



Accreditation Council for Continuing Medical Education

Responses to Call-for-Comment

"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."

October 2008

ACCME Proposes Additional Features of Independence in Accredited Continuing Medical Education

For Comment

In August 2007, ACCME announced a revised definition for an ACCME-defined commercial interest.

“A ‘commercial interest’ is any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients.”

The ACCME Standards for Commercial SupportSM stipulate that commercial interests cannot control the content of continuing medical education. The people within ACCME-defined commercial interests cannot control the content of continuing medical education. This further defines the independence of continuing medical education.

The ACCME now finds that there are individuals who are directly involved in the promotion of products and services of commercial interests but who are not employees of the commercial interests, e.g., medical writers who create promotional material for FDA-regulated firms or physicians who are paid by commercial interests to deliver promotional content to other physicians. Some of these same writers may be involved in writing or editing the content of accredited CME activities. Some of these same physicians go on to control the content of accredited CME activities on the same subject for which they have been paid to deliver promotional content. Participants in such activities have asked the ACCME if they are, in effect, ACCME- defined commercial interests – and therefore excluded from controlling the content of CME.

The ACCME has considered the following questions,

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

The ACCME notes two recent significant external actions relating to this area of concern.

In May 2008, the Attorney’s General of thirty U.S. states won a judgment against a commercial interest that included the stipulation that a promotional speaker for that commercial interest could not also be a CME speaker, on the same class of drugs discussed in the promotional activity, in a CME activity that received funding from the commercial interest.ⁱ

In July 2008, the Task Force on Industry Funding of Medical Education of the Association of American Medical Colleges issued a report which stated, *“...academic medical centers should make clear that participation by their faculty in industry-sponsored speakers’ bureaus should be strongly discouraged.”*

Persons paid to create, or present, promotional materials on behalf of commercial interests may be considered to be acting on behalf of that commercial interest. Organizations that participate in marketing products have already been deemed to be commercial interests by the ACCME and excluded from controlling the content of accredited continuing medical education.

In order to further define the independence of accredited continuing medical education the ACCME proposes, 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 order to comment, please go to <https://accme.wufoo.com/forms/call-for-comment-3/>

(Comments may be submitted through September 12, 2008.)

Please note that ACCME reserves the right to publish information describing or summarizing comments for others to read. No attribution to any Provider will be made.

ACCME Commentary --

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 SCS 1 of the ACCME Standards for Commercial SupportSM. This would be the case under this policy.

Physicians paid by a commercial interest to do promotional presentations on a product could not teach in accredited continuing medical education on the same product. Anyone creating content for promotional activities would be excluded from creating content on the same product for accredited continuing medical education, for example.

The intent of the policy is to further separate promotion from education and to ensure the independence of accredited CME from commercial interests.

This does not mean that every financial relationship a person has with a commercial interest would implicate this policy. For example, persons conducting research funded by industry would not necessarily be affected by this policy. Reporting on the results of industry funded research would not necessarily be affected by this policy. These persons would only be affected by the proposed policy if they also participated in promotional activities on the same content.

ⁱ Revised 8/7/2008

RESPONSES TO ACCME Call-for-Comment

Subject: 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.

Response received	Organization Type
<p>To start with, I think that the definition of commercial interest needs to be rewritten. A hospital or health care organization could be considered an "entity distributing health care services used on patients". A private physician's office also would fall under the same definition. Of course, these are not considered commercial interests. So what is really a commercial interest? They do what they do for profit, they benefit from the sale of their products, among other things. The definition is not clear, and needs to be improved.</p>	Accredited CME provider
<p>I agree. Currently we request the presentation in advance. It is difficult to find a speaker who isn't paid by a company to do presentations for them. When we receive the actual presentation we review it for commercial bias, or product bias. If we find anything in the presentation we ask that it be changed to not reflect any commercial or specific product information.</p>	Accredited CME provider
<p>This ill-defined policy is unworkable, insulting and frankly cowardly. It presupposes guilt without evidence, fails to define either "control" or "same content," sets no time limit on prior associations, and makes no allowance for the intensity or exclusivity of an association. Many speakers and writers have produced content for multiple products from multiple "commercial interests" and can fairly be said to be without bias simply because of the multiplicity of their associations. Indeed, this policy would needlessly put entirely out of business many writers who depend upon both promotional and CME contracts. There does not exist a non-competition clause anywhere in industry that has an unlimited duration of effect. Furthermore, this policy completely vitiates ACCME's entire Resolution of Conflict process simply by assuming universal guilt by association. This is not even true of Congressmen, let alone medical professionals. (These comments are entirely the opinion of the writer and in no way reflect that of his employer.)</p>	Accredited CME provider
<p>There is a growing outcry against commercial influence in CME and the arguments range from legitimate to totally groundless. Sadly, while many voices are participating in this dialogue there seems to be an absence of leadership from within CME. I begin with this observation because this proposal represents little more than reflexive behavior on ACCME's part at a time when it should be doing more to defend the collective interests of CME that it embodies. Yes, CME continues to need improvement and refinement and there have certainly been abuses. But this proposal creates as many problems as it solves. Because as long as drugs and medical devices are produced within a capitalist society it will never be possible to legislate away every perceived nuance of bias. ACCME should, instead, design measures that address the actual cases of bias that have been going on under its watch. ACCME should continue to define what real CME is, rather than reflexively acting on what others are saying about it.</p>	Accredited CME provider
<p>I commend the Board for coming to grips with a contentious, but critically important issue in achieving true independence for accredited CME. I enthusiastically support this policy revision</p>	Accredited CME provider

<p>This statement does not go far enough to remove the perception of bias that exist in the industry. If a professional is involved in the designing material for 'marketing' of a drug, product etc, they are lending their expertise, knowledge on what will 'sell' the drug to the professionals who will prescribe, recommend and and yes, influence decisions. How could the same professionals be expected to be objective in working with an Accredited Provider in creating a CME presentation? In my opinion, the statement should read: Persons paid to create, or present, promotional materials on behalf of commercial interests cannot be involved in the creation or presentation of continuing medical education on the same content. This gives the professional a clear choice as to 'what side' they want to be on and gives clear direction to the accredited providers as to who they should tap into as thought leaders to design and present continuing medical education activities. This type of fire wall has been in place for organization who work in the continuing education field for several years. You choose if you want to be on the marketing side or the side of designing continuing medical education. Companies have had to spend thousand of dollars to start new companies to comply with rules. Professional should be held to the same standard.</p>	<p>Other</p>
<p>The root of the issue is whether the person CREATES both promotional or accredited material at the same time. The policy should include a period where a person may transition from one to the other if they change position, employers etc. ie. Persons who, within the preceding 6 months, have been paid to.... (or some other defined period of time). Including 'PRESENT' in the policy would exclude Investigators/Researchers/Key Opinion Leaders from presenting in an accredited CME setting. (ie. Those physicians who are leading the research improving the treatment of specific diseases or conditions.) Research which is funded by commercial interests. Including this group in the policy (...or present,...) will deny these researchers, who by their research, know the therapeutic area best. Most of these same people are the writers of the therapeutic guidelines as published by the appropriate medical specialty society/association or ABMS.</p>	<p>Accredited CME provider</p>
<p>I have no problem with this proposed new policy</p>	<p>Accredited CME provider</p>
<p>I manage the CME Program at our facility [REDACTED] and I network with many others who administer CME programs. I feel that we can go too far with this and I think this policy crosses the line. I have several physicians who are paid by drug companies to do private training/talks to various groups. However, they are big supporters and proponents of our CME Program. The openly discuss their relationships with the drug companies and provide further education/CME for the best of patient care -- not because they're paid by the company. When they give CME presentations they cover many options and don't try to bias the presentation with a company's product. They recognize the value that drug companies provide CME and the minimal support/grant that is given enables our CME program to "happen". This proposed policy doesn't recognize a physician's ability to distinguish between the marketing objectives by a drug company -- that would not be appropriate to discuss at CME -- and the educational value of treating a condition with a new treatment -- no matter what product is used. This policy, taken to the extreme, would not allow any physician to participate in presenting CME if he/she believed strongly in some brand of product over anyother. How do we screen this? Let's let some common sense take over here and allow physicians, with the clinical knowledge of various treatments, to present their CME -- whether or not they are paid in some capacity by a drug company. My vote is "no" to this policy. I know many hospitals are considering stopping their CME Programs because regulations have grown so restrictive that resources are drying up, the hopsital can't pay for everything, and more staff/resources are needed to continue CME programs which just aren't there. Do we want to keep CME Programs at the hospital level? I know the other major medical center in our city just decided to discontinue their CME program because it has become prohibitive to administer. [REDACTED]</p>	<p>Accredited CME provider</p>
<p>This proposed policy assumes that all paid promotional work a healthcare provider does on behalf of a commerical interest would so bias their thoughts that they would be unable to participate in the creation of a fair and balanced CME activity. I'm at a loss at how such a blanket statement could be made by the ACCME and wonder what kind of message that sends to the thousands of healthcare professionals that work full time treating patients or teaching future physicans and give of their personl time to help their peers improve their standard of care by participating in the creation of CME, but do promotional work. While I firmly believe and uphold the mandatory need for CME to be free of promotion, this would drastically limit the pool of faculty MECCs could pull from to create quality activities. I feel there are current guidelines in place that allow for responsible MECCs to resolve any form of bias, use of independant third-party reviewers is just one example. This policy would punish all MECCs for what is assumed to be a small number of abusers. If you make physicians choose between their promotional work and CME, I truly feel the CME industry and quality offerings, especially in specialized fields, will suffer as a result.</p>	<p>Accredited CME provider</p>

<p>Give me a break. It is hard enough to get speakers already! You act as if physician writers are all a bunch of money grubbing morally and ethically empty flunkies working for pharmaceutical companies. Many excellent, academic, knowledgeable and well respected speakers present programs for commercial interests. They are often the foremost in their fields! We already insist they disclose their "connections." To eliminate these people from the speakers pool will only reduce educational opportunities. It is already just about impossible to put on programs thanks to ACCME's regulations. You are only making it more difficult. Accredited CME has quite enough safeguards at present. Please don't over regulate and stifle growth. The smaller organizations are particularly vulnerable as they may not have the resources that large hospitals and academic institutions take for granted. Your proposed policy is way too broad.</p>	<p>Accredited CME provider</p>
<p>This is a sound proposal and should be supported.</p>	<p>Accredited CME provider</p>
<p>Such a policy presumes that what is taught in promotional programs is either wrong or "contaminated". In actual fact it is now tightly regulated by the FDA. So long as the content of CME consists of material from peer reviewed publications and is reviewed, and declared to be unbiased and fair balance by the CME provider, there should not be conflict for physicians to do both types of teaching. Your proposal runs the risk of excluding most academic physicians from all promotional lectures. Thus the quality of these programs may deteriorate, leading to more biased education of primary care providers who attend them, and jeopardizing patient care.</p>	<p>Accredited CME provider</p>
<p>I believe the persons to whom this proposed policy should be excluded from participation determining content of accredited CME about the topics/products for which they are paid. It can be very difficult to segregate information in such a way as to resolve this sort of conflict. For instance, if someone is on a speakers bureau regarding a new drug for DM it would effectively exclude that person from presenting an update on therapy for DM (or planning content), as a credible job could not be done regarding topic without discussing the drug they are paid to promote (along with all other appropriate choices). I view it as appropriate to exclude this person from giving such a talk or being involved in planning such a program. Unfortunately, this is the price some academic (and other institutions) will have to pay when faculty/employees are on speakers bureaus. Honestly, I believe until we entirely eliminate ANY sort of involvement of commercial interests (or folks acting as their agents) in accredited CME these sorts of issues, investigations, senate hearing, etc. will persist. The public simply doesn't understand why commercial involvement (or involvement of agents thereof) IN ANY WAY with CME is necessary. I really feel they don't understand why docs can't pay the true cost of CME. This whole area of regulating interactions commercial entity regarding education activities with CME providers is proving too difficult to find a common ground that will satisfy all relevant stakeholders particularly the public which is the ultimate stakeholder. I think we simply prohibit ALL sorts of interactions (grants, faculty previously paid to promote in other venues, etc.) related to educational programs between accredited CME providers and commercial interests (or their agents) as it seems that is where we will eventually end up as we chip away at this issue.</p>	<p>Accredited CME provider</p>
<p>While undoubtedly conflicts exist and need to be monitored and reduced, the idea of preventing Pharmaceutical companies from contributing to CME programs basically will kill the programs. Health industry, government is not likely to fund this billion dollar enterprise any time soon. Therefore CME education will not be available for practicing physicians who will lack this important unbiased educational program and will receive their education directly form the industry through some mechanism-so called "cut your nose off to spite your face".</p>	<p>Accredited CME provider</p>
<p>This person(s) would be considered having a conflict of interest --and possibly biases--if presenting CME programs due to their relationship with commercial interests. I would strongly urge ACCME to lead the charge and adopt a policy of "just say no" to commercial interest, particularly in this very contentious healthcare climate. This adopted policy would truly define CME independence from commercial interest.</p>	<p>Accredited CME provider</p>

<p>The policy is a good attempt to reduce the influence of commercial interests in CME through practices such as speaker's bureaus, consulting arrangements, planning and advisory panels, and similar promotional tactics. As currently worded, however, the policy has a number of loopholes and ambiguities that will limit its effectiveness in achieving the policy intent. Focusing only on creation or presentation of promotional materials is too narrow to achieve the policy intent. The policy should address a broader range of paid promotional activities, including, but not limited to, providing consultation and advice, planning, and participating in product staging and marketing campaigns. This is a minor point, but easy to address. Persons may be paid directly by industry, as well as on behalf of commercial interests. The policy should address payment both directly by and on behalf of commercial interests. In practice, it may be difficult to determine who has been paid by a commercial interest to promote products and services, particularly when funding is channeled through intermediary organizations. Voluntary disclosure is one approach. Audits of provider financial records would be another approach. Consideration should be given to the procedures and resources that will be necessary to implement this aspect of the policy in practice. Determining that the content of promotional activities is the same as the content of an accredited continuing medical education activity or program will be problematic in practice. The definition of "same" content will be open to wide interpretation, ranging from identical on one end of the spectrum to marginally related on the other end. This is a major weakness of the policy, at least a huge loophole, and perhaps a fatal flaw in achieving the policy intent. It would be much more effective to simply prohibit persons who are paid by commercial interests to promote products and services from participating in any aspect of accredited CME. The research example in the ACCME commentary is a legitimate exception, but it does not represent a broader class of exceptions to persons being paid by industry to promote products and services. In fact, the research example is the only exception. Taking these issues into account, a suggested rewording of the policy is provided as follows: Persons paid by or on behalf of commercial interests to plan, create, or present promotional content, activities or materials, or to provide consultation and advice on promotional activities, are prohibited from participating in the planning, creation, or presentation of accredited continuing medical education. Thank you for the opportunity to comment on this policy.</p>	<p>Accredited CME provider</p>
<p>My thoughts...presenter should make his or hers own slides and be only given topic...they decide whats in it...obviously fair balanced....if we can operate on a patient I find it difficult we cannot give a lecture to physicians...maybe we should not operate on patients? if people feel physicians cannot tell unfair material from fair....then we have more of a problem than deciding who can lecture at what.... I Hope my family gets treated by someone who knows the drugs or devices he is using by the designers and makes of these items. I feel physicians need to go to training by the company...and they should listen to what is said and decide themselves...what is real and not ...if you cannot do this...should not give lectures/practice medicine? A presenter should make his own material...that way he is aware of the data and he picked it...not produced by third party....they should not give lectures if they cannot do the background work...this is unbiased... clearly some compounds will be better than others....i dont consider it biased if another drug is better to say so...but with data to back it up... The so called CME that is accredited...is also needing help...if you only have speakers with poor knowledge base because they dont do research or go to training on new items....we will be in the stone age again....</p>	<p>Other</p>
<p>You need to be careful about taking your CME requirements to an extreme. To be frank, it is not that hard to get enough CME to maintain licensure/hospital privileges. As someone who works to put on many meetings, I would far sooner stop offering CME than compromise the quality of my meetings. The nature of technology-based medicine is that thought leaders have relationships with industry. This is how industry knows what we need to meet our patients needs. By essentially requiring that no one with any potential commercial bias participate in an CME program, I am left with no truly knowledgeable speakers. My dilemma then becomes deciding between a course taught by individuals who do not have insight into and expereince with the newest and most innovative technology, are not at the forefront of our industry, and do not have recognizable names or a program taught by high integrity, well known and respected thought leaders who do most of the research, publication, and advancement of our field but who could have commercial bias. Which conference would YOU rather attend??</p>	<p>Accredited CME provider</p>

<p>I am a member of the board of the [REDACTED]. I am very disturbed by the recent draconian effort to prevent industry representation at scientific meetings. We often have presentations by industry regarding the development of gene therapy products (none of which are yet approved for clinical use). My interpretation of the recent language is that industry speakers cannot speak at CME-accredited symposia. I believe that this is very bad and excessive. The following in particular seems draconian. Physicians paid by a commercial interest to do promotional presentations on a product could not teach in accredited continuing medical education on the same product. Anyone creating content for promotional activities would be excluded from creating content on the same product for accredited continuing medical education, for example.</p>	<p>Other</p>
<p>I am a board certified [REDACTED] and an assistant professor of [REDACTED] training residents from a teaching hospital for the past 20 years. I am also currently on the CME committee of the [REDACTED] and am periodically called upon to approve CME programs in that position. I am the past chair of the [REDACTED] CME committee and am currently a CME site investigator for CME providers receiving accreditation through the [REDACTED]. I have previously been on the council organizing the annual meeting of the [REDACTED] where attendees are provided with hundreds of hours of free CME. I am on the Board of Directors of the [REDACTED] which puts on free CME programs all over the state of [REDACTED], with grants from pharmaceutical companies who have no input into our program content. I am also on the speaker's bureau for 3 different drug companies I have seen CME as a lecturer, an organizer of meetings, and as a reviewer of CME activities. During that time I have also been paid to provide non-CME lectures for drug companies. Obviously, I do not feel that these different activities limit my abilities to function in any of my other roles. Most of the best teachers I know supplement their income by speaking for drug companies. What you suggest is that that relationship should disqualify them from overseeing CME educational programs. That is impractical and totally unwarranted. As a person involved in CME at multiple levels and with experience in organizing CME meetings, it is my opinion that removing drug company funding from the providers of CME programs is unnecessary if those providers are following current guidelines and there is a clear separation of development of curriculum from the sponsoring entity. Removing pharmaceutical sponsorship would require an enormous shifting of cost to individual physicians and CME providers. This will result in a significant reduction in the amount of CME that is available, and will reduce the ability and desire of physicians to participate in CME programs. Is there any chance that the "benefit" of completely separating the pharmaceutical industry from physician education is worth the loss of millions and millions of dollars worth of educational programs? The answer is no. In fact it's hell no.</p>	<p>Other</p>
<p>This will likely limit the available pool of experts in each particular field. It will essentially split experts into two groups who never participate in the other type of event. Thus, the CME audience will hear opinions from a restricted group of presenters. The audience will lose the benefit of hearing diverse, possibly opposing viewpoints. The best way to handle these type of entanglements is full, open disclosure of potential conflicts of interest. Let the CME audience apply their own judgement based on that---they are smart people.</p>	<p>Other</p>
<p>Dear Sirs, At the present time, some of the finest educators are called upon by industry to help develop balanced educational materials for promotional programs. The industry sponsors have already placed strict oversight and restrictions on their promotional slides to avoid overstating the benefits of their products and to make sure that no off label uses of the product are promoted. The usual role of a paid thought leader in developing such materials is to make sure the content is appropriate and supported by high quality science and therefore buffers any attempt by the sponsor to place too much marketing "spin" in the materials. I believe that national thought leaders would never threaten their reputation for any level of honorarium. If an industry sponsor did find a more mercenary "expert" than the current practice of reviewing the CME and resolving conflicts should be adequate to see an obviously biased opinion. At the present time, almost all of the nationally recognized experts in their fields have been involved in presentation or development of industry sponsored non CME programs, many of which have been outstanding, and have received some type of honorarium for their time or input. Often they have done so for multiple sponsors who needed their scientific input on a disease state which may have been relevant to multiple pharmaceutical products or devices. By restricting such individuals from presenting at CME events, not only will the pool of experts in a scientific area be markedly diminished for high quality CME, but also, the availability of credible expert opinion to "balance" non CME activity will also be diminished. In summary, I urge you to reconsider restricting educators who have been involved in non CME activities for honoraria from presenting at CME activity. I would also voice my support for continued attempts by CME sponsors and program chairs to resolve conflicts of interest, review materials to make sure they are balanced, and avoid using speakers who are obviously unbalanced or biased as they do at present. I, for one, object to the notion that all national thought leaders, or local speakers, who have received an honorarium, are hopelessly biased and can't be trusted to present data in a</p>	<p>Other</p>

<p>fair and balanced manner. Disclosure remains critical, but exclusion seems ill-advised.</p>	
<p>I am supportive of a policy that limits and/or eliminates the use of speaker's bureau participants in accredited CME activities on topics and in disease domains that coincide. My concern is that the definition of a speaker's bureau is key to this as it can mean many things to many people. In the actual call for comment the word promotional materials is utilized and this is also vague...to paraphrase..... One person's promotional materials will be another's educational materials. Thus a clear and distinct definition will be key. We have banned SBs from our institution in a policy just released. We characterize these as follows (I offer these as a suggestion): a company has the contractual right to dictate the content a company creates the slides or materials and has the final approval for all content and edits (we do permit them to review for proprietary material only) The faculty members receives compensation and acts as the company's employee or spokesperson for the purpose of dissemination of material We state that if it has all three characteristics "no can do" if it has even one it is probably a "no can do". Our faculty shouldn't proceed even if it carries a single characteristic, but we do permit them to place an inquiry to our conflict management group for clarification and possible to allow a given unique circumstance. An example of one we would permit is if the education is mandated by the FDA (not regulated, not overseen, but MANDATED). Hope these thoughts are helpful and I am happy to share our new policy with you if you believe it would be useful.</p>	<p>Accredited CME provider</p>
<p>We agree entirely with this policy. It's absolutely necessary to distinguish promotion from education. Nevertheless, what about the hidden forms of commercial interests like ghostwriting ? This policy needs full disclosure of all COI and the means to get it.</p>	<p>Other</p>
<p>August 15, 2008 Murray Kopelow, MD, MS (Comm), FRCPC Chief Executive Officer Accreditation Council for Continuing Medical Education 515 North State Street, Suite 1801 Chicago, IL 60654 Dear Dr. Kopelow: The [REDACTED], representing more than 500,000 physicians, appreciates the opportunity to comment on ACCME's position that "the manner of interaction between potential commercial supporters, or their agents, and some Accredited Providers may need to be altered." I.tCall for Comment: ACCME will ensure current processes of attaining commercial support will not undermine the independence of continuing medical education: Limiting the Interactions between Accredited Providers and Commercial Interests over Commercial Support ACCME call for comment item 1: "Accredited providers must not receive communications from commercial interests announcing or prescribing any specific content that would be preferred, or sought-after, topic for commercially supported CME (e.g., therapeutic area, product-line, patho-physiology) – as such communication would be considered 'direct guidance on the content of the activity' and would result in Non Compliance with Standard 1 of the ACCME Standards for Commercial SupportSM." [REDACTED] position: The [REDACTED] supports the clarification of the ACCME Standards for 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 Gerber Foundation whose mission is "to enhance the quality of life of infants and young children in nutrition, care, and development" would most likely not support a CME program that addresses Alzheimer's dementia in the older patient. SCS 1 rightly places the burden of documentation and truth upon the provider to ensure complete independence from commercial interest bias or control. Commercial interests in the pharmaceutical industry have recently changed their behavior to comply with regulation from the OIG, and in so doing, are avoiding communicating desired content areas for grants to be submitted for potential support. In this light, the proposed ACCME clarification would be consistent with current behaviors of commercial interests and CME providers, and of the intent of the ACCME Standards for Commercial Support. ACCME call for comment item 2: "Receiving communications from commercial interests regarding a commercial interest's internal criteria for providing commercial support would also be considered the receipt of 'guidance, either nuanced or direct, on the content of the activity or on who should deliver that content.'" [REDACTED] position: The [REDACTED] supports the clarification of the 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</p>	<p>Other</p>

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.

Call for Comment: The ACCME believes that due consideration be given to the elimination of commercial support of continuing medical education activities: The proposal is that the commercial support of continuing medical education end. [REDACTED] position: The [REDACTED] does not support the proposal that commercial support of continuing medical education end. Background: [REDACTED] fully supports the ACCME Standards for Commercial Support and enthusiastically champions the 2004 updates. These Standards require that CME providers, in this case medical specialty societies, clearly and completely separate educational content from commercial bias, which may be perceived as resulting from commercial support. CME providers may offer and physicians may claim CME credit for participating in certified CME activities. The public and political climate in the United States, particularly concerning the high cost of drugs in the Medicare program, has resulted in intense scrutiny of ACCME, as well as of many CME providers. This climate of fault-finding, blame and threat, couched as inquiry, has understandably stimulated organizations to react, and to sometimes over-correct in immediate response. The ACCME has current and relevant criteria requiring all CME providers to focus the goals of CME toward improvement of physician practice, thus improving the quality of patient care. These criteria include stronger guidance on complete independence from bias associated with commercial support, as well as stronger procedures for the identification and resolution of conflicts of interest. ACCME is poised to assume a position to strictly enforce its criteria, thus providing evidence to outside pressures that the system of professional voluntary self-regulation works well. Although there is the potential for added burden to medical specialty societies and other CME providers, the environment, and professional reaction, is stimulating debate in the societies about commercial support. Debate among leaders, executive staff, and members is occurring in many medical specialty societies concerning the levels of industry support they receive for CME activities. Several societies have plans to reduce or curtail industry support and move to alternative types of funding for CME. [REDACTED] agrees with ACCME "that the profession (taken to mean physicians), the public (taken to mean patients) and the CME enterprise (taken to mean accredited CME providers) weigh in on the subject...with colleagues (taken to mean other accrediting organizations), with other professions (taken to mean nursing and pharmacy), with students (taken to mean participants in the continuum of medical education), with government (taken to mean agencies related to Medicare/Medicaid), and with stakeholders of CME (taken to mean commercial/non-commercial interests related to CME), including the public." [REDACTED] suggests that the venue for this discussion, with the potential inclusion of additional interested parties, exists in the [REDACTED] ([REDACTED]). The [REDACTED] is a "multi-organizational committee, members of which are key stakeholders in the continuum of medical education." [REDACTED] participating organizations include: the Association of American Medical Colleges (AAMC), Accreditation Council for Continuing Medical Education (ACCME), Accreditation Council for Graduate Medical Education (ACGME), Alliance for Continuing Medical Education (ACME), American Academy of Family Physicians (AAFP), American Board of Medical Specialties (ABMS), American Hospital Association (AHA), American Medical Association (AMA), American Osteopathic Association (AOA), Association for Hospital Medical Education (AHME), Council of Medical Specialty Societies (CMSS), Federation of State Medical Boards (FSMB), Joint Commission (JC), Liaison Committee on Medical Education (LCME), National Board of Medical Examiners (NBME), and the Society for Academic Continuing Medical Education (SACME). This Committee was initially convened in 2002 and has sustained an active, stimulating dialog about CME and more broadly, the continuum of medical education in the United States. The [REDACTED] has prepared a report, Reforming and Repositioning Continuing Medical Education, that contains recommendations and next steps in seven key areas related to CME: 1) the medical education continuum; 2) self-assessment and lifelong learning; 3) core curricula and competencies; 4) valid content: evidence-based medicine; 5) performance and continuous improvement; 6) metrics to measure and recognize physician learning and behavioral change; and 7) resources and support. [REDACTED] recommends that the [REDACTED] be tapped to frame and conduct this debate and examine the three scenarios proposed by ACCME: 1) the status quo with commercial support of CME as an acceptable funding mechanism (governed by tight adherence to the ACCME SCS) 2) the complete elimination of commercial support of CME, and/or 3) a new paradigm (for commercial support of CME as well as other possible scenarios which may emerge from the Committee's discussions). [REDACTED] further suggests that the [REDACTED] be provided with adequate funding, time, and proper resources to engage this debate in a form and fashion as to realize the end result of settlement of this debate and an action plan for the future. Such funding should

include the necessary monies to conduct research into the possible effects of influence and reciprocity on physicians' behavior. ■ should be asked to begin to address this task as soon as possible. III. Call for comment: ACCME proposes a new paradigm where ACCME accreditation will continue to reflect only what is in the best interests of the public. The ACCME proposes that if the following conditions were all met, then the commercial support of individual activities would be in the public interest and could continue to be allowed: 1) When educational needs are identified and verified by organizations that do not receive commercial support and are free of financial relationships with industry (eg, US Government), and 2) If the CME addresses a professional practice gap of a particular group of learners that is corroborated by bona fide performance measurement (eg, National Quality Forum) of the learner's own practice, and 3) When the CME content is from a continuing education curriculum specified by a bona fide organization, or entity, (eg, AMA, AHRQ, ABMS, FSMB), and 4) When the CME is verified as free of commercial bias. Alternately, these conditions could provide a basis for a mechanism to distribute commercial support derived from industry-donated, pooled funds. ■ position: The ■ does not support the new paradigm in its current draft format, as described above, but rather recommends modifications to ensure the separation of bias from commercial support of CME, and further recommends a process for debate and discussion of the proposed new paradigm, so that it may ultimately come to be as universally accepted as are the ACCME Standards for Commercial Support.. Background: 1) "When educational needs are identified and verified by organizations that do not receive commercial support and are free of financial relationships with industry (eg, US Government), and..." Currently, accredited providers are charged with the responsibility of determining educational needs. Medical specialty societies, in particular, consider it their responsibility to fulfill needs assessment in planning CME for members. It does not seem logical to separate needs assessment from those providers which are in the best position to determine needs, and which are responsible for designing CME to meet those identified needs. It appears that the intent of "new paradigm 1)" is to ensure that needs assessment is separated from commercial influence, a premise with which ■ completely agrees. Divorcing the CME provider, particularly the specialty society, from needs assessment appears to be "throwing the baby out with the bathwater." 2) "If the CME addresses a professional practice gap of a particular group of learners that is corroborated by bona fide performance measurement of the learner's own practice, and..." On January 1, 2005, a "new CME" emerged as Performance Improvement CME, with criteria approved by the three national CME credit granting agencies (AAFP, AMA, AOA). PI-CME is standardized and designed to "address a professional practice gap of a particular group of learners that is corroborated by bona fide performance measures of the learner's own practice." PI-CME is offered by a variety, albeit still a few, CME providers, most notably medical specialty societies. Performance measures incorporated into PI-CME are generally, and should be derived from those endorsed by bona fide national organizations, such as NCQA, PCPI, NQF and AQA. ■ recognizes the need and opportunity to facilitate the development of PI-CME among medical specialty societies. This should be a goal of ACCME, as well. That said, a requirement that any industry-funded CME be based on established guidelines and parameters would eliminate much of the educational programming currently offered and needed. Many conditions do not yet have established practice parameters, as the data necessary to create these care standards are still being developed. Prohibiting commercial support for CME on such conditions would arbitrarily eliminate CME for many conditions for which needs assessment demonstrates a need, which would ultimately have a negative impact on patient care. It appears that the intent of the proposed "new paradigm 2)" is to ensure the separation, from commercial bias, of the identification of physician practice gaps, as well as the inclusion of performance measures into physician education, a premise with which ■ completely agrees. Divorcing the CME provider, particularly the specialty society, from identifying practice gaps measured against nationally accepted performance measures appears to be abrogating the CME provider from its educational responsibility in, and ability to offer PI-CME. 3) "When the CME content is from a continuing education curriculum specified by a bona fide organization, or entity, and..." While ■ agrees with the premise in 2) above that bona fide organizations should be charged with endorsing nationally accepted performance measures which are incorporated into PI-CME, we recognize that the bona fide organizations in the best position to develop educational curricula for medical specialists are medical specialty societies. The role of certifying boards (represented by ABMS) is to certify individual physicians, of state medical boards (represented by FSMB) is to license individual physicians, and of medical specialty societies (represented by ■) is to educate individual physicians. The appropriate role for specialty societies is to identify practice gaps of its members, as a group and as individuals, to create an educational curriculum based on practice gaps, and to incorporate nationally accepted performance measures into CME to address identified gaps among its members. This educational design is part of the responsibility inherent in professionalism. It appears the intent of "new paradigm 3)" is to ensure the separation of commercial bias from the design of educational curricula, a premise with which ■ completely agrees. Divorcing specialty societies from designing curricula for the education of its members appears to be a Solomonian solution of cutting a whole entity in half, resulting in non-viable educational programming. 4) "When the CME is verified as free of commercial bias." It appears that the intent of "new paradigm 4)" is to ensure that by separating 1) needs assessment; 2) identification of

<p>practice gaps of physicians, measured against nationally accepted performance measures; and 3) educational curriculum design, from entities that receive commercial support, even when those entities are in exemplary compliance with the ACCME Standards for Commercial Support for CME, only then can and will the perception of bias be eliminated from CME. Ironically, verification is the desire in this premise. Verification requires assessment of actuality, not design changes (1, 2 and 3 are design changes), and not management of perception. ■ does not believe that the proposed extreme solution to the problem of the perception of commercial bias in commercially supported CME, as outlined in the proposed "new paradigm", is appropriate or necessary, as it removes the responsibilities of CME providers, particularly specialty societies, from the design and implementation of CME which is free from commercial bias. It is important to pause to recognize the practical realities of corporate support. In the absence of support for CME, currently approximately \$1 Billion annually, the likelihood that such support will find its way into Direct to Consumer Advertising, and more problematic, into promotional education, is strong. If the goal is to eliminate product bias from the education of physicians, it will be critical to avoid an unintended consequence of stimulating significantly increased product biased education through the mechanism of promotional education. ■ considers the concept of pooled funds for the commercial support of CME to be one of a series of potential viable options worth pursuing. ■ recognizes that the perception of the incorporation of commercial bias into commercially supported CME is real. We offer the venue of the ■ as an immediate vehicle for furthering the discussion, leading to a national solution that is as universally lauded and accepted as are the ACCME Standards for Commercial Support of CME. Sincerely, ■</p>	
<p>I think the spirit of this proposal is all well and good, but the fact is that many of the thought leaders in one of our major fields of CME (■) have conducted research on the very pharmaceuticals they are discussing at activities. Do you have people with less knowledge of the subject present the material simply because they don't have a relationship with the commercial interest? It seems to me that in the long run, that kind of thing may actually compromise the quality of the CME presented. I think we should give the learners a little more credit for being able to discern where bias and promotional interests are present in CME. We certainly let them know all the relationships involved in each CME activity, from Faculty/Planner disclosures, grantors involved in the activity, etcetera AND have peer-review of the material to be presented or published. It is getting to the point where we are turning ourselves inside out to accommodate all of these regulations, when in fact, if all commercial support was completely removed from CME, there would still be some with a promotional agenda who would find a way to push their message.</p>	<p>Accredited CME provider</p>
<p>I agree with the proposed policy as there is a high probability that the presentation would be the same (or nearly the same) and that the presentation would be promotional in content. Many times a speaker is brought to the area by a commercial interest representative and also presents also for the Grand Rounds the next day (or the same day). I doubt that 2 different presentations are give.</p>	<p>Accredited CME provider</p>
<p>1) Should those who write promotional materials be excluded from having any role in writing CME content? Yes. Those involved in promotion are interested primarily in selling. the goal of medical education is to improve knowledge of medical practice. Medical education should be unbiased however with commercial support extensive biases exist. 2) Should those who teach in promotional activities be excluded from teaching in independent CME activities? Absolutely! There is a huge element of bias when one is involved with promotional activities. Those involved in promotion are unable to be objective as their livelihood depends on promoting product. Sales representatives, marketing managers usually do not have the depth of scientific knowledge as highly trained professions. Sales reps and marketers are aggressive narcissistic and will use unethical means to promote their product. Medical education companies ususally serve as an intermediary to "influence" speakers on behalf a commercial organization. the Medical Education company is somewhat shielded from regulatory and compicance guidelines and hence are used by commercial organizations to do their dirty work. This policy is definately needed in order to support high quality, unbiased medical information that benefits society and not the pharmaceutical company.</p>	<p>Other</p>
<p>I think the ACCME should butt out. We physicians do not need another big brother deciding what can be presented; we are generally smart enough to weed out biases.</p>	<p>Commercial Supporter</p>

As a CME professional representing my organization [REDACTED], I wish to express our concerns with the proposed definition of “an irreconcilable conflict of interest” and its implications for anyone involved in content development of certified CME activities. **Legal Liability and Implications** We anticipate that the restriction that “Persons paid to create, or present, promotional materials on behalf of commercial interests cannot control the content of accredited continuing medical education on the same content,” will be viewed as a violation of the First Amendment right of freedom of speech. This effort, designed to prevent persons from speaking on subjects of their expertise because they receive compensation from a commercial interest for promoting these same subjects, further complicates the conflict of interest (COI) issue and creates the real risk that individuals will allege such restrictions blatantly violate their freedom of speech. Moreover, this restriction presumes that persons who fall in this COI category are already guilty of wrongdoing and denies them their legal right of due process. It is important to note that persons afforded the rights of freedom of speech and due process are themselves responsible and accountable for their professional, ethical, and lawful behavior. There is a great likelihood that parties injured by virtue of this restriction will seek legal recourse to address violations of personal legal rights, resulting in lawsuits against the accredited provider and the ACCME, its directors, and parent organizations. As a CME provider, [REDACTED] is gravely concerned about our legal liability and litigation expenses. Costs in time and monetary resources could be tremendous. [REDACTED] recommends that the proposed action regarding COI be referred to a well-qualified expert in constitutional law and personal human rights for an assessment of potential and real legal liability. [REDACTED] also recommends that the ACCME consider other options which mitigate legal liability while addressing COI. The complexities of resolving COI are not unique to the ACCME. Many other organizations face similar concerns and mandates to eliminate COI. The AAMC, NIH, FDA, and peer-reviewed journals, to name a few, face the challenges associated with COI. These organizations have elected to pursue other means of managing and resolving COIs without imposing an “all or none” disposition of irreconcilable COI and subsequent disqualification. [REDACTED] recognizes and respects the ACCME’s commitment to prevent COI in all its manifestations in CME. We fully support the spirit and intent of ACCME’s attempt to do so. We also recognize that efforts to do the right thing can inadvertently result in great harm. Therefore, we prevail upon the ACCME to consider all viable options with the intent to do no harm before taking action that may very well cause irreconcilable damages. These observations and recommendations are offered in pursuit of excellence in professional conduct, in recognition of our litigious society, and in the effort to share perceptions and experiences that could have significant adverse implications for the ACCME and its accredited providers.

