United States Senate
COMMITTEE ON FINANCE
WASHINGTON, DC 20510–6200

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Via Electronic Transmission

Murray Kopelow, MD, MSC, FRCPC
Chief Executive
Accreditation Council for Continuing Medical Education
Suite 2150
515 North State Street
Chicago, IL 60610-4377

Dear Dr. Kopelow:

Thank you for your informative response to our letter of December 14, 2006. The insight you provided on the accreditation process for continuing medical education (CME) helped us in our exploration of the pharmaceutical industry's use of educational grant funding. Given the increasing Medicare and Medicaid expenditures on prescription drugs, the United States Senate Committee on Finance (Committee) has an interest in reviewing how pharmaceutical manufacturers use grant funding in ways that may increase program costs or endanger beneficiaries. On April 25, 2007, we released a Committee Staff Report summarizing the results of our inquiry, and provided you a copy. The full text of this report is available on the Committee's website at http://www.senate.gov/~finance/press/Bpress/2007press/prb042507a.pdf.

Our inquiry revealed that the pharmaceutical industry spends more than a billion dollars a year to fund CME programs that are accredited by the Accreditation Council for Continuing Medical Education (ACCME). Funding of ACCME-accredited programs represents a substantial portion of drug company spending on educational grants. Our inquiry also revealed that drug companies typically fund CME as part of a broader business strategy to support the company's brands. Many of the drug companies informed us that they rely on a provider's ACCME-accreditation to demonstrate that their grant money is spent on education and not on marketing. In keeping with ACCME's policies, ACCME-accredited CME should differ from the drug company's own marketing and promotional activities in that the drug company should not exercise control over the content of CME. Our letter to ACCME sought information about how ACCME ensures that the CME providers it accredits actually operate with the required level of independence, and without allowing program content to be controlled or influenced by the drug company sponsors.

Your response helped us understand the process by which ACCME oversees the activities of CME providers. You reported that ACCME reviews accredited CME providers at intervals of two, four, or six years, depending on the CME provider's past history of compliance. In conducting these re-accreditation reviews, ACCME primarily relies on three sources of information: (1) self study reports – written by the CME

provider and submitted to ACCME; (2) accreditation interviews – conducted by two individuals from ACCME involving an interview of representative(s) of the CME provider; and (3) sampling of CME activities – ACCME selects a sample of the CME provider's CME activities (usually 15 activities per provider) and asks the CME provider to submit a documentary file on each activity. ACCME then reviews the documents submitted to look for policies and procedures indicating that the CME provider complied with ACCME policies.

Based on your response, it appears that ACCME review of CME providers relies exclusively on information supplied by those providers. ACCME review also appears to focus on the documentation surrounding the process for funding and creating CME activities, as opposed to the substance of the activities themselves. For example, it does not appear that ACCME review involves analyzing the content of the educational activities created for accuracy, to determine whether the activities include a fair and balanced discussion of competing therapeutic options, or whether the activities favor products manufactured by the commercial sponsor.

We understand that CME activities typically involve in-person lectures, broadcasted lectures, web-based content, self-assessment questions, and various other types of written materials. In addition to the scripted material, CME programs may involve answering questions from the audience. ACCME representatives conducting re-accreditation reviews do not sit in on CME lectures, or review recordings of these lectures, to assess the speakers' core presentations or their responses to audience questions. Similarly, ACCME representatives conducting re-accreditation reviews do not routinely assess the written materials used in CME activities for scientific accuracy or balance.

Based on your response, it appears that ACCME conducts a retrospective review that relies on information supplied by the CME providers, and does not involve independent investigation by ACCME staff or collection of information from physicians or other audience members who participated in CME activities. Given the nature of ACCME review, it does not appear that ACCME would detect CME providers' voluntarily catering to their drug company sponsors by developing CME content that favorably presents the sponsors' drug products, nor would this practice necessarily violate ACCME policy. Although we suspect that the drug companies preferentially fund CME activities that they expect will promote sales of the company's products, we do not know how pervasive this is. ACCME does not collect data on whether ACCME-accredited CME providers produce activities that disproportionately discuss favorable messages, either on-label or off-label, for products marketed by the drug companies that fund the activities.

ACCME uses the re-accreditation review process to determine whether the CME provider should retain accreditation. Your response indicates that ACCME conducts this review to determine whether or not a CME provider generally complies with ACCME standards, as opposed to whether an individual CME activity was conducted in compliance with ACCME standards. Your letter described the re-accreditation process as follows: "ACCME compliance findings are determined at a provider level, not the activity (or presentation) level. Generally speaking, when the ACCME finds that 80% of

activities are found 'in compliance' from documentation review, then the ACCME will find the provider 'in compliance' with the accreditation element." The Committee found this troubling, to the extent it means that a CME provider would be deemed to be in compliance with ACCME standards even if ACCME determines that some of the provider's educational activities failed to comply with all ACCME standards.

