

United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510-6200

January 24, 2008

Via Electronic Transmission

James T. Dove, M.D., F.A.C.C.
President
American College of Cardiology
2400 N Street, NW
Washington, D.C. 20037

Dear Dr. Dove:

The United States Senate Committee on Finance (Committee) has jurisdiction over the Medicare and Medicaid programs and, accordingly, a responsibility to the more than 80 million Americans who receive health care coverage under these programs. As Ranking Member of the Committee, I have a duty to protect the health of Medicare and Medicaid beneficiaries and safeguard taxpayer dollars authorized by Congress for these programs.

For the last three years, the Committee has been investigating various aspects of the pharmaceutical industry, including consulting arrangements and industry funding for Continuing Medical Education (CME). My staff has also examined several issues related to non-profit organizations, and I have read newspaper accounts documenting the strong ties between the pharmaceutical industry and non-profit charities. I am hoping that you can provide me with some additional insight into these relationships.

Based upon reporting in the *New York Times*, I have come to understand that money from the pharmaceutical industry shapes the practices of non-profit organizations which purport to be independent in their viewpoints and actions.¹ Specifically, it is alleged that pharmaceutical companies give money to non-profits in an attempt to garner favor in ways that increase sales of their products.

Accordingly, I would appreciate an accounting of industry funding that pharmaceutical companies or foundations established by these companies have provided to the American College of Cardiology (ACC) and its foundation, the American College of Cardiology Foundation (Foundation). (The term "industry funding" means any transfer of value from a pharmaceutical company, including but not limited to grants, donations, and sponsorship for meetings or programs, etc.) This request covers the period of January 2003 to the present.

¹ *The New York Times* "Charities Tied to Doctors Get Drug Industry Gifts," June 28, 2006.

Because reporting practices vary widely from one charitable organization to another, I would appreciate you also placing this income into a chart, detailing annual amounts of industry funding from pharmaceutical companies. For each year, please provide the following information for both the ACC and the Foundation:

1. Year;
2. Name of company;
3. Amount of funding; and
4. Reason(s) that the funding was provided.

In addition, please explain the ACC's and the Foundation's policies for accepting industry funding by answering the following questions. For each question, please respond by first repeating the enumerated question followed by the appropriate answer.

1. Please describe the policies for accepting industry funding and whether or not the ACC and/or the Foundation allows companies to place restrictions or provide guidance on how funding will be spent.
2. If the ACC and/or the Foundation allow companies to place restrictions on industry funding, then please explain all restrictions and/or guidance for each transfer of value from a pharmaceutical company since January 2003. For every transfer of value with a restriction, please provide the following information: year of transfer, name of company, and restriction placed on funding.

Further, I have noticed that the ACC released a statement on the ENHANCE trial by Schering-Plough and Merck (the companies). While I do not disagree with the ACC statement, I am interested in whether or not the ACC also urged Schering-Plough and Merck to release the ENHANCE results when it was discovered that the companies were delaying the release. Accordingly, please name all individuals involved in drafting the ACC statement on the ENHANCE trial. Please provide all pertinent documents and communications, to include emails and early drafts of the statement.

In cooperating with the Committee's review, no documents, records, data or information related to these matters shall be destroyed, modified, removed or otherwise made inaccessible to the Committee.

I look forward to hearing from you by no later than February 8, 2008. All documents responsive to this request should be sent electronically in PDF format to Brian_Downey@finance-rep.senate.gov. If you have any questions, please do not hesitate to contact Angela Choy or Paul Thacker at (202) 224-4515.

Sincerely,



Charles E. Grassley
Ranking Member

GENERAL INSTRUCTIONS

1. The terms “American College of Cardiology” and “your company” mean its corporation, or one or more of its divisions, subsidiaries or affiliates, or related entities, including any other companies or corporations with which “American College of Cardiology” entered into a partnership, joint venture or any other business agreement or arrangement.
2. In complying with this document request, produce all responsive documents that are in your possession, custody, or control, whether held by you or your past or present agents, employees, and representatives acting on your behalf. In addition, produce documents that you have a legal right to obtain, documents that you have a right to copy or have access to, and documents that you have placed in the temporary possession, custody, or control of any third party.
3. No documents, records, data or information requested by the Committee shall be destroyed, modified, removed or otherwise made inaccessible to the Committee.
4. If the document request cannot be complied with in full, it shall be complied with to the extent possible, which shall include an explanation of why full compliance is not possible.
5. In complying with this document request, respond to each enumerated request by repeating the enumerated request and identifying the responsive document(s).
6. In the event that a document is withheld on the basis of privilege, provide the following information concerning any such document: (a) the privilege asserted; (b) the type of document; (c) the general subject matter; (d) the date, author and addressee; and (e) the relationship of the author and addressee to each other.
7. Each document produced shall be produced in a form that renders the document susceptible of copying.
8. It shall not be a basis for refusal to produce documents that any other person or entity also possesses non-identical or identical copies of the same document.
9. If any document responsive to this request was, but no longer is, in your possession, custody, or control, identify the document (stating its date, author, subject and recipients) and explain the circumstances by which the document ceased to be in your possession, or control.
10. This request is continuing in nature. Any document, record, compilation of data or information, not produced because it has not been located or discovered by the return date, shall be produced immediately upon location or discovery subsequent thereto.
11. All documents shall be Bates stamped sequentially and produced sequentially.