Definition of the Term “Same Content” A second concern with the proposed “Definition of Irreconcilable Conflict of Interest...” is within the definition itself regarding the term “same content.” While we realize that this is a definitional statement, it does raise complex questions as to what is meant by “content.” Does “content” mean? ~ The specialty and/or subspecialty field of the person ~ The disease state (i.e., diabetes, CNS, cardiovascular disease, etc.) ~ The “topic” on which the person will create and/or present ~ The field of expertise and/or the scope of practice of the person ~ A specific product in the same or similar therapeutic class With regard to “content,” what is its definition relative to a presentation at a future or past promotional activity? What are the relevant criteria and mechanisms to determine if the “content” is the same, similar, tangentially related or not the same? Will the person in question self-report all “content” presented at promotional venues and disclose how it may be assessed as “the same?” If not, will the provider and/or an independent reviewer do so? What if the person disagrees that the “content” is not the same? What redress will the person have to make a case that the “content” is not the same? **Clarification of the Term “Paid”** The term “paid” also raises questions. Does “paid” mean? ~ Non-personal payment but rather payment to charity or other third party on the person’s behalf ~ Payment to the person’s institution of employ and not to the individual personally ~ Payment of travel and related expenses and not an honorarium or other personal remuneration? **Use of the Term “Product”** In the ACCME Commentary Section of the call, reference is made to promotional presentations on a “product” and exclusion of persons from presenting content on the same “product” in accredited CME. We find this example very odd since CME should never be developed or delivered on or about a “product,” but rather on a specialty or subspecialty field of medicine, a disease state, identified medical and clinical knowledge and performance gap, etc. To associate CME with a “product” violates the spirit and intent of independent CME. The “product(s)” cited in a certified CME activity should always be cited based solely on their relevance and appropriateness to the scope of the content as it relates to therapeutic options, their safety, and efficacy. Determining, disclosing, and disqualifying creators and presenters of content based solely on “product” considerations, in our opinion, has no place in CME.

Proposed Policy Implications A broader question is to what degree will ACCME’s definition limit or eliminate the pool of experts qualified to speak on topics at CME venues? In some cases there is a small number of persons qualified to speak about very specific, cutting-edge areas of importance to medical education. If those individuals are disqualified from CME venues, there will be no one to provide valuable medical and clinical information to CME audiences. Peer reviewed journals experience this problem engaging the best qualified persons to serve on editorial boards and finding these individuals are also valuable as reviewers of manuscripts. Because of irreconcilable COIs according to the respective journal’s criteria, talented individuals

<p>are disqualified from service. Should highly qualified, sought after persons elect to participate in promotional activities, they will not only eliminate themselves from involvement in CME, but also will raise the appeal of promotional activities to showcase the best of the best in their venues. Diminishing the quality of CME and enhancing the quality of promotional venues will further the advancement of commercial interest promotion at the expense of independent, certified CME. We commend the ACCME in affording [REDACTED] the opportunity to comment on critical issues impacting CME. We request and appreciate ACCME's consideration of our concerns, questions, and recommendations.</p>	
<p>I agree that "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". The following proposition is fair: "The ACCME proposes that if the following conditions were all met, then the commercial support of individual activities would be in the public interest and could continue to be allowed. 1) When educational needs are identified and verified by organizations that do not receive commercial support and are free of financial relationships with industry (eg, US Government agencies), and 2)If the CME addresses a professional practice gap of a particular group of learners that is corroborated by bona fide performance measurements (eg, National Quality Forum) of the learners' own practice; and 3)When the CME content is from a continuing education curriculum specified by a bona fide organization, or entity, (eg, AMA, AHRQ, ABMS, FSMB), and 4)When the CME is verified as free of commercial bias.</p>	Other
<p>Well we have finally gone INSANE!!!!!! First: I have been born under the Communist rule and lived in Poland for the first 27 years of my life! Second : One of the reasons that I have come to USA was the fact that I have cherished the freedom of speech and all that it means, as well as the rest of US Constitution and its Amendments. - I have been licensed physician/researcher/teacher in Poland, subsequently I have my US licensure and license in few states of the nation to practice Medicine, I have Internal Medicine Board Certificate, I teach students and YES!, I do speak about medicine and medications frequently and on behalf of multiple Pharmaceutical Companies. And YES I do receive honorariums for my time as I AM OBVIOUSLY NOT AT MY OFFICE SEEING PATIENTS SO I THINK IT IS FAIR!!!!!! Never did I think that I should keep myself isolated in the IVORY TOWER OF SCIENCE AND MEDICINE in order to preserve my integrity and good judgement. TO THOSE WHO WILL NOT SEE PHARMACEUTICAL REPRESENTATIVES BECAUSE THEY HAVE TO ATTEND TO THEIR PATIENTS AND HAVE NO TIME TO EAT SLEEP ADEQUATELY NOR EVEN USE THE BATHROOM - I SAY - I AM REALLY SORRY AND I UNDERSTAND THE REALITY THAT SOMETIMES CREATES THE JAM LIKE THIS IN OUR LIFE. TO THOSE WHO WILL NOT SEE THE PHARMACEUTICAL INDUSTRY REPS, FOR THE WELL FOUNDED FEAR OF BEING SUBJECT TO THE BIASED INFORMATION, I SAY - WAKE UP!!!! IT IS GIVEN, THAT THE INFORMATION PROVIDED BY REPS IS OBVIOUSLY BIASED, BUT IT IS ALSO, THANKS TO FDA, PRESENTED IN THE AS FAIR OF A DICLOSURE FORM AS IT IS ONLY POSSIBLE (AND THE FDA SEES TO IT THAT IT IS, OR ..ELSE.....) WE ALL KNOW HOW STIFF THE PUNISHMENT OF THE FDA CAN BE FOR THOSE WHO DISOBEY!!!!!!!!!!!! MY ONLY QUESTION IS, AND I AM ASKING EVERYBODY, THE WHOLE MEDICAL ESTABLISHMENT AND INDUSTRY AND YES ALL THE CITIZENS OF THE COUNTRY: PLEASE TELL ME, DO YOU KNOW ANYBODY, ANYWHERE, SPEAKING ON ANY TOPIC ANYTIME, WHO IS NOT BIASED!!! We all have bias and it is OK! WE JUST NEED TO COME TO GRIPS WITH IT!! REMEMBER! NEITHER THE DRUG REPS NOR ANYBODY FOR THAT MATTER IS OR HAS TO BE OUR ONLY SOURCE OF INFORMATION, THERE ALSO IS LIBRAY AND INTERNET AND FRIENDS AND FAMILY AND YES EVEN THE GOVERNMENT, ALTHOUGH MANY COMPLAIN THAT GOVERNMENT IS ALSO BIASED AND ITS REPRESENTATIVES SOMETIMES LIE... AND FREQUENTLY THERE IS NO WAY OF SAYING WHEN...AND WHERE....WELL WE ALL KNOW THE FACTS!!!!!! Once the obvious is accepted we always have to look into our better judgement and INTEGRITY unless we feel that our government, as usually well intended, will enact the set of laws upon the recommendations of the paranoid "DO-GOODERS" and will see to it that we will finally accomplish the dream of the TOTALITARIAN SYSTEM and institute: THE MIND AND INTEGRITY CONTROL! PS: WHEN I WAS YOUNG AND NAIVE IN MY NATIVE COUNTRY LIVING THE DREAM OF "SOCIALIST DEMOCRACY" (INTERESTING HOW THEY FELT TO ADD THE QUALIFIER TO THE WORD - DEMOCRACY) WHENEVER THE RULING COMMUNISTS WERE KICKED OUT BY THE WORKING CLASS THAT HAD ENOUGH OF THE HIPOCRISY AND ABUSE, THE NEW EQUIPE CAME TO POWER. AFTER A WHILE WE WERE TOLD THAT THE SYSTEM IS GREAT BUT THE PEOPLE DID NOT LIVE UP TO IT! IT MEANT THAT ONLY IF THE PEOPLE WERE PERFECT! THE SYSTEM WOULD HAVE SUCCEEDED!!!!.....IF ONLY! REMEMBER: BE CAREFUL WHAT YOU WISH AND ASK FOR , BECAUSE YOU MAY INDEED BE GRANTED YOUR WISH!!!</p>	Other

<p>The statement, as proposed, is much too vague and open to too broad an interpretation. -What constitutes "promotional materials"? Is it ANY non-CME material? Would it include all patient education, journal articles, executive summaries of advisory board meetings, white papers, and non-CME newsletters regardless of who's publishing them? Or would it only include advertising and corporate training materials? -Does "on behalf of commercial interests" refer only to jobs for which the writer accepted payment directly from the commercial interest or does it apply to jobs in which the writer was hired by an agency, publishing company, or medical education company that received funding from the commercial entity? -What does "the same content" mean? Does it mean the same commercial product, the same disease state, or the same general medical specialty area? -What is the time frame? Do you mean that a writer cannot work on the promotional content and the CME content concurrently? within 6 months of each other? within 12 months of each other? within 5 years of each other? Or do you mean that once a writer has done a promotional piece, he/she can never again work in CME related to that content? Left open to such broad interpretation, this statement has the potential to put a lot of legitimate, unbiased professional freelance writers out of business. Since it was posted for comment, I have already received feedback from one regular CME client, advised by their CME consultants, that they may no longer be able to hire me if I have ever done any non-CME work in the same disease state as their CME project. My client has indicated that if your ruling passes, it may push them to hire on-staff writers rather than continue to use freelances. Does the ACCME truly have any evidence that professional writers are unable to develop CME materials without bias if they have ever worked on similar non-CME content? In my 15+ years as a medical writer, I have not found this to be a problem. On the contrary, I have often found myself in the position of stressing the need to maintain high standards of balance and scientific integrity in CME materials and non-CME materials alike. As a writer, I stake my reputation on meeting those standards and do not accept assignments that would require me to do otherwise. Please carefully think through the intent and all of the implications of this statement before it becomes a rule.</p>	<p>Other</p>
<p>I do not think it is necessary to automatically exclude individuals, who write or teach promotional activities, from writing or teaching CME activities. For writing of enduring and live presentations, I believe that conflict resolution activities, such as independent peer review, are sufficient to eliminate bias and induce fair-balance. The review should consist of members who do not have a conflict of interest. For teaching live activities, I agree that these individuals should be excluded from presenting on content in which they have a conflict. There is more opportunity for a speaker to inject opinions and bias. I would not preclude them from being a part of the live activity. For example, if the live activity has a non-medical therapy component of which the speaker has no conflict, then they should be allowed to participate.</p>	<p>Accredited CME provider</p>
<p>This proposed policy is a strong step in the right direction. I would like to see it further strengthened to forbid : 1) those who own substantial stock in a relevant commercial interest to control the content of the accredited CME that relates to that commercial product and 2) those who are paid consultants to companies whose products are covered in the particular CME content to control the content of accredited CME on that same content.</p>	<p>Accredited CME provider</p>
<p>Why would you exclude someone with knowledge of the content from teaching in independent activities? In an attempt to become "pure", the ACCME is moving headlong into an environment when, ultimately, the only person who can speak about a subject is one who knows nothing about the subject, and has no experience with use, less he/she be biased. I do not believe a "promotional" speaker should unilaterally control content, but this is why we have "CME planning committees". The person could disclose his association with commercial interests when pertinent to his/her fellow members (or audience), and they could determine the best course of action at their discretion (ranking from suggesting recusement to requesting input). The more CME activities are separated from support (which, due to restricted funding is becoming increasingly commercial or self), the less likely the target audience will be reached. If improving patient outcome is the goal, why would you not avail yourself of an important (albeit not sole) source of information? Sadly, the ACCME (primarily "educators", and mostly lacking medical knowledge), is taking an increasingly paternalistic attitude that physicians "must be protected from the big, bad commercial interests", and doctors, bless them, are just too naïve to be able to protect themselves without the benevolent sheltering provided by ACCME. In reality, ACCME is increasingly attempting to wrest control of medical education from the traditional and historic providers in order to justify their existence. As a Professor of Pediatric Infectious Diseases I often speak about vaccines and immunization policy, because I truly believe population immunization is one of the most cost-effective activities we do in the practice of medicine. If I didn't receive support from vaccine manufacturers, frankly acknowledged, I could not reach the audiences that I do, as public health and school nurses (both critically important in applying vaccine policy to "real people") are so poorly funded that they generally cannot host and support presentations by "external speakers". If a vaccine manufacturer doesn't support me – a Professor of Pediatrics (Infectious Diseases) – to speak about childhood immunization, then these audiences hear "one of their own" cover the same subject. One of the tenants of education recognizes</p>	<p>Accredited CME provider</p>

<p>the importance of "outside" educators to minimize "academic inbreeding" and the perpetuation of misinformation and incomplete knowledge. Without being immodest, my presence at such a program provides a level of expertise that cannot be met by public health clinic nurses or district school nurses. If the ACCME proposal becomes policy, then I would be excluded from speaking at our [redacted] ([redacted]) or " [redacted] " or [redacted] – if I was also supported by a vaccine manufacturer to drive to [redacted] and [redacted] speak about influenza to nurses and administrators working for the [redacted]</p>	
<p>I completely agree with the above policy.</p>	<p>Accredited CME provider</p>
<p>As an educator who has both presented promotional materials on behalf of commercial interests and at the same time has extensively lectured, written and commented on many aspects of the management of diabetes, I think that it is clear that those who are most knowledgeable are best able to appropriately present promotional material and at the same time to give ongoing medical education about these areas. There are many potential conflicts of interest encountered in all interpersonal communications, and to identify one such as being a disqualification for another communication is not only simplistic, but ignores the very real need for true ethical understanding of the importance of being an "honest broker" able to interact in multiple areas of communication. [redacted]</p>	<p>Other</p>
<p>I agree that speakers who participate in Industry Sponsored Speakers Bureau presentations should be excluded from CME events when the topic are either the same or closely related.</p>	<p>Accredited CME provider</p>
<p>I disagree with this statement. They have been invited to promote material on behalf of commercial interests based on their reputation, expertise, and research in certain areas. We need to hear what these speakers have to teach us, to expose us to current and new therapies. I believe that they can control the content of their lectures, to avoid biased presentations.</p>	<p>Other</p>
<p>Experts in any area of disease management whose opinion is valued by peers will accept invitations to lecture by multiple entities, including physician groups, medical societies, hospitals, universities, CME networks, agency conferences, drug companies, and medical education companies. The objective is always the same, to educate physicians on standards of care and inform them on promising new research in the field. None of the colleagues I know and respect as lecturers in the area of CV prevention would say anything within a sponsored presentation that would not be appropriate for a CME presentation. On the contrary, CME lecturers are likely to apply similarly rigorous standards in preparing and delivering sponsored presentations. Creating a firewall between promotional and CME presentations will only result in a reduction of the educational value of promotional presentations, as the experts will go the CME route whereas the promotional side will be taken by less qualified physicians (and more likely to be influenced) . Keep in mind that industry-sponsored educational activities represent the main avenue for most physicians to keep abreast of the advances in the field. This will not change anytime soon. We should aim at improving the quality of such programs, rather than relegating them to an isolated and nonregulated compartment. I recommend not going forward with this policy.</p>	<p>Accredited CME provider</p>
<p>The issue is not the individual or the sponsor or the project. The issue is disclosure and fair and balanced presentation. ACGME does not need to be a COP on the beat. The audience is smart enough to know when presentations are not balanced.</p>	<p>Other</p>
<p>Some of the top thought leaders in the world have performed "promotional" activities and it would be the height of hypocrisy to think they could not develop unbiased professional CME products, which should be judged on their own scientific merit. Also to think someone doing research would be any less biased than someone who does promotional activities is wishful politically correct thinking but actually an absurdity on face value. I have done promotional activities for Merck on ezetimibe. I also authored a thirty page chapter in a peer reviewed state of the art textbook, called [redacted] on how the human intestine and liver handles sterols. There would be only few people who could put together a thorough, top notch cutting edge CME program on this topic than I -- yet I presume I would be barred from doing so. Idiiotic!</p>	<p>Other</p>

<p>This proposal is terrible and degrading. It assumes that we all are dishonest or have such mental deficiencies that we can not distinguish Many of the people who create a program for, or lecture on behalf of a commercial entity are fully capable of being independent and participate in CME activities. All commercial programs, including the speakers, have to follow FDA guidelines of fair and balance. You are proposing that if a speaker participate in a promotional program the speaker loses his or her objectivity! I am personally offended on my and most of my colleagues behalf. get off this high road. You have done more damage lately in destroying medical education and thus quality medical care than could be imagine. You are now proposing the destruction of education and insinuating that so many physicians have done bad. Your time will be better spent by helping to get funds and quality education across this nation. Please, Please, Please. Stop nitpicking, get off the high road. This country needs so much medical education. I speak on my behalf and not on behalf of the organizations that i am associated with</p>	<p>Accredited CME provider</p>
<p>I could see where people paid to create, promotional materials on behalf of commercial interests could be bypassed enough to control the content of accredited continuing medical education on that same content. However, I disagree on the second premise, mainly, that speakers who present promotional material (which is clearly advertised as such), can not present independent fair and balanced data at a CME event without necessarily promoting a product, as long as they are given the opportunity to present any slides they want. I would suggest making the audience be made aware of what individuals have been involved in creating promotional materials on behalf of the commercial interest, and that speakers themselves should disclose at the beginning of a CME event if they have been involved in the development of the material they are presenting on behalf of commercial interest. However, I would not prevent a Physician who presents at promotional events from also presenting accredited CME programs</p>	<p>Other</p>
<p>As a physician who presents CME materials and who also occasionally gives "promotional talks", I find it personally galling that the presumption is present that I cannot tell the difference between science and promotion and that I cannot convey that to the audience whether that audience is private practice individuals or medical faculty or students.</p>	<p>Accredited CME provider</p>
<p>Everyone deserves compensation for their time, expertise and work - including physicians. Whether physicians have their paycheck signed by a university or a private practice administrator does not determine their ethics. I give both CME talks and industry sponsored talks. On any particular topic, regardless of venue, I give the same presentation. With all of the scrutiny toward medicine, physicians should not be viewed with suspicion but should be recognized as a profession steeped in honesty and integrity, as well as for the hard work and the overriding desire to improve patient care that physicians put forth every day.</p>	<p>Other</p>
<p>There is a proposed policy change to make it not allowable for a speaker to speak at a CME event on a topic and also speak at promotional events on the same topic. As a physician in academics in cardiology there are certain messages that I think are very important to transmit to as wide a population as possible, and I look for any opportunity to address these issues. To be specific, research has shown that 15% of people after receiving a coronary stent do not take the prescribed medication - aspirin and clopidogrel. Those individuals have a 10 fold higher mortality, and have been found to have lower educational level than those that are compliant with their medications. From my standpoint this is alarming, and could be impacted by more education and awareness of this problem. Therefore, I find it valuable to have any forum to spread the message that we need to do a better job of educating our patients, and ensuring their compliance. Since it coincides with the interests of those who market clopidogrel, that forum arises, and is the only circumstance in which I have participated in non-CME speaking. In this manner, I feel that I am able to provide a wider audience for something that is important to me. This policy change would inhibit that opportunity, and I think is "throwing the baby out with the bathwater". I would prefer if we did not limit educational opportunities, but ensure there is transparency in issues regarding potential conflict. Additionally, there is inconsistency in allowing a company to have a research relationship with a CME speaker, why not be able to provide financial support for that speaker to speak on areas in which they are expert. It strikes me as hypocritical.</p>	<p>Other</p>
<p>To suggest that an individual conducting a clinical trial on a therapeutic agent has less of a commercial interest than a physician giving a "promotional talk" is ludicrous. Many promotional talks are in fact up to date disease based educational programs. As long as the talks are clearly defined as promotional and the physician discloses any conflicts these programs provide an important educational format that is unavailable to many physicians in their community.</p>	<p>Other</p>

<p>The recent published regulation on academic physician and scientists resulting in potential invalidation of the academicians to continued medical education creates a paradox and may render several individuals incapable of propagating science that is (and could be) sold and some concepts without commercial value. I personally restrict my commercial conferences to those products that were studied and analyzed by our clinical researchers and investigators at large, and I have no conflict in disclosing my attachments to companies interested in the results. On the other hand, I accept and actively participate in many CME intramural academic activities and discussions around topics of commercial and non-commercial value. After all, we are the investigators!!</p>	<p>Accredited CME provider</p>
<p>The ACCME is way off base in this proposed policy. This will seriously limit the freedom of academics, and will cause a limitation of qualified faculty for CME presentations. This policy is an example of what one author has called the "New McCarthyism", and should be resisted vigorously. What has become of the notions of academic freedom and freedom of speech.</p>	<p>Other</p>
<p>Thank you for taking this positive stance to limit conflict of interest in physician education. The research is clear, pharmaceutical marketing practices are very effective. As a doctor, if I ignored such clear and convincing evidence about say, the risks and benefits of hormone replacement therapy, I would be doing my patients a disservice and be at risk for litigation. Yet, doctors are choosing to look the other way on this topic, and it has to stop. Again, thank you for doing the right thing. It's hard to be the first ones to lead any change, but in the future doctors will wonder why it took so long to make this change.</p>	<p>Other</p>
<p>I find this proposal insulting, unprofessional and counterproductive. It implies that by giving a promotional talk I am in some way compromising my scientific integrity. I have given numerous talks- both sponsored by Pharma companies and as independent CME programs. The Pharma programs are actually much more regulated for content and accuracy by the FDA than the CME programs. I believe your proposal has very little factual basis to suggest that the overwhelming majority of speakers have or would misrepresent or slant scientific evidence based on the source of an honorarium. [REDACTED]</p>	<p>Other</p>
<p>I am writing to comment upon the ACCME proposal that physicians who teach in promotional activities should be excluded from teaching in independent CME activities. I think this proposal will significantly limit the availability of experts who are qualified to educate on a specific topic, in particular, in areas that require sub-, sub-specialty training. The potential adverse harm and adverse patient outcomes because of inexperienced educators or because of the lack of the presentation of balanced opinions may result in poor patient care. Certainly, any potential bias/conflict of interests should be disclosed and there should be transparency with re to these relationships (perhaps even to the point of disclosing the type of relationship and the total amount of any honoraria paid) but to exclude experts because of this potential conflict is not wise. Finally, bad character can not be completely controlled even with rules [REDACTED]</p>	<p>Accredited CME provider</p>
<p>I want to object on your proposal to exclude physicians who speak at promotional programs from CME programs. I feel the current FDA and legal regulatory environment already provides sufficient oversight on the process</p>	<p>Accredited CME provider</p>
<p>This proposal is too vague, too broad and unnecessary provided we follow existing rules regarding CME. 1) too vague - if someone is provided an honorarium to give a talk about a trial in which they participated to test a drug, device or product they would be considered "persons paid to present promotional materials on behalf..." even if they are only presenting the published results. 2) too broad - controlling the content presumably seems to include using data from one's own published trials (if industry sponsored) in a CME event. Essentially this excludes those who know the most about the trial from presenting if they have also presented in the format of item # 1 above; 3) unnecessary - I participate in enough CME activities to understand that biased content is readily recognized, weeded out >90% of the time and counter-productive the other 10%. Current ACCME guidelines are clear, comprehensive and effective. In my opinion, the proposed change will do nothing to reduce bias, which seems to be at an all time low, but will deprive CME audiences from hearing from the most knowledgeable speakers.</p>	<p>Accredited CME provider</p>

<p>The following is a common scenario, A research investigator is involved in the development or evaluation of a pharmaceutical product. By virtue of that working knowledge the investigator is invited to help write an article for the reviewed literature or work with the company to develop educational materials. That individual has a better working knowledge than people who have not engaged in these activities. This individual is also in a good position to know who other researchers/educators are in the clinical area. The current proposals would preclude that investigator/educator from presenting at CME. The current proposal precludes this person from making recommendations about other speakers for a CME program. This deprives the audience of perhaps the best expertise available. The current CME guidelines require that each of these relationships be disclosed, so the audience (presumably an intelligent group) can make the decision about whether there is potential bias. Current guidelines are also quite clear in outlining the need to declare any off label use. Strict enforcement of CME guidelines including duality declaration, vetting of slides and evaluation of whether there is evidence of duality are currently generally sufficient to insure fair balance in presentations. More detailed declarations of duality (how many promotional talks? annual income for consulting/talks? how much research funding? payment for written articles?) would provide greater transparency for the audience without seriously jeopardizing the overall educational process. ACCME should consider approaches to greater transparency rather than cutting out some of the best educators from the CME process. As a final comment: I am a physician educator who has participated in multiple CME courses, course planning committees and been involved with pharma at many levels (investigator, speaker, ad boards, development of educational materials). I would now be precluded from participation. (The fact that I am leaving my current position and severing ties with all companies, except one, means that none of the proposed changes will affect me personally).</p>	<p>Accredited CME provider</p>
<p>We have an ethical mandate to present CME programs without bias, as much as possible. At the same time, many of us who teach, also teach about commercial products to peers when these tools are available to improve our standards of care. It is not unethical to promote products which improve the lives of patients and to teach fellow physicians about proper usage and clinical information. Teaching about disease states and related information, non-branded, non-commercial...is a different activity and one which can be accomplished when the ethical physician pledges to leave commercial bias out of the presentations. I think it is demeaning to imply that physicians cannot discern when non-commercial presentations require unbiased information. Many of our finest teachers are encountered at both types of meetings, and it would be a great loss to think it is either "one or the other" allowed. This is a great infringement of a physician's right to exercise professionalism and ethical conduct.</p>	<p>Accredited CME provider</p>
<p>The exclusion of people who present promotional materials inevitably decreases the pool of excellent lecturers and presumes that such individuals are not capable of giving fair and scientifically meritorious lectures. Given the policies that are already in place to ensure the fairness and scientific merit of both promotional programs and CME lectures, this proposal is an unnecessarily punitive measure that only threatens to lower the quality of CME education.</p>	<p>Accredited CME provider</p>
<p>The presenter should be free to modify add or delete information in the presentation to best accomplish the educational objectives of the presentation which may or may not have associations with commercial interests.</p>	<p>Accredited CME provider</p>
<p>I believe that you should rethink this proposal. There are many honest, intelligent, and skilled physicians who work with the pharmaceutical industry to provide quality, unbiased educational programs and would be very qualified to provide CME. If you have an issue with bias, rather than make a blanket rule to apply to quality educators, spend your time and resources to find and remove the few physicians who are not acting in the best interest of the patient. If you pass this provision, it may become VERY difficult to find educators to provide quality CME programs. [REDACTED]</p>	<p>Other</p>

<p>As long as persons who are paid disclose ALL potential conflicts and amount of funding received (modest, significant), then it is reasonable for them to also be able to present in CME programs. The most expert people in the field are the ones developing the materials for the commercial interests. There would be almost no one left. Conflicts of interests need to be up front and the group being educated can decide on the influence of the conflicts on the content. Someone without any ties to commercial interests is getting harder and harder to find these days. Major societies (██████████) allow presenters with commercial ties-as long as they are fully disclosed.</p>	<p>Accredited CME provider</p>
<p>Other than finding this policy offensive, condescending, divisive, wrong-headed and totally out-of-touch with reality, I have no substantive problems with it.</p>	<p>Accredited CME provider</p>
<p>While goals are laudable, the regulations as proposed are overbearing and will worsen and inhibit medical education. At every major national meeting (██████████) which I have attended in the last 10 years, the industry sponsored CME symposia were staffed by nationally and internationally recognized speakers, usually providing some of the more concise education available at those meetings. As not only members but leaders of the speaker bureaus, these professors are our leaders and to inhibit their ability to pass on their expertise or to develop the CME programs can not be inhibited.</p>	<p>Other</p>
<p>Let me see if I get this. So, if one is an expert in the area, and one is retained by a commercial interest specifically to see that the material is fairly presented and unbiased (so as not run afoul of the FDA), then that expert may no longer give CME in their area of expertise? On the face of it, this makes no sense. If the integrity of the "expert" is in question, then this may be understandable although unfortunate. But that is precisely why, I thought, we have the full disclosure and and conflict of interest statements we must submit before speaking and why we are not allowed to deviate from the slide deck in the affirmative section of a lecture, isn't it? This action may actually decrease the educational - and I understand that this is also promotional - work companies are likely willing to do which I believe will not be in the best interests of the physicians wishing to learn nor patients who might benefit. Just my 2 cents.</p>	<p>Accredited CME provider</p>
<p>I understand the intent to limit bias and ensure balance, but as somebody within academia that has done both I find it insulting and unnecessary. ACCME cannot thought control individuals speaking and thinking within medicine where there is often more art of interpretation than strict straightforward scientific interpretation. Industry interests rely on thought leaders for their teaching skills; to restrict such individuals to not participating on development of CME activities which extend to national scientific is too restrictive. The purpose of the accreditation process is to promote fairness and absence of bias through disclosures and affirmations. This process should continue in its present form.</p>	<p>Other</p>
<p>I think there is a very large difference between creating promotional materials, and presenting a talk. I would be a bit more fine in how to separate the different aspects of this. 1) Somebody who does a great job at creating educational materials should not be barred from creating CME educational materials that are unrelated to their non-CME activities. I would suggest the following wording: People who create promotional materials may not control RELATED CONTENT in a CME program. 2) I would be extremely careful about regulating speech. If it is going to be regulated, it should be topic specific, i.e., a speaker may present at a CME event if the topic is different from the promotional topic that was presented. However, regulating speech is a tremendously slippery slope. I would prefer that all speech be unregulated with the provision that it must be fair and balanced for all presentations.</p>	<p>Accredited CME provider</p>
<p>There are many safe guards in place. There will always be those who are not forthright in disclosing their relationships but I believe they are in the minority. Most disclose all relationships and the audience can make their own decisions. I believe those who violate disclosure requirements or who have a non-disclosed COI or bias should be banned from participating an an accredited CME program for 2 years. Programs that choose to use these speakers despite the ban will not receive accreditation for CME. Punish the offenders not those who adhere to the requirements.</p>	<p>Accredited CME provider</p>
<p>I believe that the best and most qualified physicians educators should be educating us. The fact is the best and brightest usually are the ones who are actually conducting the research and ergo are also presenting the data at sponsored educational meetings. There are plenty of provisions in place to cover disclosure, besides our audience is not stupid and is able to separate opinion from fact.</p>	<p>Accredited CME provider</p>

<p>Don't you think the more important issue is whether the content of the CME program is fair, balanced, and of educational value to the audience and to the patients. By excluding qualified persons in the academic community, you open the opportunity for unqualified persons to simply fill in the gaps because they are not necessarily governed by any conflict of interest policies. Where is the evidence that this cross polinization of promotional and CME programs has been subverted in a biased fashion. I suggest that the ACCME put it's effort into the promotion of programs of benefit to patients and to physicians who are seeking up to date information in a format that allows them to update their knowledge base in an effective fashion. As a person who often presents educational lectures in a variety of settings, I find that my independence and ability to present a fair and balanced and I hope valuable lecture is actually being hampered rather than helped by the proliferation of "regulations," allegedly designed to avoid bias. The sponsored CME programs in which I participate never allow me to "control" anything!</p>	<p>Other</p>
<p>This is a very difficult issue. The problem begins with the fact that much of the clinical research being done is funded by pharmaceutical companies and other commercial interests. There is , lliterally, not enough money to "go around" from the NIH or other "neutral" agencies. Even these "neutral" agencies develop their own biases in funding based on the make-up of review committees , government mandated initiatives, decisions on the overall derrection of a foundation , etc. The funding that has come from the phrmaceutical industry, for instance, has made the great progress in the area of headache medicine over the last 20 years possible. There was (and still is to some extent) a great bias against headache in the academic medicine world. Without the funding from Pharmaceutical Industry, funding for the research and progress that has been made would not have been possible. A second issue is that of education. Again using Headache Medicine as an example, most physicians receive only 1 or 2 lectures on headache during medical school. Primary care physicians may receive 1-2 more lectures during residency. This is the time devoted to a condition that affects 80+% of the population. The professional advisory boards for the companies that produce triptans were all given the recommendation of educating physicians about headache so they would be aware of the condition and the therapies. The current level of headache knowledge of primary care physicians in this country is, by and large, a result of this recommendation. The Pharmaceutical industry has provided and immense amount o education about headache to physicians over the last 15 years. I believe, the same can be said about depression. The other side of the issue has been more apparent recently. When the educational material noted above was delivered as CME and required a balanced presentation, the wystem worked fairly well. In the last 4-5 years, the presentations have been much more "promotional" and the presenter is not given an opportunity to provide a balanced presentation but must use a predetermined set of slides and information for presentation. The presenter is asked to act as an agent for the company and not as a "presenter of educational material. I would suggest that if an individual is being sponsored to present a bona fide CME activity, this should not impact on their ability to work in the CME area. I would agree that individuals that have agreed to word for a company in producing promotional materials or delivering education for a company that deals only with that product, not a balanced presentation, are conflicted and should not be involved in producing CME materials.</p>	<p>Accredited CME provider</p>
<p>I think this should absolutely be true if one has any ownership interest, and if one has an ownership interest, one should also not lecture on a subject, except in the case of an orphan disease or device, or if demonstrating how a novel device should be used. In contrast, there are many circumstances where an expert in a field will be sponsored to give a lecture at a course supported by industry. This support is of crucial improtance, as in many areas of health care we depend on unrestricted support from industry to be able to train young physicians, because health care institutions cannot fund these processes and courses themselves. Therefore, I think this new policy will actually significantly limit the ability of many experts to teach and direct courses. We will then be in a situation where less qualified people will either be controlling the content of courses, or will be the ones providing the training - neither a good situation. Therefore, I believe that the only change to the current policies for conflict of interest should be that in cases of ownership interest (stock, royalties, etc) should those people not be involved in organising courses, or even lecturing, outside of rare exceptions as mentioned above. [REDACTED]</p>	<p>Accredited CME provider</p>

<p>As a colorectal surgeon I have given presentations several topics including laparoscopic colorectal surgery, and postoperative ileus, in both CME and nonCME format. I do so to provide a nonbiased review of the current surgical literature to surgeons around the country. My presentations remain the same as do my comments to the audience whether it is a CME or nonCME format. I have not allowed sponsors to modify my talk or presentations to provide the most unbiased opinion to my audience. If a company wished to modify my comments or presentation i would not perform the talk. The current management of conflict of interest at CME programs I believe adequate safeguard the audience from receiving biased information. I do not believe further regulations are necessary as long as physicians remain firm in their relationships with industry.</p>	<p>Accredited CME provider</p>
<p>I strongly believe that the proposed policy of excluding physicians who speak for promotional programs from CME presentations is counter-productive and will actually harm CME. It will also harm the quality of promotional activities, as I believe even those should be of high educational value. We all share the desire to maintain independent CME. Under current guidelines,the programs and sprakers are carefully vetted. The information to be presented (in both promotional and educational programs) is carefully reviewed. Adopting the proposed exclusionary approach will limit the number and quality of physicians available for CME presentations. The current policies ensure that the content of the presentations is fair and balanced, and the sprakers are under obligation for full disclosure. I hope that ACCME recognizes that current policies address potential conflicts of interest and ensure high quality programs. The proposed changes are unnecessary and potentially harmful.</p>	<p>Accredited CME provider</p>
<p>I think there is no reason for concern in this regard;many of the best qualified physicians who speak are indeed the very ones with the most experience academically and professionally; they are frequently the people most audiences prefer to hear...those with academic,research and practical experience that are credible. The current exvironment precludes bias in these presentations and audience responses confirm this. The honoraria by no means approach the time committment needed, but to not have one would mean no-one would be interested in volunteering to give away that much time as a favor.</p>	<p>Accredited CME provider</p>
<p>The policy statement is ambiguous. What does "cannot control the content of accredited CME" mean.Can a speaker for a pharmaceutical company's symposium or dinner program not PARTICIPATE in an accredited CME program or can that person not CONTROL,i.e. be the chair or selector of a CME program. As one who has given talks at many pharmaceutical companies-sponsored programs,I find the entire concept of preventing me from ever participating in an accredited CME program offensive and abusive. This looks like a Bush/Cheney abrogation of an individual's rights.If passed,law-suits will surely follow--or have they already,from the 30 AG's action.</p>	<p>Accredited CME provider</p>
<p>This would be a very foolish step.The elimination of speakers who do commercial talks would almost totally deplete the pool of talented speakers for CME.Please accept that physiciens have opinions and have a right to express these opinions.Also,please respect the integrity that the vast majority of speakers have.</p>	<p>Other</p>
<p>To ACCME members: I oppose this policy. The implication that ALL commercial interests are incompatible with CME is wrong. I reject the premise that good medical education and factual presentations created by commercial interests are not worthy of CME. Most new science comes from researchers who work with industry colleagues. These same researchers are the ones who most often help develop the educational materials that are used by "commercial interests". These same researchers are also the ones that participate in the dissemination of this new information. Your proposed policy would barr the researchers who have the first hand knowledge from educating their peers in CME venues. The implicit corollary to this is that education would be done by people without the first hand knowledge of the clinical trials. In my opinion ACCME is out of line and moving in a direction detrimental to medical education in the United States. Physicians should have access to every source of information, and ACCME should limit its recommendations to suggesting full disclosure for accreditation.</p>	<p>Other</p>
<p>It would be wise to have those who create the content for educational material be responsible for presentation of such material since they are more aware of the up to date evidence for effectiveness or lack of it of the substance or material in question. As long as the presentors are not paid directly by a company for presentation of the data, they remain most competent to design the educational material with expert colleagues. As long as the presentors do not have a conflict of interest with the company, they seem to be best qualified to be the presentors of the edicational material that they create with expert colleagues.</p>	<p>Accredited CME provider</p>

<p>I have recently become aware that the ACCME is seeking comments regarding the proposal that physician/providers who teach in promotional activities be excluded in teaching in independent CME activities. I would like to add my comments for review. With all of the emphasis over the past couple of years for any provider, not just physicians, who provides continuing medical education to disclose his or her relationship and clearly inform the audience whether a lecture will be promotional or is independent of sponsorship, I feel that today's lecturers are clearly well-versed and recognize and adhere to the need to ensure that the lines between promotion and independent education are not blurred. Many of today's best and brightest lecturers both participate in the development of promotional materials and also both provide and develop non-biased/independent medical educational toolkits and lectures. To bar any physician from providing CME because he or she develops educational materials that are unrelated to their non-CME activities is crossing the boundaries between compliance and disclosure and the restriction of free speech.</p>	<p>Other</p>
<p>I must take issue with this policy - it is erroneous to assume that faculty or those who create medical educational activities for commercial sponsors cannot or should not independently participate in accredited CME programs - even with overlapping content. This is unduly restrictive. There are numerous, effective safeguards in place for CME programs in the USA - all this latest policy will do is reduce the pool of effective teachers in medical education and increase the cost of creating medical educational programming.</p>	<p>Other</p>
<p>Sirs: I want to express my absolute opposition to your proposed policy change. Having persons expert in a therapeutic area possibly involved in a "promotional" activity helps ensure that the "promotional" activity maintains balance and objectivity, rather than somehow tainting the CME. This is because the INDIVIDUAL's professional integrity and reputation is at stake in both circumstances - something that I for one trust far more than the allegedly "uncorruptable" institutions for which the individual often works. All CME providers are currently required to make full disclosure of all real or apparent conflicts of interest (COI), a policy that should continue. In this manner, each member of the audience can assess objectivity and bias for him or herself. To exclude all speakers and other providers of CME from "promotional" activities would do more to insure that less qualified and more biased persons participate in these activities than just about any other action that the ACCME could take - and thus should be avoided. Please recall that one of the principal values that ANY academic institution must espouse and protect - medical or otherwise - is freedom of expression and freedom of ideas. This includes freedom to express one's opinions, favorable or unfavorable, about a commercial product or service. Even blatantly "commercial" speech is protected no less than any other. Consider this issue in another context, one subject to far deeper beliefs and prejudices than use of one drug or another - political speech. A professor of political science might have very outspoken liberal or conservative beliefs, write for partisan publications, or even work (on a volunteer or paid basis) for a political candidate or party. Yet I have never heard such a "biased" professor being excluded from teaching classes for credit in a political science curriculum at a college or university. Presumably, the professor should be open-minded enough to assess his/her students' work objectively (some might question this assumption in all cases), and the students (often undergraduates likely with less maturity and sophistication than practicing physicians) can evaluate course content in light of the lecturer's position on the political spectrum. If this is done in the social sciences in universities all the time, surely the same approach is appropriate for medical CME as well. Finally, I exhort the medical establishment in all its incarnations to stop focusing exclusively on the "low-hanging fruit" of commercial interests, and to devote some real attention to the myriad other forms of "bias" that infuse many aspects of American medicine (academic and otherwise): Biases in self-referral, in recommending procedures over conservative therapy, in health care coverage from government and private payors, in the peer-review process for the awarding grants and the acceptance of papers for publication, and in promotion and tenure, just to name a few. Only if the medical community broadens its focus to these other areas will our efforts be credible both within the profession and within society at large. I would welcome any feedback on my comments, via e-mail. Sincerely, [REDACTED]</p>	<p>Accredited CME provider</p>
<p>there is no reason to change the guidelines.they work well and the propose changes will only hamper medical education. [REDACTED]</p>	<p>Accredited CME provider</p>
<p>Additional response: I'd love it. It would make our (in CME) jobs SO much easier particularly with respect to resolving COI. [REDACTED]</p>	<p>Accredited CME provider</p>

