United States Senate

Committee on Finance

Washington, D.C. 20510

For Immediate Release
Tuesday, May 1, 2007

Baucus, Grassley continue work for independence of continuing medical education

WASHINGTON — Sens. Max Baucus and Chuck Grassley are continuing their effort to diminish the influence of drug companies on medical education programs.

In a letter sent to the Accreditation Council for Continuing Medical Education, the senators urged greater oversight by the council to better ensure that the content of continuing education programs is independent from the business interests of the drug companies who fund the programs. Their letter follows an extensive report issued by the senators last week.

The Finance Committee report was two years in the making and addresses the pharmaceutical industry's use of educational grant funding to promote the use of their drugs, including unapproved uses of some medicines. Earlier today, Eli Lilly and Company announced that it will begin posting online all educational grant funding that it provides. Lilly is the first pharmaceutical company to disclose its grants to medical societies, academic centers, patient groups, commercial continuing medical education providers, and non-profit institutions in the United States. Baucus and Grassley said they hoped that other drug companies would take similar action.

Baucus is Chairman and Grassley is Ranking Member of the Senate Committee on Finance.

The text of their April 25, 2007 letter to the Accreditation Council for Continuing Medical Education is below, along with the text of news releases describing the April 23, 2007 Finance Committee report on medical education grants and the initial Grassley-Baucus June 10, 2005 letter of inquiry to drug makers which ultimately resulted in the Finance Committee report.

April 25, 2007

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 of Montana
United States Senator
Chairman of the Committee on Finance

Chuck Grassley of Iowa
United States Senator
Ranking Member of the Committee on Finance

For Immediate Release
April 25, 2007

NEW FINANCE COMMITTEE REPORT FOCUSES
ON DRUG COMPANY GRANTS FOR MEDICAL EDUCATION
Inquiry reveals educational grants as common business practice, but potential for abuse remains

Washington, DC – Senate Finance Committee Chairman Max Baucus (D-Mont.) and Ranking Republican Chuck Grassley (R-Iowa) today released results of a Committee inquiry into drug company grants to fund continuing education for medical providers. Baucus and Grassley launched their probe following allegations that drug companies were using educational grants for improper purposes, such as rewarding physicians for prescribing their drugs, influencing clinical practice guidelines and Medicaid formularies, or promoting drugs for uses that have not been approved by the FDA – an illegal practice called "off-label promotion." Guidance on keeping education programs independent of drug company influence has been issued by numerous organizations, including the Accreditation Council for Continuing Medical Education (ACCME). The report includes information from ACCME suggesting that some purportedly independent educational programs may still be influenced too much by their pharmaceutical sponsors. It appears that ACCME's oversight of accredited CME providers is insufficient to guarantee the required independence.

"American taxpayers spend billions of dollars every year on drug treatments for Medicare and Medicaid patients, and those scarce dollars need to be spent wisely. Medical education funded by drug companies has to be real education, not a soft sell designed to sway treatment decisions," said Baucus. "This report shows some separation between medical education and marketing efforts, but this process still isn't clean enough. As long as drug companies' medical education efforts can influence Medicare and Medicaid spending, the Finance Committee has to insist that there be more improvement."

"We need to make sure educational grants serve appropriate purposes. I take seriously my obligation to the taxpayers to make sure dollars for Medicare and Medicaid are spent properly. I also take seriously my obligation to help make sure the 80 million beneficiaries of these programs receive appropriate care. What drugs doctors prescribe for patients, and what drugs federal health care dollars buy, should be made based on accurate scientific information and what is best for that particular patient, not on improper influence from any drug maker," Grassley said.

The full Finance Committee report is online at http://www.finance.senate.gov/press/Bpress/2007press/prb042507a.pdf . The Committee contacted 23 drug manufacturers in the course of their investigation, and all 23 cooperated fully. Drug companies reported that they continue to fund educational grants as part of a broad business strategy to sell their products, but that they have set policies to distance educational grant funding from marketing. Committee staff concluded that the pharmaceutical industry has focused more on compliance with guidance for educational grants, but risks still exist for kickbacks, veiled advertising of drugs, efforts to bias clinical protocols, and off-label promotion.

Baucus and Grassley said today that the Committee will follow up on its findings with participating drug companies and with organizations that have issued guidelines for medical education grants, including the FDA, the Inspector General at the Department of Health and

Human Services, the participating drug companies, and ACCME.