GENERAL DEFINITIONS

1. The term “document” means any written, recorded, or graphic matter of any nature whatsoever, regardless of how recorded, and whether original or copy, including, but not limited to the following: memoranda, reports, statistical or analytical reports, books, manuals, instructions, financial reports, working papers, records notes, letters, notices, confirmations, telegrams, receipts, appraisals, pamphlets, magazines, newspapers, prospectuses, interoffice and intra office communications, electronic mail (E-mail), contracts, cables, notations of any type of conversation, telephone call, meeting or other communication, bulletins, printed matter, computer printouts, teletypes, invoices, transcripts, diaries, analyses, returns, summaries, minutes, bills, accounts, estimates, projections, comparisons, messages, correspondence, press releases, circulars, financial statements, reviews, opinions, offers, studies and investigations, questionnaires and surveys, and work sheets (and all drafts, preliminary versions, alterations, modifications, revisions, changes, and amendments of any of the foregoing, as well as any attachments or appendices thereto), and graphic or oral records or representations of any kind (including without limitation, photographs, charts, graphs, microfiche, microfilm, videotape, recordings and motion pictures), and electronic, mechanical, and electric records or representations of any kind (including, without limitation, tapes, cassettes, discs, and recordings) and other written, printed, typed, or other graphic or recorded matter of any kind or nature, however produced or reproduced, and whether preserved in writing, film, tape, disc, or videotape. A document bearing any notation not a part of the original text is to be considered a separate document. A draft or non-identical copy is a separate document within the meaning of this term.
2. The term “records” is to be construed in the broadest sense and shall mean any written or graphic material, however produced or reproduced, of any kind or description, consisting of the original and any non-identical copy (whether different from the original because of notes made on or attached to such copy or otherwise) and drafts and both sides thereof, whether printed or recorded electronically or magnetically or stored in any type of data bank, including, but not limited to, the following: correspondence, memoranda, records, summaries of personal conversations or interviews, minutes or records of meetings or conferences, opinions or reports of consultants, projections, statistical statements, drafts, contracts, agreements, purchase orders, invoices, confirmations, telegraphs, telexes, agendas, books, notes, pamphlets, periodicals, reports, studies, evaluations, opinions, logs, diaries, desk calendars, appointment books, tape recordings, video recordings, e-mails, voice mails, computer tapes, or other computer stored matter, magnetic tapes, microfilm, microfiche, punch cards, all other records kept by electronic, photographic, or mechanical means, charts, photographs, notebooks, drawings, plans, inter-office communications, intra-office and intra-departmental communications, transcripts, checks and canceled checks, bank statements, ledgers, books, records or statements of accounts, and papers and things similar to any of the foregoing, however denominated.

3. The terms “relate,” “related,” “relating,” or “regarding” as to any given subject means anything that discusses, concerns, reflects, constitutes, contains, embodies, identifies, deals with, or is any manner whatsoever pertinent to that subject, including but not limited to documents concerning the preparation of other documents.
4. The terms “and” and “or” shall be construed broadly and either conjunctively or disjunctively to bring within the scope of this document request any information which might otherwise be construed to be outside its scope. The singular includes plural number, and vice versa to bring within the scope of this document request any information which might otherwise be construed to be outside its scope. The masculine includes the feminine and neuter genders to bring within the scope of this document request any information that might otherwise be construed to be outside its scope.
5. The term “communication” means each manner or means of disclosure or exchange of information, regardless of means utilized, whether oral, written, electronic, by document or otherwise, and whether face to face, in a meeting, by telephone, mail, telexes, discussions, releases, personal delivery, or otherwise. Documents that typically reflect a “communication” include handwritten notes, telephone memoranda slips, daily appointment books and diaries, bills, checks, correspondence and memoranda, and includes all drafts of such documents.