<p>This proposed policy has, at its base, a number of assumptions that need to be carefully examined. The first assumption is that promotional presentations are always biased and CME presentations are always unbiased. The truth is probably somewhere in the middle but it leads to another assumption about our faculty. The policy suggests that faculty are giving unbalanced and biased presentations when they are speaking at promotional meetings. The faculty that I'm familiar with place a great deal of value on their reputations and would not want to be seen as "promoting" anything that is not substantiated by evidence. Conversely, faculty who are willing to sell their reputation to promote a drug, will do so in CME activities as easily as in promotional activities. I would feel better if the new policy was designed to eliminate these individuals from our CME faculty. The faculty that I've talked with, who present at both CME and promotional events, admit that they often give the same lectures at both types of events. However, all of them indicated that they give evidence-based presentations, rather than biased presentations, at all events. I agree, in principle, that we do not want our faculty doing promotional talks and we would like to have them resign from pharmaceutical company speakers bureaus. I'm not certain that, faced with the loss of additional income, that faculty would choose to leave the speakers bureaus. One possibility is that we could lose some good faculty who would no longer speak at CME events.</p>	<p>Accredited CME provider</p>
<p>I think disclosure of interests should be required but I don't think there is any more bias to commercial interests as so-called non-commercial interests and so I think this is an undue stricture and I would be against this recommendation as worded</p>	<p>Other</p>
<p>I agree. To me this shows that the persons do have a financial relationship with a commercial interest, and may be biased when planning the content of accredited CME on that same content.</p>	<p>Accredited CME provider</p>
<p>August 28, 2008 Murray Kopelow, MD, MS (Comm), FRCPC Chief Executive Officer Accreditation Council for Continuing Medical Education 515 North State Street, Suite 1801 Chicago, IL 60654 Dear Dr. Kopelow: The [REDACTED], representing more than 500,000 physicians, appreciates the opportunity to provide feedback to the ACCME call for comment on the following two questions; 1. Should those who write promotional materials be excluded from having any role in writing CME content? 2. Should those who teach in promotional activities be excluded from teaching in independent CME activities? In response to these questions, ACCME is considering the following new policy: "Persons paid to create, or present, promotional materials on behalf of commercial interests cannot control the content of accredited continuing medical education on that same content." [REDACTED] position: Persons paid to create or present promotional materials on behalf of commercial interests (who therefore disclose a conflict of interest) need not be excluded from accredited continuing medical education on the same subject if and only if their conflict of interest can be resolved. Background: The ACCME, currently and appropriately, requires accredited providers to implement a mechanism to identify and resolve all conflicts of interest prior to the education activity being delivered to learners (C7, SCS 2.3). Additionally, accredited providers are required to design educational activities that actively promote improvements in health care and NOT proprietary interests of commercial interests (C10, SCS 5). As such, accredited providers undergo additional rigors to ensure that CME activities and related materials promote improvements or quality in healthcare and that CME presentations give a balanced view of therapeutic options. Since the dissemination of the revised ACCME Standards for Commercial Support of CME, accredited providers have invested significant resources to move beyond identification and disclosure of conflicts of interest, to management and resolution of such conflicts. These efforts have served to ensure that CME activities remain fair and balanced in nature. When conflicts of interest cannot be sufficiently managed and resolved to eliminate commercial bias from CME, then such conflicts are considered irreconcilable. This has particularly been a question when accredited providers, especially in small specialties with small pools of experts, approach individuals considered the "best and the brightest" available to teach physicians, but who disclose relationships that constitute a conflict of interest. Accredited providers have, however, been creative and successful in implementing at least four interventions to ensure that commercial bias is eliminated from CME. Learning from the experience and demonstrated success of societies in managing and resolving disclosed conflict of interest, [REDACTED] recommends a formalized approach that could be standardized across all providers. [REDACTED] recommends: That one or a combination of the following options be considered as universal criteria for resolving disclosed conflict of interest. - Peer review: members of the planning committee, or other authors/speakers without a conflict of interest, review the content an author/speaker plans to use in a CME program, after which the author/speaker may not change that content. - Evidence-based presentation: the author/speaker is required to present an evidence-based CME program that conforms to nationally accepted standards of Evidence-based CME (not just having the speaker say "this is an evidence-based presentation"). - Modify content: the author/speaker may present on patho-physiology, research data, and other content, but not make practice recommendations (these are</p>	<p>Other</p>

<p>made by another speaker, who discloses no such conflicts of interest). -\tOn-site monitoring: trained monitors (volunteer physician and staff) attend the presentation and determine if subtle or overt biased crept into the talk, with significant consequences. ■ recognizes that the perception of the incorporation of commercial bias into CME is real. We applaud ACCME for requiring accredited providers to identify and resolve all conflicts of interest prior to the education activity being delivered to learners. We believe that the creative experience of accredited providers can be generalized to prevent the incorporation of commercial bias into CME, and thereby protect not only the education of the learner, but the integrity of the ■. Sincerely, ■</p>	
<p>I am concerned about the proposed change which would effectively limit the available supply of physicians that conduct continuing medical education. There is value provided to physicians from both promotional talks and independent Continuing Medical Education. Many of us are involved in both aspects of this educational service and, in my opinion, little would be gained if faculty had to choose between participating in promotional and independent medical education. Most of us who are involved in promotional talks make great effort to remain fair and balanced. This is an ethical obligation and we take it seriously. Physicians at large need access to experts, and the public as a whole would be ill-served by limiting the input of clinical experts. I hope you take my comments into consideration as this policy is developed. Sincerely, ■</p>	<p>Other</p>
<p>I have read the Aug 2008 ACCME proposal for changes in CME. These recommendations will put further restrictions upon speakers in CME events and will drastically affect the quality of the presentations. Having been a speaker for 25 years and having a special interest in delivering good medical education to practicing docs, I believe this proposal will end up making future CME programs dull, boring and useless to the practicing docs. American medicine needs improved CME, not more restrictive CME with poor quality programs (because of all the restrictions). The ACCME needs to look at the last 20 years of CME and see how the programs have become of lesser and lesser quality because of increasing restrictions. We need to teach our PCPs in the US about new products, new guidelines and better ways of diagnosing and treating their patients. I meet with many PCPs in my community for lunches to discuss diseases in my specialty (Allergy/Immunology) and they are very hungry for new knowledge. If you keep adding more restrictions to CME you will ruin the medical education that is sorely needed in our society.</p>	<p>Other</p>
<p>it is my understanding that all CME presented material is factual with scientific data support. Further, CME presentations do not reflect bias or promotional info regardless of the commercial support of the program. My greatest dissatisfaction with any material that is approved by the sponsor, is the inability to personalize factual info or evidence based scientific data. This removes the "personality" of the speaker and his ability to "teach". He, with the current limitations cannot interject emotion, charisma or character to his talk. In CME presentations, you ,at least, can be selective and are not mandated to present each and every slide in the core presentation. You can change font size, line colors, effects and transition that add life and attractiveness to the presentation. I hope that my experience from the past 30 years and 350 presentations, be helpful for your survey.</p>	<p>Accredited CME provider</p>
<p>1)Should those who write promotional materials be excluded from having any role in writing CME content? Reply: Those who write promotional materials should be excluded from having a role in writing CME content IN THAT PARTICULAR TOPIC, i.e. a physician who writes about Natrecor should be restricted from writing about congestive heart failure and other areas where natriuretic peptides may be used. 2)Should those who teach in promotional activities be excluded from teaching in independent CME activities? Reply: Those who teach in promotional activities should be excluded from teaching in independent CME activities, IN THAT PARTICULAR TOPIC. (same as above). Such restriction may cause a mass exodus of a academic physicians, many of whom subsidize substantially lower incomes and greater work hours (versus their non academic peers) with industry relationships. Many of these people are excellent educators and would be lost to their residencies and their departments for these educational activities. Imagine a grand rounds series, devoid of most academic chairmen and with significantly reduced number of visiting professors. Such restrictions, however, would be useful in improving many CME programs, but should be limited to the particular topic from which the commercial interest lies. The difficulty is in determining where the boundaries lie and administrating oversight. (An all exclusive policy would definitely be easier to implement.) Thank you for the opportunity to comment, Looking forward to hearing the decision,</p>	<p>Accredited CME provider</p>

<p>In an effort to comply with FDA requirements on appropriate promotion of products, commercial entities seek input from medical and basic science experts. In an effort to provide audiences with up-to-date and accurate medical information, CME programs typically rely on these same experts. It is a bit insulting to assume that ALL such relationships should be subjected to the above stipulation because of the inappropriate behaviour of a few. Unintended consequences always follow efforts to control the flow of ideas, information, or money. One such consequence is for experts to forgo CME programs altogether. Given the financial pressures of academic and private practices at this point, the time and effort required to comply with ACCME guidelines simply is not worth the effort. Simple economics will prevail; CME programs will suffer. The disclosures already required serve to inform the audience that they should be on the alert for promotional messages. The audience evaluations of CME programs typically identify those speakers who serve more a promotional role than an educational one - those speakers are not invited back. Perhaps a better approach would be to standardize such an evaluation. Scores could be submitted to a central location. Failure to achieve a certain score would preclude participation in future programs for ANY sponsor. The proposed guideline presupposes a gullible audience and an avaricious presenter - it is a short-sighted solution that should not be implemented.</p>	<p>Other</p>
<p>Having gone to promotional activities to earn CME has always been a standard to include a question regarding content bias. If there is bias noted, the health care professionals will list this, and I believe the CME is then requested to be reviewed and adjusted. I think by proposing this measure, there is discrimination towards writers of CME's/ speakers. Allow the health care professional/participant to determine what is biased or not. With this revised measure, this type of protection is truly not protection, it is control.</p>	<p>Other</p>
<p>Since all promotional materials presented by speakers supported by industry must stay on label and use appropriate peer reviewed references I am not sure the reason for this new proposal. Therefore it is very difficult to understand the purpose of this policy. While I am not a physician, I find such a policy demeaning and so far beneath the dignity of intelligent healthcare professionals it is difficult to understand where all of this is going. Enough is enough - the pharmaceutical industry is an american treasure and many of us owe our lives to the wonderful innovations coming from this industry. My father's blood pressure was controlled by chlothiazide and mine with an ARB and beta-blocker - wow what a difference. Why do we continue to bash this wonderful american industry.</p>	<p>Accredited CME provider</p>
<p>I agree with the proposed policy and do not disagree with its intentions.</p>	<p>Accredited CME provider</p>
<p>This would assume that a physician who helps create a promotional talk for a pharmaceutical company would actually try to promote the product. In my experience, physicians who help write promotional talks for pharmaceutical companies actually try to present the data and the interpretation of the data in a fair balanced manner and mitigate much of the promotion of the product. By not allowing physicians to do this and write CME talks, the fear is that promotional talks by the manufacturers would be less fair balanced and more promotional. With respect to giving a promotional talk, many physician speakers, although they stay on label, try to present the content fairly and accurately, as though they were giving a CME presentation. The physician writer and/or presenter who is not fair balanced, will do the same with a CME talk no matter how it is written. I do not think this is reasonable for the reasons stated above. This will not help CME providers in assuring that CME talks are fair balanced and delivered in a fair balanced manner. That is up to the CME provider to be sure that talks produced are fair balanced and given in a fair balanced manner. This is not a black and white situation. The same physician can write and deliver a promotional talk and write and deliver a perfectly fair balanced CME talk.</p>	<p>Other</p>

<p>Some of the very best teachers, the most effective communicators and the folks that engage learners the most effectively are selected by the pharmaceutical industry to do their promotional presentations. If these people are disqualified from CME activity then the entire educational system will suffer. Some even educators present for a variety of medications within a class. They know the class very well and bring a tremendous amount of experience to the CME world. I believe that any affiliations, promotional activity and consulting should be disclosed at the beginning of any CME presentation. People have their biases even if they do not speak for pharmaceutical companies. Let's not be naive and say that presenters are not biased just because they do not speak for pharma. Let's just disclose our affiliations up front and let the audience decide. We are all educated enough to make informed decisions with regard to the appropriateness of a particular medication for a particular patient. When a speaker gives full disclosure at the beginning of a presentation I can consider the presentation in light of the disclosure. If we disqualify presenters from the CME world because of their pharma experience the entire post-graduate educational system will suffer tremendously. In the long run, our patients will have physicians that are not as well educated and up to date.</p>	<p>Non-Accredited CME provider</p>
<p>I do not agree with the above statement, for it assumes that educators cannot distinguish between unbiased and biased material. It assumes that we sell our souls to the devil and can never again work in an unbiased manner again. I propose that educators should know the difference and respect those differences. If they cannot, they should not be able to do promotional nor CME activities, that they should not be involved with residents, medical students, or even patients. For as an educator, I must be able judge the material that I read or come in contact with and determine what is best for the care of my patients and the education of my students. I believe there are psuedo educators who do not adhere to these principles and they should be discovered and removed from education and patient care. All educators who are involved in promotional development need to be thinking unbiased adults for their entire life and should respect the differences and do what is best, and We are able to do this.</p>	<p>Accredited CME provider</p>
<p>If I read this right, a speaker on a speaker's bureau of a product marketed in a certain disease e.g Pneumonia, cannot give a CME grand rounds on pneumonia. The connotation is as follows. By giving a clearly promotional program, where the audience and speaker clearly know that the intent is promotional, the speaker has become so biased, he or she is incapable of presenting an unbiased talk in a completley different forum, without commercial sponosorship, on the same topic. This is clearly ABSURD. Please allow us the benfit of doubt. We all have the intelligence and integrity of knowing what forum we are speaking in and clearly distinguish between proptional and non-promotional talks. Most speakers at large international confernces, including me, have served on speakers bureaus. How many of these CME talks get rated as biased?? What is the evidence for this carry over bias that this new rule is supposed to control? A promotional talk also does not make the speaker biased. Most of us find them an excellent forum to teach, to reach out to community based physicians and exchange ideas. I do promotional talks for products I believe are good for our patients and should be used in the appropriate setting. Does that compromise my integrity to the extent that I can no longer give a CME talk? There are enough safeguards in the current system against bias in CME talks, with ratings by the audience, disclosure etc. This idea is unnecessary and an indiscriminate condemnation of a lot of good teaching being done today in the community by people with integrity.</p>	<p>Other</p>
<p>It has been my experience over the last 10 years on speakers bureau that leaders in the field of ID mostly as it relates to conducting research and publishing on specific topics have been also involved in speakers' bureau at some level. Preventing the leaders from giving CME lecture because the are associated with a speakers' bureau would diminish the quality of the CME and exposure to expertise in the area. Most Grand rounds today given at medical centers involves leaders in the different field whom are also on speaker's bureau. Moreover, most of them may not be allowed to give CME because of this policy however they would still be the faculty responsible for the education in medical schools and other professional school. This appear to me as a double standard. Disclosure of the association with the commercial entity should be sufficient for the audience to recognize the bias if it exists.</p>	<p>Accredited CME provider</p>
<p>This proposal makes no sense. Presenters must be free to speak their minds and educate others as they see fit. Good educators cannot be removed from the CME loop just because they lectured on an area in the past for a firm. Disclosure tells the audience what the speaker has already done. The audience must judge the validity of the content no matter what the background of the presenter.</p>	<p>Accredited CME provider</p>

<p>CME programs that are not promotional in nature yet subsidized by a pharmaceutical company should have the content completely controlled by the presenter and not be under the strings of the company. Otherwise all CME will be by definition promotional and will always be biased toward the product or company.</p>	<p>Accredited CME provider</p>
<p>I do not agree with the proposed changes. Promotional presentations provide a valuable service to the community of practicing physicians by making available medical experts to help educate them on the FDA-labeled indications of treatments. These same experts are often involved in the studies of these treatments, the development of critical educational materials on disease state and treatments, and have helped to advance the understanding and treatment of many disorders. Understandably, these experts are also called upon to present CME talks at other meetings. I think that the proposal would be overly restrictive in preventing these experts from providing education at CME activities. The proposal is also somewhat unclear. If the person has already worked on promotional materials or presented an FDA-regulated promotional talk, the proposal states that that person cannot "control the content" of the CME activity. Does this mean the person can still present the material at a CME meeting, if they did not create or "control" the content? I think it would be better to state that all CME content will have external review to ensure balance. So the policy could state: "Persons paid to create, or present, promotional material on behalf of commercial interests must disclose their relationships with the commercial interests when participating in any accredited continuing medical education activity. Furthermore, the content of the activity must undergo external review by members of the ACCME to ensure the material is fair and balanced and adequately supported by medical evidence."</p>	<p>Other</p>
<p>I believe that the present accrediting mechanisms in place are adequate to ensure that CME programs are balanced and fair. I believe that the present mechanisms also ensure that any potential bias in favor of a pharma company that is providing support for the program through an independent third party (CME provider) is nil to minimal. It is not realistic to assume that medical schools, universities, hospitals, and non-profit organizations will assume fiscal responsibility for CME programs. Further, it is ironic that while the ACCME suggests an end to pharma support of CME, there is no mention of "speaker's bureau" or "promotional" lectures, which serve little or no educational function. The end of pharma financial support for CME will be the end of CME.</p>	<p>Other</p>
<p>I'm concerned with the definition of "control". Could this be interpreted to mean ONLY the course director and/or planning committee "control" the content?</p>	<p>Accredited CME provider</p>
<p>I appreciate the opportunity to comment. I work for select companies and products and I speak promotionally. I work for companies whose products I use and find work well. I do not work for companies with inferior products or whose products I do not use. I am biased in that respect. The PHARMA code dictates that I follow a set of slides FDA scrutinized that show the good and bad of each medicine. In these talks, I am biased in that I am talking about one product only. I am biased as I use that product in my practice and I am fond of the product.. I follow the 'rules' 100%. I also speak regionally and nationally at CME events. Some of these I create my own material and sometimes that material is created for me. In these, I follow the CME 'rules' and there is fair balance. Even products I do not 'like' are included as every product has a positive value somewhere. I do not make statements in the CME talks favoring my favorite products but present the evidence base as such. I have reviewed my CME ratings and local and national events and have not been accused of bias and been warned or sanctioned. In fact I have received comments stating that the audience did not know which company was underwriting the CME event.... I do think there are some 3rd parties who work with industry, using industry scientific writers or even 'big name' clinicians to develop content and national widespread CME events are sanctioned. I agree this is blurry in that the content is somewhat controlled or biased by the 3rd party vendor and the writers. Perhaps on these, the writers should not speak? These large national events also may have the most impact and should be better scrutinized. I think the smaller, regional events are 'safer' and would have less impact if a biased speaker occurs. I think a black and white rule like you propose will hurt people like me who seem to be able to follow both sets of rules and live in both worlds. Also, if you cannot promotionally speak and CME speak due to the conflict, must I stop any research activities where I am working for [REDACTED]? I actually get paid more to work on studies... I am also biased in my clinical practice and there are some meds I use a lot whose company I do not research for or speak for their company, but am 100% personally biased towards that product.. Cannot I not now speak promotionally or for CME for products I use fondly in my practice. Many of the large 'thought leaders' may not work promotionally anymore, but run studies, consult and have stock holdings, will they not be allowed to work on CME? Some of the smartest, best published clinicians now cannot teach us? I guess, where does it stop? Will there be anyone to give a CME talk? I think the old policy and rules make a lot of sense. However the policy is not enforced, bias exists and no one is punished? If we followed current policy then</p>	<p>Other</p>

<p>this may not be an issue. Finally, this would take manpower but who polices CME activities? Should there be a national watch dog? At beginning of every CME event or content, list an 800# if bias is detected that it can be reported. With cell phones in every audience, I suspect you would get instant info. Why not catch presenters, companies, etc who put out biased materials and speakers- this is why you have the CME system in the first place. If a report is called in, ask for the course handouts. Frankly you could force all CME activities to audio tape and hold the tape for 1 year in case there are allegations. I would suggest we do a better job policing the current system as is. There is a bell shaped curve , like any profession, in that some folks are poor speakers and fairly biased...They can be weeded out. There are an equal number of great speakers/educators who the 'new' policy may hurt. Then for all of us middle of the road speakers, we can keep doing a good job.</p>	
<p>I believe that those who present industry programs should be allowed to continue to teach CME programs as long as potential conflicts of interest are clearly stated. The comment that a speaker could not present on an entire class or therapeutic area because of industry involvement will unnecessarily isolate students/participants from many very talented speakers in areas in which they have significant expertise, as well as limiting the opportunity for participants to directly challenge data from those most intimately involved in its development.</p>	Other
<p>This policy, if interpreted broadly would have significant negative impact on a lot of ways. The specific definitions would be important , and need to be fairly detailed. As a person who does CME talks, and delivers (but not develops) promo talks would have to pick one or the other. I think that would be overkill. In a narrow sense I would never cover thr the same content in a CME and Promo talk. The content is by definition different. I use this analogy w/ audinces to illustrte the distinction. If we were fire-fighters we could go to a talk about "high -rise fires" (like CME), or we could go to a talk about how to use the "new Br-43 firew extinguisher" (Like a promo). I believe both types of talks can have utility, and people that don't vote w/ their feet. The current pharma rules if adhered to make this clear. We are educated adults, and when someone doesn't adhere to pharma the are repercussions. It has gotten better over the years , but I suspect that this is aimed at the high profile CME talks done at APA .etc that may be subtly (years ago not as subtly) influenced by the financial affiliatyipons of the distinguished faculty. It may be reseonable , and sufficient to bar people who develop prmo talks from develpoing CME, but it seem waste to take it down to the foot-soldier level. I'm on eof the onyl docs around her ethat will do etither type of talk. Since this effects m directly I have an obvious potential bias.</p>	Other
<p>If the purpose of this regulation is to minimize the chance that ones financial relationships with an industry would cause one to alter their opinions and conclusions in the CME material, then I would suggest that ALL potential conflicts of interest be included in the regulation. For example, if one receives grant money from the industry; they should not control the CME content. Even if the grant money is indirect via the institution they work for; since the institution could put pressure on the researcher to alter the content in favor of the corporate sponsor of the institution. Also, no one in control of CME should have any stocks or mutual funds which tie that person's financial well being to the industry. Furthermore, those working for large medical institutions as an employee should also be excluded; as many of these institutions are putting pressure on those physicians not to prescribe non generics; such pressure could lead to UNDER- emphasizing the role of industry related products for fear of retribution from their employer. These conditions may exclude most of the researchers and professors of most of the teaching institutions and corporate medical facilities of the country from participating in CME activity. This may be good; but it may keep our field's best from being able to share their insights. My point is that if conflict of interest is really the point; then look at all potential conflicts and not just those posed by the speaking/consultant relationships physicians have with the pharmaceutical industry. If regulations such as these are meant to appease a hostile congress; then get a backbone and have a real discussion of the role of ALL potential conflicts and the benefits vs. down side of such regulations. As physicians we make medical decisions with many forces pushing and pulling at us....It is our Hippocratic Oath which should direct us. The world is full of forces wanting us to do one thing or the other... It is the professionals' responsibility to weigh those choices. It is impossible to regulate all possible conflicts away. But it is reasonable and possible to hold a licensed professional responsible if they are swayed to put ones own financial well being over the safety and welfare of those that license allows them to treat. If one is determined to be acting unethically after a due process hearing; then they should have their license suspended.</p>	Other

<p>I BELIEVE THAT THE PROPLE WRITING THE CME MATERIAL SHOULD BE FAIRLY INDEPENDENT. I BELIEVE THAT A SPEAKER CAN BE FAIRLY SAVVY ENOUGH TO KNOW THE DIFFERENCE BETWEEN A PROMOTIONAL ENGAGEMENT AND A CME EVENT</p>	<p>Commercial Supporter</p>
<p>Obviously, this initiative is aimed at the problem we now have in medicine with contamination of the Medical Knowledge Base with Drug and Product Industry promotional literature. We in practice are very aware of the contamination bias and we have trouble sorting out the truth. Most blatant is the 2003 report on Vaccine safety, from an NIH committee completely composed of researchers for Vaccine Companies, many of whom did not disclose their close relationships to the companies. Pure research is hard to find, hard to fund, and hard to do. Another problem we have is that young and inexperienced researchers eager to make their mark and "change the world," interact with the hungry news media, eager to shock the world, and release research results early, partially, and incompletely. The 1999 release of the Prem-Pro study from NIH on the Goodmorning America show 2 weeks before publication still has patients and doctors confused and unnecessarily worried about estrogen. So, it is not just about banning certain persons from writing CME programs, because good lawyers and executives will understand that rule better than any judge. We need to address the content and intent of literature for CME's, and we need to address the intimate relationship of researchers to their funding parties. 1. Every piece of promotional material needs to be marked largely on every page. 2. Literature from drug company promotional material needs to be compared to CME text and research papers for contamination. CME and Promotion can reference published papers, but not vice versa. 3. Every teacher, speacher and writer has to devulge their relationships to any funding entity. 4. Researchers who early release to the media need significant reprimands. 5. Drug representatives need strict regulations for education and supply. 6. Off label advertising needs to be banned and fined. 7. Public advertising of drugs needs to be banned. 8. Medical websites need to fully disclose their content as advetisements or research, and to avoid blending the two. 9.A government controlled medicus needs to be available online to produce and maintain accurate drug information that is uncontaminated with industry hype. Currently the PDR only lists drugs that they are paid to list, and they leave out most generic medications. 10. Medical education programs funded by an entity should not be produced, trained, supplied by that entity. Thus, a Visiting Speakers type Bureau can have slides provided by a company, training paid for by the company, but the company should not have control of the training or the slide content. That is a difficult needle to thread!</p>	<p>Other</p>
<p>Commercial interests are some of the best educators. The info they provide is beneficial in developing educational tools. This is useful for a speakers education as well as what they are able to impart to their audience. Some good examples of educational info are those that are used before a med is fda approved. for instance, when kineret was coming on to the market we were educated about il-1 and its role in rheumatic diseae. Now with il-6 coming out we are being educated about this molecules' role. Without the pharma companies, we would not hear about these topics. The major problem I see with pharma sponsored talks is the lack of ability to say what we want. We have lost freedom of content. i dont think docs want to go and hear a commercial, and most on the vsb are probably not comfortable being a salesperson. vsb -type programs can be educational and cme like in their content. It's a type of program i personally am more comfortable with.</p>	<p>Non-Accredited CME provider</p>
<p>The speakers of a pharmaceutical product chosen from private practice should pick and choose the data and slides they feel is approprite to present to their peersin a meeting rather than the speaker being made to present all slides prepared by the pharmaceutical company.</p>	<p>Other</p>

<p>The [REDACTED] is a not-for-profit medical specialty society representing more than 5,600 surgeons and allied health care workers worldwide who provide heart, lung, esophageal, and other surgical procedures of the chest. Founded in 1964, the mission of the Society is to enhance the ability of cardiothoracic surgeons to provide the highest quality patient care through education, research, and advocacy. [REDACTED] is providing comment to the ACCME proposed policy that "persons paid to create, or present promotional materials on behalf of commercial interests cannot control the content of accredited continuing medical education on that same content." We respectfully disagree with this proposed policy. We are concerned that ACCME has not defined what it means by promotional. If there is a presumption on the part of ACCME that any presentation made, or print material created – other than a report of research findings – is considered promotion, there is very real cause for concern. First and foremost, this proposed policy would then suggest that physicians are incapable of differentiating between promotional education and certified continuing medical education and could not take the appropriate goals and objectives into consideration when developing and presenting either. Further, it presumes that a physician speaking on a speaker's bureau of a company is actively marketing a product rather than teaching how to use the product – an activity the FDA expects the device industry to do with new devices. We believe, when possible, it is far better for a surgeon to be teaching other surgeons about new products than having an industry representative do so. The proposed policy would ban these surgeons from speaking or helping develop content for certified continuing medical education activities even though these very surgeons are most likely to have the greatest expertise in the area. With the many checks and balances already stipulated by the ACCME to manage the development of certified activities and any potential conflicts of interest, we believe this proposed policy is excessive and indeed will likely restrict the most qualified and experienced speakers from being able to contribute to the development and presentation of certified continuing medical education activities. The ACCME fails to share the data they have that suggests that a real problem exists that would mandate such a change in policy. Indeed, as with previous comments we have made, we question what research ACCME has conducted since it updated the Standards for Commercial Support in 2004 and provided updated criteria for accreditation in 2006. To the best of our knowledge, this research does not exist. We therefore question why a change is being recommended when no empirical evidence exists to support the notion that there is a problem. We encourage ACCME to avoid making changes based upon anecdotal information. ACCME requires accredited providers to utilize the highest level of evidence available in the creation of certified educational activities and we would like ACCME to do the same when establishing policy. We would welcome the opportunity to work with ACCME on a research project that analyzes the relationship between an educational contributor's financial relationships and actual bias presented in certified continuing medical education. We appreciate the opportunity to provide comment and look forward to working with ACCME to ensure the development and presentation of the highest quality certified medical education.</p>	<p>Accredited CME provider</p>
<p>I feel that professionals can make the distinction between commercial bias and interests and attempted unbiased CME educational material. No one is without bias. I believe it should be up to the individual speaker to decide if a CME event can be given without his/her undo commercial bias.</p>	<p>Other</p>
<p>I believe this statement gives tremendous latitude when it says "promotional materials" and does not define what promotional materials are. May "academic" speakers talk about a topic that has specific relevance to a product that a pharmaceutical company or manufacturer of a device make that suggests that that test, drug or devise is appropriate in the context of the talk. I believe your statement should specifically prohibit talks by speakers that have anything to do with any pharmaceutical, test or devise that the company sponsoring the talk has an interest in. This would stop most of the "guest speaker" programs that really are "promotional" events.</p>	<p>Accredited CME provider</p>
<p>The basic problem is that CME is not at all free of major commercial biasing, if not quite so obvious, and promotional activities are many times unbiased - it is clearly dependent on the speaker. I have indeed participated in CME programs approved by major university CME activities convey, if subtly, the sponsor's message. This may be simply that Drug Y is equivalent to Drug X. While I would like to see all promotional activity go away, mandating the burden of CME approval (isn't that a bit self-serving of the ACCME?) should not be the only alternative. I have not thought about this enough to identify an alternative. Perhaps require that the activity be located at a healthcare facility (not a resort or restaurant), that a code of conduct be in place, and that some form of monitoring (even comment cards appropriately worded?) be utilized. I think the ACCME has to own up to its own potential biases as a trade group in part dependent upon commercial funding.</p>	<p>Accredited CME provider</p>

<p>The policy may be noble in its intent however a result may be to exclude some of the most knowledgeable experts. If the policy is not followed there is a potential conflict of interest. If the policy is followed, the quality of the product may be diminished.</p>	<p>Other</p>
<p>It is true that people paid to deliver promotional information must provide the information approved by the company paying that person. It is also true that a person selected to provide accredited continuing medical education Category one, can provide unbiased unfettered by industry information to the audience. I believe that medical professionals who teach in an educational environment have the integrity to provide information with evidenced based science. I believe that medical professionals in teaching professions should not be limited from working with industry to develop educational materials or provide promotional presentations for pay.</p>	<p>Accredited CME provider</p>
<p>I believe the proposed policy to be excellent</p>	<p>Other</p>
<p>Although I am strongly in favor of reducing the influence of Pharma on ACCME programs and activities, I am strongly AGAINST the proposed policy. I must admit that I occasionally will give a presentation that is sponsored by a drug company. However, I try diligently to make my remarks as unbiased and truthful as possible (I have my reputation at stake). Most of these talks review general information on particular disease states and have only a brief mention of the sponsor's particular medication. However, because they are not "CME" presentations, they are classified as being "promotional". I also am asked to give ACCME presentations. The content of my CME presentations are not influenced by the fact that I occasionally give talks that are sponsored by drug companies. I would not like to have to choose which type of presentations that I will give in the future. There are many fine clinicians who give presentations sponsored by various drug companies. I would hate to not be able to hear these individuals give ACCME presentations. If this proposed policy is implemented, there is a chance that many excellent speakers will not be able to give CME talks, and these CME talks will then fall to those who are less qualified.</p>	<p>Other</p>
<p>I am a board-certified psychiatrist and child psychiatrist. I have a private practice specializing in psychopharmacology, am a principal investigator and have given lectures and seminars throughout the US. I have also presented talks for pharmaceutical companies on antipsychotics, anxiolytics, ADHD meds, sedative-hypnotics and antidepressants. As both a clinician and researcher, I believe that a presenter can maintain objectivity and provide fair balance. I would hate to see our most respected researchers and clinicians being prevented from presenting at CME functions because they helped write the promotional material for some of the meds they have investigated. They help practitioners by providing insight into new drugs they have worked with during phase 2 and 3 trials.</p>	<p>Other</p>
<p>This is absolute nonsense. I am on the speaker's bureau of 3 different pharmaceutical companies. Next week I am presenting a broad psychopharmacology update. If I were to omit any references to these particular drugs, I would be influencing in the other direction for their potential competitors. In psychiatry, if you prohibit anyone who is on a speaker's bureau from presenting CME, you will eliminate 90% of the academicians and experts in our field. Who do you think is funding medical research these days? The rules you keep coming up with are oppressive. You are severely handicapping continuing education.</p>	<p>Other</p>
<p>Too vague and restrictive. Content needs to be better defined.</p>	<p>Accredited CME provider</p>
<p>I think those actions that would preclude a person from controlling CME content need to be better defined. For example, some people are paid to give presentations on a specific topic, as part of industry-sponsored symposium, but have complete control over the content of their talk. In that instance, I don't think the person should be excluded from CME activity. On the other hand, if that same person is paid to give a presentation in which the content was dictated by a commercial interest, then that person is essentially a paid spokesperson & I think should be excluded from controlling CME content for some time. Another issue is the length of the exclusionary period - often these paid services for commercial interests are one time deals - I don't think that should lead to a permanent ban - perhaps a period of 6 or 12 months?</p>	<p>Accredited CME provider</p>

<p>This policy is demeaning and disappointing, that lecturers with pharmaceutical funding are considered reprobates and treated as outcasts. It would further suggest that physicians listening to the lecture are undiscerning. We already have disclosures regarding pharmaceutical ties, but apparently physicians attending the lecture are not able to make up their own minds, now they need to be "protected" from tainted information. We seem to find ourselves in a field of regulatory land mines. This is just one more. This policy seems disadvantageous because it will necessarily exclude some excellent clinicians from participating with pharmaceutical companies, a practice which for all intents and purposes is being criminalized. Is there not some duty to provide well balanced material that is scientifically based? Does this mean that the physicians that adjudicate the content of pharmaceutical materials also should be held suspect? Is the problem that physicians are getting paid for their time? At this point the payment for giving a lecture is a best a break-even proposition for time away from the office. Physicians giving CME lectures are, in general, not paid for their time – unless there is pharmaceutical funding, which will henceforth be considered an oxymoron. This policy will favor physicians who are paid a salary because they may be willing to lecture without compensation. Salaried physicians are not necessarily the most clinically active individuals; therefore, the physicians with the most experience may be, by regulation, excluded from teaching other physicians. I think that this will serve to exclude community physicians from participating in educational opportunities both from a teaching and a learning stand point. It will be like a library only allowing librarians to read the books. CME will be reserved for academic physicians. The rank and file community physicians will have little incentive to participate with CME. This is a little like banning children from swimming in the swimming pool because one child soiled the pool. I think that this regulation is a draconian step. This policy infers that the only funding source outside of endowments, pharmaceutical company compensation, is prima facie evidence of corruption. This is a sweeping and far reaching policy that I believe will have a great number of unintended consequences ultimately degrading medical education. It will serve to drive a wedge between academicians and community physicians, a relationship which is already strained. It is a castigating policy which will further isolate the community practitioner. This seems to be the nail in the coffin regarding any semblance of collegiality in medicine. I remember a time when physicians were considered professionals, experts in their field of study, and trustworthy.</p>	<p>Other</p>
<p>I believe that physicians are thoughtful individuals who can decide for themselves if information they receive is biased, clinically useful or educationally relevant. I feel that industry sponsored programs are just another source of information and that physicians are swayed by information that is clinically relevant and logical. I do not believe physicians are swayed by gratuities if the products are not clinically sound, relevant or useful. Therefore I only see industry sponsorship as a means of gaining attention for a product or device but its actual clinical applicability and usefulness influences its ultimate acceptance and use. I feel it is irrelevant if the source of CME content is also the writer of promotional material. In fact those individuals may have the most intimate and relevant information on the issue being outlined and to silence that resource would be counterproductive.</p>	<p>Other</p>
<p>I strongly disagree with this. This implies that anyone who creates promotional material is biased concerning that topic. Is that so? Here's an example: a pharmaceutical company has a new drug for heart disease. It convenes a panel of the country's leading experts on heart disease to develop a promotional slide kit, so that the slides are accurate and address the pertinent questions doctors will have. Now, under this scenario, if there is a CME talk at a national convention, those experts cannot be speakers??!?? This is absurd, and inappropriate. Oh, and insulting to the physicians, saying that their opinions can be bought.</p>	<p>Other</p>

