

United States Senate

Washington, D.C.

For Immediate Release

Thursday, October 16, 2008

Grassley, Kohl seek information about money going from medical device makers to doctors

WASHINGTON – Senators Chuck Grassley and Herb Kohl are continuing their campaign to shed light on financial relationships between the pharmaceutical and medical device industries and medical doctors.

Today the senators sent letters asking for detailed information about industry dollars going to research physicians affiliated with Columbia University and to the Cardiovascular Research Foundation.

The inquiry responds to information about the Cardiovascular Research Foundation's support for an annual conference promoting cardiac devices and techniques and additional financial relationships between professors of medicine and cardiac devices companies featured at this conference. The text of the senators' letters is below this news release.

Last fall, Grassley and Kohl introduced S.2029, the *Physician Payments Sunshine Act*, which would require companies that make pharmaceuticals, medical device and biologics to disclose payments they make to physicians. The information would be made publicly available online by the U.S. Department of Health and Human Services. Congress has not yet taken up this reform legislation.

Both Grassley and Kohl have conducted oversight of the financial relationships between doctors and industry. Kohl has chaired hearings of the Senate Special Committee on Aging and continues to pursue an ongoing investigation of such relationships, having recently sought information from the American College of Cardiology. Grassley has conducted an extensive review of industry payments to leading research doctors and called on the National Institutes of Health to fully exercise its authority to achieve disclosure of financial relationships between industry and the doctors who conduct \$24 billion each year in federally sponsored medical research.

October 16, 2008

Lee C. Bollinger
President
Columbia University
2960 Broadway
New York, NY 10027

Dear Mr. Bollinger:

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 funding for Continuing Medical Education (CME). We have compiled evidence documenting the strong ties between these industries and physicians.

As part of our oversight responsibilities, we have been analyzing the policies and practices that universities and hospitals have in place requiring their physicians to report outside income. We have concluded that there is a lack of transparency in this area.

To help us better understand these relationships, we would appreciate your office providing our Committees the following information detailing the outside income from the following persons from January 1, 2003 to the present:

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;
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 Dargas, MD;
21. Manuela Negoita, MD; and
22. Victor Yick.

Because reporting practices vary widely from one institution to another, we would appreciate you also placing this income into a chart, detailing compensation from outside sources to the persons referenced above. For each payment to the persons mentioned above from a company or organization, please provide the following information:

1. Name of payment source;
2. Date of payment;

3. Payment description (CME, honorarium, research support, etc.);
4. Amount of payment; and
5. Annual total from the payment source.

We would also appreciate a report of all funding provided to Columbia University from the following companies and organizations from January 1, 2003 to the present:

- a. Abbott Laboratories;
- b. Medtronic Inc.;
- c. Medinol;
- d. Boston Scientific;
- e. Johnson & Johnson; and
- f. Cardiovascular Research Foundation.

Also, please explain the nature of the relationship between Columbia University and the Cardiovascular Research Foundation (CRF). In response to this request, please provide all pertinent documents and communications between the University and CRF. The time span of this request covers January 1, 2003 to the present.

In cooperating with the Committees' review, no documents, records, data nor 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.

Sincerely,

Herb Kohl
Chairman
Special Committee on Aging

Charles E. Grassley
Ranking Member
Committee on Finance

October 16, 2008

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 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.

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.

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.

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;
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12. Warren Sherman, MD;
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15. Giora Weisz, MD;
16. Gary Mintz, MD;
17. Steven Wolff, MD;
18. Alexandra Lansky, MD;
19. Roxana Mehran, MD;
20. George Dargas, 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.
 - a. Abbott Laboratories;
 - b. Medtronic Inc.;
 - c. Medinol;
 - d. Boston Scientific; and
 - e. 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.

Sincerely,

Herb Kohl
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