Your response included results of re-accreditation reviews recently completed by ACCME. You reported that ACCME has reviewed 76 accredited CME providers for compliance with the ACCME standards for commercial support that were promulgated in 2004. ACCME found that 18 of these CME providers were not in compliance with at least one element of the ACCME standards. Examples from ACCME's written findings of non-compliance include:

- "The provider does not ensure that decisions regarding the planning and implementation of CME activities are made independent of commercial interests. A commercial interest influenced where and how many presentations were scheduled for three years of a CME activity."

- "The provider does not ensure that decisions regarding the planning and implementation of CME activities are made independent of commercial interests. Evidence from one activity reviewed indicates that a commercial interest was involved in the selection of faculty and other activities that interfered with independence."

- "The provider does not ensure that a mechanism(s) has been implemented to identify and resolve all conflicts of interest prior to education activities being delivered to the learner."

- "The provider does not demonstrate appropriate management of commercial promotion associated with educational activities. One commercially supported activity contains recurring use of one company's product trade name at the exclusion of other products."

Your response also described the series of events that may occur if ACCME determines that a CME provider is not in compliance with ACCME standards. To summarize, the CME provider enters a multi-year corrective action process that might eventually result in losing accreditation. You informed us that when ACCME finds that an accredited CME provider is not in compliance, the CME provider is afforded an opportunity to provide ACCME with a written submission that describes the provider's compliance. The CME provider is generally allowed one year to submit this progress report to ACCME. If ACCME decides that the progress report adequately demonstrates compliance, no further action is taken. If ACCME decides that the progress report does not adequately demonstrate compliance, then the provider may be allowed six additional months to submit another progress report. If that second progress report also does not demonstrate compliance, ACCME may put the provider on probation. If the CME provider does not resolve the problem after two years on probation, ACCME may rescind accreditation. ACCME's finding of non-compliance is merely the first step down a long road to

potentially losing accreditation, which may occur up to 3.5 years after the initial finding of non-compliance and, depending on the review cycle, as many as nine years after the problematic educational activities occurred.

The Committee's inquiry suggested that whether an educational program is independent is a critical feature distinguishing CME from advertising and promotion. Because drug manufacturers cannot legally promote their products for uses that have not been approved by the FDA, it is particularly important for education programs that discuss off-label uses to be independent. Whether a drug company is breaking the law by promoting off-label use of its drugs hinges on whether a CME provider independently touts an off-label use or whether the promotion can be attributed back to the drug company.

Given the importance of the concept of independence, the Committee's request for information from ACCME also sought delineation of the scope of independence the CME provider must have in selecting the topic for a commercially-sponsored CME program. ACCME's response indicated that a commercial sponsor can designate the topic (e.g., diagnosis or treatment of a particular disease) for the CME activity, without being determined to control content or otherwise violating ACCME policies. This would appear to afford drug companies substantial opportunity to direct their grant funding to support programs that are likely to promote sales of their products.

We do not have information about the extent to which this is the case in practice. ACCME does not keep track of how many CME programs favorably discuss a drug sold by the commercial sponsor, either for an FDA-approved indication or for an off-label use. ACCME does not gather information regarding whether the CME providers' educational activities favorably discuss uses of the commercial sponsor's products in a fashion that is disproportionate to what might be expected from an independent activity that does not cater to the sponsor's commercial interests.

Our review suggests that CME providers could say that they "control content" and have "full independence" in developing CME activities, even though they allow the commercial sponsor to influence content. The drug companies' response to our queries indicate that some companies' policies for funding CME allow the drug companies to offer CME providers suggestions for CME topics and speakers. Some policies also allow the drug companies to provide data, including data regarding off-label uses, for inclusion in CME programs, so long as the CME provider requests this assistance. Thus, the CME provider can technically maintain "control" of content – to the extent that the commercial sponsor's suggestions are not imposed in an explicitly mandatory fashion – while continuing to accommodate suggestions from the companies that control their funding.

Based on our analysis of the information you provided, we find it interesting that, even though ACCME's reaccreditation process relies almost exclusively on information supplied by the CME providers under review, ACCME still detects a significant number of incidences of noncompliance. It also appears that compliance with ACCME standards still allows CME providers to accommodate the business interests of their commercial sponsors and affords drug companies the ability to target their grant funding at programs likely to support sales of their products. The full extent to which drug companies

influence the content of putatively independent CME programs cannot be estimated from the information we currently have.

Thank you for your assistance with this matter. We greatly appreciate your cooperation with the Committee's inquiry.

Sincerely,

Max Baucus
Chairman

Charles E. Grassley
Ranking Member