<p>Although in principle I agree with the goal of the proposal, its execution will sanitize CME presentations for the following reasons: If we eliminate researchers who receive pharm clinical trials, then clinicians will not be able to hear from these researchers in CME programs thus losing the developing information on the state of the art in medicine; If we eliminate any speaking faculty who participates in promotional programs (who are often leaders/experts in their field because that is who pharma seeks out) then we have the same outcome. If we only have CME speakers who have received no funding from pharma, the question is how much do they really know about the state of the art since they have little access to information. (excluding federally funded and foundation supported researchers) Clinical audiences now applaud when a speaker declares no conflicts of interest. I scratch my head and say "then what access to information and research does he/she have and what unique insight will be conveyed in the absence of information?" Expertise does not come from reading journal articles but by creating the data and writing the articles. I agree that ACCME ought to route out the for-profit CME vendors who pander to their pharma clients to solicit business and in the process need to satisfy the unspoken promotional agenda of pharma to maintain the business. I liked Pfizer's recent position to no longer deal with these vendors and support CME through academic and hospital organizations. Perhaps other companies will watch the outcome and agree to do the same. My cautionary word is be careful not to throw the baby out with the bathwater. Unintended consequences befall the reactionary. I would vote for a stronger vetting process on speakers before we eliminate whole lots of well meaning teachers/experts attempting to move their field forward while educating the clinicians.</p>	<p>Other</p>
<p>There are a variety of levels of interaction between investigators and pharmaceutical sponsors. The scale of these vary widely, and this policy emphasizes one with relatively little importance and magnitude, although thankfully above the level of "office supplies" and suppers. In particular the proposed policy implies that preparation or presentation of promotional materials is an activity that creates a high level of conflict of interest, but that "academic" interactions do not. Considering my field, I view that the policy proposal entirely distorts and shields the real, massive flow of resources to academic physicians from pharmaceutical sponsors. Pharmaceutical companies routinely use hundreds of millions of dollars to invent or buy a drug and then run a pivotal trial in 30 or 40 countries only to then gift the attribution of the work resulting from that allocation of resources to a small group, typically well positioned politically, who become the publishing authors of a pivotal trial in a major journal. Such a trial represents the work of hundreds of staff across several continents, but is published in English, with a few American or European department heads as primary authors who disclose "no conflicts of interest" and are labeled "new drug clinical thought leaders" and dominate podium presentations at international meetings. Similarly, in trials with a new drug, the commercial investment to actually produce the drug is a huge donation to a investigational project that could not conceivably obtain the product anywhere else, at any cost. The impact of this pharma-to-investigator interaction can be gigantic for securing career advancement and further pharmaceutical and federal funding, but entirely transparent to the current proposal. At worst, this proposed policy is a political cop-out, demonizing individuals engaged in the legitimate dissemination of on-label information. It needlessly generally mislabels their capacity to be trusted to present information in their fields of expertise in different forums (to patients, in commercial content, in CME, in scientific literature), and the capacity of a CME audience to critically assess the importance of a prior interaction. An individual can have an entirely distorted view as a consequence of their "legitimate" pharma interactions, or from a just generally-limited capacity to develop independent opinions (that's a nice way to say it!) more so than as a consequence of direct above-the-table cash payment. Further, the proposed policy is entirely vague on a statute of limitations after which an individual could again be rehabilitated to be a CME provider, and introduces an inexplicable "zero tolerance" standard starkly different from a more conventional dollar-amount threshold that can be easily assessed, and is routinely used on FDA 1572 forms. Disclosure I work in kidney cancer therapy, and I would reference the published trials of [REDACTED] [REDACTED] (buried in the footnote as far as authorship; no I'm not mad about that), and of the oncophage vs placebo study. As I can recall, I have received direct cash payments and travel-related reimbursement for scientific or sales meetings from [REDACTED] (now absorbed by [REDACTED]), [REDACTED], [REDACTED], [REDACTED], and [REDACTED], but these are a low percentage of my annual income. Further, I consider the corresponding sales representatives to be legitimate professionals capable of understanding and applying professional rules to their conduct and statements, and with the capacity to expect the same of me.</p>	<p>Other</p>
<p>I agree with the proposed statement. Prohibition would be too drastic as it would limit the pool of people providing good quality CME materials and, I think (personal opinion) infringe on the right of a person to earn a living in a free society. It is the responsibility of the CME staff at a site to police speakers and materials, and at that level take action. Best, [REDACTED]</p>	<p>Accredited CME provider</p>

<p>It is high time that ACCME took this action. I am glad that finally you have reached this conclusion. As a physician, I used to attend many CME programs, but it was very disappointing as most programs were/are slanted in favor of the sponsors product.</p>	<p>Other</p>
<p>This might be reasonable if the exclusions are very specific: e.g. someone who speaks for industry on marketed products for rheumatoid arthritis could not address the treatment of RA in a CME setting but could discuss etiopathogenesis or other aspects of the disease.</p>	<p>Other</p>
<p>I disagree with the above policy. For purposes of my rebuttal I am going to assume that the policy applies to physicians. The policy implies that there is a conflict of interest when one is paid to create or present promotional materials on behalf of commercial interests while also creating and/or presenting CME programs of the same content. This is not true, even if the content is the same, for the following reasons: 1. Promotional programs and CME programs are two different entities, the former being much more restrictive and constrained (rightfully) by FDA regulations in its format. The latter covers a wider data base of knowledge, including off label information as well as incorporating popular biases of clinical diagnoses and treatment of thought leaders. 2. Unless a physician is bound by contractual obligation to a commercial enterprize not to utilize the content in a CME presentation, restricting the physician from dissipating such information to other colleagues violates Constitutional Rights of different sorts,e.g Free Speech; the Right to earn a livlihood, etc. The way to address the concerns which have given rise to the proposed creation of the above policy is: 1. Review of proposed CME presentation material by the accrediting agency or its representative. 2. Full disclosure by the CME creator/presenter of commerical affiliations. 3. Reporting of a CME creator/presenter to a regulatory agency if there is lack of fair balance by a presenter with the power to impose sanctions to such a presenter. With due respect to my ethical responsibility, I would like to disclose that I am a speaker for several pharmaceutical companies as well as a CME presenter. Consequently I am taking the above positions based upon my own personal experience.</p>	<p>Other</p>
<p>It is impossible to separate these entities entirely for physician speakers and educators. The model for fair balanced talks has been adhered to on every program I have ever been too in the last 20 years. If this policy is to be taken at complete face value there will be absolutely no one educating any other physician on the planet! Physicians are free thinking intelligent beings who can discern the difference. We should be allowed to continue to advise, write, and educate ourselves with our current model. This language is being utilized poorly and could end the education of generations of physicians.</p>	<p>Other</p>
<p>I think this whole issue is getting totally out of hand and is soon to become a laughing stock to other industries that can simply conduct whatever acts of marketing that they please without any regulation. The current system of unrestricted grant monies given by industry for symposiums etc at meetings I think works fine. Internal monitoring occurs for example at the [REDACTED] meetings for any promotional bias on the part of the presenter. All presenters disclose their agreements previous to speaking which are usually with numerous companies that eliminates the notion of speaking only for 1 product and not giving fair balance. Most speakers are recognized thought leaders and the support of industry allows exposure of these individuals and the valuable information and experience that they bring to large audiences and at an affordable price. The end result is a better informed practitioner and ultimately a higher standard of care for the patient. I am truly at a loss for the current level of disregard for the valuable support of industry that truly does this when they really don't have to. Also the current practice being adopted by medical schoold departments of forbidding industry representatives to speak or present programs to students, interns and residents is another example of American Education moving away from education and becoming fundamentalist with ideology. Working with industry teaches you to work with colleagues. The communication skills of most of our graduates are poor at best. This further segregates and teaches them to have a narrow minded approach and in my opinion be ill prepared for the realities of the practice of medicine. If I sound passionate and upset I for one am. My background is Pharmacy and I hold 2 professional degrees BS Pharmacy and a Doctor of Osteopathy Degree. I do speak for several pharmaceutical companies of which ALL mandate the presentation of fair balance slides at all promotional talks and go strictly by the FDA guidelines on such. I also work in community mental health and all pharmaceutical companies unselfishly help the indigent population with their needs in any way necessary and appropriate by making sure compliance facilitating devices, ie pillboxes, samples for those falling out of entitlement programs, patient assistance programs etc. I would really like to see someone utilize some common sense in all of this and realize what is being done is harming are allies or partners in improving patient care, access to care and quality. Perhaps the government should take on other more pressing industries that play by their own rules ie the INSURANCE INDUSTRY! Why is it ok that insurance companies can award top selling agents with all expenses paid trips to Europe validating the award only by providing a 1099 for the trip? That makes it ok I</p>	<p>Other</p>

<p>guess? If this was done in Medicine who would be accused of what? Why shouldn't we all play by the same rules? Do not insurance companies get federal monies if they are involved in Medicare underwritten programs? By the way I don't buy their little spin off companies that are detached from the parent company or whatever either. I will agree that there was some merit in detaching the spouse from events as that may be distracting from the presentation and make it more of a social event than a true presentation. Having presented many times in such settings I don't think it set the greatest of tones for educational process. However now I think the whole Phrma thing has gone too far! No note pads, pens because this effects what we order!!!! To the people putting these rules out there find somewhere else to cause trouble, please!</p>	
<p>Although it would be nice to have some input on the promotional materials we do not always know all the specifics of a particular product. What I would like to do is be able to use some educational pieces that may not be part of a companies promotional materials in my presentations. [REDACTED]</p>	Other
<p>This policy is not clear and can have many interpretations. The presenters do not create the promotional materials - as these are made by the companies and vetted by their attorneys. To present the material - one must understand the field and present according to the FDA rules. The speaker has no freedom beyond following the script but can reply to unsolicited questions. CME is much different and does not have these restrictions. Those who create and present CME have no such rules. Anyone who knows the field would in no way be restricted to a commercial product. Their CME would be a flop. The presenters should be allowed to present in both formats. These are very different speaking experiences and if one would give the promotional talk for CME it would be an immediate failure. If that was tried at our CME meetings the speaker would be drummed out. The problem with interpretation of these policies is that there are many definitions that are not spelled out. How broad is the interpretation of "content"? What is content? Is content one product? Is content one disease? Is content an entire field? How is the writer of a promotional material to be defined? Those who write the final draft? Those who offer suggestions to the topic? Those who suggest a promotional topic to help clarify the information? Those who ask a question to the company? Those who are employees of the company? Only those who are paid to develop the promotional program? How is the teacher defined? Can a teacher only teach one topic or by their understanding of the field, the implications of the field, their own personnel insight, etc can they give not only a very restricted topic talk but also a very open talk with many implications? The question has already been answered by this communiqué - they can talk about research without restrictions of this policy. How is research reporting of a product not a promotional activity? If they can do that, then they can talk in any of these venues and the presenters should be allowed to also. Teachers are a rare commodity, can develop CME and can present complex topics and make them clear. Why try to throttle them? This policy will. Medicine needs policies that develop education, enthusiasm in learning and thinking to engender new approaches to diseases. This policy will not. Exclusion should be replaced by inclusion. We need further information on medications, we need to foster drug development and we need to educate physicians as more new ideas and products become available. These policies should be encouraging this and yet they have the opposite effect. I would not recommend adoption of these policies.</p>	Accredited CME provider
<p>have had 30 years experience giving hundreds of paid and non paid medical talks to community physicians, residents, and lay groups and have a firm grasp of the potential undue influence of pharmaceutical companies on medical education. I am strongly against excluding promotional speakers in CME. It would make many excellent teacher unavailable for CME and deny the right of pharmaceutical companies to access outstanding CME speakers. Current policies are much more stringent and effective than the "hands off" approach in the past. It is sufficient to give the CME audience information regarding the speaker's financial relationship with pharmaceutical companies as is currently done. It should be specified that any relationship in the past few (3-5) years should be reported and not just the current year. Medical audiences are intelligent and savvy enough to decide for themselves if a speaker is unduly biased. I agree with the philosopher Shopenhauer that bias, financial or otherwise, is an inevitable result of the human condition and going to such extreme measures to exclude certain speakers from CME programs would likely just substitute one form of bias for another. I give a few promotional talks per year but more CME talks that usually are not compensated. It would be an infringement of my right to free speech to deny my availability for CME lectures merely because I had participated in a compensated promotional talk. Promotional talks nowadays are strictly regulated and unless someone gives an exceedingly large number of them the financial incentive for bias is just not that great. Many other non scientific factors influence physicians much more than this such as the good or unfortunate experience a physician may have had with the most recent patient he/she treated with a certain drug. Please do not proceed with this proposed Draconian measure. [REDACTED]</p>	Other

<p>The FDA, Federal Government and ACCME should be in charge of commercial advertising of medications, CME and deciding which medications each individual should take on an individual basis as physicians are clearly unable to make appropriate decisions upon how to treat patients in this day and age as they receive too many pens, note pads and dinners from companies to make appropriate medical decisions.</p>	<p>Other</p>
<p>Clear distinction between "promotional material" and "CME content" needs to be made. Agree completely that CME material intended for educational purpose should be absolutely free of bias and therefore may not be influenced by persons creating promotional material.</p>	<p>Other</p>
<p>In my opinion physicians presenting industry sponsored lectures should not use academic titles or indicate they represent a specific faculty. I do not see an inherent conflict when presenting a CME utilizing one's academic title. In 40 years of practice, I have never let my participation in sponsored lectures influence my prescribing patterns. Further, for many physicians in primarily private practice without university stipends/income, participation in sponsored lectures is a way of dealing with the ravages of managed care on physicians' income. This is particularly true in primarily cognitive specialties. I am in a cognitive specialty in an economically depressed area with high HMO penetration. Were it not for industry lectures, the inequalities between public and private compensation would be worse. The average age in my specialty is 62 and as I prepare to retire, I am unable to replace myself. In my opinion, academics on salary should tread carefully on this matter and not further damage a fragile delivery system that accounts for substantial patient care volume.</p>	<p>Other</p>
<p>Understanding that the US government and its bureaucracy is directly or indirectly related to this issue, understanding the landscape of medicine related to working in a teaching center, understanding that I teach, see patients 5 days / week, occasionally publish in the peer-reviewed medical literature, work as a PI, Co-I in clinical trials, and understanding that in RHEUMATOLOGY, that Rheumatologists are experts in RA and related diseases, understanding that CME is a serious entity/business and understanding what content development is and what true 'expertise' is on a topic, disease state, drug, etc, I offer these honest comments FIRST, your policy is heading in a direction that underscores TRUE HYPOCRISY FACT: I do serve on speaker's bureaus and do 'promotional speaking' for the Pharmaceutical industry, as well as working with certain companies in regard to clinical trials FACT: I am a board-certified rheumatologist, clinically active 5 days a week- and I teach at a medical center with an internal medicine teaching track in outpatient rheumatology as well as teach within the context of a fully [REDACTED]-accredited [REDACTED] I recently gave grand rounds at the [REDACTED] on the following topic: [REDACTED]: Addressing Clinical Care Gaps in day to day clinical Osteoporotic Care I followed the CME requirements, fully implemented by [REDACTED], signed my 'conflict statements', prepared my talk- fully in sync with the guidelines, etc- I appropriately listed ALL companies for which I spoke over the past 12 months, in addition to listing the companies that I currently serve as a clinical investigator Additionally, I sent my talk to [REDACTED] as requested before the scheduled talk and used appropriate drug terms- not brand names etc The focus of my talk was 1) to emphasize that there are serious care gaps in the day to day care of osteoporosis 2) I reviewed the available FDA-approved therapies and I cited the pivotal registration trials that the FDA reviewed prior to drug approval- really to highlight that we have SEVEN (7) FDA-approved agents 3) I reviewed the new NOF/WHO absolute fracture risk assessment methodology 4) I reviewed and illustrated the use of the FRAX tool 5) I highlighted the utility of VFA methodology When I arrived and entered the lecture hall, and viewed the ad for the grand rounds, the disclosure statement appeared to me 'offensive, and insulting' - essentially making me feel somewhat 'unwholesome', jaded, whose reputation was tarnished or adversely affected even before the delivery of my first words Within a 200 mile radius of [REDACTED] or larger, on this specific topic, I am wholeheartedly and steadfastly confident that few have the energy, experience, clinical and densitometry skills, and qualifications to have mastery on this clinical arena - in other words, I know that I was and am qualified to be speaking in this CME venue and delivering unbiased, evidence-based education on such an important topic I am more than happy to send you my talk and slides - I did not 'compare RX's- We know there are no head to head fracture trials!! I tried to help the audience apply the current medical technology and use clinical risk factors, knowledge of fracture, etc to 'stratify' those patients more at risk for complications such that intervention is inaugurated to reduce future fractures and complications Given where your policies are headed, I WOULD BE EXCLUDED FROM BEING A CME SPEAKER, CONTENT DEVELOPER, etc because of my 'apparent conflict of interests' or the 'perception' of such Your current policy and disclaimers already allow 'pre-judgement' and lead to pre-lecture 'prejudice'. more importantly, given where this policy is sloping slipperily towards, you are going to create a structure where the most qualified may be excluded Assume a group of physicians, after a needs assessment want to learn about new cytokine pathways in inflammation, and the translation of that scientific discovery to drug development- Do you not think that some of the experts will be those who may in fact have a clinical trial, and/or advisory board relationship - And often, those clinical investigators, will likewise be excluded given where these policies are headed!! Getting back to my institution, I pride myself in wanting to and actually</p>	<p>Accredited CME provider</p>

<p>presenting a grand rounds at least yearly - in the past 8 grand round series at [REDACTED] ([REDACTED]), I have presented at least yearly - Despite getting paid ZERO DOLLARS- you see, at my institution, this is called [REDACTED], I have still had to disclose my 'conflicts', etc - and in the arena of RA, Vasculitis, Osteoporosis it is rheumatologists who have the expertise to speak on such - As I look into the audience each year, after hearing my 'disclosure announcement', it seems inconsistent with my intent and I feel with each passing year that I am more and more 'tarnished' by this policy, again receiving ZERO Dollars Our government wastes millions and millions of dollars - Our government has 'assumed that physicians are fraudulent' with level of service auditing, malpractice and evidenceless claims against physicians abound, our reputation continues to get bashed and now this policy - ENOUGH is ENOUGH First, CME consumers are 'intelligent' - give the people who choose to pay for learning some say and some respect Second, and most importantly, it seems easier with your policy to actually have physicians do PROMOTIONAL SPEAKING and the policy will threaten, perhaps cripple, or retrad ongoing CME progtrams in areas where it will be more difficult to so 'ATTRACT' CME speakers, maintain a CME faculty, etc In conclusion, the policy is hypocriticla I am going to [REDACTED] - some of the brightest speakers, best speakers, best suited to speak on comment areas of expertise will DISCLOSE - Unfortunately, you are forcing institutions to prohibit their faculty from Pharmaceutical affiliations Hypocrisy - not in alignment with what most physicians are trying to do - Is it wrong for physicians to try to make 'additonal' income - not by abandoning their patients or their duties, buit by agreeing to do EXTRA WORK - If everyone else in AMERICA can do this, why can't physicians, especially withg rising practice expenses, rising malpractice, rising gas prices, rising overhead, etc If you really look carefully at what these policies are likely to do, they will change the landscape of CME - and the landscape is very liklely to be such that it is harder for many CME providers to continue to do the work they do- Quality and education may suffer Most importantly, if you really see the changes likely to be enacted, those most qualified are likely to be ineligible for CME lecturing or content development Essentially, you are forcing physicians to decide - Promotional speaking or CME, but not both and for many institutions, they are likely to prohibit physicians from Pharm affiliation in a speaker's bureau/advisory/ other capacity -- IS THAT LEGAL ??? Is that restraint of 'TRADE', if in fact speaking, consulting (without interfering with one's practice/work) constitutes some of their 'trade' - I simply ask you to respect the fact that it is possible to do promotional speaking and clinical trial work and CME lecturing and be an honest, hard-working American physician while still being devoted to your patients and being their advocates! Respectfully</p>	
<p>I am responding to the above in my role as a longtime CME faculty member at [REDACTED] This policy would imply that faculty that participate in activities on behalf of a commercial interest would not be permitted to present CME activities on the same topic, thus resulting in either the commercial interests relying on others with less expertise or CME activity participants receiving their information from those with less expertise. This would appear counter intuitive and not in the best interest of physician education. This proposal once again takes the worst view of physicians and pharma and assumes that physician-faculty are not able to think and speak independently and that any connection to pharma is contaminating. I believe it is a question of whether you want the current material developed and delivered to physicians to be done by experts or not.</p>	<p>Other</p>
<p>It seems to me either unnecessarily restrictive or too ambiguous. For instance, someone who is a promotional speaker for a specific drug may be no [REDACTED] speaking in a CME setting on the disease for which that drug is used, example, [REDACTED] used in treating [REDACTED].) Would that speaker now be barred from speaking on management of ERA in general, or allowed to speak on ERA but not mention [REDACTED] specifically or would that speaker only be barred from giving a CME lecture specifically on the uses of etanercept in rheumatic diseases? What if [REDACTED] comes up on discussion in a totally unrelated CME topic, for example, systemic lupus, for which there is no current indication for the drug? What if the speaker is giving a general discussion on immunology about targets in treating autoimmune rheumatic diseases in general, of which, [REDACTED] as part of the family of drugs used to affect TNF would play a role. Is that speaker now be barred from speaking on that topic too? In view of the interrelated nature of many key drugs and the diseases they treat, speaking promotionally for any one drug may preclude that speaker from engaging in any topics of his specialty that may even have a remote link to that drug. for [REDACTED] that includes [REDACTED], and the list may go on if new indications are found.</p>	<p>Other</p>
<p>The current policy is okay. The proposed policy states "cannot control" but does not answer whether "they may contribute" The quoted Task Force recommendation that all be separated by a wall is a disservice, withholding and hiding information is less protective of patients than the current transparency policies.</p>	<p>Accredited CME provider</p>

<p>I am delivering lectures CME format and can control content without commercial balance.</p>	<p>Non-Accredited CME provider</p>
<p>I think they should be able to give a CME presentation as long as they only mention the product by drug class,or the CME committee reviewing the presentation in advance does not see any biases.....i.e. each of 5 drugs are mentioned in equal fashion.</p>	<p>Accredited CME provider</p>
<p>Many physicians also receive research funding from industry to research new treatments. They are the experts on the subjects and should be considered in the same way as commercial speaker, as they have received money from industry. If all of these people are excluded from CME, then you will not have the leaders in the field creating and delivering CME. Is it the intent to block all providers that have received industry money for if you block the speakers, you need to block the researcher also. This does not seem to be in the best interest of new knowledge. The speakers need to be free of bias and this needs to be monitored but the ethics of most of the speaker and researchers is such that I have never seen a real problem. Are you creating a problem that does not exist? I would hate to see CME suffer with the researchers are excluded. [REDACTED]</p>	<p>Other</p>
<p>I think the spirit of this limitation is fine but I think it totally disregards that those who are most familiar with the science of a product should be those who critique and create the teaching materials. The line between what is constitutive of "promotional materials" and education is not very well defined!!! I think while the intent is to avoid bias the ruling may actually end up like HIPPA and be more of head ache regulatory control than a benefit to being clear of bias. I disagree with this becoming a standard.</p>	<p>Other</p>
<p>The assumption appears to be that persons who 'create or present' promotional materials will be inappropriately influenced by that fiduciary arrangement and therefore would be biased and thus should not be involved in creating CME material. If this is correct, and I personally do not, it is nonsensical to exclude those who have research funding from this policy. It seems, on the face of it, that persons, or for that matter, institutions receiving research support have an even greater potential for undue influence. If it is correct that a single clinician can become influenced and biased by hundreds to a few thousand dollars, then it seems clear that a person whose laboratory is funded by 10s or hundreds of thousands of dollars would also be influenced and should be excluded from CME. Likewise, institutions, many of which are ACCME accredited, also receive millions of dollars in research. If one assumes that a lone clinician can be influenced, then one must acknowledge the likelihood of undue influence at an institutional level, regardless of "firewalls". Therefore, no institution receiving pharmaceutical funding should be CME accredited. Clearly, the only appropriate short-term approach is to reexamine the assumptions and rely on safeguards revolving around output rather than exclusionary process approach. Litigation will surely follow implementation of this policy as it stands.</p>	<p>Other</p>
<p>I believe this is utter nonsense and is an insult to the intelligence and common sense of any physician who participates in creating or presenting promotional materials. If you truly believe that these physicians can so easily lose their objectivity, then they should not be practicing in the first place. To me this is an example of associations worrying about P.R. and not reality. It mimics the stupidity of states such as my own which just passed a law preventing pharmaceutical companies from giving physicians pens, post-its, and pizza. The reasons are ostensibly that by stopping this practice, it will drive the costs of medicines down, which is totally absurd and naive, and that physicians prescribe based on these trinkets. If I am that feeble minded that a pen or post-it or pizza will control my prescribing habits it's time for me to find a new career.</p>	<p>Other</p>
<p>These regulations are getting more and more moronic. Doctors are generally intelligent and self-aware. A speaker does not risk credibility by presenting a sales job. And most doctors in the audience are aware of promotional material. A monkey can present a pre-packaged slide show. As a presenter, I prefer to include cartoons or video clips to increase interest. I would also prefer to edit some slides which I feel are confusing. The audience is interested in clinical experience and practical applications, which are discouraged by lawyer-vetted programs.</p>	<p>Accredited CME provider</p>
<p>I guess it is more important to not appear to be than whether one is or not, since the helpless professionals with all their years of training are unable to think for themselves and will be totally swayed, unable to think for themselves. The problem is that commercial speakers usually speak for multiple commercial interest even among same type drugs for example, within same class by different companies.</p>	<p>Commercial Supporter</p>

<p>\tThis policy appears to be a very slippery slope. What clinic, or hospital, or lab, or procedure center, or even academic center would not be considered, "A commercial interest" (" any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients.)? Even some professional societies market educational materials and conferences for a profit. If a physician speaks in their area of expertise in a way that might promote the use of these services, they would appear to be in violation of this policy if they then also spoke at Grand Rounds or any CME offering from these institutions. Perhaps the stipulation that they could not speak "in a CME activity that received funding from the commercial interest" would have some merit, but even that would be problematic, in that the medical staff associated with or paid by entities such as those above could not contribute to content or speak at conferences sponsored by that entity (such as a hospital-sponsored CME event). For example, if a diabetes center sponsored a CME conference on diabetes, would their paid physicians have to be excluded from speaking? The policy as stated would seem to say yes. \tWhere do you draw the line, and then protect one medical entity (that profits from providing medical services) from being considered "a commercial interest" and another entity as not? \tAn additional problem would be the loss from CME of many of our best teachers, who are often those invited to speak or advise on creating accurate content for promotional education activities. Would there be enough CME opportunities alone to satisfy some of our best educators desire to teach? Some physicians who provide badly needed but poorly remunerated services can only continue to do so because of teaching income. \tI can surely understand the desire to remove conflicts of interest, but this policy seems way too broad to be practical.</p>	<p>Other</p>
<p>As a private physician and speaker for wyeth I can assure the investigators I have no control of the content. We are given a non changable slide deck to use and are prohibited from adding any personal slides.- [REDACTED]</p>	<p>Other</p>
<p>With regard to physicians, this policy assumes that physicians promoting a particular product are bribed by speaking fees into becoming full time employees (spokes-persons) for the drug companies they speak for. Such a policy ignores the fact that many physicians actually speak for several competing products in a class of drugs. Such a policy treats all physician speakers as myopic, weak, easily influenced and essentially idiots. This policy ignores the possibility that physicans recognized as being bright enough to promote a particular product might actually be bright enough to speak about a much larger context than the limited applicability of one drug. Such a policy would deny an entity offering CME the resourcefulness, intelligence, and creativity of those physicians smart enough to be successful in private practice, essentially saying that only those in academic medicine are smart enough, resourceful and creative enough to produce totally unbiased didactic content. As I understand it, at all CME events, attendees are always asked to rate not only the educational value of the activity but if there was any evidence of bias. Is the recommendation of this policy based on a substantial number of evaluations suggesting bias? To limit the poole of bright educators available for CME activities by depriving them the extra income afforded by drug company speaking engagements is short-sighted, irresponsible, silly and paranoid at a time when we need these people to teach and keep medicine as professional and advanced as it can be, so that the consumer, the patient benefits most. [It doesn't take much to see that those physicans who are the brightest and the best in their fields will continue to accept generous industy sponsored stipends, leaving to others to formulate CME activities that will be balanced but potentially less instructive and even less educational.] This policy is myopic, uninspired and paranoid -- that's probably why it will be adopted.</p>	<p>Other</p>

<p>With regard to physicians, this policy assumes that physicians promoting a particular product are bribed by speaking fees into becoming full time employees (spokes-persons) for the drug companies they speak for. Such a policy ignores the fact that many physicians actually speak for several competing products in a class of drugs. Such a policy treats all physician speakers as myopic, weak, easily influenced and essentially idiots. This policy ignores the possibility that physicians recognized as being bright enough to promote a particular product might actually be bright enough to speak about a much larger context than the limited applicability of one drug. Such a policy would deny an entity offering CME the resourcefulness, intelligence, and creativity of those physicians smart enough to be successful in private practice, essentially saying that only those in academic medicine are smart enough, resourceful and creative enough to produce totally unbiased didactic content. As i understand it, at all CME events, attendees are always asked to rate not only the educational value of the activity but if there was any evidence of bias. Is the recommendation of this policy based on a substantial number of evaluations suggesting bias? To limit the pool of bright educators available for CME activities by depriving them the extra income afforded by drug company speaking engagements is short-sighted, irresponsible, silly and paranoid at a time when we need these people to teach and keep medicine as professional and advanced as it can be, so that the consumer, the patient benefits most. [It doesn't take much to see that those physicians who are the brightest and the best in their fields will continue to accept generous industry sponsored stipends, leaving to others to formulate CME activities that will be balanced but potentially less instructive and even less educational.] This policy is myopic, uninspired and paranoid -- that's probably why it will be adopted.</p>	<p>Other</p>
<p>I agree that the content of CME should not be controlled by the sponsoring parties. CME should be generic, informational and devoid of corporate allegiance. However, I also encourage the continuance of allowing sponsorship whether it is by a pharmaceutical company, the local diner or a university regarding CME activities. Most of us in medicine do have integrity and are intelligent enough to delineate what is educational fact and what is advertisement. The current guidelines regarding CME work well. Do not fix what is not broken!</p>	<p>Accredited CME provider</p>
<p>This is like suggesting that persons paid by any entity to develop ideas, cannot be involved in the content even though they may be the leading experts on the content. It is ridiculous to exclude the expert opinions from the content, the end result would be information provided by a very limited source, and not necessarily the best, or most unbiased source. The medical profession is not as a whole an unethical biased population, that should be excluded from providing materials, and information solely because persons may be receiving payment for their expertise on a subject, it only enriches the information. It would not be worth my time to listen to material that does not have the expert information included.</p>	<p>Non-Accredited CME provider</p>
<p>ACCME has begun down a slippery slope. Industry of any sort seeks input from experts in the field whenever developing a product. This investment is made to assure that the product incorporates all of the knowledge available on matter and that the product does not incur the up front expense prior to market release only to be withdrawn due to an unforeseen problem recognized by such experts after its release. This process serves the public as well as the manufacturer. Most people outside of the ACCME would consider it absurd to have rule that would exclude an orthopedist who helped create a prosthetic and advised on an instruction manual on its use from teaching other orthopedic surgeons on its use. Industry currently undertakes painstaking efforts (and expense) to produce educational material that is understandable to physicians, acceptable to physicians, and within the limitations set forth by regulatory bodies, e.g. the FDA. To be sure that the industry achieves this goal, it goes to experts in the field and solicits their assistance in developing research on such products and materials about those products. Like any industry, they seek the best experts that they can afford. Some academic institutions have tried to discourage physician experts from participating in such endeavors. This is done, ironically, with no data demonstrating a benefit to the public or even within the academic institution itself. This is done in an environment where many would be outraged at starting a medication without evidence-based indications to do so. It is the same environment that pushes for Board ReCertification from certified individuals who have taken most of their CME's in that area of specialty and work every day in that same area. Again no evidence that recertification does anything beyond increasing enrollment in their own Board Review courses (no conflict of interest is acknowledged here, however), and increasing revenues for Board personnel involved in such testing. Experts who have enough knowledge and stature in their respective fields to be consulted by industry to develop educational materials for commercial use are the same experts who have been conducting CME courses for years, developing training curricula and teaching in many formats. Oftentimes, they are the same experts who diligently comb through medica scientific literature in search of new knowledge in their special areas of interest. The idea that providing expert advice to a company that pays them (usually based on experience and expertise demonstrated in an environment where they've been woefully underpaid) somehow then prevents them from giving their best advice and instruction to those that don't is generally absurd and</p>	<p>Accredited CME provider</p>

<p>insulting. Marketing goes out to many individuals in many formats. A few people will change behavior as a direct result. Most do not. Sticking our head in the sand and pretending that industry doesn't exist is not the solution. Withholding expertise from industry serves neither industry nor the profession well. Most importantly, it does serve our patients or the public at large. As an individual who participates in CME from both sides, I would advocate that people who have served such roles and work in the development of CME continue to do so. They are usually the best and brightest in the field. I am interested in what they have to say. Don't stifle us any further. The government has done it, our own academic institutions are trying to do it, and now ACCME is considering doing it. My counsel is caution in laying the road ahead. If you are overly concerned about those few individuals who are adversely influence for their own financial gain, then develop a mechanism that requires revelation of prior activities. I for one, believe that the audience will exaggerate the impact of activity with receptive ears that will actually be excessively biased against the speaker or curriculum being presented. It is sometimes helpful to remember that companies don't make drugs and devices, people do. Most are well-intentioned and do great things for mankind. The greatest evil is not rendered directly, but by all of the good that gets diverted because of the discouragement, fear, and suspicion towards those who continue to work in similar arenas with good hearts. If you've read this far, thank you for doing so and forgive my verbosity in trying to get my point across.</p>	
<p>This is too restrictive. We live in a free society, not a police state. Simply because an educated physician is paid to serve as a consultant and/or speaker on behalf of a specific disease state and/or therapeutic option as an expert should not preclude him from participating in CME programs relating to similar topics. Most frequently, the best communicators, speakers and educators are called upon by several sectors to help with medical education. As long as disclosure policies are followed and any conflict of interest is reported to CME bodies, this is most adequate in ensuring unbiased information. As a physician educator, I used to organize more CME programs than I do now because the 'policies' have become already so restrictive and time consuming that I have less time to devote to organizing CME programs. If further restrictions are promulgated by the ACCME then I think this may be the death knell of grass roots CME and many intermediate levels of CME. We live in an era of obnoxious 'Viva Viagra' ads where pharmaceutical companies use their monies on TV advertisements directly to consumers. Meanwhile, it is difficult to get monies to support CME which will go much farther in improving patient care than DTC advertising so by making it even more difficult for experienced speakers and educators to put on high quality programs with high quality experienced speakers is ironic. Overregulation does not lead to more balanced or fairer presentations.</p>	<p>Accredited CME provider</p>
<p>Dear colleagues: This is akin to throwing the baby out with the bath water. We can find a middle ground, but it is going to require all of us admitting that we have biases and that we have played a role in creating the situation we are in. Respected, legitimate physicians in and outside of academics should be the physicians who speak at promotional events and at "independent" CME. If we do not, promotional events will be just that- just promotion and marketing- and CME events will suffer from not having all of the nation's best physicians available. There is abundant information of clinical interest in a promotional presentation. The "efficacy data" can be seen, if you would like, as drug-company sponsored data, but the level of detail on pharmacology and potential side effects (including the FDA voluminous warnings) are reviewed in more detail than most CME formats. A promotional presentation gathers together large numbers of practitioners to discuss a particular medication in detail. People learn from each other. My experience with promotional presentations is that they are fairer and more balanced than some CME presentations. I realize this experience is not universal. Do we think CME presentations are unbiased? At least at promotional presentations, speakers are forbidden to speak on off label topics. If they do go "off label", they risk severe sanctions. At CME presentations, the speaker is encouraged to stay with "evidence" and "on label" but is free to volunteer whatever they would like as a part of their "clinical impression". There is evidence of widespread bias in medical research and practice, according to evidence and opinion. We physicians have only ourselves to blame for this. We need to correct it. Returning control of research funding, methods, and publication standards to the academic medical center would reduce the appearance of drug company bias (but do nothing for other individual biases that exist in all of us). If those of us physicians who care about unbiased information would agree to speak for promotional events, then there would be far less confusion about what is marketing and what is education. In my specialty of psychiatry, there is no compelling evidence in treating depression to suggest the use of less than 2 generics before trying a branded drug, at least for the average patient. The local representatives of drug companies I speak for have told me that they support this opinion. I am not under pressure to say otherwise, and I feel a educational responsibility to do my best to represent the voice of "unbiased reason" as I participate in promotional activities. What if we did not have people at promotional activities that were willing to provide this reasoned opinion? Someone needs to reach the practitioners who start with samples of a branded drug, only to have the patient stop the drug 2</p>	<p>Other</p>

<p>weeks later because it is not on their formulary. If the academic community and other fair-minded individuals refuse to participate in promotional presentations, we are going to get more of this misguided approach. As a former academic faculty member at a major institution, and as a clinical faculty member now at another, I stake my medical license and reputation every day on making my promotional speaking as useful and unbiased as any CME I have ever conducted. Let's revise and improve our system but keep our best and brightest teachers involved.</p>	
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<p>As a physician I believe that the government restrictions of content and discussion during lectures for commercial products has served to decrease quality of care. I have never given or heard information that blatantly supported products without the care of patients being the first priority. It is absurd that if giving lectures on medications is sponsored by industry or by medical learning institutions that the content of my lectures would drastically change. I would never support any medication without giving pro/cons and fair balance. This would be prostitution of values. It is insulting that I would not be able to discuss various problems with balance to areas of patient care assisted and areas of problems. I always attempt to do this. Current government restrictions actually prevent open discussion. To place such restrictions on physicians only serves to insult their intelligence and their honor. Certainly I hope the ACCME avoids hunting witches and continues to promote good education.</p>	<p>Other</p>
<p>This potential rule/guideline would definitely reduce education to physicians. Many speakers that are asked to speak for industry are experts in that particular field, and therefore, are considered for CME programs as well. By not allowing this, one lecture (industry sponsored) or another(CME activity) will be given by a less knowledgeable individual, and therefore, potentially cause misinformation to propagate throughout the healthcare community. ACCME should be trying to assist in good and appropriate education, regardless of whether it is industry sponsored, or CME, and not build guidelines that inhibit education. As someone who has done lectures in both environments, I can say, without hesitation, that the purpose is to educate. I am very concerned that this proposal will promote industry and other organizations to choose non-experts in the field that is being discussed.</p>	<p>Accredited CME provider</p>
<p>I disagree with the current proposal by the ACCME accreditation Council. This policy is an overreaction to a particularly egregious situation that transpired with [REDACTED] and its overpromotion of [REDACTED]. While there are and have been abuses in promotional and CME presentations, this policy lumps all speakers in the category of having inappropriate conflicts of interest. Current CME guidelines are more than adequate to address these issues. Having spoken at numerous Grand Rounds over the past 30 years, presenters are asked to use generic names and appropriate evidence based support for their presentations. In the vast majority of cases this is more than adequate to give a fair and balanced presentation. Institution of this new proposal will severely restrict most community hospital grand rounds and medical conferences, as numerous medical opinion leaders will be "banned" from presenting important new material. These conferences are the most valuable source of medical education for local physicians. Furthermore, if there is widespread abuse in the system then we need "evidence" of such abuse. Where is the evidence that this is a widespread problem throughout most or all of the CME activities that are a mainstay of education of physicians? Your proposed policy further suggests that a physician receiving a few honoraria is irrevocably corrupted by such payments. However, you exclude all the clinicians receiving research money and clinical study grants in the tens and hundreds of thousands of dollars. This fine line of who is more or less influenced makes little sense and assumes that some money is free of influence and other money is not. I hope the Council will take a closer look at this proposed policy which I and many of my colleagues find unwarranted. Current guidelines are more than adequate to guarantee balanced CME presentations.</p>	<p>Other</p>
<p>who are you people lets face those who provide us superior info should be allowed to do both we live in America not some third world country physicians don't earn enough for what we do they should be allowed to provide all activities if they are so knowledgeable to do so stop this nonsense</p>	<p>Other</p>
<p>We physicians know where information comes from and are intelligent enough to know that ALL medical writing can have bias. Even articles from journals furthest away from commercial interests, such as the [REDACTED], have to be read with scrutiny. We NEVER swallow anything whole, incorporate nothing without careful thought, and are NOT biased by anything. We are not sheep that follow any key opinion leader's opinion blindly, or any commercial presentation. Why is there this inherent notion that physicians are idiots that can be swayed so easily? STOP this nonsense and let things be!</p>	<p>Other</p>

