge gaps among physician learners. Of course, commercial providers should not be allowed to influence the content of CME—including choice of topic, learning objectives, faculty selection, and educational design and outcomes. This goal can be effectively achieved by creating reasonable firewalls with CME provider organizations where the staff involved in content development is kept strictly independent from the staff that communicates with commercial supporters. The updated accreditation requirements, Standards for Commercial Support, and the current regulatory environment affecting all stakeholders in the CME enterprise, including the Senate and House inquiries and Department of Justice investigations, have resulted in the self-correction of the appropriateness of provider-industry communications. Even if commercial support of CME is eliminated, it is naive to think that there will never be any communication between providers of CME and commercial entities. The integrity of CME can best be maintained by achieving as much transparency as possible in these communications. o\tThe [redacted] position is also grounded in the belief that over the past year the ACCME has put forth rules and regulations that address independence. The Updated Accreditation Criteria put the onus of ensuring independence on each accredited provider who accepts commercial support for any of their specific activities. Let accredited providers be empowered to fulfill their responsibilities without the ACCME continuing to put forth 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 for the ACCME to consider "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 potentially 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. Ø\tWe do believe that ACCME can help design a 'safe harbor" of communication between accredited providers and commercial interests. Based on the above data and experiences, [redacted] submits that it is appropriate for both accredited providers and supporters to have a 'safe harbor' of communication around mutual interests that are transparently held; this 'safe harbor' would respect the need for appropriate communications that would enhance provider efficiency in securing education support and would be based in credible and clearly articulated informational exchanges regarding demonstrable and measurable clinical gaps and educational needs. It is the accredited provider's responsibility to ensure that the communications are held only in that context. o To that end, an ACCME-defined "request for proposal" (RFP) model would help define the level of communication that would then allow both accredited providers and supporters to engage in appropriate communications. o A model RFP would include: 8 Scope of topic support that maps to the medical mission of that supporter and not a promotional interest 8 Attestation to the effect that the cost of care will not be inappropriately driven up 8 Consensus document that validates the need in this area 8 ACCME would allow	Accredited CME provider

communication between provider and supporter over defined educational issues surrounding the Criteria for Accreditation 8 ACCME Web site becomes the locus and clearinghouse for approved and qualified sanctioned communications concerning grant availability 8 Clarification that by communicating a RFP, it does not mean 'receipt of guidance'; that's over-interpreting the situation; we believe it is merely a way of limiting requests for grants to areas of general interest by that company 8 Posting of RFPs to ACCME's Web site can serve as a clearinghouse for RFPs and allow for maximum access and exposure to all providers 8 ACCME's Web site could include the use of a self-assessment point system that will assist providers in identifying and documenting the needs of their learner community, and proactive mapping to identifiable clinical practice gaps and needs that can be supported with funds from commercial supporter(s) reflected in any individual RFP. This can enhance provider efficiency and effectiveness in determining when, if, and how to seek commercial support for any of their educational offerings. For the ACCME, it would offer an RFP monitoring mechanism. [redacted] is available to work with ACCME and other providers on the development of a model RFP.	
