



September 11, 2008

Accreditation Council for Continuing Medical Education
515 N. State Street, Suite 1801
Chicago, IL 60654

Dear Dr. Kopelow,

In response to both of the recent requests for comments, Pfizer is pleased to provide the following commentary.

June 2008 Policy Announcement and Request for Comments

Issue 1:

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

Response:

If the intent of ACCME's proposal is that no form of communication will be allowed by commercial supporters that identifies where funding may be available, then we disagree with this proposal. We do, however; support any policy revisions intended to ensure specific content is not communicated or controlled by commercial interests either directly or by proxy.

It is appropriate for commercial interests to clearly communicate areas of available funding in order to benefit providers' search for a balance of available funding support resources. If efficient mechanisms are not available for providers, a great deal of operational efficiency is lost by both the provider and commercial supporter community. In addition, providers are much

more likely to become overly dependent on fewer sources of commercial support funding if these efficient transparent mechanisms are not encouraged.

A lack of transparency also contributes to a culture where “business development” models of engaging industry gain a strong advantage over “educational support” models of communication. Any policy that discourages transparency will have the unintended adverse consequence of encouraging practices that are more highly dependent on personal interactions between provider business development personnel and commercial supporters. These business development practices, which may employ financial incentive systems that potentially overshadow patient health concerns, pose a much greater risk to content validity and issues around independence than transparent communications. Finally, it remains important to honor provider independence by recognizing they have a choice about whether to pursue funding, and to optimize their ability to seek balanced funding for programs.

There is a spectrum of risk in terms of what is being defined by terms like “topic”, and a great deal of heterogeneity around the use of this term. The spectrum as we define it is outlined in the table below. Ultimately, what is appropriate should be defined by what is in the best interests of patients. The table is intended to be a general guide where the accurate decision can only be determined by the patient-centric facts and circumstances of the situation. In general we view the first three levels as consistent with ACCME standards and therefore appropriate in descending order of preference while those that follow are almost universally inappropriate.

Funding Area Statement Type	Example	Risk of Content Control	Provider Benefit (Efficiency)	Comment
1. Performance gap based on publicly available measures	Patient non-adherence to treatment plan as measured by HA1c	Low	High	Program level communications where commercial interests identify evidence based gaps in healthcare performance around which mutual patient-centric interests might align represent the optimal balance

				between risk and efficiency. This does not focus on content at all but encourages providers to seek funding for PI CME initiatives much more efficiently. We believe that commercial supporters using this framework can most effectively function within the spirit of Standard 1 of the SCS.
2. Clinical area	Diabetes	Low	Moderate	Appropriate to efficiently communicate budget support areas for providers but still leaves them “guessing” about specific areas of diabetes support. This in turn wastes grant application resources.
3. General Topic	Current update on treatment options for diabetes	Moderate	High	Appropriate in most cases if they are not specific to a method of treatments, but can blur the line if not carefully delineated
4. Prescribed Topic	<i>Update on specific therapeutic option (compound specific) or an exclusive focus on a single content focused learning objective that is associated with a new drug launch (ex: mechanism of action)</i>	<i>High</i>	<i>High</i>	<i>Inappropriate in most cases when topics prescribe specific content in a manner that does not reflect what is new, true and/or important to patients or where there is not an opportunity for a broad fair balanced discussion of all available options</i>
5. Prescribed Content	<i>Anything specific from learning objectives to content elements</i>			<i>Unless externally mandated by government agencies to address public safety concerns, we can not envision a scenario where this would be appropriate</i>

<i>6. None Allowed</i>	<i>No information available</i>	<i>Low at the activity level, but potential for high at organizational COI level</i>	<i>Low</i>	<i>Undermines transparency and favors providers who expend greater resources to determine funding areas through business development rather than educational development practices.</i>

Issue 2:

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

Response:

This proposal raises two issues. The first is the *nature* of the commercial supporter’s criteria being referenced here. The second is the *transparency* of the actions of commercial supporters in this regard.

Certainly criteria established by commercial supporters that attempt to influence content in any way are inconsistent with the spirit of the Standards. Beyond these kinds of attempts to influence providers, we believe that commercial supporters can and should set out precepts that embody their philosophy about quality CME; Pfizer is currently doing this. We also think that full transparency is central to avoiding the traps that internal, opaque criteria can create. To that end, we support the principle of transparency wherever it can be practically implemented. In our view, commercial interests have internal criteria whether they are public or not. Without transparency, there is no opportunity to understand if the criteria are appropriate. In addition, today’s system creates an un-level playing field that disenfranchises many “duty of care” providers who simply do not have the administrative resources to understand the basics of such “black box” systems.