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For Immediate Release
Friday, June 10, 2005

Drug companies asked for more information
about grant money awarded to promote particular medicines

WASHINGTON — Sens. Chuck Grassley and Max Baucus have asked a number of large drug makers to explain a marketing practice where the companies give money to state governments and other organizations in the form of grants. The drug companies call the awards "educational grants," but the senators are concerned that the dollars are more focused on product promotion than education.

The senators said they want to know more about the practice to ensure that it's not just a "backdoor way to funnel money to doctors and other individuals who can influence prescribing and purchasing of particular prescription medicines, including off-label prescriptions." They said their inquiry of the drug manufacturers is based on reports that some companies have awarded these grants to health care providers as inducements to those providers to prescribe medications the companies produce. In other cases, such grants to state agencies may have prompted those agencies to develop programs leading to over-medication of patients at the expense of patient health or to unnecessary expense for taxpayers.

"We need to know how this behind-the-scenes funneling of money is influencing decision makers," Grassley said. "The decisions result in the government spending billions of dollars on drugs. The tactics look aggressive, and the response on behalf of the public needs to be just as vigorous."

"I support drug companies giving back to the community through grants for educational programs used to educate state governments and health organizations about products that could lead to improved health," Baucus said. "However, I am concerned that some grants may be for purposes other than education. These grants need to be driven by good intentions instead of motivation for larger profits."

Grassley is chairman and Baucus is ranking member of the Senate Committee on Finance, which has legislative and oversight responsibility for the Medicare and Medicaid programs. The first-ever prescription drug program within Medicare will begin in January, and federal expenditures on prescription drugs through both Medicare and Medicaid are estimated to reach $100 billion in 2006.

The text of their letter follows here. It was sent to the following drug manufacturers: Pfizer, Inc., GlaxoSmithKline, Johnson & Johnson, Merck & Co., Inc., AstraZeneca Pharmaceuticals LP, Bristol-Myers Squibb Company, Novartis Pharmaceuticals Corporation,

Amgen, Inc., Wyeth Pharmaceuticals, Eli Lilly & Company, Sanofi Aventis, Eisai, Inc., Boehringer Ingelheim Pharmaceuticals, Inc., Schering-Plough Corporation, Hoffman-LaRoche, Inc., Forest Pharmaceuticals, Inc., Abbott Laboratories, Genentech, Inc., Biogen Idec Inc., Genzyme Corporation, Chiron Corporation, Serono, Inc., and TAP Pharmaceutical Products, Inc.

June 9, 2005

Dear _____:

The U.S. Senate Committee on Finance (Committee) 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. During this legislative session, the Committee will continue its review of issues relating to these programs' coverage of prescription drug benefits, including marketing practices that could have an impact on physicians' prescribing patterns. As Chairman and Ranking Member of the Committee, we ask that _____ cooperate with the Committee and provide it with 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. The Federal government will spend even more on prescription drugs with the addition of a prescription drug benefit to the Medicare program. Marketing practices that increase the rates at which drugs are prescribed, particularly for off-label uses, are of concern because they have the potential to increase program costs and may encourage the use of typically newer, more expensive drugs that have not been proven superior to existing treatments.

The Committee has identified the use of grants, particularly educational grants, as a practice with potential for abuse and has gathered the following background information on this topic. The use of educational grants was an element in a recent settlement involving off-label promotion of a prescription drug. Also, educational grants were identified by the Department of Health and Human Services Office of Inspector General (HHS OIG) as a key risk area in its OIG Compliance Program Guidance for Pharmaceutical Manufacturers (OIG Guidance), issued in 2003. In addition, existing Federal and industry guidance is not specific about what activities educational grants may be used to support or what kinds of organizations may provide those activities, and it appears that some manufacturers may be using educational grants to fund activities primarily to promote their products.

Programs and materials performed and disseminated by drug companies are subject to the labeling and advertising provisions of the Federal Food, Drug, and Cosmetic Act, and as such are subject to regulation by the Food and Drug Administration (FDA). The FDA does not regulate truly independent and non-promotional activities supported by industry. However, the line between activities performed by or on behalf of companies and activities that are independent of their influence has become increasingly blurred as the role of industry in supporting continuing education for healthcare professionals has grown. Consequently, in 1997, FDA issued Guidance for Industry, Industry-Supported Scientific and Educational Activities. The FDA guidance lists 12 factors the Agency will consider when evaluating activities and determining independence.

These factors relate primarily to the independence of the provider of scientific and educational activities but do not explain how the Agency will determine whether an activity is educational or who qualifies as a provider.