<p>I believe this to be an overreach on the part of the ACCME and implies that there is already bias on the part of lecturers. It is well understood that CME should be (and is) free from commercial bias. I believe this to be the spirit of the May 2008 legal ruling referenced in the call for comment. Many of us in full time academic medicine are on various industry sponsored speaker bureaus and are asked to give lectures, etc. on behalf of products pertaining to our field of expertise. These are not CME programs (nor are they ever touted to be) and disclosure reveals that these are company directed events in which content is company controlled. The lecturer and the attendee understand this and bias (if present) is subsequently not the intent of the lecturer. CME disclosure requires us to disclose all pertinent corporate relationships in order for the attendees of CME to decide if our presentation is free of commercial bias. Company directed programs and CME programs are (and absolutely should be) clearly identified as to intention. The assumption that academic medical faculty (the vast majority of physicians affected by this) cannot be objective and thus require policing is frankly insulting. This policy in effect questions the integrity of some of the most well respected physicians and scientists in the world and I truly hope that the ACCME recognizes the negative impact of this proposed policy.</p>	<p>Accredited CME provider</p>
<p>Comment from the [REDACTED] on the ACCME Proposal for Additional Features of Independence in Continuing Medical Education. The ACCME has proposed the following policy: Persons paid to create, or present, promotional materials on behalf of commercial interests cannot control the content of accredited continuing medical education on the same content. The [REDACTED] does not support this proposed policy. Processes to resolve conflicts of interest and validate CME content ensure that CME does not promote a specific proprietary entity and does not contain promotional messages. Excluding potential CME faculty in this way would have a negative impact limiting the pool of experts available for consideration for presenting in CME activities and therefore could negatively impact the quality of continuing medical education. As noted in the [REDACTED] comment regarding the consideration to eliminate commercial support, insufficient time has elapsed to determine the success or failure of the current ACCME Standards for Commercial Support. Until these standards are evaluated to determine deficiencies, if any, sweeping changes to the current system should not be made. Respectively submitted, [REDACTED]</p>	<p>Accredited CME provider</p>
<p>In principle this is a noble stand, but this will weed out 100's of highly distinguished physicians, who have a lot to offer to the education of their peer & society as a whole.</p>	<p>Non-Accredited CME provider</p>
<p>[REDACTED] [REDACTED] RESPONSE TO PROPOSED ACCME RULE THAT DEFINES SPEAKERS AND AUTHORS WITH PROMOTIONAL RELATIONSHIPS WITH COMMERCIAL INTERESTS ON THE SAME TOPICS AS THEIR PRESENTATIONS AS HAVING AN IRRECONCILABLE CONFLICT OF INTEREST AND THEREFORE INELIGIBLE FOR CME. SUMMARY STATEMENT: As a [REDACTED], the proposed rule will severely cripple our efforts to offer CME to our membership and other healthcare professionals that count on the [REDACTED] to provide them with the most up-to-date scientific information that affects the quality of care of our patients. We respectfully oppose this rule as being unnecessary in the context of our thorough efforts to identify and resolve conflicts of interest in CME in accordance with the ACCME Standards for Commercial Support. DISCUSSION: Since the updated Standards were published and implemented in 2005, [REDACTED] has established a thorough vetting process for faculty that present at its live CME activities, authors of its enduring materials, planners, reviewers and others associated with the content of CME. In this process, the [REDACTED] requires early identification of conflicts of interest with the manufacturers of any healthcare product relating to the commercial supporters of CME activities or manufacturers whose products are referenced in the CME activity through the process of completing a detailed financial disclosure form. While all CME activities are reviewed by an independent and qualified physician member of the [REDACTED] in accordance with the ACCME Content Validity Value Statements, reviewers also are aware of identified COI from the disclosure process and scrutinize the content prepared by persons with reported COI. This process is documented and included in all compliance materials associated with every activity certified by [REDACTED]. In fact, the vetting and review process is successful in that real, apparent, or nuanced commercial bias, when discovered (in approximately 7% of these reviews) results in recommended changes to content. When reviews identify areas for modification, the [REDACTED] assures that those recommended changes are made. We stand behind this process. It is effective and still permits the nation's best experts in epilepsy to teach our members and general neurologists. Because the treatment of persons with epilepsy is primarily one involving multiple anti-epileptic drugs to manage symptoms, leaders in our field are the same ones that the manufacturers of these treatments seek out to advise them regarding the scientific basis for choice and use of drugs. While such relationships necessarily remunerate those individuals for their time and expertise, to arbitrarily label those scientists and respected members of our profession as having "irreconcilable" COI is inappropriate. In general, our judgment is that this proposed rule is overly</p>	<p>Accredited CME provider</p>

<p>I am a rheumatologist. I feel the proposal is really "dumbing down" physicians who attend lectures. What I read from the proposal is that the listening physician is not trusted to have enough knowledge to know when he or she is being strictly given commercially biased information vs good clinical research results. When I am lectured by a physician who has done a lot of research on the topic, I find that physician is able to better handle questions that the audience asks. I feel these proposed rules are too harsh. When I knew a great researcher was coming into town to lecture, I was more inclined to go to the lecture than listen to an unknown speaker and the audience attendance was always greater. I am satisfied that lecturers now begin their talks by identifying for whom they have done research and also for whom they have lectured. Please reconsider the proposed policy. Thank you, [REDACTED]</p>	<p>Other</p>
<p>I first want to comment that overall I feel that the policies that have been put into place to help clarify conflict of interest and promote fair and accurate information has been helpful to the practice of medicine. I appreciate also the thoughtfulness in allowing clinicians and educators to comment on any proposed policy change. I feel that the current proposal has a number of limitations and both is potentially unfair to clinicians/educators and also needs significant clarification. If the proposal is specifically targeting the practice of individuals potentially using an unrestricted educational grant to allow the discussion of a topic (e.g. M.D. discussing a topic on depression at a CME talk funded by a grant by the pharmaceutical company that makes an antidepressant), then there would be potential merit in this because there can be a direct line drawn to potential conflict of interest as there is money "changing hands." However, as a clinician and educator who participates in promotional talks/is a member of pharmaceutical company speaker bureaus, I have concerns that I cannot educate students, residents, and fellow attendings because of this association. What is being suggested is that any educational material is tainted by "guilt by association" because I have been on a speaker bureau. It is unclear if because I am on a speaker bureau for an antidepressant I cannot talk on any subject that concerns depression, bipolar disorder, any anxiety disorder, PTSD, OCD, PMS, chronic pain, hot flashes, addictions, eating disorders, etc... It should also be noted that during many of these lectures or case conferences that medication treatment is only a small part of the discussion. However to omit discussion of medication treatment during the talks would also be unacceptable for the education process. I want to note that my giving a number of grand rounds at hospital medical staff meetings, having resident rounds at the hospital, and giving lectures to medical students are all done for free without any pharmaceutical company discussion. In fact nobody in the pharmaceutical industry knows of these talks and would have no access to these discussions. My association in a speaker bureau is an independent contractor and with all the guidelines in place, the pharmaceutical company has no access to my clinical practices nor what I say outside a pharmaceutical sponsored talk. In any CME discussion or when discussing my content of material at the medical school/residency program, there are checks and balances by the CME and education committees where I educate. These individuals and ultimately the audience (my students or fellow attendings) also become the best peer-review I have found. That is the role of these organizations and they can look at the specific issues with any of my CME or other educational talks. To regulate by the just the presence of an independent contractor relationship with a pharmaceutical company is potentially very inconsistent, arbitrary, and ultimately endless in coming up with the "next conflict of interest." I feel that in a CME or other educational talk that is not connected with pharmaceutical money, the CME body and the peers are the best and most consistent way of insuring fairness in educational presentations.</p>	<p>Other</p>
<p>Dear Sirs and Madames, A curious phenomenon appears to be sweeping the country. Anyone who has an association with a money making enterprise in this country is consider a puppet of that enterprise and should face banishment from associating with other apparently vulnerable persons, you know other Doctors and everyone else!! I, for one, am sick and tired of being told who I can associate with by those who, through philosophical sameness and finger pointing, believe no one can catch the difference between a promotional talk and a CME event without a long written disclaimer and/or a note from the CNN. Do you think a physician who "controls" (an interesting choice of word) the content of a CME event will appear suspicious because he gave a promotional talk in Toledo 3 nights earlier? Boy, I feel the throbbing conflict of interest all the way to my colon. Speaking of taking it in the behind, I have a suggestion for a new product that I'm sure will fly off the shelves in supermarkets adjacent to doctors offices everywhere-"Senator Grassley in a can". One spray and magically the ubiquitous conflict of interest bug is driven into oblivion. the problem is the residual odor stinks up such ideals as free enterprise, making an honest dollar through hard work and, despite proper disclosure, the freedom to associate with industry and academia alike without the constant accusation stated or implied that you are a whore of industry. If you want to run around with your tail between your legs until the House on Un-American Activities chaired by one of the these drones of the late infamous Republican Senator Joseph McCarthy with a manifesto in hand proclaiming that if you associate with members of "Industry" you must be a subversive-be my guest. What is the next step, senate hearings, special prosecutors and public humiliation and sanctions. It happened over the threat of communism before; what do the numerous enemies of medicine (witness the medicare reimbursement bill year after year) within the</p>	<p>Other</p>

<p>legislative branches of our government need to develop their marching orders. Doctors are responsible for "drugging" our kids, we prescribe powerful meds that people can misuse. When people sense wrongdoing even without merit they can talk about little else. These officials in power have an ready audience, a sense of ideological superiority and filled with righteous indignation and they have used that advantage unfairly in the past rendering thoughtful discussion impossible. If you all want to jump in the box cars for a trip to the relocation and Ideology Retraining Camp, again, be my guest!! When they turn on the gas, just remember you chose the path of least resistance, God be with you. Sincerely, [REDACTED]</p>	
<p>Industry and certified medical education rely on the expertise of the key opinion leaders. We need key opinion leaders to provide their expertise in speakers' bureaus and other promotional venues and we need those same people to present at certified programs. The public and our patients will all benefit if our best experts are available to all. To regulate this in such a way that collaboration with both is prohibited appears pointless. The CME provider should be responsible for vetting content in order to eliminate bias from a certified activity. Then, the ACCME should ensure that their providers are doing their jobs.</p>	<p>Non-Accredited CME provider</p>
<p>September 12, 2008 TO: Murray Kopelow, M.D., MS, FRCPC, Chief Executive Director Accreditation Council for Continuing Medical Education [REDACTED] [REDACTED] Responds to ACCME Proposes Additional Features of Independence in Accredited Continuing Medical Education The [REDACTED] is a professional, scientific and medical society established to bring together clinical and experimental scientists involved in the study of bone and mineral metabolism. [REDACTED] is pleased to provide comments to the Accreditation Council for Continuing Medical Education (ACCME) on the document entitled, ACCME Proposes Additional Features of Independence in Accredited Continuing Medical Education. While [REDACTED] applauds your efforts, we have the following concerns about the draft policy statement: 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. Issues of Concern •What is "promotional materials and content?" [REDACTED] recommends providing a clear definition of what is/is not considered "Promotional materials and content" by AACME. The current wording is too vague and will lead to different interpretations of the policy which would undermine the policy. For example, does "promotional materials and content" include images from pharmaceutical ads, written content such as "Buy drug X because it is better than drug M" or even the name by which the drug is marketed? Without a clearer definition, an academic could conclude a written presentation and/or slides have no "promotional content." To further address this, a description of a "promotional presentation" could be included in the document with specific examples of a presentation that would be deemed "promotional." •How long after someone gives a promotional talk would they be barred from CME activities? In the ACCME Commentary section the document states: Physicians paid by a commercial interest to do promotional presentations on a product could not teach in accredited continuing medical education on the same product. Issue of Concern •How long after someone does a promotional talk are they barred from CME activities? [REDACTED] believes that if there is no set duration of time by which someone would again be eligible for CME activities, it would deter important researchers from teaching at CME-accredited meetings. [REDACTED] would support a restriction of one or two years. Additionally, instead of a time restriction, ACCME could consider a monetary amount (i.e., compensation for promotional talks of more than \$10,000 per year then individual would be excluded from participation in CME activities). Thank you again for the opportunity to comment on this important document. [REDACTED] believes that with further clarification, the ACCME policy will help to remove the perception of bias from CME educational meetings.</p>	<p>Non-Accredited CME provider</p>
<p>Being involved in writing promotional materials should not automatically exclude one from having any role in CME content. The main issue would be that the CME be free of any commercial bias. However, medications are used to treat various disorders, and to mention them would in no way prejudice the program in favor of a particular drug. The people who would be involved in writing CME content would be educators who receive honoraria from various pharmaceutical companies and support for research. To exclude them would take away the ranks of our foremost educators. I do not believe that being involved in promotional activities should be exclude one from independent CME activities provided their lecture is free of bias. I believe that industry has always used the most talented teachers and professors. To exclude them would be to deprive the psychiatric audience of the most able and talented speakers. Besides, even if one does not have an ties to pharmaceutical companies, one still can have prejudices in favor of one treatment or another. Thus, no person can truly be unbiased.</p>	<p>Accredited CME provider</p>

<p>ACCME currently prohibits, or strongly discourages, CME faculty from referencing specific brand, trade or manufacturer's names when discussing technology, technology-related research or technology-related education. Only the use of generic descriptions are permitted. The stated intention of this policy is "balance and objectivity". Editors of peer-review uniformly insist that authors list product model and manufacturer as a condition of publication of any manuscript whose results may reasonably depend on technology. It is well-known that not all products cleared by FDA for a common indication are equally safe or effective. ACCME insistence on generic product descriptions irresponsibly assumes comparable performance and outcomes. ACCME should follow the example of scientific peer-review on the issue of product and manufacturer identification when technology is central to education and its consequent impact on medical practice.</p>	<p>Commercial Supporter</p>
<p>During the many years that we have sponsored CME activities, we have found our faculty selection methods and our evaluation tools to be very effective in detecting and eliminating bias. We see no reason to change the current rules concerning faculty selection for those who develop content and teach in our activities.</p>	<p>Accredited CME provider</p>
<p>Instituting this policy would disqualify some of the best and brightest expert faculty from participating in CME activities. Physicians who are well informed and good speakers are in high demand for both promotional and educational services. Forcing physicians to choose to operate in one arena or the other will necessarily decrease the availability of well-qualified faculty in both arenas. In addition, because the ACCME is recommending a "carve-out" for researchers, the focus of CME may inadvertently move from one of clinical applicability to one with more of an academic or research focus, by virtue of the expertise of the faculty available for recruitment. While researchers can adequately speak to data from rigorously controlled clinical trials, they may be less well equipped to speak to the day-to-day implementation of practice strategies based on that information. It would seem that the best way to effect a positive impact on clinical practice is to have access to the most qualified individuals, regardless of what roles they may play in non-CME arenas. As CME providers, we require faculty for our CME activities to attest to their intention to present fair-balanced, evidence-based CME, and we have a variety of safeguards in place (COI resolution, content validation, peer review) to assure that the content developed meets those standards. To arbitrarily limit access to expert faculty solely on the basis of other professional services they may render seems to be to be an overreaction to a concern that has been addressed through the various safeguards already in place. All of us in the CME profession recognize the imperative that the education we provide to physicians result in the best of patient care. Restricting access to the best and brightest in a field seems to run counter to that imperative. Given the multiple levels of checks and balances required by current ACCME policies, I question the need for the addition of a policy that will increase barriers to development and dissemination of high-quality education. Regarding implementation of such restrictions for freelance writers, my concerns are similar---that those with the most knowledge of a given therapeutic area may not be available to assist in the development of CME--to the detriment of the quality of the final product. Freelance writers are professionals who offer their services as works-for-hire. They are paid on a project-by-project basis, with full understanding of the requirements and demands of each new job. The expertise they provide, regardless of whether they are being hired for the development of promotional or educational content, is a combination of their knowledge of the literature relevant to a given therapeutic area, their familiarity with expert faculty in that area, and their ability to clearly convey complex information. Requiring freelance writers to choose between promotion and CME would seem to set up an arbitrary restriction of trade, and would diminish the number of qualified writers available for either enterprise. Again, the current policies for resolution of COI and for content validation, coupled with the multiple rounds of review by expert faculty, which are the norm for content development, would seem sufficient to offset any lingering concerns regarding potential for bias.</p>	<p>Accredited CME provider</p>
<p>I find this absurd and insulting. Many commercial speakers are the most qualified to expand on information about an illness and treatment options. To think that these speakers would prostitute their basic beliefs and give false information strictly because they have also given talks about a product used for that illness is again, insulting. I think the pendulum has swung much too much to the left of clarity and judgement.</p>	<p>Commercial Supporter</p>
<p>I agree. I'd like to have more freedom giving presentations</p>	<p>Other</p>

<p>Thank you very much for allowing me the ability to comment on something on which I feel very passionate. I am a rheumatologist in private practice with 30 years of clinical experience. Not only do I maintain an active practice, but I have a non-paid clinical faculty appointment at a medical school. As such I have allowed medical students, interns and residents to rotate in my office to be exposed to people with arthritis and learn about the specialty and what we do. I believe there are two types of experts in medicine. There are those that are experts in the world's literature and research, and those who are experts in the practice of medicine. Even though I do no research and do not contribute to the literature, I have been associated with many pharmaceutical companies as a trained speaker for promotional talks, consultant, and member of advisory boards. My expertise brings benefit not only to the the pharmaceutical companies, but as a consultant and member of boards with other experts, and as a "trained speaker", I bring additional knowledge and value to my patients, doctors in my community, and those fortunate enough to hear me speak. Doctors in my community look to me for leadership because of my "expertise." But does this compromise my ability to be fair-balanced in developing CME materials, or presenting in a CME environment? A resounding NO! As an example: The [REDACTED] was given a grant by a pharma company to develop a CME program on osteoporosis to be given at several medical state society annual meetings. As an expert in osteoporosis, I and 3 others were chosen by the [REDACTED] met via several telephone conferences, divided the workload, each of us worked on our assignments, the materials were distributed to each of us for review, and a final draft was made, and submitted to the [REDACTED] for approval. At no time did the sponsoring pharma company have any input in the content or development, and I would challenge anyone to review the presentation and determine the sponsoring company. I have developed several other CME-related activities with similar results--no pharma input. I gave 2 CME talks in August at a state family physician conference. These were fair-balanced, not sponsored by any pharma company, and no preferential treatment to those companies with whom I am associated. In fact on an evaluation one of the docs commented that it was great to hear a talk not sponsored by a company since it did not promote any one product. There are many of my colleagues around the country that are similar to me. We have tremendous knowledge and enjoy sharing it with others. Our clinical experience, our travels interacting with each, the education presented at ad boards and speaker training allows us the opportunity to provide needed education to physicians in practice. We can wear multiple hats and not mix our tasks. Please for the sake of our patients who benefit from medical education, and for those of us who are passionate about educating community docs, don't limit what we are able to do. Thanks for your patience in reading this and if desired I would be willing to communicate further either by email, phone, or even in person. Sincerely, [REDACTED]</p>	<p>Other</p>
<p>We applaud ACCME for providing this opportunity for comment. The proposed policy change is not in the best interests of health care providers or the public and should not be adopted. The current proposed policy change is consistent with a number of other controversial initiatives by segments of organized medicine, including AAMC, the AMA's Council on Ethical and Judicial Affairs (CEJA), and others. ACCME undoubtedly feels special pressure from its recent summons to testify before the Senate Finance Committee. It is instructive to observe the significant disconnect between those who strive to make policy about the proper role of industry involvement in the medical education enterprise, and the medical community these agencies serve. For example, CEJA recently proposed elimination of industry funding from medical education, except in cases where technical training in the use of a new technique or device is required. At the AMA's annual House of Delegates meeting, June 2008, speakers representing more than 40 organizations, including the Alliance for CME, and the Council of Medical and Specialty Societies, spoke out against CEJA's recommendation, while just a handful spoke in support of it. After hearing all the testimony, AMA's Reference Committee decided to refer this report back to CEJA. The House of Medicine has spoken loudly and clearly against introducing unnecessary constraints without clearer evidence of need. Our major concern with the current proposed policy change is based on the following principles: a) it is overly restrictive and will result in the elimination from CME programs of many of the best top tier experts; b) it is based on confusion over the critical difference between commercial bias, and the much more elusive concept of "perception of commercial bias" or "possible perception of commercial bias;" c) the proposed policy derives from a delphic process, rather than empiricism (systematically collected data from the contemporary world of CME programming); d) it will reward smaller local CME providers who typically produce programs for in house audiences (mainly regularly-scheduled conferences) but serves as a major impediment to larger more innovative cutting edge CME providers whose experts frequently work with industry to innovate and improve the quality of diagnostic and therapeutic tools available to practitioners; e) it erroneously embraces a spurious inevitability of an unmanageable incompatibility of interests between industry and academia. Additionally, the term "promotional" is unacceptably vague. Our organization, one of the largest [REDACTED] members, responsible for [REDACTED]. We produce many Summits, designed to provide the newest information about the management of a variety of disorders. [REDACTED] database that can help provide prospectively- gathered information about the scope of the commercial bias problem and the effectiveness of current oversight. We are preparing a manuscript that explores the level of perceived bias in</p>	<p>Accredited CME provider</p>

<p>CME activities with no commercial funding source (46%), those with a single funding source (23%), and those with multiple funding sources (31%). Information was collected for a total of 397 different CME activities with a median of 244 participants in each. Overall, 98.7% of the participants of a particular activity responded that they considered there was no commercial bias. There was no significant difference in perceived bias between different types (live, on-line, enduring, journal-based) of activities or different support types (single-, multiple-, or no-commercial funding source) ($P>0.05$ for all comparisons). A different smaller study designed to drill down to the particular policy change proposed by ACCME studied a single recurring update/board review course in cardiology. We looked at the [REDACTED] (49 faculty teaching 61 sessions over five days) and asked the following question: What is the level of perceived commercial bias in speakers who have no membership on speakers bureaus compared to those who do? Again, we found very little evidence of commercial bias overall or in any sub group. Specifically, there was no higher rate of perceived commercial bias for those speakers who are members of speaker's bureaus. Our data supports the conclusion that policies and procedures currently in place are overwhelmingly successful in reducing to very low levels commercial bias in CME programs. We urge ACCME to refer the proposed policy change for further study, including systematic prospective collection of relevant data. The goal of ACCME should be to create a regulatory environment that is finely tuned and calibrated to reduce to very low levels commercial bias in CME activities, and to create an environment where transparency exists about the relationships that exist between commercial sources and those who are in a position to control CME content. The proposed policy change is a very blunt instrument not suitable for the task at hand. [REDACTED]</p>	
<p>I am writing as an individual to express my concern in response to the ACCME request for comments regarding the proposal to increase the restrictions for participants in continuing medical education activities. I am opposed to the ACCME proposal to implement the following policies: \tPersons paid to create, or present, promotional materials on behalf of commercial interests cannot control the content of accredited continuing medical education on that same content. My concern rests around the burden that CME planners would have in implementing this ban. My concern is that a speaker for a CME activity with a slide set that has been reviewed still exerts a significant amount of control over the CME presentation through focusing on certain material, emphasis on recommendations, interpretation of the data and answers to questions from the audience. Without a scripted, tightly controlled presentation, this ban would be impossible to implement with any significant meaning and would restrict organizations from using experts in the field that have some relationships to commercial interests. The task for CME planners is to identify and resolve conflicts of interest. We already have strict guidelines and high expectations for CME activities. This results in a balanced and fair discussion of the topic with the audience from a speaker who is often an expert or highly regarded in their field. To put a ban on this level of faculty would harm CME greatly and I fear would result in speakers who are either parroting or presenting other peoples' work or the literature. Our task is to remain diligent about identifying and resolving these conflicts and disclosing these relationships to the audience and then monitoring whether those presentations are objective and free of bias.</p>	<p>Accredited CME provider</p>
<p>In general promotional presentations focus on specific drugs and are created and marketed by the company and their employee reps (with strict oversight/approval by the FDA of the materials used which greatly limits what is presented to fact). On the other hand, CME presentations are controlled by the entity sponsoring the event with selection of speakers independent of the source of funding (and the funding is often from multiple sources-both industrial and independent of industry). The charge for speakers in this format is usually to present cutting edge/state of the art data regarding a disease and/or modality of therapy. Since the speaker is usually unaware of the source of funding, to speculate that they are somehow biased by their prior presentation of FDA supervised data sponsored by a company is simplistic. Recently, CME companies have been sponsoring the creation of slide decks to be utilized in CME activities. This is a new development which is somewhat more to the point of the above. Speakers forced to use the slide decks do not and can not know if some bias based on funding to the CME provider went into the deck formation. I would prefer to see the ACCME insist on the continued independent selection of speakers for CME events free from industry input, and the elimination of paid creation of slide decks for CME purposes as this seems to deviate from the goals of CME. Persons paid to create materials or slide decks for promotional or CME purposes cannot control the content of accredited continuing medical education on the same content would be more to the point of your goal.</p>	<p>Accredited CME provider</p>

<p>As a medical writer for 12 years, my experience has been that CME development, by definition, requires the medical writer to place topic A within the context of clinical trials, evidence-based medicine, and the full range of therapeutic options. A professional medical writer carries that approach to her work and that knowledge base to every project, whether it has a CME or commercial purpose. Additionally, structures are in place within the CME system, such as peer review and the ACCME accreditation and review process, to guard against and detect the introduction of bias. A medical writer involved in developing content for an unbiased vetted CME activity on topic A is more likely to approach content for a "commercial" document on topic A with greater accuracy and less bias than is a medical writer who has never developed CME material on that topic, and as a professional, will not bring any marketing fluff back to CME.</p>	<p>Other</p>
<p>If someone is paid by a commercial interest to create and/or present promotional materials of that interest, I feel they could easily develop an allegiance to that interest. Whether it is formal or informal, spoken or unspoken, if someone is receiving payment, they are likely to align themselves, to some degree, with the entity that is paying them. Though we should be able to assume the person would not receive payment (from the commercial interest) for influencing CME content such that it promoted the interest, there could still be that underlying allegiance which may in fact affect what or how the person creates or reviews CME content.</p>	<p>Accredited CME provider</p>
<p>I disagree. Persons sought for content creation are often the experts doing the research on the topic. I think a degree of judgement is required, but I think a good knowledge of all the pharmaceutical products is needed for dissemination of information.</p>	<p>Other</p>
<p>The members and leaders of the [REDACTED] feel very strongly, as does the ACCME, that Continuing Medical Education (CME) should be free from commercial bias. In fact, it is a requirement. We make every effort possible to follow the criteria established for accredited CME activities, and take seriously our responsibility to adhere to the Standards for Commercial Support. These standards clearly state the expectations for appropriately managing conflicts of interest of activity planners and presenters and provide a framework on which we have developed procedures for doing so in the development of our educational program. We collect and review disclosure information for all designers and faculty members working on CME activities, communicate with these individuals when a resolution is required to manage a potential conflict of interest, collect feedback from learners on possible bias in an activity's content, and review and monitor this feedback to inform future selection of activity designers and faculty. As a result of this process, the feedback we receive shows that speaker and content bias have rarely been identified in our educational activities, which indicates that these financial relationships, and the potential they present for undue influence in our educational activities, can be appropriately managed. This is one of several reasons why we do not support the ACCME's proposal that "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." As stated above, providers have integrated the management of relationships with commercial interests into their practices and have a number of methods available for identifying and resolving potential conflicts that may involve either planners or faculty involved with CME activities. Clearly this is easier to manage in enduring materials, when the content can be carefully monitored in development and is fixed once it is made available to learners. But even for live activities, steps can be taken to eliminate undue commercial influence. Before an activity takes place, these can range from limits on an individual's involvement to evidence-based content to a full review of the educational materials to be presented. In the event of an irreconcilable conflict, this individual should be disqualified from participating in the activity. During an activity, targeted evaluators can monitor an activity's content for bias. Following an activity, participant feedback can easily identify biased content. While these last two types of feedback are only available after the fact, they can be used to improve these processes for future activities. This can include exclusion of biased planners and presenters. Physicians and other health care professionals who have spoken on occasion in a promotional program on behalf of a commercial interest have likely been invited to do so because of their personal research contributions and/or clinical expertise related to a given issue. Eliminating these experts from the development and presentation of CME activities will only serve to stifle the exchange of scientific information that is needed to advance the practice of medicine and adversely affect patient care. This will have a pronounced impact on smaller specialties and subspecialties with smaller provider populations. In these groups it is not uncommon for the leading researchers to consult with industry organizations because of their mastery of the same science they are called upon to share in CME activities. These thought leaders fully understand their responsibilities to the field and are able to distinguish between promotional and educational activities. The cited case involving a speaker who was banned from presenting in CME activities likely involved an abuse of the system, but should not be generalized to apply to all physicians and researchers who choose to share their expertise with both the scientific and industry</p>	<p>Accredited CME provider</p>

<p>communities. The Call for Comment also mentions the recommendation by the AAMC that faculty should be discouraged from participating on industry speakers' bureaus. These faculty members could have other types of non-employee relationships with commercial interests, serving as research consultants or on advisory boards. Many faculty members are encouraged by their institutions to create start-up companies to market the results of their research and provide a revenue stream for the medical school. The AAMC does not recommend limitations on these relationships, recognizing that every relationship between a scientist and a commercial interest does not a priori constitute an irreconcilable conflict of interest. The same standards can be applied to continuing medical education. Any relationship between two parties has the potential to present conflict of interest, depending on the context in which it is viewed. The automatic assumption of bias that is inherent in the ACCME's Call for Comment ignores the system of checks and balances already in place, and ignores the ability of highly trained medical professionals to distinguish between product promotion and scientific advancement, and their responsibilities to the field of medicine. We strongly urge the ACCME to reject this proposed change to the Essential Areas and Policies.</p>	
<p>██████████ believes that although a speaker has created or presented promotional material, he or she is very capable of presenting a balanced, unbiased view of a topic related to the product in a controlled CME environment. We have copious data that supports this in our speaker evaluations. Consistently less than 1% of responses indicate a speaker is biased, yet a variety of our speakers work with pharma in other capacities. Even those speakers who we know are working with pharma as creators or presenters have consistently low bias scores on audience evaluations. It is up to ██████████ to follow its internal guidelines which have been created in response to the ACCME's SCS to closely screen and monitor speakers who have potential COI's for bias and to make our own determination on how to handle this, as long as it fits with the ACCME's mandates. We must monitor audience's responses to all speakers, those with conflicts and those without. ██████████ also believes that bias can exist without a COI or paid relationship with pharma, eg- the physician's affinity for drug reps visiting offices, for products they just personally like, etc. Basically, all speakers must be monitored for bias, not just those involved with pharma, and this is the provider's responsibility. The issue of new device and equipment training (ie Implanon, IUDs, equipment, etc.) also comes up here. If a physician is a trainer for a company on a new device, is he or she then banned from presenting on a topic which might include that product? This will have significant impact on the training physicians receive on new products since it will undoubtedly be relegated to non-medical company reps. The ACCME is slamming its providers with a number of new policies and proposals, some of which are reasonable and some of which need further consideration. It will be difficult to evaluate which are accomplishing your goals if all are implemented at once. Give this one (and us) a rest until we have time to digest and implement some of the other changes. It appears that the ACCME is becoming very heavy-handed and controlling and I would encourage you to trust your providers to respond to the SCS responsibly. If you have violators of policies, please deal directly with them. Don't make us all pay. Thanks!</p>	<p>Accredited CME provider</p>
<p>The ██████████ strongly opposes the ACCME's proposal to ban faculty who are paid to create or present promotional materials on behalf of commercial interests. The ██████████ and its "parents", the ██████████, have delivered the highest ██████████. Our reputation for excellent multidisciplinary teaching of ██████████ is well established in the fields of ██████████. Our educational activities are planned and presented by tens to hundreds of surgeons, united by their passion for the care of patients with head and neck cancer. We view the recent ACCME proposal as an assault on medical education. We are struck by the vague and overly broad scope of the requirements. If enacted in its current form, application of this policy will result in a significant reduction in the numbers of individuals permitted (and inclined) to serve as teachers. The ██████████ educational mission will certainly suffer if the profession's most qualified clinicians and researchers are prevented from sharing their understanding and expertise because commercial concerns have also solicited their opinions and advice. Make no mistake—corporations have strong incentives to offer the necessary resources to retain the profession's most qualified consultants. This policy will place an untenable burden upon these prominent and highly regarded individuals: they will be forced to choose between advancing commercial interests (in drug or medical device development) or teaching other physicians and scientists. Which of these two choices will best serve the nation's patients? The overwhelming majority of doctors work in concert with commercial entities in an effort to improve patient care, rather than for profit. Additionally, this proposal assumes that once a speaker or writer of content receives compensation from a company then he or she will cease to think or speak on their own behalf. For example, a surgeon giving a seminar on the principles of ultrasound typically receives a stipend from an industrial concern to do this. The surgeon does not promote any particular product during the presentation, but the industry sponsors typically bring an ultrasound machine that they hope to sell so that participants may view and evaluate the equipment. Is the surgeon "promoting" this product? Should their participation in this activity render them unfit to deliver a similar lecture in a purely educational venue? In the ██████████, our faculty disclosure management system would evaluate this potential conflict of interest and additional scrutiny ensures that any lecture offered at a CME</p>	<p>Accredited CME provider</p>

<p>activity was scientifically sound and free from bias. In a statement to the Institute of Medicine Committee on Conflict of Interest in Medical Research, Education and Practice (2008), the ACCME states that “although it has been speculated that commercial support produces bias in CME programs, no published studies have examined this question. Therefore, there is no evidence to support or refute this assertion.” Opinion pieces in the lay press and the medical literature should not sway the regulatory community. Before promulgating policies with potential to devastate the medical education community, studies should be conducted to discern whether there is a relationship between participation of faculty who have received money from industry and bias in CME. [REDACTED] is proud to provide the highest quality education at the lowest cost to our target audience. We rely upon experts in the field not only to teach our audience (largely, and often entirely as volunteers), but also sometimes to collaborate with commercial interests in an effort to improve patient care. Please do not deprive the [REDACTED] of many of its most insightful faculty. [REDACTED]</p>	
<p>I am very concerned that this policy will limit the number of experts who will be able to plan and speak at CME functions. Often the clinical experts are asked to educate other health care providers. If these same experts prepare information for pharmaceuticals educational programs and/or patient pamphlets, then they will not be able to oversee a CME program. Although this will decrease the possibility of bias, I think that overall it will decrease educational activities for health care providers. Since pharmaceutical companies can no longer provide CMEs. More CMEs will need to be offered to maintain educational opportunities. I think the pendulum is swinging too far to one side. This needs to be looked at in a less stringent manner. Even with this regulation in place, it would not guarantee that there is no bias.</p>	<p>Other</p>
<p>I raise concerns that many "speakers bureau" participants show independently validated materials that are not " promotional" . These individuals have not created their materials for promotion but may use some of the same peer reviewed public data that the speakers bureau uses. The exclusion of these individuals most of whom show publically available peer reviewed data and speak independently as clinical trialists is not in the best interest of unbiased discussions of issues of practice and scientific evidence. Specifically this regulation is likely to require some of the best experts to choose between contacts with Pharma and contactws with the CME community. A regulation barring these individuals from one of these forums will detract from the quality of content and discussion in both. Secondly the definiton of the scope of a promotional or commercial relationship will be difficult to faccuratel articulate and impliment or regulate. I believe the States attorney generals settlement with Merck over Vioxx is not the correct precedent around which we want to organize CME discussions regarding the use or non use of pharmaceuticals. I believe tsuch discussions are legitamate in CME venues and need to be informed by individuals who work in both the pharma and independent trials environments. I do not feel the ACCME should promote segregaton of who can discuss what. I think a better focus is to make the disclosure process more detailed and transparent.</p>	<p>Accredited CME provider</p>
<p>I strongly believe that this exclusion is neither necessary nor even effective in maintaining the integrity of CME content. Virtually all experts qualified to develop CME content are exposed to and familiar with promotional materials in the same topic area. Experts who are not pharmaceutical industry employees who have been paid to create or present promotional materials are NOT inherently biased nor are they incapable of controlling CME content on the same topic in an unbiased fashion. Payment for such promotional activities is NOT tied to development of bias in favor of the promoted interest, in fact it tends to be tied to a lack of such bias. Even in promotional presentations, any commercial bias detectable by physician (and other HCP) listeners/learners negates the efficacy of the presentation. Thus, there is a strong disincentive for pharma to use biased presenters, and an equally strong disincentive for presenters to harbor such bias. Thus, the very premise of such an exclusion is flawed. To optimally maintain scientific rigor and lack of bias in CME content it is far easier and far better to continue (and enhance if needed) direct review of the CME content itself, rather than hoping that the proposed upstream exclusion of otherwise qualified experts will somehow maintain (or even contribute significantly) to the achievement of the desired lack of bias.</p>	<p>Accredited CME provider</p>

<p>As a nurse speaker for several pharmaceutical companies, I have found the content of the programs that I have been requested to present has been previously published information available to all health professionals regarding the agent for which I am speaking. I have not been prohibited from expressing my personal experiences regarding that product or any other product in the same class of agents. Additionally I speak for companies that are competitors and they are well aware of that fact. The speakers that I have been associated with have not expressed concern about conflicts of interest over data, product safety, experience. To the contrary...they are well versed on most of the agents within that class of pharmaceuticals, and are valuable observers as well as practitioners who bring practical expertise to the subject. That kind of expertise should never be underestimated or undervalued. Most of these speakers do not make their livelihood speaking for pharmaceutical companies. The ethical professional with minimal monetary interest should certainly be able to produce fair and balanced educational programs. Who better to create these programs than those who prescribe products and have experienced various outcomes. How insulting that professionals who wish to assist their colleagues by providing educational material that is practical and clinically relevant might be excluded from that activity because they may have a minor financial link to a sponsor due to a speakers' bureau participation. I believe that most professionals are well aware of the difference between scientific evidence and marketing BS.</p>	<p>Other</p>
<p>PHYSICIANS ARE AMONG THE MOST EDUCATED IN THE WORLD. ALSO, WE ARE TRAINED TO USE CRITICAL THINKING TO MAKE OUR DECISIONS. SCIENCE, STATISTICS, CLINICAL ACUMEN, AND INDIVIDUAL PATIENT NEEDS ALL INFLUENCE OUR DECISIONS ON BEHALF OF OUR PATIENTS. PROBABLY, ALMOST MORE THAN ANY OTHER PROFESSION WE MAKE EVERY EFFORT TO MAXIMIZE A POSITIVE CLINICAL OUTCOME FOR OUR PATIENTS. AS LONG AS WE KNOW WHERE AND WHO OUR DATA IS COMING FROM THERE SHOULD BE NO CONFLICT OF INTEREST IN WHO PRESENTS THE DATA WE USE. IF A MEDICAL SCIENTIST PERFORMS HONEST RESEARCH WITH THE ECONOMIC SUPPORT OF THE NIH OR A PHARMACEUTICAL COMPANY OR INDEPENDENT FUNDS WE SHOULD TRUST EACH OTHER TO MAKE AN HONEST JUDGEMENT ON THE DATA PRESENTED. CONSIDER ME AN HONEST PHYSICIAN WHO APPRECIATES THE HARD WORK OF INVESTIGATORS AND ALL I ASK IS HONESTY REGARDING THE DATA AND FUNDING. I REJECT THE NOTION THAT ONLY DOCTORS ARE SUSCEPTIBLE TO BIAS AND LOSS OF JUDGEMENT BECAUSE THE INVESTIGATOR OR RESEARCHER OR PHYSICIAN PRESENTING THE DATA HAS A SMALL INTEREST IN THE RESEARCH. PRESENT THE DISCLAIMERS PRESENT THE DATA HONESTLY, BE AVAILABLE FOR QUESTIONS AND HONEST SCIENTIFIC CRITICISMS AND LET THE BEST PRESENTOR AND INFORMATION PREVAIL. SINCERELY, [REDACTED]</p>	<p>Accredited CME provider</p>
<p>I am opposed to the ACCME proposal as above. I have given both CME and promotional talks for 19 years both as a full time rheumatology faculty member at [REDACTED] for 6 years and now in private practice for 13 years. Most community physicians, especially primary care, get their updated medical information through local hospital/community based CME programs. Most of these are funded through grants by pharmaceutical companies, though the company does not restrict the content. The CME guidelines are clear that the presentation must be fair and balanced and without bias in regards to treatments. Since I speak for several companies, even competing ones, I do not have any difficulty discussing all the treatments available in a CME talk for rheumatoid arthritis or fibromyalgia, for example, since I use all the medications that are available in my practice already. Even at my promotional talks, I often reference the drugs as a class, such as TNF inhibitors, and make it clear that I have expertise with all the treatments for RA, since I have extensive personal experience with their usage. It is clear that no one would choose to attend a program that I would give, if I was giving only one sided information; I would lose my credibility. If the ACCME proceeds with this proposal, then the monies for CME programs at local hospitals currently sponsored by pharmaceutical companies will dry up, which will not help the dissemination of new information to treating doctors. I would hope that the ACCME would have more faith that those of us that are involved with both promotional and CME speaking are able to deliver teaching to practitioners under the already well outlined guidelines rather than place more restrictions on us. The new proposal will only serve to limit the pool of speakers whom will be available to deliver CME presentations.</p>	<p>Other</p>

