United States Senate

WASHINGTON, DC 20510

October 16, 2008

Via Electronic Transmission

Gregg W. Stone, MD
Chairman
Cardiovascular Research Foundation
111 East 59th Street
New York, NY 10022-1202

Dear Dr. Stone:

The United States Senate Special Committee on Aging has jurisdiction over and a duty to, among other things, the continuing study of all matters pertaining to problems and opportunities of older people, including their health. The Committee on Finance has jurisdiction over the Medicare and Medicaid programs and, accordingly, has a responsibility to the more than 80 million Americans who receive health care coverage under those programs. As Chairman and Ranking Member of these Committees, respectively, we have a duty to protect the health of Medicare and Medicaid beneficiaries and safeguard taxpayer dollars authorized and appropriated by Congress for those programs.

For the last several years, our Committees have been investigating various aspects of the pharmaceutical and medical device industries, including consulting arrangements and industry funding for Continuing Medical Education (CME). Our Committee staffs have also examined several issues related to non-profit organizations, and we have read newspaper accounts documenting apparently strong ties between the medical device industry and non-profit organizations. Senator Kohl recently wrote to the American College of Cardiology (ACC) regarding its dealings with your organization. Senator Kohl appreciated the ACC's response to his letter and one of his staff subsequently attended ACC's legislative meeting to discuss the Physician Payments Sunshine Act (Sunshine Act), of which we are both sponsors. The pending Physician Payments Sunshine Act, S.2029, which we introduced last fall, seeks to provide additional transparency by requiring disclosure of financial relationships between these industries and medical professionals.

Based upon reporting in the *New York Times*[1] and *Business Week*,[2] along with other evidence, we are also concerned that funding from the medical device industry may influence the practices of non-profit organizations that purport to be independent in their viewpoints and actions. For instance, the President of the American College of Cardiology (ACC), Dr. Douglas Weaver, recently wrote in an editorial that industry funding "constitute about 38% of the College's revenues" and that "without this support, the registration fees for the Annual Scientific Session and i2 Summit would have to be

1 *See, e.g.*, Reed Abelson, *Charities Tied to Doctors Get Drug Industry Gifts*, New York Times, June 26, 2008, at A1.
2 *See, e.g.*, Arlene Weintraub and Amy Barret, *Medicine in Conflict*, Business Week, October 23, 2006, at 76.

more than double their present amount, and member dues would have to increase substantially."[3]

Although such associations do not necessarily exert improper influence upon medical practice, serious questions remain. For instance, despite controversy over the safety and efficacy of stents, CRF board member Dr. Jeffrey W. Moses was quoted by the *New York Times* stating that, in regard to stents, "[s]afety is not the big issue any more."[4] As you are no doubt aware, there are divergent scientific opinions concerning such products, the safety and efficacy of which are a matter of dispute among cardiologists.

Accordingly, we would appreciate an accounting of industry funding that medical device companies or foundations established by these companies have provided to the Cardiovascular Research Foundation (CRF). (The term "industry funding" means any transfer of value from a medical device company, including but not limited to grants, donations, and sponsorship for meetings or programs, etc.) This request covers the period of January 1, 2003 to the present.

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

1. Name of company;
2. Date of payment;
3. Payment description (CME, honorarium, research support, etc.);
4. Amount of payment; and
5. Annual total from the company.

In addition, please provide a detailed account of payments and/or benefits of any kind that your organization has given to the following persons from January 1, 2003 through the present time:

1. Martin B. Leon, MD;
2. Gregg W. Stone, MD;
3. Jeffrey W. Moses, MD;
4. Mark A. Apfelbaum, MD;
5. Stephane Carlier, MD, PhD;
6. Michael B. Collins, MD;
7. Antonio Colombo, MD;
8. William A. Gray, MD;
9. Ajay J. Kirtane, MD, SM;
10. Susheel K. Kodali, MD;
11. Edward M. Kreps, MD;
12. Warren Sherman, MD;
13. Robert Sommer, MD;

---

3 W. Douglas Weaver, MD, *President's Page: Understanding the Implications of Conflict of Interest Issues*, 52 J Am Coll Cardiol 1274 (2008).

4 Barnaby J. Feder, *A Heart Stent Gets a Reprieve from Doctors*, November 12, 2007, nytimes.com *quoting* Dr. Jeffrey W. Moses.

14. Paul Teirstein, MD;
15. Giora Weisz, MD;
16. Gary Mintz, MD;
17. Steven Wolff, MD;
18. Alexandra Lansky, MD;
19. Roxana Mehran, MD;
20. George Dangas, MD;
21. Manuela Negoita, MD; and
22. Victor Yick.

The time period of this request covers January 1, 2003 to the present. For each payment to the physicians mentioned above from a company, please provide the following information:

1. Name of company;
2. Date of payment;
3. Payment description (CME, honorarium, research support, etc.);
4. Amount of payment; and
5. Annual total from the company.

Finally, please explain the CRF'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 CRF allows companies to place restrictions or provide guidance on how funding will be spent.

2. If the CRF allows 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 1, 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.

3. Please provide the CV's and financial disclosures filed with the CRF by all senior officials and members of the CRF board.

4. Please provide all communications between the CRF and representatives of the following companies. The time span of this request covers January 1, 2007 to the present.

    1. Abbott Laboratories;
    2. Medtronic Inc.;
    3. Medinol;
    4. Boston Scientific; and
    5. Johnson & Johnson.

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

We look forward to hearing from you by no later than October 30, 2008. If you have any questions, please do not hesitate to contact Jack Mitchell or Adam Weaver (202-224-5364) of Chairman Kohl's Special Committee on Aging staff and/or Paul Thacker (202-224-4515) of Ranking Member Grassley's Committee on Finance staff. All documents responsive to this request should be sent electronically, in searchable PDF format to Adam Weaver at Adam_Weaver@aging.senate.gov and to Brian Downey at Brian_Downey@finance-rep.senate.gov.

Sincerely,

Herb Kohl
Chairman
Special Committee on Aging

Charles E. Grassley
Ranking Member
Committee on Finance

Attachment

GENERAL INSTRUCTIONS

1. The term "Cardiovascular Research Foundation" means its corporation, or one or more of its divisions, subsidiaries or affiliates, or related entities, including any other companies or corporations with which "Cardiovascular Research Foundation" 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.