The lack of transparency is part of the culture that has contributed to the creation of a “business development” rather than “educational model” of interaction. It rewards those providers who invest in business development personnel who spend time developing relationships with commercial supporters. In our view, this approach has more universally succeeded in understanding what is in the “black box” of criteria in a manner that creates an unfair advantage for these providers. This in turn contributes to an issue we believe still remains at the core of the more serious conflict of interest issues currently facing the CME community where provider financial incentives can potentially overshadow public health concerns. We would suggest that providers should only be allowed to seek support from commercial supporters who are publicly transparent about their criteria for decision-making coupled with transparency about the decisions they have made.

With respect to the specific issue of Requests for Proposals or Calls for Grant Applications, we also feel this is an effective mechanism to more efficiently align resources with public health needs in a manner that is transparent. In an ideal future state, CGAs should not be necessary when there is a clear emergence of robust national needs and corresponding proposals, but that is not today’s reality. Prior to the use of CGAs, it was extraordinarily rare to receive a grant request for performance improvement CME. Almost universally, the only grants received have been “one and done” didactic lectures of limited benefit to patients. We do think CGAs need to be based on some very clear principles.

- Limited to defining the evidence based performance gap where funding is available. Anything beyond this infringes on provider independence with respect to all of the other areas of educational planning.
- Universally available to all providers. The prior selection of which providers will receive these creates its own set of potential bias issues.

We would also encourage ACCME consideration of endorsing acceptable independent review standards for CGA responses. The CGA mechanism modeled after NIH type RFP’s is an efficient vehicle to more clearly communicate the availability of resources and encourage performance improvement approaches. The only criticism we have heard of this practice has

been the perception that the recipients may be pre-determined. That could be handled by requiring that CGAs are sent out broadly. We would like to address that by transparently posting all responses in the future, but the provider community has not been universally supportive of that to date. Short of a future independent review mechanism, ACCME might consider this transparent disclosure a mandatory requirement for any provider responding to an RFP or CGA.

Under separate cover, we are sending examples of two Calls for Grant Applications along with all responses received.. One is for the area of smoking cessation and the other is for improving patient adherence to treatment plans. We hope you find them useful in your review.

Issue 3:

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

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

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

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

General Statement:

Fundamentally, we believe that using commercial support as a resource to improve performance around professional practice gaps, is clearly in the public's interest and we have enthusiastically aligned our processes and procedures behind those standards. This transformational approach to viewing industry support in the context of performance improvement initiatives holds great promise to more effectively manage current issues related to commercial support. We do not believe that either the status quo or the complete elimination of industry support is in the best interests of patients. If, however, the profession determines that commercial support does not contribute to patient care, then industry should respond with reallocating these funds to other areas as rapidly as possible.

Response to Specific Conditions:

Condition 1: We do not feel that needs assessments need to be free of commercial support. The issue is management of conflict of interest. There are limitations to an approach where all educational needs are identified and verified by organizations that do not receive commercial support and are free of financial relationships with industry. Needs assessments conducted by NGOs rarely address the multiple levels of data needed by the CME community in order to devise strategies for planned change. Most do little to address domains of learning that include the various attributes contributing to the learner's motivation.

Often, NGO type needs assessments may be based only on an epidemiologic view. They can also contribute to the lag in translating new evidence based research into practice if not conducted on a very timely basis. To this end, we feel that one of the more important contributions commercial support can make is to provide funding for needs assessments that are more tailored to the needs of the professional CME community. These kinds of assessments must span the horizon from traditional epidemiological data to barriers and facilitators of care. They need to take into account the availability of public domain resources that may be of help to CME planners. Realistically any nationally based needs assessment must be viewed as but one cell in a complex matrix of assessments that includes regional and local inquiries that align to form a framework for educational intervention design. A typical example of this may be statewide quality improvement initiatives where commercial support is sought.

We are attaching a Call For Grant applications in the area of adherence along with the responses we received to illustrate one such approach. We do believe that better mechanisms need to be found to avail the CME community of this type of support in order to avoid both real and perceived risks of bias. One option might be to include an external independent review board; another is to solicit an existing organization like SACME to take on this role. To that end, we would enthusiastically endorse any approach that could set up an independent review mechanism for aligning commercial support resources with the development of needs assessments.

A foundational principle to industry support of needs assessment work is that the same standards applied to clinical research should apply here. For example, it should be mandated “a priori” that any needs assessments funded in this manner are to be part of the public domain. Anything less is unacceptable and represents a clear risk to introduce bias into the provision of needs assessment data.

