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

December 19, 2006

Via Electronic Transmission
Via Facsimile: (312) 755-7496

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

Dear Dr. Kopelow:

The U.S. Senate Committee (Committee) on Finance has jurisdiction over the Medicare and Medicaid programs, and accordingly, a responsibility to oversee the proper administration of those programs which provide health care coverage to more than 80 million Americans. The Committee continues to review issues relating to these programs' coverage of prescription drug benefits, including marketing practices that influence physicians' prescribing patterns. As Chairman and Ranking Member of the Committee, we ask that the Accreditation Council for Continuing Medical Education (ACCME) cooperate with the Committee and provide information regarding these matters as requested.

In recent years, the cost to Medicaid of reimbursement for prescription drugs has grown faster than any other area of the program. This year, the Federal government's total spending on prescription drugs has increased dramatically with the expansion of the Medicare program to include an outpatient prescription drug benefit. Marketing practices work to increase the rates at which drugs are prescribed to program beneficiaries. This is problematic when the marketing encourages overutilization or drives the use of newer, more expensive drugs, even though they have not been proven clinically superior to less costly alternatives. Marketing practices that increase the rates at which drugs are prescribed for off-label uses raise additional concerns. Besides increasing program costs, such practices may endanger beneficiaries by encouraging physicians to prescribe drugs that have not been proven safe and effective to treat the beneficiary's medical condition.

For good reason, pharmaceutical manufacturers are prohibited from marketing or promoting their products for off-label uses. This prohibition on off-label promotion limits the manufacturers' activities, but does not extend to other parties, such as continuing medical education (CME) providers, if they operate independently from the manufacturer. A substantial potential for abuse arises when pharmaceutical

manufacturers use CME providers to deliver promotional messages that the law prohibits the companies from making directly. Even where educational activities relate to labeled indications for the sponsor's drugs, such that the manufacturer could legally deliver the message directly in the form of advertising, there is a significant risk of misleading physicians if manufacturers co-opt CME providers to deliver the message for them, as physicians may attribute greater weight to information that they learn from an entity that they view as an independent source.

We understand that ACCME is responsible for accrediting CME providers. The ACCME imprimatur identifies an activity as educational, as opposed to promotional, and thus, lends credibility. Also, ACCME accreditation largely determines whether a physician's participation in a particular activity will qualify as continuing medical education to satisfy professional licensure requirements. As such, the potential physician audience is greatly increased for activities offered by CME providers that have ACCME accreditation.

ACCME data suggest that provision of CME has become a $2 billion a year industry, about half of which is funded by commercial interests, such as manufacturers of pharmaceuticals, biologics, and medical devices. Given this level of industry funding, it is important to ensure that the commercial interests do not drive the messages that are delivered to health care professionals through CME. We know that ACCME has promulgated policies that allow accredited CME providers to accept industry funding to sponsor educational activities, but require the activities to be independent. Specifically, ACCME's "Standards for Commercial Support: Standards to Ensure the Independence of CME Activities" require CME providers to ensure that the following decisions are made free from the control of the commercial interest: (1) identification of CME needs; (2) determination of educational objectives; (3) selection and presentation of content; (4) selection of all persons and organizations that will be in a position to control the content of the CME; (5) selection of educational methods; and (6) evaluation of the activity." ACCME policies further require that "Presentations must give a balanced view of therapeutic options."

We appreciate that ACCME, in its role as the accrediting body for CME providers, requires these indicia of independence. We are interested in learning how ACCME ensures that CME providers actually satisfy these goals in practice, as well as any incidences of failure to comply with the standards that ACCME has uncovered. As Chairman and Ranking Member of the Committee, we request that ACCME provide the following information:

1. How does ACCME ensure that CME providers make the following decisions free from the control of the commercial interest:
    (a) Identification of CME needs,
    (b) Determination of educational objectives,
    (c) Selection and presentation of content,
    (d) Selection of all persons and organizations that will be in a position to control the content of the CME,
    (e) Selection of educational methods, and
    (f) Evaluation of the activity.

2. What actions does ACCME take to verify the accuracy of CME providers' self-reported or self-certified assurances of compliance with the above?

3. What does ACCME mean by selection of content? Please define the scope of content that should be within the control of the CME provider and free from commercial interest. For example, would specifying a disease state as a topic for CME constitute selecting content? Would specifying a program about improving diagnosis for a particular disease state constitute selection of content? Would specifying a program about pharmacologic treatment options for a particular disease state constitute selection of content?

4. How does ACCME ensure that CME presentations give a balanced view of therapeutic options?

5. During the years 2004, 2005, and 2006, did ACCME determine that any presentations that were included in accredited CME activities failed to give a balanced view of therapeutic options? If so, please describe the circumstances, as well as how the information was brought to light.

6. During the years 2004, 2005, and 2006, what was the number or percentage of industry-funded CME activities that discussed a disease or condition for which the commercial sponsor manufactured an approved therapy?

7. During the years 2004, 2005, and 2006, what was the number or percentage of industry-funded CME activities that discussed a disease or condition for which the sponsor had a product in development for which it was seeking FDA approval to treat the disease or condition?

8. During the years 2004, 2005, and 2006, what was the number or percentage of industry-funded CME activities that discussed an off-label use of the sponsor's drug?

9. What is ACCME's process for gathering reports of potential or suspected failure to comply with the Standards for Commercial Support?

10. What reports has ACCME received of potential or suspected failure to comply with the Standards for Commercial Support?

11. During the years 2004, 2005, and 2006, how many accredited CME providers has ACCME investigated for potential failure to comply with the Standards for Commercial Support?

12. Since the adoption of the Standards for Commercial Support in 2004, has ACCME determined that any CME providers failed to comply with the Standards for Commercial Support? Please provide details regarding any findings of failure to comply.

Thank you for your prompt attention to this matter. We would appreciate answers to the above questions no later than January 4, 2007. In complying with this request, respond by repeating the enumerated question, followed by the accompanying response. Should you have any questions regarding this matter, please contact our Committee staff, Dan Donovan or Julie Taitsman (majority) at (202) 224-4515 or David Schwartz (minority) at (202) 224-5315. All formal correspondence should be sent electronically in PDF searchable format to thomas_novelli@finance-rep.senate.gov.

Sincerely,

Charles E. Grassley
Chairman

Max Baucus
Ranking Democratic Member