The OIG Guidance, likewise, does not define educational activity or provider but it does state that support for educational activities sponsored and organized by professional organizations raise little risk as long as the grant is not restricted with respect to content or faculty. The OIG Guidance also advises manufacturers to separate their grant-making functions from their sales and marketing functions and establish objective criteria for awarding grants that ensure that the funded activities are bona fide.

The Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals (PhRMA Code) also addresses third-party educational conferences and professional meetings. The PhRMA Code states that support for a conference or meeting, defined as an activity "where a) the gathering is primarily dedicated to promoting objective scientific and educational activities and discourse (one or more educational presentations should be the highlight of the gathering), and b) the main incentive for bringing attendees together is to further their knowledge on the topic(s) being presented," is permissible. However, the PhRMA Code states that such support should not be given directly to healthcare professionals but should be given to a conference's sponsor, who should maintain control over the selection of content, faculty, educational methods, materials and venue.

The Committee seeks further information on this topic so that it can assess how educational grants are used, in what contexts and for what purposes, and who receives them. This will assist us in determining whether and to what extent educational grants are used to support activities that are not sponsored or organized by professional organizations or do not involve formal educational presentations, and whether further guidance or legislation is needed. Therefore, as Chairman and Ranking Member of the Committee, we request that your company provide the following information and data to the committee:

1. Identify the person(s) and/or agent(s) (including, name, title and contact information) within or affiliated with your company who is/are currently responsible for evaluating requests for educational grants.

2. Identify the person(s) and/or agent(s) (including, name, title and contact information) within or affiliated with your company who is/are currently responsible for approving or awarding educational grants.

3. State whether your company has a formal, written policy regarding the use of educational grants, or if your company relies on an unwritten policy. To the extent a written policy exists, attach copies, including all versions and revisions of the policy since its inception. To the extent an unwritten policy exists, describe it in detail, including but not limited to describing any criteria used in evaluating, approving, awarding, authorizing, implementing and/or monitoring educational grants.

4. Describe the factors and circumstances your company takes into account when

determining whether or not to award an educational grant.

5. State whether your company has offered or provided educational grants to organizations that are not accredited by the Accreditation Council for Continuing Medical Education (ACCME) since January 1, 2000. If so, please describe what other types of organizations receive educational grants from your company and indicate whether they are accredited by an organization other than ACCME.

6. State whether your company has offered or awarded an educational or other grant to any state Medicaid agencies or other state agencies, or to one or more employee/agent of a state Medicaid agency or other state agency since January 1, 2000. If so, please describe your company's policy for making such grants and the factors and circumstances your company takes into account when determining whether to award an educational or other grant to a state agency or an employee/agent of a state agency. In addition, please describe your company's rationale for this practice.

7. Identify the total number and dollar amount of educational or other grants your company made to state agencies or state agency employees/agents during its fiscal years 2003 and 2004. Of those amounts, identify the total number and dollar amount of educational or other grants awarded and list them by state, by agency, and by agency employee/agent.

8. State whether your company has offered or awarded an educational or other grant(s) as a substitute or alternative for price concessions since January 1, 2000. If so, please describe your company's policy for making such grants and the factors and circumstances your company takes into account when determining whether to award an educational or other grant as a substitute for a price concession. In addition, please describe your company's rationale for this practice.

9. Identify the total number and dollar amount of educational grants your company made in its fiscal years 2003 and 2004. Of those amounts, identify the total number and dollar amount of educational grants that were made to organizations accredited by ACCME.

10. In accordance with your company's response to #9 above, indicate the source of the funds for educational grants in your company's fiscal years 2003 and 2004. For example, if your company budgets for educational grants by product line, please indicate the dollar amount of educational grants funded by each product line.

11. State whether your company has an annual budget for educational grants. To the extent that your company budgets for educational grants, please identify the dollar amount budgeted for educational grants in fiscal year 2005 by funding source.

12. State whether your company has provided educational grants for programs or activities that may promote or discourage off-label use of drugs since January 1, 2000. If so, please describe your company's policy for making such grants and the factors and circumstances your company takes into account when determining whether to award an educational grant for an activity that may promote or discourage off-label use of drugs.

Please provide the information and documents requested in questions 1-12 by June 30, 2005. In complying with this request, respond by repeating the enumerated request, followed by the accompanying response; attach and identify all relevant documents or data by title and the number(s) of the enumerated request(s) to which they are responsive. Finally, in complying with this request, please refer to the attached definitions concerning the questions set forth in this letter.

Sincerely,

Chuck Grassley of Iowa
United States Senator
Chairman, Senate Committee on Finance

Max Baucus of Montana
United States Senator
Ranking Member, Senate Committee on Finance