<p>I understand that there is at times a fine line that is walked when a medical educator/presenter is participating in teaching endeavors for both CEU purposes as well as commercial/product education/promotion. I do not believe it is possible to restrict the "trade " of professionals in insisting that they choose and there fore limit there abilities to practice in a variety of educational arenas. The Pharmaceutical companies have become extremely sensitive to such conflicts and are relentless in reminding those of us who do programs on their behalf that w must stay within the limitations of our contracts when speaking on behalf of one of their products. It is this same pool of educators who are also the majority of major researchers, clinicians and educators who participate regularly (professionally) in teaching ,supervising, and mentoring others in our chosen fields. An attempt to restrict the common duel roles that we play would essentially be limiting professionals on both sides of the professional education model and serves no purpose. It is better to continue to be clear with the audience at the beginning of a program with full disclosure what the relationship is and therefore the role that you play at that given time.</p>	<p>Other</p>
<p>September 11, 2008 Murray Kopelow, MD, MS, FRCPC Chief Executive Accreditation Council for Continuing Medical Education 515 N. State Street, Suite 1801 Chicago, IL 60654 Dear Dr Kopelow, Re: June 11, 2008, ACCME Policy Announcements and Calls-for-Comment We are writing in support of the following proposed ACCME measure to strengthen the standards protecting CME activities from commercial influence. "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" The [REDACTED] [REDACTED], was launched in [REDACTED] to promote evidence-based use of drugs and address problems caused by aggressive pharmaceutical marketing to physicians. The [REDACTED] works on a range of [REDACTED] policy issues and has collaborated extensively with leaders in the academic medical center community on the creation of new conflict-of-interest policies. The proposed ACCME standard is consistent with a national trend that recognizes the problems inherent with physicians and other persons being simultaneously involved in industry promotion and education. For example, the Association of American Medical Colleges (AAMC) now recommends that faculty refrain from participation in industry-sponsored promotional programs such as speaker's bureaus.(1) Prior to the release of the AAMC guidelines, many medical schools and teaching hospitals had already moved to limit or prohibit faculty participation in speakers' bureaus. CME must serve the greater needs of public health, and should not be a strategy to promote use of particular products. Further, this policy rightly acknowledges that prevention of bias depends on organizational standards, not self-regulation. CME faculty may feel reticent to speak ill of a product they have supported in a different capacity for fear of disrupting their relationship with the manufacturer.(2, 3) Moreover, social science research clearly establishes that individuals cannot objectively assess their own biases, particularly when interactions provide them with financial benefit.(4) Some may argue that disclosure of financial conflicts of interest is an adequate protection. However, transparency is not adequate to remove the potential influence that financial relationships exert. Therefore, it is appropriate that ACCME establish a standard that precludes individuals involved in promoting a product from attempting to also provide an unbiased perspective on the disease or condition under discussion. The ACCME's proposed policy will help individuals involved in CME by limiting conflicts of interest and increasing clarity. The proposed standard will also help prevent the potential for speaker selection bias by ensuring a physician is not chosen for his or her history promoting a certain drug or therapy.(5) Updated 2008 ACCME guidelines stipulate that industry may not influence CME speaker selection, but third-party medical communication companies (MECCs) funded by industry may still perform this function. Many MECCs identify and train physician speakers as part of their services to pharmaceutical companies. New ACCME policies (2008) prevent a MECC from being accredited if it develops promotional education, However, non-accredited MECCs can assume a large role in CME jointly sponsored with an accredited organization, often overseeing speaker selection and content development. Pharmaceutical companies may also selectively provide CME grants to university departments headed by faculty who favor or speak on behalf of their products.(6) Whether bias in speaker selection is subconscious or otherwise, this new language will help ensure that those chosen to speak have as little real or perceived conflict of interest as possible. We do, however, suggest clarification of the intent of the phrase "control the content" so that it clearly applies both to CME speakers and to medical writers who both work on promotional materials and create CME content. Such individuals have significant influence over the content of CME activities without having final control. It is appropriate that the revised standard preclude overlapping CME and promotional relationships for both CME faculty and medical writers. In conclusion, this proposed policy is a valuable addition to standards meant to ensure the independence of CME. This new step will protect the integrity of CME by limiting real and perceived conflicts. This will benefit CME providers, participants in CME activities and, ultimately, patients. Respectfully Submitted, [REDACTED]</p>	<p>Other</p>
<p>\tThe [REDACTED] is pleased to submit comments in response to Call-For-Comment 3 on the proposals announced by Accreditation Council for Continuing Medical Education</p>	<p>Other</p>

(ACCME) related to commercial funding of continuing medical education (CME) [REDACTED] appreciates the opportunity to provide these comments to ACCME. [REDACTED] supports independence in the medical education conducted by ACCME- member educational providers (referred to generally as Providers). We also support ACCME's efforts to ensure that Providers conduct their own needs assessments and develop their content for their educational activities. At the same time, we believe that recent changes made by both ACCME and [REDACTED] in our respective Standards for Commercial Support and [REDACTED] further promote the independence of CME from commercial bias and that more time is needed for full implementation and assessment of their impact before further changes relating to commercial support of independent education are contemplated. ACCME's Standards for Commercial Support already contain very valid criteria and we believe appropriate monitoring and enforcement of those criteria are important before further refinement is considered. In response to ACCME's Call for Comment and as described in greater detail below, [REDACTED] recommends that ACCME reconsider its proposal to ban physicians from serving as speakers for promotional speaker programs and for CME that may include a discussion of the same product or related disease state. We note that ACCME's proposal would ban physicians from teaching CME on the same product. However, as noted in our letter, CME is not offered on a particular product but may be on a range of treatments in a particular clinical area. Transparency and conflict management are the hallmark of all other guidance in this area and should be maintained by ACCME.

I. Introduction

A. Purpose of CME and importance of independence CME is a critically important mechanism for physicians and other health care providers to obtain information and insights that enhance their knowledge and skills and improve patient care and clinical outcomes. It is vital that such education be current, address knowledge, competence, and performance gaps of learners, and be free of commercial bias.

B. Industry funding of CME Pharmaceutical manufacturers may support CME for a wide range of reasons. Central to their support is a belief that they are participants in the healthcare system, and therefore should participate in the educational process by which physicians and other health care professionals remain current. The pharmaceutical industry is an evidence-based industry, and thus it supports inclusion of all evidence-based scientific exchange to promote optimal patient care. Such support of activities is critical to the industry's mission and should not be construed as an intention to create bias or control the content of educational activities. There is also a great deal of literature on the underutilization of medicines, and barriers to adherence and noncompliance with treatment regimens. To the extent that Providers independently identify specific performance gaps or barriers, and educational activities can address some of these issues directly or indirectly, patient outcomes are improved and there is evidence that overall health care spending could be reduced. Providers have an obligation under ACCME accreditation standards to assess the outcome of their activities on learners and understand the educational value of the activities and whether they meet their objectives. Outcomes measurements may also provide information on new or remaining educational needs among activity participants. These assessments are beneficial but add cost to the activity. Industry support can provide an additional source of funding to conduct these assessments. We also note that manufacturers have medical education departments, staffed with professionals whose sole focus is to ensure that educational funding is provided to support the company's patient care driven mission. To further strengthen and promote the independence of these departments, the revised PhRMA Code on Interactions with Healthcare Professionals, discussed below, calls for company grant-making functions to be separate from sales and marketing departments. Many companies may already have taken that action after the OIG Compliance Program Guidance for Pharmaceutical Manufacturers in 2003 (the "OIG Compliance Program Guidance") made such a recommendation. Companies have policies and procedures in place to assure compliance with regulatory guidance and industry standards. Companies conduct internal training with respect to their grant-making functions. For these reasons, we hope that ACCME understands that the grant-making function is consistent with industry's overall mission to help patients.

C. PhRMA Code on Interactions with Healthcare Professionals In 2002, PhRMA adopted its current Code on Interactions with Healthcare Professionals (the "PhRMA Code"). The PhRMA Code covered a wide range of topics relating to interactions between pharmaceutical manufacturers and health care professionals, including support of CME. The PhRMA Code provided that funding should be given to the Provider and not to the physician, that the Provider should determine the content, faculty and educational methods, materials and venues of the activity and that payment should not be made for non-faculty healthcare professionals attending the CME or to compensate for the time spent by healthcare professionals attending the CME. Nevertheless, in response to recent concerns by policymakers and others, PhRMA determined that it was time to review the PhRMA Code, and on July 10, 2008, announced the adoption of the revised PhRMA Code that will take effect in January 2009 (the "Revised PhRMA Code"). The Revised PhRMA Code has been positively received by various stakeholders. It includes a number of new provisions specifically related to industry funding of CME. Those provisions include:

- Funding should be intended to support a full range of treatment options and not to promote a particular product.
- A company should separate its CME grant-making decisions from its sales and marketing departments.
- A company supporting CME should respect the independent judgment of the CME provider and should follow standards for commercial support established by ACCME or other entity that accredits the CME provider.
- Companies

should not provide any advice or guidance to CME providers regarding content or speakers for a particular CME activity, even if asked by the CME provider. Companies should not provide meals or receptions directly at CME events. A CME provider, at its own discretion, may apply the financial support provided by a company's grant to provide meals for all participants at a CME activity. In addition, PhRMA strengthened its section on Adherence to the Code which now includes that all companies that engage in pharmaceutical marketing should: (1) publicly state their commitment to abide by the Revised PhRMA Code; (2) self-certify annually with signatures of the Chief Executive Officer and Chief Compliance Officer that they have policies and procedures to foster compliance with the Revised PhRMA Code; and (3) authorize PhRMA to post names and contact information for company Chief Compliance Officers. In addition, companies are encouraged to obtain periodic, external verification of their compliance policies and procedures. PhRMA will post on its website the names of companies that indicate a commitment to abide by the Revised PhRMA Code, the status of annual certification, and when a company has sought and obtained external verification of compliance policies and procedures. Thus, the Revised PhRMA Code is enhanced both with respect to its specific provisions on industry support of CME as well as its provisions that encourage adherence to the Revised PhRMA Code and public accountability.

In light of the Revised PhRMA Code, the ACCME Standards for Commercial Support, the OIG Compliance Guidance, the FDA Guidance on Industry Supported Scientific and Educational Activities, we offer our comments on the specific proposals made by ACCME. II. ACCME Proposal on Additional Features of Independence in Accredited Continuing Medical Education

ACCME proposes as a policy to further define the independence of accredited CME: "Persons paid to create, or present, promotional materials on behalf of commercial interests cannot control the content of accredited continuing medical education on the same content." In its commentary, ACCME states that "Physicians paid by a commercial interest to do promotional presentations on a product could not teach in accredited continuing medical education on the same product. Anyone creating content for promotional activities would be excluded from creating content on the same product for accredited continuing medical education, for example." [REDACTED] shares ACCME's interest in ensuring that promotional speaker programs sponsored by pharmaceutical companies are separate and distinct from CME and that such distinction is clear to an audience. [REDACTED] promotional speaker programs play an important and distinct role in pharmaceutical company efforts to communicate about their products and convey new information and developments; "Healthcare professionals participate in company-sponsored speaker programs in order to help educate and inform other healthcare professionals about the benefits, risks, and appropriate uses of company medicines." These company-sponsored events are promotional programs and not CME, but these promotional speaker programs are regulated by the FDA. By way of example, companies must submit all promotional slide decks to the FDA when they are used. The FDA frequently provides comments on such materials and may take enforcement action if necessary. Health care professional speakers are chosen because they meet criteria such as medical expertise, reputation, and knowledge in a particular therapeutic area. They are required by law to present information that is consistent with applicable FDA requirements. Internal legal and medical review is conducted of material before used by a speaker. [REDACTED], speakers must "receive extensive training on the company's drug products or other specific topics to be presented and on compliance with FDA requirements for communication." We understand that some healthcare stakeholders have expressed concern that audiences may be confused at times regarding whether a physician might be speaking on behalf of a company at a company sponsored promotional speaker program or as the faculty for CME. Consequently, [REDACTED] addresses this concern by requiring increased transparency. [REDACTED]: "While speaker programs offer important educational opportunities to healthcare professionals, they are distinct from CME programs, and companies and speakers should be clear about this distinction. For example, speakers and their materials should clearly identify the company that is sponsoring the presentation, the fact that the speaker is presenting on behalf of the company, and that the speaker is presenting information that is consistent with FDA guidelines." (emphasis added) Similarly, ACCME currently has disclosure requirements as part of its Standards for Commercial Support. The current conflict of interest standards require individuals who serve as CME faculty to disclose any financial relationship with a commercial interest and require that the Provider manage any potential conflict by defining the role of faculty in developing content related to the therapeutic area in which that commercial interest offers products or services. ACCME has not indicated that the current disclosure/conflict management mechanism is not working and as noted above, both in the report supported by ACCME and in ACCME's response to the Senate Aging Committee's inquiry, there is no evidence that commercial support is creating bias. Moreover, the FDA, in its Guidance for Industry: Industry Supported Scientific and Educational Activities (the "FDA Guidance") requires disclosure and not a ban in connection with determining whether financial relationships disqualify the independence of industry supported education. The FDA considers "whether there was meaningful disclosure, at the time of the program to the audience of: (1) the company's funding of the program; (2) any significant relationship between the provider, presenters or moderators, and the supporting company (e.g., employee, grant recipient, owner of significant interest or stock); and (3) whether any unapproved uses of product will be discussed." The FDA expressly supported

disclosure and rejected a ban in response to a comment to the proposed FDA Guidance that a significant financial relationship should preclude an activity from being independent. Specifically, the FDA responded “[i]t is neither practical nor justified to make a potential conflict of interest an absolute bar to participation in an independent educational activity. Disclosure of such potential conflicts is a workable means to address the potential for bias in medical and scientific contexts, and there is no reason to believe that it will be any less workable in addressing the potential for bias in the context of industry-supported scientific and educational activity.” Thus, the FDA Guidance requires disclosure, and not a complete ban. Likewise, ACCME should not institute a ban. ACCME should enforce the provisions of the Standards for Commercial Support, monitor Providers to ensure that they follow the conflict of interest guidelines and resolve any potential conflicts appropriately. ACCME notes two recent external actions related to this area of concern. In fact, neither support ACCME’s most recent proposal. The first relates to a recent settlement between a pharmaceutical manufacturer and 29 states and the District of Columbia that included provisions regarding speakers who are engaged in promotional activities and also serve as CME faculty. The public settlement (which did not include any acknowledgement of wrongful activity), does not prohibit a physician from serving as both a promotional speaker for the commercial interest and as a faculty member for a CME activity funded by the same commercial interest. Rather, the settlement requires that a physician who serves as a promotional speaker for the company must disclose to CME participants orally and in writing the nature of the speaking arrangement if (1) the product promoted was in the same therapeutic class as the subject of the CME activity and (2) the CME activity occurs within 12 months of the speaker performing work or receiving compensation from the company. Thus, the settlement required transparency and does not support a total ban on individuals engaged in promotional activities from serving as CME faculty or providing content for a CME activity and should not be cited as the basis for it. The second external event cited by ACCME is the recent report issued by the Task Force on Industry Funding of Medical Education of the Association of American Medical Colleges. While the report states “academic medical centers should make clear that participation by their faculty in industry-sponsored speakers’ bureaus should be strongly discouraged”, the recommendation did not amount to a ban and the report did not attempt to justify the recommendation by citing a concern that participation in speakers programs would bias the academic medical center physician’s work or any involvement in CME. Moreover, the Report anticipates that academic medical centers may choose to allow faculty participation in promotional speaker events and therefore includes recommendations that such medical centers require full transparency and disclosure and the receipt of payments that are at fair market value. Thus, the AAMC’s recommendation should not be taken out of context to support ACCME’s more rigid proposal. If executed in accordance with applicable FDA regulations and industry standards such as those set forth [REDACTED], company-sponsored promotional speaker programs can provide worthwhile information about the benefits, risks and appropriate uses of medicines. Physicians generally find the information that they receive from pharmaceutical manufacturers to be very useful to them. Physicians may not always have the time to meet with manufacturer sales representatives during the course of their busy day. Moreover, many physicians would rather learn about a product from a peer physician. While the programs are not a substitute for and should not be confused with more broad-ranging CME activities, these promotional speaker programs provide important information for physicians on specific products and their risks and benefits. The quality of any informational program – be it a promotional speaker program or a CME activity – turns in large part on the expertise and skill of the presenter. It is natural that companies should seek out the most qualified physicians to address attendees at promotional events, and likewise, CME. Providers may independently turn to many of these same experts to serve as faculty in a CME activity. The consequence of implementing ACCME’s proposed policy is either (1) physicians no longer serve as promotional speakers for companies, which eliminates an important source of information about products for physicians or (2) physicians choose to continue to contract with companies to serve as promotional speakers and no longer serve as faculty for CME activities. Either result is a loss for physician education and ultimately impacts the healthcare patients receive. As long as the message being delivered in each forum is accurate and not misleading and otherwise complies with the applicable laws or rules governing the event, and the audience is provided with sufficient disclosures about the speaker’s relationship to the company funding the event, there is no need to force physicians to make such a Hobson’s choice. ACCME should reconsider its proposal to ban physicians from serving as speakers for company sponsored promotional programs and also for CME. It is the responsibility of the Provider to require appropriate disclosure of all financial relationships, to manage the conflicts and ensure that the content is objectively presented. There are many mechanisms available to Providers to fulfill those responsibilities. A complete ban is an unnecessarily blunt tool, which is not supported by any other regulatory or other guidance in this area, and which could ultimately reduce the opportunities for physicians to receive information and education, to the detriment of patient care. We would be happy to have further discussions with you on these proposals. We look forward to continuing to work with you in this important area. Please feel free to contact us if you have any further questions.

<p>Adoption of this proposal could discourage key thought leaders and innovators from participating in CME activities. [REDACTED] CME activities focus specifically on oncology and hematology disease states. Education of cutting-edge oncology and hematology treatment options is best given by individuals who have been the leaders of clinical trials. Most key thought leaders serve in teaching roles at the nation's most prominent teaching institutions and hospitals. It would be a great disservice to community physicians and their patients for thought leaders to be removed from CME activities. Experts with experience should be teaching CME. [REDACTED] proposes that ACCME focus its efforts on refining the Content Validation Policy in order to further define the independence of accredited continuing medical education for accredited providers.</p>	<p>Accredited CME provider</p>
<p>ACCME poses two questions in its August 2008 call for comments: 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? As an ACCME-accredited provider and as an [REDACTED] CME accreditor, [REDACTED] agrees with ACCME on the importance of assuring independence of those involved in writing CME content or in teaching CME activities. However, [REDACTED] disagrees that individuals involved in independent promotional education should automatically be excluded from having any role in certified CME. Specifically, [REDACTED] agrees with the position of the Council of Medical Specialty Societies on this matter, in which it asserts that: "Persons paid to create or present promotional materials on behalf of commercial interests (who therefore disclose a conflict of interest) need not be excluded from accredited continuing medical education on the same subject if their conflict of interest can be resolved" via peer review, evidence-based presentation, content modification, and/or on-site monitoring of the activity.</p>	<p>Accredited CME provider</p>
<p>Dear Sirs, I have been a medical editor and writer for more than 30 years, and we have always had a very clear ethical understanding that promotional and educational materials are in two distinct worlds--and the worlds never collide. Most of my fellow independent medical writers and editors have no control over medical education materials after they have completed their work. I see no problem with your proposed addition. Thank you for the opportunity to comment on this topic. [REDACTED]</p>	<p>Other</p>
<p>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 from 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]</p>	<p>Accredited CME provider</p>

<p>COMMENT FROM ██████████ Members of a focus group for the ██████████ ██████████ met to discuss the questions posed regarding Additional Features of Independence in Accredited Continuing Medical Education proposed by ACCME. The consensus of the group is as follows: Excluding persons who write or teach in promotional activities from teaching or having any role in writing CME content would be counterproductive, time consuming to validate and generally detrimental to the business of continuous professional development. The exclusion of this group would construct a barrier between the producers and developers of the most recent innovations in medicine and education. The exclusion assumes that physicians and other healthcare providers are unable to assimilate the information provided to them currently regarding disclosure and make their own decisions between bias and evidence. The group agreed that the guidelines set forth in the 2004 Standards for Commercial SupportSM regarding disclosure and content can result in quality education with independence from commercial interest. Rather than add new restrictions, our group would support the current guidelines and encourage adherence by all providers documented in their reaccreditation process.</p>	<p>Other</p>
<p>I am commenting on the ACCME revised definition of commercial interests and concerns regarding healthcare professionals who write promotional based programs or teach promotional based activities being excluded from CME activities. To implement such a draconian edict would prevent the vast majority of researchers and thought leader clinicians from participating in CME activities. In order for new drugs to come to the market, appropriately trained specialists in both academics and private practice must complete the research protocols mandated by the FDA. Once this is done, these physicians are the most knowledgeable regarding the positive and negative aspects of the particular drug in question. They then are the best suited to provide input regarding the presentation of the database in an on-label promotional venue. The promotional talks are by law required to be on-label, which means obviously all data approved by the FDA. This should not preclude discussion of disease specific diagnosis and treatment in a CME format. The small amount of money paid for these talks is minimal compared to the hundreds of thousands of dollars of grants that teaching institutions receive from drug companies. If ACCME chooses to prevent individual healthcare professionals from providing both CME and promotional talks, then why should researchers and faculty from academic centers who receive large grants from pharmaceuticals companies be allowed to participate? By doing this, the available pool of healthcare providers to impact educational messages, both promotional and in the CME format, will be dramatically affected. CME programs must be approved by a very labor intensive process with subsequent monitoring of the presentation by the attendees and the program committee of the event. This would be a major disservice to the medical community and a deathblow to medical education if this rule is adapted.</p>	<p>Other</p>
<p>The ACCME would be wise to seek informed legal counsel before adopting such a restriction. The restriction indicates that the ACCME is entertaining limitations on who can produce or deliver CME--a restriction that may well encroach on First Amendment rights, given that CME is a state (government) requirement for the maintenance of physician licensure. It is this (and any other) juncture of government and speech restrictions that mandates consideration of the First Amendment.</p>	<p>Other</p>
<p>The ██████████ administers the CME programs developed for their membership through the ██████████. We are an accredited provider by the ██████████ (██████████). 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. ██████████ is opposed to the adoption of this policy. The proposal 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. Based on the Updated Criteria, the CME provider determines the needs and develops objectives before selecting the speaker and providers are responsible for identifying and resolving conflicts of interest, disclosing financial relationships to the audience, and monitoring whether presentations are objective and free of commercial bias. When following the ACCME criteria, there should not be a problem having these speakers participate at CME activities.</p>	<p>Accredited CME provider</p>
<p>Any discussion of commercial support, independence, and conflict of interest first requires reflection, perhaps introspection; I am commenting here on the substrate of accreditation, the foundation that offers us the opportunity to build defensible continuing medical education policies and procedures regarding "persons paid to create, present, or promote materials on behalf of commercial interests." The ACCME proposal includes the following condition to determine public interest: When the CME content is from a continuing education curriculum specified by a bona fide organization, or entity, (eg, AMA, AHRQ, ABMS, FSMB) I urge a thoughtful examination of our biases. With the above proposed condition, the ACCME asserts the AMA and</p>	<p>Accredited CME provider</p>

<p>AHRQ are organizations (bona fide) to prescribe or suggest curriculum content; yet, there appear to be conflicts of interest structured in to the ACCME system. For example, AHME and the AMA are ACCME council members. The AMA and AHME also are ACCME accredited sponsors. In addition, the AMA promotes the accreditation and recognition of its state societies; it trademarked Category 1 credit to be issued only by accredited providers, and it sells labels used to promote or announce Category 1 CME activities. The AMA might be seen by many (but certainly not all) as less altruistic or bona fide than AHRQ and less likely than AHRQ or an otherwise less invested organization to recommend a value free or patient focused curriculum. The legitimacy of the ACCME is being questioned by government, industry, and select organizations within the medical profession. I count myself among the supporters of our program of accreditation and among the grateful admirers of AMA and AHME leaders - - past and present - - who have provided extensive backing and resources to development of our accreditation systems. I count myself, too, among those willing to work to improve the effectiveness of accreditation. To assure public and professional confidence in the ACCME and its system for assuring independence, the structured conflicts of interest must be resolved; then, we can address - - with higher standards and perceived measures of integrity - - the notion of whether there is a principled role for commercial support of CME, and whether persons paid to create, or present, promotional materials on behalf of commercial interests, add value to ACCME and extended CME community efforts at improvement.</p>	
<p>The [REDACTED] supports the intent of the ACCME proposal detailed above. CME presentations should be free from bias and inappropriate product promotion from any source. In its straightforward simplicity, however, the ACCME proposal does not address certain realities that apply especially to international subspecialty societies and organizations, such as the [REDACTED]. In so doing this proposal becomes either too restrictive if interpreted in its strictest sense, potentially causing unintended harm to the educational mission of the [REDACTED], or too vague if interpreted in a more nuanced fashion. As an international subspecialty organization, the [REDACTED] takes very seriously its role as an important and impartial source of educational material and presentations for its members and others interested in movement disorders. Planning for its annual [REDACTED] is carried out by the [REDACTED], while planning for other educational programs is carried out by the Education Committee of the [REDACTED]. Both committees are composed of individuals who are deemed by the [REDACTED] to be among the most knowledgeable and accomplished representatives of the membership. Many of these are the same individuals who, for the very same reasons, are often approached by commercial interests to assist with and participate in both product development (clinical trial steering committees, clinical trial site investigators, etc.) and in the creation and development of promotional programs and materials once a drug or product is approved for use (courses, enduring materials, speakers bureaus, etc.). The ACCME proposal states that individuals who "are paid to create, or present, promotional materials on behalf of commercial interests" will not be permitted to "control the content" of accredited CME "on that same content." Lectures and themes in [REDACTED] congresses and courses typically do not focus on a single product or drug, but on more general topics in which multiple drugs may be discussed (e.g., "[REDACTED]"). In its strictest sense, the ACCME proposal would exclude any individual involved with promotional activity of any sort involving one product or drug from serving on any committee designing course content for, or providing any lecture in, a course or symposium in which that same drug or product is discussed, even if the lecture is on a more general topic in which the drug or product is mentioned along with others. This interpretation would have the effect of severely limiting the pool of candidates for committee membership. This represents a tremendous burden for a relatively small, narrowly focused subspecialty organization such as the [REDACTED]. Since many countries do not discourage interaction between commercial interests and academia as actively or forcefully as in the USA, a possible secondary effect would be to jeopardize the international scope of the [REDACTED] by aggravating the lack of involvement of non-Americans in committee activities, a problem the [REDACTED] has fought vigorously. The same chilling effect on committee recruitment would be operative with regard to speakers, with the result that the [REDACTED] membership might be denied the expertise and advice that those individuals and teachers most knowledgeable about all aspects of a drug might otherwise provide, including most of the past and present officers of the Society. It is one thing to prohibit a speaker who has developed promotional materials for a drug from giving an accredited CME lecture on that drug alone; it is quite another to prohibit him or her from discussing the treatment of Parkinson's disease in which that drug might play a part, and to prohibit him or her from serving on an [REDACTED] committee in which the drug in question may be one of many topics covered as part of a course or symposium. The policy in its current form does not make any such differentiation. Beyond this, the proposal seems to paint with far too broad a brush all educational activities performed on behalf of commercial interests as being in some way unsavory, with the troubling added effect of attaching a stigma to the participants. In fact, many such activities have genuine and unique value to both patients and physicians, and in some instances address broad topics with little or no mention of specific products. To categorically exclude individuals participating in these programs from participation in accredited CME programs seems excessive and even potentially injurious to the quality of CME programs that the Society might offer. Finally, the proposal in question seems unneeded and redundant given that the [REDACTED] and</p>	<p>Accredited CME provider</p>

<p>other organizations already have in place mechanisms to monitor conflicts of interest and prevent biased or unbalanced presentations at our CME programs. Furthermore, promotional programs have in recent years been subject to increasingly stringent regulation from the FDA. We believe that our current procedures – extending from the broad representation of membership on our Congress Scientific Program Committee and on the Education Committee down to the monitoring activity of our CME Committee – already provide an effective deterrent and barrier to biased and unbalanced presentations at CME accredited courses created by our Society. Evidence to support this can be found in members’ recorded responses to direct questions on evaluation forms, in which they overwhelmingly indicate that presentations are free of commercial bias. \tAt the very least, the current ACCME proposal requires extensive reworking and clarification if it is to be of any value, much less not injurious, to societies such as the █.</p>	
<p>Accredited CME educational activities and industry-supported, FDA-regulated promotional programs are both important educational activities because they provide information needed by health care professionals. Accredited CME is one mechanism for health care professionals to obtain evidence-based, data driven medical information that will enhance their knowledge and skills to improve patient care. The 2004 revised ACCME Standards for Commercial Support went beyond just disclosure of relevant financial relationships between faculty and industry to require management and resolution of such conflicts for all individuals who are in a position to control the content including planning committee members, teachers and authors. Industry-supported, FDA-regulated programs provide a venue for sharing product-specific information. These types of educational programs are on-label and must be fair-balanced with safety and efficacy data provided as defined by the FDA. Experts involved in company speakers’ bureaus are trained, must use company-approved presentation materials and have service contract agreements with the company. Speakers and medical writers need to understand the distinction between the two and if they choose to participate in both, then they need to know how to conduct themselves in both forums. We urge ACCME to reconsider this change in policy. An alternative focus is to ensure adherence to the ACCME standards of Commercial Support by accredited providers. This should be a priority for the ACCME as you develop the enhanced monitoring and oversight of the CME system. In particular, adherence to these guidelines on resolving conflicts of interest will be important. █ appreciates your consideration of our comments. If you have any questions, please contact me.</p>	<p>Commercial Supporter</p>
<p>The █ was started as healthcare professionals started to realize that Blood Management ought to be the standard of care, and that blood transfusion should be viewed as the alternative. █ 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. █ is recognized as the key educational resource for Blood Management in the United States. █ 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 Blood Management and utilization. This is done by creating a source of knowledge for all types of Blood Management 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 Blood Management, █ 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. █ strongly disagrees with this proposed feature. Because Blood Management is a highly specialized area that has very limited experts in the field, it is not uncommon for our leadership to be called on to represent industry presentations. We can assure you that those leaders would only present information for company products for which they completely supported the efficacy and safety. So to suggest that these same leaders would not be allow to present at our annual conference, grand rounds, or other educational settings on that content is completely unacceptable and damaging to the advancement of science. It is suggesting that if a professional accepts a fee for something that they have “sold” their integrity. Persons who are paid to create or present promotional materials on behalf of commercial interest should go through the same disclosure process as any other person who has any relationship to disclose. Individual society’s policies and procedures are designed to deal with perceived conflicts of interest. An individual society may suggest that someone presenting at a promotional meeting within a 12 month period may not present at the annual meeting program, or someone presenting at an adjunct promotional symposium may not speak at that particular annual meeting, but these policies should be left to the individual societies. We would ask that the ACCME take pause and consider</p>	<p>Non-Accredited CME provider</p>

<p>that sound, logical, and incremental steps will take time to correct the course, but taking a number of quick, irrational turns may cause serious unintended consequences. We are all in this together and are willing to do whatever is reasonable to elevate the [REDACTED] to a higher place.</p>	
<p>We don't feel these examples are necessarily irreconcilable conflicts. We feel these should be considered in the same way as other conflicts of interest. It should be the responsibility of the provider to determine if resolution is possible or if the COI is irreconcilable. The planners might design the activity so that the speaker is teaching about management of the disease, not discussing the specifics of one product. In the case of a medical writer, content review by reviewers without relevant relationships could be a way of mitigating the conflict. Perhaps additional checks and balances can be implemented to ensure that the person with the COI doesn't have sole responsibility for the final product. It doesn't seem to be in the best interest of professional education to automatically exclude experts, whether they are teachers or writers. Instead of excluding these experts, perhaps ACCME could develop an approved mechanism for managing this type of COI.</p>	<p>Accredited CME provider</p>
<p>I believe, the person who is paid to be representative /supporter of promotional material should be allowed to participate /control the content of accredited C.M.E on the same content . This person may be more knowledgeable than the counter part on that subject due to preparations for presentations &etc. Obviously this individual knows that while involved in C.M.E activities won't have any obligation to promote any product & can be objective & neutral & present facts at CMEs</p>	<p>Commercial Supporter</p>
<p>Comments by [REDACTED] does not support this policy. Promotional education and CME should be differentiated. Quality of CME presenters would be greatly reduced since commercial interests also look for the best qualified speakers/authors in the respective clinical area. Speakers/authors would be forced to choose between promotional education and CME. Through planning and appropriate mechanisms, CME providers can resolve any conflicts of interests created by speakers/authors who have financial relationships with commercial interests. Subsequent disclosure to the learners and evaluation of bias by learners completes the process as required in the ACCME Standards for Commercial Support. [REDACTED] believes this process is adequate.</p>	<p>Accredited CME provider</p>
<p>As a medical writer, instructional designer, and health care provider with experience working on both sides of the "firewall", I would like to comment that the key issue in interpretation of the proposed policy centers on the interpretation of the term "control". When developing promotional materials for a client, the writer has an opportunity to explore both the positive and negative sides of a particular product and/or the disease or symptoms it is labeled to treat, as well as the pros and cons of alternative, adjunctive or competing therapies. A great deal of insight is to be gained by understanding the issues that the client directs the writer to avoid or to "talk around". These are the very same issues that need to be illuminated in order to present a balanced view when developing CME materials. In my discussions with many other medical writers in the pre-firewall era, most were thrilled to have an opportunity to work on the CME side of a product and to be able to deliver a more robust and balanced picture of a given topic. As medical writers, we are committed to the truth, to let the science tell the story. Problems arise when control is given over to a commercial interest, and the concerns regarding payment of physician advisors for both promotional and nonpromotional activities remains paramount even while divorcing direct control by \$ponsor\$. The professional medical writer serves as catalyst to transform scientific information into a form that can be applied in daily practice, taking into account the myriad factors that impact the choice of treatment options, including evidence-based treatment guidelines, payer issues, and labeling. We have become experts at adapting our communications styles to diverse target audiences and have learned to struggle against the inappropriate influences that often come to bear upon our craft. However, the medical writer does not, and should not, exert control over the content of any medical communications piece, but practice within a system of checks and balances to ensure that all objective are met - objectively!</p>	<p>Other</p>

<p>continuous medical education (CME) is required to EVERY practicing physician in the US. As such this must be provided by best qualified and experienced clinicians (educators) with the ability to critically evaluate the evidence and present it in unbiased, and balanced fashion. The vast majority of such educators with appropriate teaching experience are employed by the academic institutions. In the reality, unfortunately, CME programs cannot cover the entire breath of new developments with FDA-approved medications/devices in a timely fashion, and by virtue of fact that participation in various CME programs is limited, all this translates in major limitation in the delivery of information to the physician, and its use in the clinical practice. CME programs therefore will remain only one of several methods of delivery of pertinent important medical information to the health care providers. Academic institutions heavily rely on the research funding from the pharmaceutical industry in a positive way. Academic institutions are best situated in monitoring Conflict of Interest and Commitment of their faculty. Pharmaceutical companies while preparing "promotional" educational materials are heavily relying on the educators. Therefore, working relationships between academic institutions and pharma should be appropriately encouraged and monitored. We must recognize that pharma participation in academic faculty development and satisfaction is crucial. We cannot allow that education to the providers will be delivered by inexperienced (both academically and clinically) educators! Pharma must continue to make further efforts to comply with the requirements of medical education, becoming less promotional, and even more balanced and evidence driven. Only close collaboration with academic educators will further ensure the implementation of this principle. Academic educators are the experts in the field, and health care providers should be getting information from them. We must encourage prevention techniques to ensure that there are no "false educators" in the field of education! By accepting the proposed COMMENT, we will actually directly contribute to creation of "false educators", who have no educational skills/expertise, provide education completely outside their "expertise", mainly doing that because of their greed, or have no long-term responsibility for CME-type education. All "promotional" material should be available for review by academic institution, and be as close as possible to CME requirements! Academic faculty may be involved in creation of the material, and its distribution in order to assure its scientific correctness! Separating academia from the pharma, rather than encouraging their collaboration, eventually will be counterproductive, although it may get immediate, and short-lived "political" gain. Work in progress is encouraging!</p>	<p>Accredited CME provider</p>
<p>The [REDACTED] appreciates the opportunity to reply to the latest ACCME Call for Comment related to the proposed 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." As outlined in the ACCME Standards for Commercial Support, everyone in a position to control the content of a CME activity must disclose relevant financial relationships with commercial interests, with potential conflicts of interest (COI) resolved prior to the delivery of the activity. In adhering to this ACCME policy, the [REDACTED] has developed processes and mechanisms to review individuals' relevant financial relationships and determine how best to resolve potential COIs without compromising the validity and content of its CME activities. Those in a position to control the content of [REDACTED] CME activities, including those who may be "paid to create, or present, promotional materials," must disclose their relevant financial relationships related to the specific content and scope of their CME activity assignment. The [REDACTED] then reviews and implements the appropriate mechanisms to resolve COIs where they may exist. Mechanisms used to resolve potential COIs include 1) using a peer review process; 2) altering the control of content; 3) documenting the best available evidence for recommendations made; and/or 4) identifying another individual to fulfill the assignment because a relationship could not be adequately resolved. COI comes in many forms. Although it is primarily associated with commercial influence, other COIs may affect CME, such as an individual's participation in a governmental project, policy, or program that is marketed as heavily as commercial products or services. Furthermore, might someone who co-authors a medical society's policy statement also be excluded from speaking on that topic, in the spirit of "promoting" the policy? Much communication with and between accredited CME providers and their volunteers/members would be needed to ensure that individuals are aware of the parameters involved in any assignment they may fulfill on behalf of a for-profit, non-profit, or governmental entity, so as not to conflict with the ACCME Standards for Commercial Support related to any CME activities at which they teach or plan. Additional clarification is needed in ACCME's proposed policy as it relates to the time frame during which one may have been "paid to create, or present, promotional materials on behalf of commercial interests." As currently defined in the Standards, relevant financial relationships in any amount and that occurred within the past 12 months must be disclosed and potentially resolved. Unless the same time frame (past 12 months) applies under the proposed policy, might someone who has participated on a speakers bureau in the past now be penalized because of their prior decision to do so? Implementation of a ban on individuals who were former members of speakers bureaus assumes a future date for taking effect, as those who served on speakers bureaus in the past should not be judged for past decisions around which the ACCME had not previously communicated or implemented policy. Once warned, persistence on a speakers bureau could be justification for formal declaration of a COI and removal from control of a CME activity. If the ACCME intends to implement this proposed policy,</p>	<p>Accredited CME provider</p>