September 12, 2008 Murray Kopelow, MD, MS, FRCPC Chief Executive Accreditation Council for Continuing Medical Education 515 N. State Street, Suite 1801 Chicago, IL 60654 Re: ACCME Policy Announcements and Calls-for-Comment Dear Dr. Kopelow: On behalf of [redacted] and its member companies, I wish to thank you for the opportunity to provide comments on the ACCME Policy Announcements and Calls for Comment. [redacted] is [redacted] association representing more than [redacted] is dedicated to the advancement of medical science, the improvement of patient care, and in particular to the contribution that high quality, cost-effective health care technology can make toward achieving those goals. Interaction between industry and health care clinicians is uniquely necessary in the field of medical devices. A close and ongoing collaborative relationship among health care professionals and medical device companies is necessary for patient safety (technique refinement/standardization, education, testing/clinical trials, product support) and medical innovation. This distinctive aspect of medical devices arises from the iterative nature of medical device development. Many who are not involved in medical device development are surprised to learn that the average life-cycle for many devices is only 18 months because improvements—frequently based on input from practicing clinicians—are often incorporated into the next generation of the device shortly after the first generation is launched. The need for such collaboration is recognized by key Food and Drug Administration (FDA) device requirements, by the Health and Human Services Office of Inspector General (OIG)[1], and by [redacted] in its Code of Ethics ("Code")[2]. Clinicians have worked successfully with device companies to create technologies that benefit millions of patients. Clinicians wear many hats - in addition to treating patients, they are inventors of new technologies, advisors to improve existing devices, researchers, trainers of other health care professionals on the appropriate use of advanced medical technology, and trainees themselves by companies developing devices requiring skilled preparation, deployment, and use. The mere presence of multiple interests, however, does not indicate bias in patient care or outcomes. The diffused roles of clinicians cannot help but create dualities of interest, but relationships between clinicians and industry do not necessarily create conflicts. As important as clinician innovation and collaboration is to saving, extending and improving lives, maintaining public trust in the integrity of medical education is an equally high priority for [redacted] and its members. [redacted] strongly believes any inquiry into conflicts of interest in medical research, education and practice must take into account the distinctive nature of devices where interaction and collaboration between industry and clinicians are necessary for product development, training and education, patient safety and advancements in patient care. [redacted] recognized this point when it adopted a revised Code of Ethics that went into effect on January 1, 2004. [redacted] shares the ACCME's goals to improve patient care and address concerns that threaten the integrity of medicine and public confidence. Our members appreciate the ACCME's efforts to the explore concepts with these goals in mind but implore proceeding with caution and an awareness of the risk that an overbroad proscription could have on the proficient use of advanced life saving technologies. We are thankful for the valuable opportunity to offer comments and would be happy to meet the ACCME personally to engage in further dialogue and provide additional information. Thank you so much for your time and consideration. Very truly yours, [redacted] Issues for Consideration Regarding Limiting Interactions between Accredited Providers and Commercial Interest over Commercial Support (Call for Comment 1) The intended scope of the prohibited "communications" (described in the manner of interaction required to maintain compliance with SCS 1: Independence) is ambiguous. [redacted] would be grateful for clarification regarding the impact on the following communications: •\tA Request for Proposal ("RFP") transmitted to an accredited provider describing educational grant availability for a practice area that a medical device company would be willing to fund; •\tA	Other

RFP posted on a medical device company's webpage describing educational grant availability for a practice area that the company would be willing to fund; and •\tA RFP posted on a medical device company's webpage describing research grant availability for a practice area that the company would be willing to fund; Although "receiving communications" suggests the passive acceptance of information, the active acquisition (e.g., an accredited provider finding RFP information intentionally or unintentionally on the company's website) results in the transfer of the same information. If it is the ACCME's intent to prevent the RFP-type of "communication" concerning the practice area that a commercial interest would be willing fund, such a framework would likely substantially increase companies' administrative burdens and costs. Accredited providers submitting grant requests for commercial support may need to shift to a mass transmittal approach. Presumably companies would receive a high volume of grant requests that would require increased human capital resources and potentially additional IT infrastructure. Furthermore, in light of developing and existing disclosure requirements, this may have the unintended effect of creating company responsibility for auditing and reporting the criteria to defend which grants were funded and which were declined. [redacted] has also been working with Senators Charles Grassley (R-IA) and Herb Kohl (D-WI) on S. 2029, the Physician Payment Sunshine Act of 2007, and gave testimony to the Senate Special Committee on Aging on February 27, 2008. This legislation would require medical device and pharmaceutical manufacturers to publicly disclose payments or "transfers of value" made to physicians, with certain exceptions. [redacted] supports appropriate disclosure of relationships between medical device companies and physicians, and we have made several recommendations to improve the legislation to ensure a fair and level playing field for companies, to provide clear, meaningful information to patients, and to preserve the relationships beneficial to patients and continued medical innovation. Though it is laudable that several companies have begun making all grant request dispositions public, the inability to specify an area of interest may overwhelm sponsors, and could negatively impact current initiatives to disclose grant support. Furthermore, the additional costs and risk associated with auditing and reporting