Condition 2: Completely concur with number 2 where those measures exist. In areas where they do not exist, the principle remains the same that commercial support should be restricted to areas that can improve professional competence.

Condition 3: We agree that CME content is ideally established from a continuing education curriculum established by a bona fide organization. The major potential gap in the above approach relates to the clarity of defining what level of curriculum is being referred to. If the level is defined too low in the structural hierarchy, then delays in incorporating new science into formal curricula could result. As long the level of detail being referred to in the curricula relates to objectives found higher in the hierarchy that define professional practice gaps, then this approach would not erect barriers to translating new science into practice. If however, the understanding was that the curriculum was explicit in all of its content without regard to the latest evidence, then the subsequent delays of incorporating new science into education would not be in the public interest.

We also take a broader view of the CME content development process. We believe the content element goes well beyond the construct of a curriculum. We envision that content development

takes into account all the elements referred to in the competencies of the ACGME for instance. In addition, practice will be influenced by external expectations of governmental bodies and others considered stakeholders in the quality of healthcare. In our view of this element great care should be taken to be inclusive of both multiple stakeholders and multiple sources of information so that the most robust and dynamic product emerges. .

Condition 4: It is important that all CME is managed for conflict of interest. If supplemental mechanisms can be developed like the ones proposed, it would have the additional benefit of streamlining grant review, where monitoring for COI has been a necessary and major focus. The elements that need to be incorporated into such a mechanism need to move beyond the process - driven current system: one in which the activity files may be entirely in order-- yet the risk for real bias existed within the actual framework of planning. From a commercial supporter perspective, we have experienced what we considered bias from providers whose paperwork was apparently exemplary. Therefore, an important element of any new system that may emerge is to ensure that commercial support does not go to organizations that have a CME structure that potentially puts financial considerations ahead of public health concerns.

Additional issues:

In addition to the issues outlined by ACCME, balanced funding is an important principle for the profession and the public. We believe that balanced funding is a strong surrogate for proposals to pool funds. Further we assert that additional mechanisms are needed to ensure appropriate utilization of commercial support both at the organizational and activity level. It is our view that support from any one commercial entity should not exceed 50% for a major activity (non-RSS) and that any organization that relies on too high a percentage of commercial support for its overall activities should also not be eligible to receive this support. In addition, we believe that commercial support should increasingly be understood as inappropriate for supporting non-educational expenses that are not directly beneficial to learning. Today, no standards exist upon which we can develop informed policies for balanced funding requirements.

August 2008 Additional Request for Comments

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

Yes. We currently expect firewall provisions to include this separation, but it is hard to evaluate and monitor from a commercial supporter perspective.

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

Our definition of promotional activities is all of those where faculty involvement is governed under FDA regulatory requirements and therefore directly controlled by commercial interests. We believe this is a discussion where views will continue to evolve over time on the basis of additional experience and discussion, and that ultimately it is a question for the medical profession to decide. We do feel that the confusion between independent continuing medical education and FDA regulated promotional programs has been a large contributor to the continuing confusion and subsequent criticism of industry's role in support of CME. We offer the following three suggestions that if implemented soon would largely ameliorate the concerns being addressed while the larger debate around this issue continues within the medical profession:

- 1) Minimally, strengthen disclosure requirements by requiring more specificity with respect to participation in promotional programs. While current disclosure requirements help the learner understand the general nature of potential conflicts of interest, they do not currently illuminate the issue of greatest concern relative to ensuring that the learner realizes the faculty may have given a promotional talk on a related topic within the same trip as the current activity is occurring. More specific disclosure of these elements would add clarity to the confusion between education and promotion and more fully inform the learner of potential bias issues.

- 2) Institute a mandatory separation in time and place between promotional programs and independent activity involvement. The most frequent example of a practice we would encourage ending occurs where a promotional speaker gives the same content area talk in the context of independent education within the same geographic area on the same trip. Even when commercial supporters have policies prohibiting this, faculty continue to occasionally encourage it through their own direct contact with providers. Many providers find this acceptable because they save on travel expenses. We think it contributes to the confusion between independent education and promotion.

- 3) Recognize educational efforts as exemplary conflict of interest management practices for elements related to this standard. Continuing professional development efforts for faculty who participate in both independent education and company sponsored speaker's bureaus in order to insure they demonstrate a competent understanding of the difference offer enormous potential to manage this issue more effectively. For example, the effort that will be launched by the Alliance for Continuing Medical Education and the Society for Academic CME later in 2008 to address this gap in CME practice may serve as a useful mechanism for providers to manage this potential conflict of interest.

Finally, we would like to express our appreciation for your proactively encouraging responses from all stakeholders to include commercial supporters.

Respectfully,

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