<p>extensive communication would be needed to acknowledge that participation on speakers bureaus or holding a similar role for a commercial interest would limit one's ability to serve as a planner, faculty, or author in an accredited CME activity.</p>	
<p>Hello, As a CME content developer and presenter, I am opposed to this proposed policy. I believe that the person who has developed the content is the individual most motivated to present the material in an interesting and understandable way. In this way, the content-developer, though presenting his/her material may enhance the learning experience and retention of the material for the listening audience. Respectfully submitted, [REDACTED]</p>	<p>Other</p>
<p>As an independent freelance medical writer/editor for the past 30 years, I would like to say that at no time was I pressured to write any unbalanced CME communications or edit as such. All CME work written by medical writers for clients is vetted by an independent CME reviewer, usually with an MD degree. I always had full control of content throughout the writing and vetting process. I hope the ACCME will not institute such a proposal, as it does not hold merit nor reflect the reality of professional medical writers.</p>	<p>Other</p>
<p>[REDACTED] maintains that this would be a draconian change in policy that does not appear warranted, given that there is little to no evidence that a problem exists. It appears that ACCME is willing to act on a belief held by some, that professionals and content experts cannot be expected to work in an ethical and appropriate manner. Should this position be adopted, ACCME will be making the statement that current policies and procedures have not adequately managed conflict of interest—yet there is no evidence that would substantiate this allegation. The weakness of the ACCME's argument is actually substantiated by its misinterpretations of one of the "recent significant external actions" that it identifies as concerning. In the judgment cited, ACCME states, "the Attorney's General of thirty U.S. states won a judgment against a commercial interest that included the stipulation that a promotional speaker for that commercial interest could not also be a CME speaker on the same class of drugs discussed in the promotional activity." In fact, the judgment made no such stipulation. Rather, it prevented the commercial interest from supporting a CME activity if it knew, at the time a decision was made to fund, that a member of its promotional speaker bureau would also be faculty member in the independent activity. This is quite different than the implication that the judgment prevented an individual from speaking in both arenas. Further, [REDACTED] feels that appropriate checks and balances are in effect if content experts are provided with the necessary information on the boundaries in which they may work, and the CME provider who is acting as the "employer" of the content expert acts judiciously and appropriately in its role. These "checks and balances" would ensure that the information being provided is based in fact, was not commercially biased, and was provided to physicians "in the best interest of the patient." The onus should be shared by both the individual responsible for developing the content and the CME provider. To arbitrarily prohibit a group of individuals from participating in the development of CME activities runs the risk of placing a major handicap on CME providers—with little rationale for doing so. It could seriously diminish the pool of qualified experts to develop independent CME activities. Rather, [REDACTED] strongly believes that policy development should be driven by sound, evidence-based data, and that change to the accreditation system should not be made in an arbitrary fashion in the absence of relative supporting data.</p>	<p>Accredited CME provider</p>
<p>We, the [REDACTED] strongly support the ACCME proposed policy that "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." Interactions between physicians and industry inherently give rise to conflicts of interest; physicians are the fiduciaries of patients and the public, pharmaceutical and device manufacturers are the fiduciaries of their share-holders. However, there is significant penetration of for-profit interests into the institutions that have laid the foundation of patient's trust in the medical profession. Roughly half of CME is funded by industry (1); industry is intimately involved in all aspects of drug and device approval (2); industry directs one quarter of all sales proceeds toward promotion (3). Efforts to mitigate the influence, including the ACCME's Standards for Commercial, are testimony to the seriousness of this problem. Despite these commendable efforts, problems still remain; recent Senate Finance Committee hearings questioning the ability of a physician to act both as a stakeholder and an independent investigator for a specific product are testament to this ongoing problem (4). It is therefore necessary to continue to take measures that separate the practice of medicine from the promotion of medicines (and devices). According to the ACCME, "it is possible that through their implicit or explicit control of, or influence on, CME content that commercial interests could create commercial bias in CME (ie, favoritism) that will result in a learner's inclination towards, or actual, use of a product or service that is more than is necessary" (5). Therefore, the ACCME does not accredit commercial interests to provide CME credit. Persons that create and promulgate promotional activities but are not directly an employee of a commercial</p>	<p>Other</p>

<p>interest are accredited to provide CME. However, the ACCME “considers financial relationships to create actual conflicts of interest in CME when individuals have both a current financial relationship with a commercial interest [writes/teaches promotional material] and the opportunity to affect the content of CME [writes CME content/teaches in CME activities] about the products or services of that commercial interest. The relationship creates an incentive to insert bias into the CME activity in favor of the product or service” (5). Surely, an individual that writes or teaches promotional material as well as writes and teaches CME would have such a financial conflict of interest and the incentive to insert bias. This is the precise reason that drug and device manufacturers are prohibited from directly providing CME. Yet, the current standards allow an ostensibly independent individual that is paid by industry to develop and promulgate promotional material to also provide continuing medical education. This inconsistency must be remedied. The new policy put fourth will accomplish this goal. As long as the profession permits the influence of for-profits interests into the advancement of the medical sciences there will be uncertainty as to the quality and commitment of its duty. Therefore, it is necessary to remain vigilant in our efforts to place the profession and industry in their proper spheres. In order for the ACCME to remain “resolute in its efforts to ensure that continuing medical education offered by accredited providers is independent and free of commercial bias”(6), it is imperative to work toward completely divorcing continuing medical education from industry influence. Therefore, it is appropriate to extend the current ACCME Standards for Commercial Support barring commercial interest from participating in CME to include those individuals who, although ostensibly independent, have previously represented pharmaceutical and device manufacturers in a promotional manner from provision of legitimate education. Lastly, we encourage the ACCME to remain vigilant in its effort to restore the status of continuing medical education by adopting a policy that would eliminate all commercial support from CME. Sincerely, [REDACTED]</p>	
<p>As written, the [REDACTED] believes the proposal by ACCME requires clearer definition to ensure scientists and clinicians working for or with commercial interests can continue to participate in medical education and where academicians can consult with industry. Academicians and industry are going to continue working together to advance science and medicine. Together we must find a viable option to manage perceived conflicts and develop guidelines for policies and procedures that will reduce bias and increase transparency while allowing for scientific exchange. CME programs must be free of marketing efforts designed to increase sales of a commercial product. Nevertheless, if ACCME is true to its goal of recognizing the important of basic science and clinical research in educating physicians, then the important work performed with industry support must be included in any reasonable attempt at assessing the state-of-the-art for diseases which lack effective therapies. The fact remains that only industry has the experience and resources to evaluate drugs for safety and efficacy. The process requires industry support and resources, along with participation by physicians and regulators to validate industry claims. This interface is key to medical advancements and must be part of the educational process. The vast majority of industry-supported scientists and clinicians have participated in CME venues and presented data in a fair and accurate manner. As stated above, professional societies such as [REDACTED] have put into place systems to ensure the integrity of the CME program so that work is limited to peer-reviewed information in a forum that is open to question and discussion. While conflict of interest is an intensely important issue that requires defined policies and procedures, preventing those involved with industry sponsored medical research from participating in CME educational programs will leave a tremendous void in learner seeking the most up-to-date information. This proposal will remove important, scientifically valid information from being presented in CME program. The ACCME can draw on accredited programs and professional societies to develop policies to ensure the information is provided in an unbiased manner, but to prevent medical researchers at the interface of science and clinical practice from sharing their work in CME programs will create tremendous knowledge gaps for CME program participants.</p>	<p>Accredited CME provider</p>
<p>The [REDACTED] disagrees with the ACCME proposed blanket disqualification of faculty from CME activities, based solely on their involvement in commercial speakers bureaus. The College agrees that a faculty person’s involvement in a commercial speakers bureau would cause an absolute conflict of interest with their involvement in any type of CME activity which is funded by the same commercial company and deals with the same content. We believe that if this conflict cannot be resolved according to ACCME’s current conflict of interest guidelines, the individual should be disqualified from their role as faculty in the certified CME activity. \tlf, on the other hand, the previous conflict of interest can be resolved (for instance, changing the content area of their involvement in the certified CME activity) we feel they should be allowed to participate as faculty. \t</p>	<p>Accredited CME provider</p>

<p>To Whom It May Concern: We are writing in response to ACCME recent “Call for Comment” to further define the independence of accredited continuing medical education by proposes of the following policy: Persons paid to create, or present, promotional materials on behalf of commercial interests cannot control the content of accredited continuing medical education on the same content. Professionals, and in particular physicians, are fully capable of acting in an ethical manner by being involved in promotional and accredited continuing medical education content development and/or a presenter of the material. For accredited continuing medical education being involved in a documented peer-reviewed environment should be sufficient to assuage any suggestion or appearance to the contrary. As stated in ACCME Standard 1 the accredited Provider controls the selection and presentation of content not by commercial interest. To ban individuals from creating content or presenting based on the type of activity would hinder improving patient care by removing a valuable resource of qualified and knowledgeable experts across therapeutic areas. We would therefore oppose the existing proposed language, and recommend provisions be included for involvement in an objective and appropriate peer review environment with full transparency and disclosure.</p>	<p>Accredited CME provider</p>
<p>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). ACCME proposal that 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. This proposal appears to suggest that ACCME believes that it is possible that a single faculty member of a CME activity is capable of controlling the content of the entire activity. This is contrary to what has always been [REDACTED] view on this topic, i.e., that per ACCME guidelines it is the Provider, not individual faculty members, who controls the content of accredited continuing education. While faculty members may develop and contribute to an activity’s content, the Provider must have mechanisms in place (such as a peer review processes) to ensure that the proposed content is balanced and medically accurate. If ACCME is concerned that certain Providers are not fulfilling this responsibility and are allowing individual faculty members to control content, ACCME may wish to consider increased monitoring and reporting requirements to ensure compliance. [REDACTED] does not believe that healthcare providers who have consulting relationships with industry should be barred from participating in CME activities in the same therapeutic area. While the nature and extent of a healthcare provider’s relationship with a commercial interest is certainly one factor that the Provider must assess when choosing a faculty member, this should be considered along with the individual’s expertise and other factors, such as the adequacy of mechanisms the Provider has in place to ensure that the content is balanced. Finally, per ACCME guidelines, disclosures must be made to the learners of any financial relationships between individual faculty members and a Supporter. This, along with the Provider’s own mechanisms to review content, is sufficient to mitigate concerns about potential bias. 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]</p>	<p>Commercial Supporter</p>
<p>The [REDACTED] feels that Proposal #3 would have the effect of removing 90% of the scientific expertise from CME activities. Speaker’s bureaus have become a significant source of income for the scientific community. Commercial interests seek out credible scientists as their spokespeople. False claims, if any, are often exposed by evidence. In addition, there are ethical and regulatory consequences of such false claims already in place (i.e., FDA regulations on discussion of off-label use of medications). Current ACCME requirements are directed at disclosure and transparency. Armed with this information, physicians can bring to bear all of the discriminatory powers developed during 10 – 15 years of postgraduate education in deciding whether claims are supported by evidence. Removing the very evidence used by the FDA to make regulatory decisions would not benefit the medical community at large. The proposal itself is also vague: is a scientific publication of industry-funded research “promotional material”? Are all of the authors therefore banned from providing CME? The [REDACTED] feels that its members are physicians with considerable expertise in the evaluation of scientific data who are eminently capable of assessing the scientific value of CME presentations. Many are not scientists, but all have participated in classes on medical decision making and the proper way to interpret scientific findings. This promotes a skeptical review of data presented, and in the CME events where disclosures are mandatory, this view takes into account known biases that are inherent in industry supported research. Our society has engaged in production of evidence-based practice parameters that support an unbiased assessment of scientific data. We frequently inform our membership on new developments in the evidence based medicine process. We feel very confident in concluding that our members would only be hurt by the elimination of all speakers with contacts to industry.</p>	<p>Accredited CME provider</p>

<p>As a professional freelance medical writer, I wish to point out that there is absolutely no conflict of interest in writing for a marketing team one month and then writing for a CME provider the next. In fact, understanding both the promotional goals and the educational objectives in a given therapeutic category are beneficial to both the content provider and the intended audience. To "separate promotion from education" is folly, and implies somewhat distastefully that promotion is less truthful than education. The health care professional, by the way, is exposed to both, making the "big picture" invaluable to a writer. As an example, an individual who understands the antihypertensives market -- the products competing for the physician's attention, the current issues among patient groups (compliance, adverse effects, lifestyle), who is prescribing what and why -- is in an advantageous position when it comes to preparing CME content for that same audience. And vice versa, obviously. Good medical promotional writers do extensive research before they put their ideas into motion. Knowledge is power. We are an increasingly sophisticated culture with access to real time information at all times. Who are we kidding by putting up false walls? As you should know from the real world model, segregation never works. We need more transparency and truth, not more boxes and blockages. Professional writers can craft a fictional story, perfect a sales pitch, compile research into coherent CME, and discuss the virtues of holistic healing in a scientific essay. Keep freelance writers out of this discussion; I cannot speak for the physician or the corporations, but as a writer I have been on both sides of the fence and, quite honestly, see no reason for the fence.</p>	<p>Other</p>
<p>September 12, 2008 Thank you for giving the [REDACTED] the opportunity to share our opinion on the recent call for comments. As you know, 2008 has been and continues to be a year of reflection, discussion, and change. The [REDACTED] firmly believes that the ACCME needs to facilitate annual strategic meetings with necessary stakeholders who can assess and provide suggestions on how best to move forward with a new quality and outcomes-based CME initiative throughout the United States. Our response to each of the questions posed to the CME community appears below and reflects this concept with responses that impact the future of ACCME policies. 1.\tAccredited providers must not receive communications from commercial interests announcing or prescribing any specific content that would be preferred, or sought-after, topic for commercially supported CME (eg, therapeutic area, product-line, pathophysiology) as such communication would be considered 'direct guidance on the content of the activity' and would result in Non-compliance with Standard 1 of the ACCME Standards for Commercial Support. We agree that specific content that reflects a specific treatment or product can be perceived as potentially influencing medical education content. However, we do not agree with completely eliminating all communication with industry about health issues that health-care providers experience daily. Company representatives hear these stories, some of which they cannot address immediately but we, as CME providers, can. If there is no communication between industry and CME providers, we lose access to potentially important information. This proposal as written should be reconsidered with a view toward permitting communication with industry and CME providers while protecting from undue influence related to a specific product line. 2.\tReceiving communications for commercial interests regarding a commercial interest's internal criteria for providing commercial support would also be considered the receipt of 'guidance, either nuanced or direct, on the content of the activity or on who should deliver that content.' We agree completely with this proposal. Having over [REDACTED] who are content experts in the fields of [REDACTED], the [REDACTED] as a CME provider has access to the best teachers on a variety of content used in our certified/accredited CME activities that are also of interest to potential commercial supporters. Using these content experts accredited providers should not ask commercial supporters to define their internal criteria, especially for the approval of financial support, so that the request can be formulated and worded in such a manner to ensure approval of financial support by the potential supporter. 3.\tThe proposal is that the commercial support of continuing medical education end. We disagree with a blanket ban on all commercial support of CME. In 2006, 61% of CME revenue was derived from commercial sources, including the pharmaceutical and medical device industries. We recognize that the problem is not the amount of revenue that is generated, but rather that 20% of ACCME-accredited organizations are in noncompliance with one or more elements of the Standards for Commercial Support. We also recognize that the ACCME reviews are done retrospectively, and that it may take months or years for a CME provider to change a program to put it in compliance. These issues must be addressed, but a complete ban on commercial support should be implemented only when there is some empirical evidence that commercial support introduces bias or influences the content of certified/accredited medical education positively or negatively; obtaining that evidence would require some further study. ACCME recently agreed to this in its own response to the Macy Foundation report. Given that statement, we propose that ACCME act by facilitating a meeting of stakeholders from the CME provider community to discuss how commercial support is identified, used and managed in CME, as well as to develop and implement ways to assure compliance with ACCME's current Standards for Commercial Support. No such task force has been convened, other than the Consortium for Academic Continuing Medical Education (CACME) attempt to address these issues with a risk stratification tool that estimates the potential for commercial influence. Collecting this type of evidence would facilitate buy-in from CME providers without resorting to the elimination of all commercial support, and the</p>	<p>Accredited CME provider</p>

<p>resulting impact on certified and accredited CME. Prohibiting industry support for CME would probably lead to a reduction of accredited CME hours and a proportional increase in industry-sponsored promotional activities. We believe that industry will spend its dollars to reach physicians with or without CME funding, and that it is in the best interests of professional learners and patients that industry funds be channeled toward CME that is in compliance with ACCME criteria. 4. Persons paid to create, or present, promotional materials on behalf of commercial interests cannot control the content of accredited continuing medical education on that same content. We disagree with a proposed policy that potentially eliminates content medical experts from participating in both promotional programs and accredited continuing medical education. Many times, the medical community seeks these key knowledge leaders' expertise. If this policy is implemented, physician learners will probably attend promotional activities to hear information from experts who no longer participate in CME programs. In our opinion, this policy would not solve the issues of potential bias by physician experts who present both in promotional and accredited medical education. In conclusion, we emphasize the need to address the issues collaboratively as health care professionals and educators to ensure that educational programming is evidence-based, free of commercial influence and with effective and measurable outcomes. Imposing additional regulations in the absence of such study and development of reasonable guidelines will probably hurt the prospects of high-quality CME, especially now when providers are working to adapt to the updated criteria being implemented this year. Thank you for your consideration. We would be happy to answer any additional questions that might develop from our responses, and look forward to future discussions on these important issues. Respectfully submitted, [REDACTED]</p>	
<p>The [REDACTED] appreciates the concerns about industry support and the importance of nonbiased CME. The [REDACTED] believes that the ACCME's new standards should be given and opportunity to be evaluated and that no further standards are needed at this time. This new policy is unclear and needs further definition to explain how it is to be implemented in practice. The ACCME has stated that "Physicians paid by a commercial interest to do promotional presentations on a product could not teach in accredited continuing medical education on the same product. Anyone creating content for promotional activities would be excluded from creating content on the same product for accredited continuing medical education, for example." (emphasis added) It is unclear what constitutes payments, what constitutes control, and what timeframe this rule would apply. If someone was ever on a speaker's bureau are they forever banned from talking about the product? Is it only the product that a speaker cannot discuss? Can they talk generally about the disease the product is used to treat? The [REDACTED] does not offer any CME base on products. The CME is based on diseases or treatments. Is this rule only trying to address product-based CME content? For example, the [REDACTED] holds a workshop on spasticity. A treatment for spasticity is botulinum toxin. The pharmaceutical company [REDACTED] creates one type of botulinum toxin. Solstice, another company, creates another form of the botulinum toxin. The speakers in the session talk about the use of the generic botulinum toxin for treating the disease. The speakers may be on a speaker bureau for one or both companies. Because they do not discuss the actual product is this acceptable under this new policy? At the [REDACTED] all CME sessions 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. In the above example, the Workshop Committee determines whether a session is needed on spasticity and chooses faculty for the session. The Workshop Committee has no knowledge when choosing faculty of whether or not they are on a speaker's bureau for a given product. They assign the faculty the topic. The faculty then presents the topic. In this scenario, who is creating the content and who is controlling the content – the speaker who actually chooses the words to say or the committee that chooses the topic? What does creating the content mean? What does controlling the content mean? Not allowing physicians to participate in speakers bureaus limits their academic freedom. Not allowing medical association to use physicians that are on speakers bureaus to speak may eliminate some of the most knowledgeable speakers on a given topic. This has a bigger impact on smaller associations or associations who focus on a narrower field of medicine. Because the [REDACTED] focuses on a subset of the broader fields of neurology and physical medicine and rehabilitation, the number of physicians that are experts on any given topic is more limited than for association with large memberships. We believe the current process assures nonbiased CME and that more restrictive rules are not needed. The [REDACTED] strongly believes that CME should be independent and free from commercial bias. We have implemented processes to assure that in our own CME offerings. The [REDACTED] believes that the ACCME's new standards will assure that CME is not undermined by commercial support. As stated above, the [REDACTED] believes that the new standards should be given time to work and that no further standards are needed. If this policy is to be adopted, further clarification must be provided to accredited providers. Sincerely, [REDACTED]</p>	<p>Accredited CME provider</p>

<p>[REDACTED]</p> <p>While I personally do not give speaker's bureau lectures (I find them boring and too restrictive), I believe that if those of us who give CME are excluded from speaker's bureau lectures, the latter will be given only by physicians who are not asked to give CME programs (and therefore they chose the speaker's bureau category). Despite the fact that speaker's bureau talks are highly restricted in content, I believe that physicians/scientists who also give CME talks provide a more balanced and scientific presentation when they give a speaker's bureau lecture compared to physicians who only give speaker's bureau talks. The proposal to segregate the two groups of lecturers will further reduce the value (there is value in reviewing the literature about a drug) of the speaker's bureau talks.</p>	<p>Other</p>
<p>ACCME Proposes Additional Features of Independence in Accredited Continuing Medical Education 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 supported by commercial interests. The [REDACTED] believes in and supports the ACCME Standards for Commercial Support. Regarding the questions posed by the ACCME, we believe the imposition of the exclusion of medical writers and faculty who participate in promotional activities from CME is overreaching, impractical, unenforceable, and damaging to the CME enterprise. The rationale for the suggested change is without basis in fact or evidence. It is not clear what 'problem' ACCME is looking to solve. The cited 'recent significant external actions' are taken out of context. The May 2008 Attorneys General settlement with a commercial supporter does not stipulate that a promotional speaker cannot also be a CME speaker. Rather it states that the supporter (in this case [REDACTED]) cannot know who the speakers will be in advance of funding the activity. The July 2008 Taskforce on Industry Funding of Medical Education states that "academic medical centers should make clear that participation by their faculty in industry-sponsored speakers' bureaus should be strongly discouraged," but does not disqualify speakers based on their participation in speaker's bureaus. Therefore, [REDACTED] strongly supports the following 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 their conflicts of interest are appropriately disclosed, vetted, and resolved. While the ACCME has expressed concern that safeguards to assure CME is free of commercial bias have not been successful, there are no studies or evidence that directly address the question of whether commercial support produces bias in accredited CME activities. There exists widespread concern about the impact of commercial support on research and education. Whether this support produces inherent bias in accredited CME activities is important but is not known. Prior to making potentially damaging changes to the CME enterprise, research is necessary to address questions about the relationship between commercial support and bias in CME. These questions include: •Does commercial support produce bias in CME activities? •What are the mechanisms by which bias is produced? •Are accreditation guidelines or other strategies effective in preventing bias? •How does commercial support of CME contribute to physicians' behavior change relative to other influences? •Does commercially supported CME lead to changes in the quality or cost of patient care? In its commentary, the ACCME outlines that "Physicians paid by a commercial interest to do promotional presentations on a product could not teach in accredited continuing medical education on the same product." The implications of this would be to limit faculty from speaking in a therapeutic area. CME content does not address a 'product,' but rather a therapeutic area with various treatment options without regard for the source of commercial support. Question 1: Should those who write promotional materials be excluded from having any role in writing CME content? [REDACTED] believes that all medical writers should disclose conflicts of interest which should be vetted and resolved, when necessary, in order to participate in CME activities. Writers should not be excluded from having a role in writing CME content in a therapeutic area because they have worked on promotional materials for a product in that therapeutic area. The exclusion of medical writers who participate in promotional activities from CME activities would be difficult to enforce and detrimental to the CME enterprise in the following ways: A)The exclusion of writers from CME would be difficult to enforce as many writers are freelance consultants. A restriction of this type is punitive and discourages disclosure of conflicts of interest and would be difficult to verify. Therefore, conflicts of interest would become more challenging to manage. B)The exclusion of writers from CME demonstrates a lack of understanding about promotional education, which is regulated by the FDA, vetted by the medical/legal process of the commercial interests, and limited to "on label" content. The content in promotional programs is more controlled and restricted than in accredited CME C)The exclusion of writers from CME will significantly impact the quality and value of CME activities. CME providers utilize staff and freelance writers to collaborate with researchers and faculty who may not possess the communication skills nor instructional design expertise to make their presentations relevant and compelling to the target audience. D)The exclusion of writers from CME will undermine the premise and credibility of the SCS by discounting the ability of compliance to resolve conflicts of interest through the defined process of CME providers. Question 2: Should those who teach in</p>	<p>Accredited CME provider</p>

<p>promotional activities be excluded from teaching in independent CME activities: PCME believes that medical professionals who teach should disclose conflicts of interest which should be vetted and resolved, when necessary, in order to participate in CME activities. Faculty should not be excluded from having a role in presenting CME content in a therapeutic area because they have worked on promotional materials for a product in that therapeutic area. The exclusion of faculty who participate in promotional activities from CME activities would be detrimental to the CME enterprise in the following ways: A)\tProfessional associations will be forced to exclude a majority of the presenters at their national and local meetings. B)\tTeaching institutions and community hospitals will face greater challenges finding faculty to participate in CME activities. Academic institutions may encounter difficulties recruiting faculty due to limited income potential from outside sources. C)\tThe overall quality of CME will be compromised because talented teachers will be forced to choose between CME and promotional programs, which have higher compensation D)\tInvestigators are often obligated to speak on behalf of the companies supporting their research in a promotional setting to ensure the dissemination of their data, thus eliminating them from CME activities. E)\tThe credibility of the ACCME and the Standards for Commercial Support will be severely compromised by a tacit acknowledgement of the ACCME's inability to manage conflicts of interest through its processes. F)\tMuch of the CME and research currently presented in the United States will be driven to other countries by forcing presenters who have participated in promotional programs to seek alternative venues. We strongly support strict adherence to the ACCME Standards for Commercial Support as the best and most appropriate means to manage conflicts of interest in CME through disclosure processes and vetting of apparent conflicts, including disclosure to learners.</p>	
<p>Comment of ██████████ on the ACCME Proposal: “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.” ██████████ appreciates this opportunity to comment on the new proposals by the Accreditation Council for Continuing Medical Education (ACCME) regarding interactions between accredited providers and commercial interests over support. As the nation’s largest medical device manufacturer, ██████████ 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 that “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.” The purposes that ACCME identified as underlying this proposal include concern over physicians who are paid by commercial interests to deliver promotional content to other physicians, who then may speak or otherwise control content at a CME program. ██████████ agrees that speakers at CME programs should present objective and unbiased information, but believes that the current proposal sweeps too broadly. First, ACCME has not indicated or explained why this particular interest is fundamentally different from other interests that physicians participating in CME may have. A physician who serves as a consultant to a company regarding development of a product, and/or who may hold patent rights to a product, or stock shares in the company that developed it, also has a potential interest in the product. Yet those physicians may participate in CME programs, with appropriate disclosure of their relationship with the product and its manufacturer. ACCME has not explained why such disclosure is not sufficient in the case of a physician who works on promotional materials related to a product. The proposed language also fails to take into account the wide range of activities that physicians may undertake on behalf of drug or device manufacturers. For example, some physicians may act as promotional speakers, using materials prepared by the manufacturer, while others may be asked to simply speak on their own regarding their clinical experience in treating a disease condition, and offer their thoughts on a product and how it is best used. It is not clear whether the latter activity would constitute “creating or presenting promotional materials” according to the proposed standard. It is also not clear that it should serve as a bar to participating in CME activities, provided that the relationship is properly disclosed in the CME program to attendees. There are numerous other activities in which physicians might participate related to development or marketing of a product that fall short of serving as an actual product spokesperson, but which would be precluded by the broad prohibition that ACCME has proposed. An inflexible approach towards the involvement of physicians who have done work for industry in CME programs will drastically reduce the available pool of speakers who can serve as faculty in CME in the future. The ACCME should revise its proposal, to allow for consideration of: (1) whether disclosure or other measures provide sufficient limitation; and (2) how to more narrowly define the type of activities that should actually serve as a bar to participating in CME programs.</p>	<p>Other</p>

<p>Proposing that faculty who teach in promotional activities be excluded from teaching in independent CME activities and authors who write promotional materials be excluded from having any role in writing CME content would prevent some of the most qualified faculty from teaching and therefore deprive learners of access to some of the most knowledgeable experts. Physicians who are sought out by accredited providers because of their expertise are those who are involved in research and, often because of that reason, are involved to varying degrees with industry. The proposed restriction on the use of such faculty in certified CME activities will ultimately have a negative impact on the quality of CME and therefore patients and their health care. The ACCME has proposed that individual academic institutions develop standards that define appropriate and acceptable involvement with industry and require full transparency and disclosure by their faculty. In the same vein, rather than exclude participation by some of the most credible and knowledgeable authorities, the ACCME should allow the current conflict of interest resolution process to work as designed. However, if the ACCME decides to restrict the use of certain faculty, it must develop clear definitions of promotional activities and clearly define the nature of relationships that would be excluded from participation in CME activities. We are not aware of any empirical data demonstrating that speakers or writers who participate in promotional activities present biased information in CME-designated educational activities. This would support the argument that Standard 5. Content and Format Without Bias is effective and should continue to be enforced as written. Physicians are intelligent consumers, and if in fact CME providers put on biased programs, physicians would stop attending them. Commercial supporters would then discontinue funding, and this alone would be a strong incentive for CME providers to continue to ensure fairness and balance in CME activities.</p>	<p>Accredited CME provider</p>
<p>████ understands and agrees with the intent of the proposed policy; however we are not at all clear why the current conflict of interest policy is not sufficient. We have not yet heard of any data being published on effectiveness of that policy. Has it been determined that the current policy was not sufficient? Is this policy meant to supplement the current conflict of interest policy by providing a definition of an irresolvable conflict of interest? If so, why was this area chosen as irresolvable vs. other relationships (i.e. royalties on products, major personal investment in a company, etc.). Does the ACCME anticipate providing other definitions? Overall, █████ is frustrated with the underlying assumption that all physicians are incapable of discerning between CME and non-CME, and that all relationships with companies are bad for patients. These suppositions are incorrect. The majority of physicians do understand the difference, and the majority of relationships between doctors and companies have led to medical advances. As accredited providers, our task is to ensure that our physicians are educated about the policies for the development and presentation of CME materials, and to ensure the materials presented are ultimately to benefit patients. We feel that the current policies are sufficient to ensure this takes place and that ACCME's move toward more active monitoring is appropriate. Our view is that changes in policy should not be made until results from the monitoring are reviewed to determine areas in need of specific policy refinements. Specifically, █████ has grave concerns regarding the wording of the policy. There is no definition of "promotional" materials. Is it the intention of the ACCME to deem all non-CME educational meetings as promotional? If that is not the intention, what is the definition of promotional? Without that definition, accredited providers would be left to creating their own definitions, and therefore the policy would end up being applied inconsistently. Additionally, the policy does not appear to take into account the potential for a variety of scenarios in physician participation in "promotional" materials. If a physician lectures 100 times in a year, and 99 of the lectures are within CME, but 1 lecture is a non-CME program internationally supported by a company, would he then be disqualified from presenting on that topic for a year (standard COI disclosure is within last 12 months). Contrast that to a physician who delivers 100 lectures and 75 of them are at company-supported dinner meetings. According to this policy, both would be treated the same with respect to their allowable participation in a CME program. The current disclosure and conflict resolution system is based upon self-reports by the participants. The assumption is that the reporting of any relationships is honest. Automatic disqualification from presenting or participating in planning an activity for reporting participation in a "promotional" activity could lead to a different scenario. Should the faculty member omit participation in a "promotional" activity in his disclosure, would the accredited provider be held accountable for it? How does the ACCME propose accredited providers verify disclosures in order to ensure we are adhering to the policy? Our understanding has been that the ACCME's intention is to ensure planners and learners have the most information possible to evaluate the speaker and the materials. Has it considered the potential negatives associated with instituting policies that might tempt individuals to be selective in their reporting (thereby leading to less information for planners and learners)?</p>	<p>Accredited CME provider</p>
<p>The ACCME has considered the following questions, 1) Should those who write promotional materials be excluded from having any role in writing CME content? •tNo, they should not be excluded as long as the CME provider can ensure that the author chosen to write CME content has not written promotional materials on a similar topic or for a commercial supporter on that topic within the last 12 months. 2) Should those who</p>	<p>Accredited CME provider</p>

<p>teach in promotional activities be excluded from teaching in independent CME activities? The ACCME has strict policies in place regarding identification and resolution of conflict of interest and it is the responsibility of the accredited provider to ensure that all content is unbiased, evidence-based, and based on standard practice in the medical community. To take away the right of an expert in a particular field to be involved in a CME activity if they also provide promotional education for a commercial supporter would be sending the message that the ACCME does not trust their providers to be effective in their resolution of conflicts of interest or in their review of content for a CME activity to ensure it is fair and balanced. Therapeutic experts, whether they are academicians, practicing physicians, professors, medical writers, or editors should have the ability to be included and/or participate in developing and/or presenting a CME activity even if they have been involved in non-CME activities within a therapeutic area. These experts are professionals who are obligated to present information that is evidence-based and validated in the medical literature. As professionals they should be given the credit that they have the wherewithal to present accurate, current, state-of-the art, and appropriate information that will be helpful and practical to the clinician in support of improved patient outcomes. It is short-sighted to think that these experts and professionals would utilize a CME activity as a venue to promote specific products. They certainly do not have the same goals or objectives as a commercial interest has in producing, marketing, re-selling or distributing health care goods or services consumed by, or used on, patients. In accordance to the ACCME guidelines, each of these individuals must provide full disclosure in all of their CME activities. The leading authorities and therapeutic experts generally have a vast amount of experience and exposure to data that is specific to a product. This does not mean they will utilize that information and knowledge to a fault by providing their experience, expertise, impressions of the published evidence-based data, and insights in an unbalanced, promotional way. These individuals strive to build their established, stellar reputations as therapeutic experts and are very capable of ensuring they are part of a well-balanced, ACCME-savvy initiative.</p>	
<p>The statement contains elements that are too vague, or too limited, to be useful. What is meant by "control"? What is meant by the "same content"? May a promotional speaker present a talk in a CME symposium that he does not chair? May a speaker who promotes the benefits of a specific drug in a promotional talk present a talk on the risks of competing drugs in a CME presentation? A bright line should be drawn between promotional and non-promotional speakers. We suggest that the statement be changed to say, "Persons paid to create, or present, promotional presentations or materials on behalf of commercial interests cannot arrange, present, or participate in any way (other than as an audience member) in any accredited continuing medical education activity that addresses the same disease or condition (including risk factors and epidemiology) or any aspects of the products, classes of products, or competing products used to diagnose, treat, or prevent the disease or condition."</p>	<p>Other</p>
<p>This will be sent as part of an overall response letter since this submission format loses some formatting intended to enhance clarity. 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</p>	<p>Commercial Supporter</p>

<p>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] 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 [REDACTED]. Respectfully, [REDACTED]</p>	
<p>The ACCME should be commended for wrestling with this difficult problem. However, the issues of exclusion of physicians as defined by the ACCME may silence some of our most respected and knowledgeable voices. It would be more useful to cap the physician involvement and continue to publish disclosures. CME activity has become burdensome to many, particularly in the university environment where the physician is expected to submit all the grants and raise all the money for a CME course often with considerable accompanying paper work. The raising of money is time consuming and not appropriately reimbursed in terms of staff or physician time. Other venues of funding would be most welcome but pharmaceutical companies have been often the only, and the most generous donor. This initiative, unless carefully done may silence much CME activity.</p>	<p>Accredited CME provider</p>
<p>Comments in Regard to the ACCME Proposal that: "Persons paid to create, or present, promotional materials on behalf of commercial interests cannot control the content of accredited continuing medical education on that same content". We at the [REDACTED] respectfully oppose this proposal and believe it to be unnecessary and punitive. In addition, we believe it will limit our ability to offer quality CME. In keeping with the ACCME's Standards for Commercial Support and in our commitment to offer CME content that meets the criteria for being evidence-based and that is fair, balanced and unbiased, the [REDACTED] engages in a rigorous process of identification and resolution of potential conflict of interest, including a stringent peer review process in which the content of each presentation is objectively validated. A Conflict of Interest Disclosure Form (COI) is provided to all individuals involved with a CME activity including the faculty and planners. Any personal, spousal or immediate family member financial relationship with a commercial entity involved in the subject of the pedagogical exercise during the previous twelve month period represents a potential conflict-of-interest and must be reported. A potential conflict-of-interest is present when a financial relationship has occurred within the preceding twelve months and the individual has the opportunity to affect the content of CME with respect to the products or services of that commercial interest. A thorough review of presentation materials is performed by [REDACTED] scientists who also have knowledge of identified potential conflicts of interest via the COI forms. Each submission for presentation is reviewed by at least two independent reviewers. These reviewers are selected from the membership on the basis of their expertise in the content and in having no declared conflicts. This review documents: a.\tThat the content reflects patient care and treatment guidelines that meet the standards of [REDACTED]; b.\tThat scientific studies have been used as the basis for the activity and that these meet the criteria for being evidence-based; and c.\tThat the activity is presented in a way that is fair, balanced and unbiased. If a conflict of interest is identified, the resolution may include one of the following: a.\tDisqualifying the presenter and substituting one with no COI b.\tRequesting the presenter sever financial relationships with the commercial interest c.\tRelegating the presenter with COI to a role in which therapeutic options will not be recommended by that individual d.\tExcluding that part of the presentation We believe these rigorous criteria assure the quality and objectivity of the activity and that no further exclusions are required at present. The [REDACTED] is committed to these policies and believes the rigorous criteria set out has and will prevent COI by faculty and is adequate to ensure fair and balanced academic content. To this end the policy is believed to be appropriate but will continue to be reviewed and, if appropriate, revised as experience and evolving standards dictate. [REDACTED]</p>	<p>Accredited CME provider</p>