may cause some small companies to loose the capacity to provide commercial support for foundations, societies and institutions pursuing grants to provide education in areas where performance or knowledge gaps exist. Public availability of a medical device company's preference for supporting education in a specified practice area does not amount to "control" of the identification of CME needs. Instead, the accredited provider authoring a grant proposal has the independent ability to identify CME needs and request grants accordingly. Moreover, the essential collaborative relationship between medical device companies and clinicians mentioned above, ideally positions companies to receive and aggregate requests concerning the availability of educational tools or programs from "on-the-ground" clinicians. The popularity of clinician requests for educational programming that is not currently available acts as an intrinsic and efficient identifier of CME needs. The popular requests logically convert into new training programs or RFPs for the identified practice area when appropriate. [redacted] affirms a position where industry is afforded the opportunity to continue to post RFPs or descriptions of programs which would likely receive funding and to provide guidance where funding was unlikely. * * * The intended scope of the prohibited "communication" of "internal criteria" is ambiguous. [redacted] would be grateful for clarification regarding elements that would be deemed "internal criteria". * * * Endnotes: [1] Gregory E. Demske, Assistant Inspector General for Legal Affairs, stated in recent testimony: "In the development of new technologies and products, the interaction between device manufacturers and health care professionals can be especially valuable because physicians play an essential role in the development, testing and extensive training involved in producing effective and safe medical devices .... Physicians also provide ideas and feedback, conduct research and clinical trials, and share their knowledge through participation in medical education programs. Device companies can legitimately compensate physicians for their actual time and intellectual contributions to product innovations and training in the appropriate use of devices." Senate Special Committee on Aging Hearing "Examining the Relationship Between the Medical Device Industry and Physicians." February 27, 2008. [2] [redacted]	
[redacted] supports ACCME's efforts to prevent the introduction of commercial bias in CME activities, and agrees that interactions between providers and commercial interests regarding commercial support should be minimal. However, we strongly encourage ACCME not to prohibit providers from obtaining information from commercial interests regarding general subject matter and venues in which the commercial interest may consider funding CME activities. Such a prohibitive policy would again make the process for providers to obtain commercial support very difficult as previously noted. We encourage a more reasonable approach involving general guidance to providers on what type of interactions between provider and commercial supporters are appropriate.	

The ACCME has proposed that the manner of interaction between potential commercial supporters (and their agents), and some accredited providers may need to be altered. The ACCME has proposed (a) that accredited providers must not receive communications from commercial interests announcing or prescribing any specific content that would be a preferred, or sought-after, topic for commercially supported CME (e.g., therapeutic area, product-line, patho-physiology), and (b) that receiving communications from commercial interests regarding a commercial interest's internal criteria for providing commercial support would also be considered the receipt of guidance on the content of the activity or on who should deliver that content. We agree with the ACCME's efforts to assure compliance with Standard I (Independence), that commercial supporters shall not provide direct guidance on the content of an activity. However, we believe that the proposed policy in section (a) above regarding interactions between commercial supporters and accredited providers is too broad in scope. Commercial supporters should not prescribe or announce specific content that would be a preferred topic for commercially supported CME activity, in those instances when the topic is so narrow in scope that it would be the equivalent of a product-line topic. However, we see no reason why a commercial interest should be prohibited from identifying broad therapeutic areas or disease categories that may receive support, and we believe that doing so, within the context of the ACCME Standards, should not pose any risk to the CME content. Similarly, we believe that the requirements of section (b) above are also too broad in scope and are sufficiently addressed by the current provisions of Standard I, which require CME providers to ensure that decisions regarding CME needs, educational objectives and selection and presentation of content be made free of the control of a commercial interest. By prohibiting the communication of any information about how commercial supporters operate their commercial support activities would stifle the ability to communicate basic information about program process that has no influence or guidance on program content. We would recommend that this provision be eliminated or more precisely defined to identify communications that could fairly be considered guidance on the content of an activity..	
My concern rests around the burden that CME planners would have in implementing this ban. My concern is that a speaker for a CME activity with a slide set that has been reviewed still exerts a significant amount of control over the CME presentation through focusing on certain material, emphasis on recommendations, interpretation of the data and answers to questions from the audience. Without a scripted, tightly controlled presentation, this ban would be impossible to implement with any significant meaning and would restrict organizations from using experts in the field that have some relationships to commercial interests. The task for CME planners is to identify and resolve conflicts of interest. We already have strict guidelines and high expectations for CME activities. This results in a balanced and fair discussion of the topic with the audience from a speaker who is often an expert or highly regarded in their field. To put a ban on this level offaculty would harm CME greatly and I fear would result in speakers who are either parroting or presenting other peoples' work or the literature. Our task is to remain diligent about identifying and resolving these conflicts and disclosing these relationships to the audience and then monitoring whether those presentations are objective and free of bias.	