United States Senate

# Committee on Finance

Washington, D.C. 20510

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