<p>Dear Accreditation Council for Continuing Medical Education, Thank you very much for providing an opportunity for public response to the ACCME proposed policy regarding independence of accredited continuing medical education by incorporation of the following policy statement: "Persons paid to create, or present, promotional materials on behalf of commercial interests cannot control the content of accredited continuing medical education on that same content." We strongly oppose this policy as it places unreasonable limits on educators/medical experts who provide valuable training and expertise for both CME and promotional educational activities. Key experts in a given disease area are invaluable in the dissemination of high quality information in both venues and they should not be prohibited from either venue since both contribute to the goal of increasing the quality of patient care. At a minimum, we believe the proposed policy statement should be modified so that: "the same persons paid to create, or present, promotional materials on behalf of commercial interests would be prohibited from controlling the content of CME on that same content if: •\ttthe activities occur at the same venue, or •\ttthe CME is sponsored by the same commercial interest" We believe that with appropriate oversight and strict adherence to current guidelines and regulations, editorial integrity and fair balance can be assured.</p>	<p>Commercial Supporter</p>
<p>See letter to Dr. Murray Kopelow, submitted September 12, 2008. ██████ Position: The ██████ strongly urges ACCME to withdraw these proposals and instead address these issues as necessary under the existing Standards of Commercial Support (SCS). At present, the ACCME has presented no record evidence that either of these activities undermines the independence of providers and programs, nor has it proffered any evidence that these proposals would further its policies of independence. At the same time, the existing SCS address the issue of inappropriate interaction between accredited providers and commercial interests to prevent any impact or influence on selection of faculty, venue, and the determination of activity content. Further, the ACCME requires all providers to institute strict policies to identify and resolve conflicts of interest for all involved in program planning and implementation. These are meaningful policies that ensure the independence of CME content. The ██████ is seriously concerned that the new proposals would increase cost and reduce the likelihood of accredited providers finding adequate grant support without a measurable increase in the independence of CME activities. Virtually all grant-giving organizations have both areas of interest and submission guidelines readily available to all those who seek funding. The ACCME's proposed position would, by suppressing this information, make it harder for accredited providers to find funding. The ACCME's approach requires an increased number of grant submissions and potentially resubmissions as providers attempt to determine exactly what any given commercial interest is willing to support. This would be a significant disadvantage to smaller providers with neither the time nor the staff to undertake such exercises. The ██████ believes there are additional actions the ACCME could propose in a second call for comment that would better achieve the goal without decreasing the efficiency of the grant seeking process. Consistent with First Amendment guidance by the Supreme Court in the commercial speech area, we believe that the ACCME should consider less restrictive alternatives than the bans suggested, before proceeding to adopt sweeping bans. For example, several narrower, less restrictive alternatives may well address concerns of ACCME, while allowing appropriate and useful communications to continue. To further the discussion of such less restrictive alternatives, the ██████ offers two such ideas for consideration by ACCME and the entire education community. Because the ██████ has not yet fully vetted these with all ██████ stakeholders, we offer them not as ██████ proposals, but possible alternatives for discussion within the entire CME community before the ACCME takes final action here. Consider the following: 1.\tTo further ensure the independence of CME activities the ACCME could limit some restricted activities by grantors, such as sending RFPs to only selected providers or sole source grants. Or, ACCME could encourage increased public announcements and communication by grantors, perhaps enabling all accredited providers and the regulatory community to view the RFPs. An open RFP process, transparent to regulators and other interested parties, may increase the efficiency of both the planning and grant seeking process. Accredited providers would be able to more quickly identify those commercial interests likely to have funds available for the practice gaps and other unmet needs identified by their research. A more transparent system may operate to prevent potential or perceived opportunities to threaten the independence of CME content. 2.\tACCME could further emphasize that needs assessment is the primary responsibility of accredited providers. The ACCME might regulate the use of needs assessment in RFPs, or limit the ability of grantors to specify needs assessment vendors or methods as a condition of receiving grant support. In sum, the ██████ believes it's appropriate that each accredited provider is responsible for the integrity of its CME program and the activities it certifies. The existing Standards of Commercial Support and conflict of interest policies of the ACCME provide excellent protection for the independence of CME content. We believe that transparency rather than prohibition would better achieve the incremental improvements sought by these latest policy proposals. If ACCME believes that further rules areas necessary, we recommend that ACCME should propose such rules in a further notice, along with evidence that the proposal would solve the problems specified. We believe that much more narrow alternatives, focused on an open and transparent RFP system might best meet the current needs of the community. The ██████ looks forward to this discussion and debate.</p>	<p>Other</p>

<p>Respectfully submitted, [REDACTED]</p>	
<p>On behalf of The [REDACTED], we appreciate the opportunity to provide the following comment: The proposed regulation may prevent CME providers from benefiting from the participation of the most qualified educators for program design and speaking. The proposal suggests that the disclosure and conflict of interest resolution system in place is inadequate. Peer review is the gold standard by which all of science and medicine has been built and should continue to operate as one mechanism to distinguish between promotional activities and accredited continuing medical education. Under the current conflict of interest resolution guidelines, those faculty members who would be impacted by this regulatory change are already required to manage these conflicts through avoiding direct discussion of specific products and services and/or submission to peer-review. Which construct is more likely to result in enhanced learner knowledge, competency, or performance: faculty participation under peer-review or non-participation? Of particular concern would be the definition of "content." If "content" is defined as a particular practice area, then the result will be the handicapping of the educational enterprise. If "content" is narrowly defined as "a particular product or service" then the regulation could possibly be implemented but would remove those individuals with the most direct knowledge of study data related to the product or service (i.e. principle investigators who do not work for industry) from participation in accredited continuing medical education. This would be extremely limiting and would not provide learners with the opportunity to get first hand information from those with the most knowledge of the data. The [REDACTED] oppose the proposed change as currently stated.</p>	<p>Accredited CME provider</p>
<p>September 12, 2008 E-Mail and Electronic Submission Murray Kopelow, MD Chief Executive Accreditation Council for Continuing Medical Education 515 N. State Street, Suite 1801 Chicago, Illinois 60654 RE: ACCME Policy Announcements and Calls for Comment Dear Dr. Kopelow: The [REDACTED] appreciates this opportunity to respond to the recent policy announcements and calls for comments by the ACCME related to critical matters of public concern regarding the process, procedures and rules of accreditation at ACCME. This response consists of two sections, the first addresses the public policy, process and procedural issues surrounding these matters, the second addresses each of the three major policy question areas placed for public comment. Stated simply, these three questions are: 1. Should commercial support of certified CME end? 2. Should all professional writers and faculty that have been employed by commercial interests for marketing or promotional projects be systematically excluded from related certified CME activities? 3. Should certain announcements by grantors be banned, specifically "internal criteria" for grant approval and "topics" of interest? 2 I. Public Policy, Process and Procedural Issues The [REDACTED] and its education members have long noted the public policy and public health importance of the ACCME. Members that are [REDACTED] 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</p>	<p>Other</p>

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 See ACCME Decision Making policy documents related to the Accreditation Process and the Recognition Process under "Reconsiderations and Appeals." These are standards employed by government agencies. 4 There is solid legal authority requiring due process from otherwise private institutions when "the government has become so entangled in the actions of a private party, it may warrant the requirement that such private conduct conform to the constitutional standards of behavior."² In this case, in addition to the regulatory functions performed by ACCME noted above: (1) ACCME standards for commercial support and independence are recognized by FDA in the agency's review of promotional claims made during CME activities;³ (2) FDA maintains a formal written procedure for ACCME accreditation of the educational and training activities conducted by its Center for Drug Evaluation and Research;⁴ (3) state medical licensing 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 ██████ 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). *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 ██████ raises the litigation possibility not because it has an intention to file a legal action. Instead, it raises it because the ██████ believes litigation is a logical reaction to ACCME's current procedural decisions and it hopes that ACCME will adjust its processes at least in part to avoid 6 "Reasoned decisionmaking" is required to not be deemed arbitrary or capricious, See *Puerto Rico Education Assistance Corporation v. Riley* 10 F.3d 847, 853 (D.C.Cir. 1993)("one of the fundamental principles of administrative law is that an agency's decision must be supported by reasoned decisionmaking."); *Olenhouse v. Commodity Credit Corp.*, 42 F.3d 1560 (C.A.10, Kan., 1994)("The duty of the court reviewing agency action under the 'arbitrary and capricious' standard is to ascertain whether the agency examined the relevant data and articulated a rational connection between facts found and the decision made."); *Wisconsin Valley Improvement Company v. FERC*, 236 F.3d 738, 748 (D.C.Cir. 2001)("[A]n agency acts arbitrarily and capriciously when it abruptly departs from a position it previously held without satisfactorily explaining its reason for doing so."); *Motor Vehicle Mfrs. Ass'n of U.S.*,

Inc. v. State Farm Mutual Auto Ins. Co., 103 S.Ct. 2856 (1983) (“An agency changing its course by rescinding a rule is obligated to supply a reasoned analysis for the change beyond that which may be required when an agency does not act in the first instance.”). 7 The federal courts have recognized the standing of CME providers to initiate judicial review of ACCME decisions; see for example *Medical CME Associates v. ACCME*, 1990 WL 160075 (N.D. Ill 1990) (accepting a case for review but ultimately dismissing a complaint by a CME provider because the elements of an anti-trust case were not properly pled or proven). 6 litigation. We strongly urge ACCME to quickly go well out of its way to ensure that its policy making processes be as fair, open, reasoned and transparent as possible. Quick action need not be expensive or unduly delay these proceedings. Due process standards are well understood, and easily followed. In the context of the rule making and enforcement actions at issue here, fundamental fairness and due process essentially require: full notice; the opportunity for all input to be heard; a public rulemaking record; and a decision-making process that is explained, reasoned and fact based. This generally means that rule changes be published for comment, giving the reasons and goals of the proposal, as well as an explanation of the underlying facts and assumptions. Interested parties are then allowed to comment for the record, including provisions for both data and arguments, and full access and the opportunity to comment upon the comments of other parties are also given. After this, the rulemaking body is expected to propose a specific rule, giving a full explanation of its reasoning based on the record of the proceedings including why certain comments prevailed and others did not. Due process does not mean, as suggested in a recent letter to NAAMECC, that ACCME “consider the comment process to be a poll or vote.” Rule making is not a voting procedure, but instead an open, contemplative process where the purpose, policy and procedures are fully vetted, and the decisions of the rule making body are based on transparent reasoning and record evidence. In the context of adverse actions, due process allows a party subject to an adverse action to be given a full explanation of the reasons for the adverse action and an opportunity to appeal to an impartial and knowledgeable decision-maker. We recognize that ACCME has a published set of procedural rules for adverse actions, and applaud this. At ACCME adverse actions arise most often in the context of the re-accreditation of providers. The procedural processes given providers in such instances are substantive rights that cannot be arbitrarily modified in a specific enforcement action – which ACCME has appeared to have done with a number of providers that have received adverse decisions. Any changes in the criteria for ruling must be subject to rule making requirements similar to those described above. 7 Therefore, we recommend that ACCME, as quickly as possible, publicly announce that it intends to adopt the following four measures. The first three involve rule making procedures, and the fourth enforcement actions. We recommend that ACCME: 1. Open the Record on the Three Previously Announced Subject Areas. This would enable all interested parties to review the comments of all other parties, and review the entire record relied upon by ACCME. Given the current requirement that comments be submitted electronically, the posting of comments at a publicly available website should involve little additional time or cost. Indeed, if ACCME does not wish to bear any of the costs associated with the public posting of all comments, the [REDACTED] agrees to organize an effort to enable this at no cost to ACCME. Meanwhile, the [REDACTED] has created a page on its website where it will be posting all comments sent to it. 2. Establish a Reply Comment Period. This would enable all participants to comment on recommendations and data submitted by others. The deadline for reply comments should be no shorter than 30 days from the date of the filing of the initial round of comments. 3. Commit to the Publication of a Further Notice. This would enable ACCME to publish specific proposed rules on each of the three topic areas after an initial two rounds of comments. This further notice should include a clear explanation of the purpose of the rule, the problem (s) the proposed rule seeks to avoid, and the procedure(s) for implementation. This notice should clearly articulate the facts in the record of the proceeding that are the basis for the rule, and review the substantive recommendations in the record, and a reasoned explanation why or why not major recommendations did or did not prevail. Interested parties should then be given a reasonable period to comment on these proposed rules before implementation. 8 4. Follow Due Process in Adverse Decisions Against Providers. ACCME must carefully review its adverse decision process rules, including strict adherence to its own rules, including recent probation decisions. For example, we note that on June 11th the ACCME announced, without seeking comment, that is “now putting more Accredited Providers on Probation— especially those found in Non Compliance with elements of the ACCME Standards for Commercial Support. The current rate of Probation has increased to about 10% of Providers seeking Re-accreditation from about 1% in the past.” While perhaps justified, the action appears to be in direct opposition to ACCME published policies regarding the process of placing an accredited provider on probation. The [REDACTED] strongly recommends that the ACCME not change its enforcement procedures in a manner that substantively denies due process and appeal rights to providers without actual notice of such changes to the entire community, including following the general rule making procedures we recommend for the three topic areas addressed above. 8 II. ACCME Questions for Comment 1. Should commercial support of certified CME end? Background: The ACCME has called for comment regarding the elimination of commercial funding of CME. In its Call for Comment ACCME notes that in January of 2007 it initiated a discussion announcing that “it would be considering taking action regarding the funding structure of continuing medical education.” It

further stated that “although CME exists in a data driven, evidence-based world, many are motivated by firmly held beliefs about propriety and professionalism. The ACCME values both perspectives and now seeks input on this matter.” ACCME acknowledged the need for identifying alternatives to the current funding scenario proposing three potential approaches: 1) no change to the 8 Although we are not privy to any individual case, we have been told informally that this change in policy has also been accompanied by a substantive procedural change that severely limits the ability of parties to review the facts leading to probation decisions and limits their ability to appeal those decisions. 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 Coalition believes that most CME activities are free of commercial bias and that physicians are well-equipped to manage bias if it occurs. We are seriously concerned that the ACCME has added its moral force to this debate by raising this question, and has done so without offering any evidence of bias from commercial support. As noted above, a fundamental principle of due process is reasoned decision making based on record evidence. ACCME has included in this record no objective evidence that commercial support of CME introduces bias. ACCME’s own recently commissioned report, The Relationship between Commercial Support and Bias In Continuing Education Activities: A Review of the Literature, failed to find “any objective evidence or studies documenting that commercially supported CME activities are biased.” That report recommends that further “rigorous scientific studies” be conducted before conclusions are drawn. It also recommended answering the question: does commercially-sponsored CME lead to better patient care? The [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 his review the \$1.2 billion dollars in commercial support only accounts for 15% - 30% of the yearly total of actual hours of instruction. While this may be true and consistent with current recertification standards, the CME community now considers measures of improved patient care much more relevant and important than counts of hours of instruction. Commercial funding accounts for a far greater portion of innovative CME activity that is focused on improvement in patient care. In particular, 11 commercial support often funds new designs for educational programs to address practice gaps and has been a driver in creating non-traditional learning venues such as e-learning and other Internet-based activities. The [REDACTED] firmly believes that proposals to end half the funding of certified CME without offering plausible substitutes for that funding have no place in a serious public policy discussion on how to improve patient care. While some believe that government programs can replace commercial support, this is not realistic. Consider, for example, the current debate in Congress around adequate funding for FDA, clearly a critical priority. While most agree that the FDA has a current budget shortfall of at least a billion dollars a year, in 2008 Congress could only find one fourth of that for fiscal year 2009 and has not developed a consensus plan for fully funding this shortfall in subsequent years. If adequate funds cannot be found for a billion dollar shortfall at FDA, it is clearly unrealistic to expect that a similar amount could be found to substitute for commercial support for CME. Even if adequate government funding were available, it may not be optimal. Government funded CME often introduces a

dangerous bias in favor of adoption of the immediately-least-expensive therapeutic or diagnostic practice. This bias is not always consistent with either the long term best interest of patients or even the government. Similarly, it is unrealistic to expect physicians, facing increasing financial pressure on their income from reduced Medicare fees and lower managed care reimbursement, to pay for their own CME. With 663,900 physicians in practice in the United States, the absence of commercial support would create a shortfall of \$1,807 per year for each physician. Today it is clear to objective observers that clinicians participate in commercially funded activities to learn about new and better ways to diagnose and manage disease, and then return to their practices better prepared to treat their patients. While these activities are supported by industry, patients are the primary beneficiaries. At the same time, commercial supporters and providers have been leaders in studies and research on the value of CME to patient care in America. The [REDACTED] does appreciate the need for ACCME to respond to the criticism and continuing pressure to curtail commercial funding. However, it is important to emphasize that much of this criticism is based on past unacceptable practices and incidents that have now been addressed by industry, provider and ACCME reforms. The CME community has taken 12 significant steps over the past decade to insure both independence and quality for CME. These steps not only help insure independence from commercial influence, they also have elevated both the scientific standards for content and improved measurement of physician change and patient outcomes. Since the 1997 U.S. Food and Drug Administration guidance document calling for clear separation between promotion and education in the US, the CME community has made consistent improvements. Pharmaceutical manufacturers have done their part as well: hiring compliance officers and instituting strict compliance policies; creating education groups and grant review committees that are independent of sales and marketing; removing all CME activity from their sales organizations; and other practices to insure the independence of the CME programs they fund. While it may be impossible to eliminate all bias, these reforms insure that any reasonable chance of introducing bias will be minimized. While the [REDACTED] applauds ACCME's effort to present a new paradigm for the commercial funding of CME, it sees several issues with the recommendations. For example, point number three recommends CME content from curriculum specified by "bona fide organizations." Unfortunately, this approach will inhibit the delivery of cutting edge education addressing the latest developments in medicine. In many instances, innovative education leads rather than follows these organizations in the development of new curricula and clinical guidelines. This is even more pronounced for government guidelines, which often are subject to several additional layers of review and regulatory process before adoption. Limiting CME programs to practice gaps "corroborated by bona fide performance measurements (e.g., National Quality Forum)" could well negate the value of the ACCME recognized advances in the current "needs assessment" processes. To only subject commercially funded CME to this criterion would, superficially, seem like a reasonable approach, but in practice would only delay and inhibit the transfer of knowledge about new treatments and breakthroughs. The CME community recognizes that conflict of interest is a legitimate concern for all in medical education. However, the elimination of commercial funding -- to address the issue of bias -- in the absence of collaborating evidence supporting such a move, is counterproductive. In fact, such a decision would cause a massive reduction in the amount of 13 available CME, hinder the dissemination of new cutting-edge medical information, undo the positive recent advancements in CME, and ultimately stifle improvements in patient care. We respectfully submit that the current Standards of Commercial Support offer strong protection and independence of CME content from any bias and that to eliminate or further regulate commercial funding is unnecessary and unwarranted.

2. Should professional writers and faculty that have been employed by commercial interests be systematically excluded from related certified CME activities? Background: In its August 2008 publication titled "ACCME Proposes Additional Features of Independence in Accredited Continuing Medical Education," ACCME proposed, for comment, the following policy: Persons paid to create, or present, promotional materials on behalf of commercial interests cannot control the content of accredited continuing medical education on that same content. In accompanying commentary ACCME elaborated, suggesting that the intent was to systematically exclude persons who have been employed by commercial supporters : " In accredited CME some conflicts of interest are irreconcilable. The only way they can be resolved is by avoiding the circumstances that create the conflict. This is the basis of the SCS 1 (and) would be the case under this policy. Physicians paid by a commercial interest to do promotion presentations on a product could not teach in accredited continuing medical education on the same product. Anyone creating content for promotional activities would be excluded from creating content on the same product ..." ACCME also noted that not every financial relationship would require exclusion, including conducting and reporting the results of industry research unless such persons also participated in promotional programs. 14 [REDACTED] [REDACTED]: 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

<p>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]. 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</p>	
<p>On behalf of the [REDACTED] not-for-profit organization of [REDACTED] and scientists dedicated to helping [REDACTED] provide the highest quality of care possible for patients—thank you for the opportunity to provide comment on the Accreditation Council for Continuing Medical Education’s (ACCME’s) proposal to include additional features of independence in accredited continuing medical education (CME) (Proposal 3). [REDACTED] is concerned that ACCME’s proposal will significantly hinder the ability of professional societies like [REDACTED] to provide high-quality CME. Proposal 3 will restrict the number of qualified physicians available to teach independent CME activities. There are many ethical, competent [REDACTED] who, because they are well respected leaders in their field, are recruited by industry to sit on boards, participate in trials, and speak on the company’s behalf. Some of the same people are recruited by [REDACTED] to present at educational conferences and participant in committees. If forced to make a choice between collaborating with [REDACTED] or a pharmaceutical company, many will select the company, especially if industry provides an opportunity for a superb [REDACTED] to advance care for patients with [REDACTED] disease in innovative ways. By removing many senior physicians and researchers from CME activities, ACCME will force societies to find speakers who are either far afield in expertise or who lack significant experience. [REDACTED] also disagrees with the notion that anyone who receives funding from a pharmaceutical company is encumbered by commercial bias. ACCME even stated in its presentation to the Institute of Medicine Committee on Conflict of Interest that, “No data demonstrating commercial content bias is found in the medical education or regulatory literature. Although it has been speculated that commercial support produces bias in CME programs, no published studies have examined this question. Therefore, there is no evidence to support or refute this assertion.” Furthermore, academic faculty have multiple roles—clinical, research, education—and are required by their institutions to regularly report and manage conflicts of interest. Having a research or educational contract with a commercial interest does not preclude someone from having a balanced view of a given field. Conflicts of interest should be managed, but speakers should not be automatically disqualified because of these conflicts. Instead, [REDACTED] requires disclosure of conflicts, a review of material prior to presentation, balanced analysis in all presentations, observation and reporting of sessions, and audience polling to ensure its educational programs are free of bias. The entire process for protecting content is governed by the [REDACTED], which includes three members of the [REDACTED] (including the committee’s chair). Beyond these actions, the [REDACTED] fears that overly prescriptive restrictions hurt, rather than improve, CME. In addition, [REDACTED] is concerned about the specifics and transparency of the policy. ACCME suggests that individuals who write and teach promotional material for commercial interests should be excluded from participating in the development and transmission of CME content. However, “write” and “teach” are broad terms and [REDACTED] feels language excluding promotional writers and teachers could lead to the exclusion of many qualified experts from CME activities. For example, [REDACTED] can envision a situation where a physician sits on a medical advisory board for a company. While this role is currently not an excluded activity, what if that physician is asked to participate in a “discussion” with physicians about recent study findings on a drug? Does participation in this discussion</p>	<p>Accredited CME provider</p>

<p>amount to engagement in promotional activity? If ACCME were to implement policies that limit CME participation based on involvement with promotional activities, ■ urges that ACCME clearly define, with examples, what constitutes a conflict of interest. ■ also questions how exceptions will be dealt with if the proposed policy is implemented. For example, while ■ precludes individuals who are employed by commercial interests from speaking or moderating at basic science and clinical science symposia, exceptions have been granted when a speaker moves from academia to industry after being invited to speak. Since medicine is often a transient profession, how does ACCME propose handling position changes? In addition, ■ offers multiple sessions at its educational conference. Are all sessions considered the same by ACCME, therefore warranting the exclusion of those that teach promotional activities from all CME activities? Or would certain sessions fall outside such a policy? If policies are implemented, ■ encourages ACCME to clarify how such scenarios will be handled. As noted above, ■ is concerned that the proposed rules are relatively vague regarding what specifically constitutes a conflict of interest. It is likely that different societies will interpret the rules disparately. ■ exists in a competitive market; the Society competes with other renal organizations to develop the best educational products, presentations, and courses. If ■ is strict in its interpretation of the rules—as it has always been—and its competition is not, the ■ will see some of its prime speakers gracing the agendas and rosters of other organizations and not its own. ■ is worried that if ACCME implements rules that are too ambiguous, societies that closely follow the regulations will be unfairly penalized. Again, thank you for the opportunity to comment on ACCME's proposal. ■ looks forward to working with ACCME and the rest of the community to continue to assess the best approach for protecting CME from commercial bias while also providing members of the renal community with high-quality, innovative educational programs. To discuss ■ comments, please contact ■</p>	
<p>The ■ has reviewed the proposed policy. Their comments are summarized below: Committee members were concerned that the proposed policy may be a bit extreme. The proposed policy would move the bar for potential speakers/writers with non-research commercial interests from “cannot control the content” to “cannot participate, period.” Geriatrics is a small field and many of our national ‘experts’ in content areas do serve on speaker’s bureaus or may received funding from pharmaceutical industries. The implication is that we (as a profession, CME-awarding entities) cannot be trusted to internally police/audit our own content – which we find sad. The ■ has implemented a robust system for monitoring its professional education programs for potential conflicts of interest and resolution of same. Each year, the ■ and relevant oversight groups (e.g., annual meeting program committee) discuss the existing system and make suggested changes as needed based on experience over the past year. The ■ also raised the questions of how the “same content” of the ban aspect gets determined – the distinctions could get pretty fine; e.g.: * can a urinary incontinence product-supported speaker still talk about, say, nursing home care practices which happens to include urinary incontinence management? (same “disease”, different context) * could a ■ talk be given by a cardiologist who is on speakers bureau for high blood pressure for a company that – obviously – also has approved ■ applications? (same drug, different disease) * could someone who received promotional payment from a wound care product manufacturer still speak about pressure sore prevention? (same field, different application) From the perspective of the ■, the new policy that ACCME is proposing to further define the independence of accredited continuing medical education is too extreme, and we believe that we do an excellent job monitoring the content and intervening with any faculty member who has a conflict of interest to ensure that the material presented is not biased. Sincerely, ■</p>	<p>Accredited CME provider</p>

<p>This new policy would be a severe restriction to CME providers hoping to plan and place the most effective and useful CME activities in the marketplace. As with the other areas being addressed in the calls for comment, the proposed policy attempts to solve a problem we do not yet know exists, instead hoping simply to improve the image of the industry with the public at large. And because we do not know the actual benefits, if any, hoped to be gained by implementing the new policy, it is difficult to weigh and assess the associated costs of the new restriction on the CME enterprise. The costs of the new policy, however, are clear. Placing these restrictions on who can and cannot participate in CME places the entire enterprise at risk. Medical professionals at the top of their fields could choose whether to assist commercial interests with the development and promotion of their products, or whether to serve the medical profession as a whole through educational endeavors. The financial reward between the two opportunities could be determinative, leaving many of the most respected and qualified voices to be speaking on behalf of commercial interests only. The effects could be overwhelming: more frequent and higher-quality information coming from commercial interests instead of educators, greater reliance within the medical community on the voices of commercial interests instead of educators, and further movement away from a medical system founded on evidence-based medicine. Conflicts of interest exist throughout our society today. Individuals have many and varied financial relationships and arrangements with other individuals and institutions. From financial advisors to lawyers to reporters to doctors, all have a financial relationship with someone else that has some effect, one way or another, on their disposition. And institutions are not immune, being nothing more than conglomerations of individuals united towards a common purpose, from financial institutions to the judicial system to media outlets to healthcare systems, associations and societies. News organizations receive advertising revenue from commercial interests and must hold themselves to the highest of ethical standards of fairness and disclosure when reporting on events to the public involving those commercial interests. Financial advisors have an obligation of fairness and disclosure to their clients when promoting financial products or services of their own organization over competing products or services of other investment houses. Lawyers wishing to represent multiple individuals or entities with competing interests must disclose the potential for conflicts of interest to each party and obtain approvals from each of them before proceeding. Conflicts exist, and we find ways as a society to work through them when they rear their heads, but we do not prohibit engagement simply because of the conflict's existence. In each of these enumerated situations, transparency and disclosure rule the day. This situation should be no different. The complexity of our growing society results in the existence of conflicts, and no one can be expected to exist in a vacuum without forfeiting the chance of having a meaningful effect on society. Let medical professionals, like the rest of society, participate in the free exchange of information and ideas, require that full and transparent disclosures be made, subject them to the rigors of the accreditation of CME activities, and let the listener be the judge of the information or idea espoused through that system. Those not participating fairly within that system will soon find themselves estranged. Fortunately, for the purposes of CME, we at least have the benefit of an educated, professional audience. Let us rely on that educated listener to make his or her own professional decision about the information being shared within the context of the accredited CME activity, including the disclosure being made.</p>	Accredited CME provider
<p>A promotional activity for a product sponsored by a commercial entity may have broad educational value beyond the information presented on the product. However, it must be kept distinct from accredited continuing medical education programs as the majority of the data usually focuses on the commercial product and the intent of the program is to encourage sales. Mechanisms are already in place to insure this separation, notably the requirement for prior review of materials to receive CME credit by the CME-granting body. Additionally, physicians at a CME event (e.g., grand rounds) can also judge if a presentation is promotional in nature and state this on their evaluation forms. The currently proposed policy is seriously flawed in that "the same content" is not adequately defined. For example, if an investigator prepares a presentation on a product or procedure that establishes a new therapeutic category, the content for a CME educational conference and an industry-sponsored event will likely be quite similar. Also, an acknowledged expert in a field may lecture on a given product at an industry-sponsored symposium and then be asked to give a CME educational conference on the class of agents including this product. Would this be contrary to the proposed policy? In a different field, what about the politician who speaks at a (partisan) political convention on a given topic and then addresses a public group on the same topic as a representative of a legislative body? There may be a conflict of interest in this, but the presenter is expected to choose the correct role of party politician vs. statesman. Again, the audience will be the judge of whether this was successful. It seems to me that individuals who are knowledgeable on a topic and teach effectively are valued by both academia / educational groups and "industry." I believe most such lecturers are very aware of the differences in promotional programs vs. CME-programs. If not, the current mechanism of prereview of materials for CME programs and use of audience evaluations should insure fair balance and prevent inappropriate promotion of products. These guidelines should be strengthened if necessary to this end rather than trying to label individuals as "commercial" or "educational."</p>	Accredited CME provider

<p>One of the two questions that the ACCME is considering is as follows: Should those who write promotional materials be excluded from having any role in writing CME content? I ask that the ACCME define what is meant by "promotional materials". For example, is a medical writer-editor who works closely with an author to prepare a manuscript for submission for publication in a professional journal working on promotional material?</p>	<p>Other</p>
<p>The [REDACTED] believes it would be inappropriate for the ACCME to institute a categorical "ban" of persons paid to create or present promotional materials on behalf of commercial interests from controlling the development of accredited continuing medical education on the same content. Over the past decade, [REDACTED] has worked with world-renowned scientific researchers to educate our health professional constituents. These individuals conduct human research with an unprecedented level of scientific rigor and integrity, as mandated by the U. S. Food and Drug Administration and other regulatory bodies. If the FDA and other regulatory agencies recognize the integrity of these researchers in protecting and advancing public health, the ACCME should as well in terms of their ability to develop and deliver evidence-based, fair-balanced professional education. Inherent in research, investigators must evaluate the efficacy of developmental therapeutics. Conducting such research makes investigators the most qualified individuals to assist pharmaceutical companies in developing information on researched drugs to be communicated to healthcare professionals and patients. Promotional materials may include recommendations for drug administration and patient education of side effects, guidance for which is reliant on patient experiences observed during the course of clinical research. We believe that it is incumbent upon researchers to uphold a scientific code of ethics that takes precedence over individual interests. Researchers are leaders in the scientific community as a result of publication in peer-reviewed journals, in which their work is scrutinized by peers and determined to be scientifically sound. It is our belief that this vetting process also supports the scientific and clinical merit of their roles as educators. In summary, we believe it is important and appropriate that scientific researchers maintain the freedom to educate healthcare professionals and patients about their life research, regardless of whether the medium of communication is accredited or promotional.</p>	<p>Non-Accredited CME provider</p>
<p>[REDACTED] strongly disagrees with this proposal. The proposal is too vague and there are many concerns regarding the issues involved, including access to experts in a very specific field and limited, definition of and extent of "same content", length of exclusion, etc. So in general, we suggest that persons who are paid to create or present promotional materials on behalf of commercial interest should go through the same disclosure process as any other person who has any relationship to disclose, but should still be allowed to speak if that is what each individual professional association or medical institution deems appropriate. Individual society's policies and procedures are designed to deal with perceived or real conflicts of interest. An individual society may suggest that someone presenting at a promotional meeting within a 12 month period may not present a program, or someone presenting at an adjunct promotional symposium may not speak at that particular annual meeting, but these policies should be left to the individual societies. Again, the individual professional society should be allowed to govern, manage and monitor it own activities using a fair system which allows learners to use their own judgment and puts the onus on the professional society to manage any perceived or real conflicts. The ACCME should set the standard and allow the individual providers to set policies to comply.</p>	<p>Non-Accredited CME provider</p>

<p>Call for comment 3: The ACCME proposes the following policy: Persons paid to create, or present, promotional materials on behalf of commercial interests cannot control the content of accredited continuing medical education on the same content. [REDACTED] comments: [REDACTED] believes that it is important to ensure a clear separation between promotional activities and certified CME activities. However, we would like some clarification on ACCME's proposed policy. Is it intended to be restricted to financial relationships within the past 12 months (as with the SCS 2.1) or is it time unlimited? SCS 2: Resolution of Personal Conflicts of Interest requires that accredited CME providers identify and resolve all relevant financial relationships prior to the educational activity being presented to participants. Providers are also required to determine that the content of presentations promote improvements or quality in healthcare and not a specific proprietary business interest of a commercial interest (SCS 5.1). Physicians also have ethical responsibilities when presenting at certified CME activities. CEJA Opinion E-9.011 states that faculty should ensure that "the content of their presentation is not modified or influenced by representatives of industry or other financial contributors, and they do not employ materials whose content is shaped by industry." ACCME's interpretation of how accredited CME providers are implementing the Updated Standards for Commercial Support is still evolving. In the absence of data that the system is not working, it is only a perceived need to change it at this time, not an evidence-based need. When physicians are involved with promotional activities, they have legal and ethical responsibilities to ensure that participants are aware of that activity's promotional nature. CEJA Opinion E-9.011 states that, "When invited to present at non-CME activities that are primarily promotional, faculty should avoid participation unless the activity is clearly identified as promotional in its program announcements and other advertising." This is also reinforced for speakers in the new version of the Code on Interactions with Healthcare Professionals that was recently released by the Pharmaceutical Research and Manufacturers of American (PhRMA).</p>	<p>Accredited CME provider</p>
<p>This proposed policy would disqualify an individual who has presented promotional materials on behalf of a commercial interest from serving as a faculty member, planner, or author for a CME activity, even if the provider limited that individual's control of the content to an area, such as pathophysiology, where the possibility of introduction of commercial bias might be minimal. We believe this policy would result in the elimination of many qualified individuals from participation in the planning of CME activities. [REDACTED] encourages ACCME to instead provide further guidance and direction to providers on its expectations regarding resolution of conflicts of interest. ACCME may also wish to recommend that providers develop their own definitions of irresolvable conflicts of interest, which would specify the conditions under which the provider would disqualify a prospective faculty member or planner.</p>	<p>Accredited CME provider</p>
<p>Issue 3: Those who write promotional materials be excluded from having any role in writing CME content. The ACCME takes the position that physicians paid by a commercial interest to do promotional presentations on a product could not teach in accredited continuing medical education on the same product. Anyone creating content for promotional activities would be excluded from creating content on the same product for accredited continuing medical education, for example. The intent of the policy is to further separate promotion from education and to ensure the independence of accredited CME from commercial interests. Below is [REDACTED] [REDACTED] response to the ACCME position. [REDACTED] believes that separation of promotion from education and the responsibility of providers to ensure the independence of accredited CME from commercial interests are critical to the CME enterprise. We believe that the Updated ACCME Accreditation Criteria, which specifically includes independence requirements, sufficiently makes the accredited provider responsible for speaker identification, selection, resolution of personal financial conflict of interest, and monitoring. In resolving conflict of interest, providers must take into account financial relationships with commercial interests, and this includes involvement in promotional presentations on products produced by individual commercial interests. Additionally, it is the CME provider's responsibility to ensure that multiple recommendations (both pharmacologic and non-pharmacologic) are represented in the curricula creating a balanced view of recommendations. Eliminating speakers solely because they have contributed to or given presentations that are part of a promotional activity casts an unnecessarily wide net of exclusion around speaker eligibility that is too distant from the day-to-day needs of providers and CME participants. There may be good reason why a speaker contributed to the content of a promotional activity: there may be limited numbers of experts in the content area, and health care practitioners need to be educated on specific products in ways that only those experts can fulfill upon. In these instances, providers and CME participants would be denied access to education and interaction with the exact content experts they need access to. Second, conflict of interest processes compel that those in the position to control content who are conflicted be removed from the responsibility of presenting data or recommendations relating to the conflict. In our role as the Accredited Provider for specific activities, we obtain, track, and monitor faculty relationships, including participation on speakers bureaus, which allows for resolution of COI. We see a consistent trend of increasing number of speakers who either have no personal financial relationships or have personal financial</p>	<p>Accredited CME provider</p>

<p>relationships that aren't directly related to the commercial supporter of a given activity. Based on our internal data, 61% of PMI faculty had no relevant financial relationships in 2007. Rather than banning speakers summarily, we propose that the ACCME require providers to assess promotional activities of potential speakers as a specific criteria that would be then acted up and documented relative to whether participation was allowed or not allowed and why and to disclose to learners their vetting process specifically related to a speaker who has engaged in promotional activities on a specific product and who was serving as a speaker for the provider's CME activity. These data would be proactively provided to ACCME as part of their activity monitoring requirements. We do believe that ACCME can help design this framework and provide guidance on better utilizing expert speakers who have worked with commercial interests in the development of promotional content. To this end, [REDACTED] proposes that the ACCME work to adopt the conflict of interest framework which already exists for other organizations, e.g., that of the Food and Drug Administration (FDA), which includes Advisory Board member recusal criteria. In this way, ACCME is building upon a system that is in place and helps to support consistent approaches in managing personal conflict of interest.</p>	
<p>I am troubled by this proposal which would divide the world into promotional and CME speakers. Many physicians have effectively functioned in both arenas. I believe that both speakers and those who attend lectures understand the difference between promotional and CME presentations. While promotional talks may be narrower in content, virtually everyone I know is careful not to act as a shill for the sponsoring company. Those who also give CME programs are committed to presenting unbiased information. In the past few years, CME vendors have been extremely careful to maintain independence from sponsors. This is even more the case for commercial vendors compared to academic institutions. How would such a ban be enforced? How long would a speaker be prohibited from giving a CME talk following a promotional presentation? What would be the affect on the annual scientific meetings on national specialty societies? Will physicians in rural areas areas be able to obtain needed CME hours if the pool of potential speakers is severely limited?</p>	<p>Non-Accredited CME provider</p>
<p>The policy as stated will be to restrictive and prevent the working relationships that have developed between pharma and the academic community. If these were in place, the dramatic developments responsible for the new treatment paradigm for advanced renal cancer would have been prevented. Financial conflicts should be avoided, but the approach suggested in this document will serve only the ACCME providers, not the academic community, pharma, & most importantly the not our patients.</p>	<p>Other</p>
<p>Dear Sirs, Your intentions are honorable but I think finally you are going too far. Do you really think that this will improve CMEs? The goal should be to improve CME activities. I don't see that the new proposal will accomplish this? CME is already independent. Quite to the contrary it will separate many experts from the frontier of medicine; which often is related to new medications/ breakthrough findings. If you really believe that everything can be 100% neutral you are wrong. It remains in the eye of the beholder. I am involved in training medical students, residents and faculty. Part of this training involves using appropriate evidence based principles and statistics. They get training in how to respond to "drug reps" as well as any information that is given to them. Even our peer reviewed journal studies are in the eye of the beholder and need appropriate interpretation. This will never change no matter what you will finally do! The present system appears appropriate and clearly differentiates CME from direct drug sponsored events. I give both CME lectures and drug company sponsored event lectures. I certainly am using evidence medicine principles/ appropriate statistics and evaluate and make up my own mind. If their material is misleading I will not use it and refuse to speak. The topics that I talk about are usually the areas that I am considered an expert. I create CME lectures and others. They all are very much based on the above principles. To give you an example of how seriously I take these issues: I was one of the first physicians in the area of recommending to stop using [REDACTED] 8 month before it was pulled of the market/given the available data. I brought this message to lay people as well as physicians by way of CME lectures and drug sponsored events. In fact I was discouraging the use of all [REDACTED] at these CME and drug sponsored events before our FDA got their act together. At this time all lectures given for CME are evaluated concerning any speaker bias by the committees/and the listeners. You wouldn't be invited back to any events and nobody would listen to you any further. Let me tell you the majority of doctors can smell bias a mile away! Let me tell you these are very bright people! Another issue is that of professional freedom. How is it that you could even propose such an artificial separation? I feel my right of free speech and professional freedom is being curtailed undue. Did you check if this proposed change is even legal? My suggestion is to leave it as is. Particular now as the incomes of doctors relating to drug companies will be made public. I guess any MD that receives a lot of money may be looked at as biased? I think the appropriate safety measures have already been taken. Sincerely, [REDACTED]</p>	<p>Other</p>

<p>This proposed policy would disqualify an individual who has presented promotional materials on behalf of a commercial interest from serving as a faculty member, planner, or author for a CME activity, even if the provider limited that individual's control of the content to an area, such as pathophysiology, where the possibility of introduction of commercial bias might be minimal. We believe this policy would result in the elimination of many qualified individuals from participation in the planning of CME activities. ■ encourages ACCME to instead provide further guidance and direction to providers on its expectations regarding resolution of conflicts of interest. ACCME may also wish to recommend that providers develop their own definitions of irresolvable conflicts of interest, which would specify the conditions under which the provider would disqualify a prospective faculty member or planner.</p>	
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