

# United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510-6200

September 20, 2007

## Via Electronic Transmission

Bill Hawkins  
President and Chief Executive Officer  
Medtronic, Inc.  
710 Medtronic Parkway  
Minneapolis, MN 55432-5604

Dear Mr. Hawkins:

The United States Senate Committee on Finance (Committee) has jurisdiction over the Medicare and Medicaid programs. As a senior member of the United States Senate and as Ranking Member of the Committee, I have a special responsibility to protect the health of Medicare and Medicaid beneficiaries and safeguard taxpayer dollars authorized by Congress for these programs. This includes the responsibility to conduct oversight of the medical industry, including makers of medical devices.

In carrying out this duty, I have been investigating various aspects of the medical industry, including the substantial financial ties between the device industry and practicing physicians. As the largest medical device company in the United States, Medtronic Inc. (Medtronic) is a corporate leader whose practices, and those of its subsidiaries, affect the industry as a whole. For this reason, I am particularly disturbed by allegations that have been made against Medtronic and I hope you will be able to help me in understanding them.

Recently, several articles in *The New York Times* reported allegations against Medtronic Sofamor Danek (MSD), your company headquartered in Memphis, Tennessee, which focuses on treatments for spinal conditions. As you know, MSD has been accused of paying doctors exorbitant amounts of money to encourage the use and promotion of its products.<sup>[1]</sup> For instance, MSD purportedly paid one prominent surgeon \$400,000 a year for a consulting contract which required only eight days of annual work. This money, amounting to tens of millions of dollars annually, appears to be paid to doctors through a variety of consulting contracts, speaking fees, and free travel to exotic locations around the globe.<sup>[2]</sup> All the while, according to newspaper reports, these same doctors are using Medtronic devices and sometimes promoting the off-label use of Medtronic devices. This has led to speculation that such compensation and perks distort decision-making among physicians and may be counter to the best interest of patients.

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[1] *The New York Times*, "Whistle-Blower Suit Says Device Maker Generously Rewards Doctors," January 24, 2006.

[2] *The New York Times*, "US: Medtronic Will Settle Accusations on Kickbacks," July 19, 2006.

For instance, I understand from MSD's website that it directly funds doctors to attend medical meetings. MSD also provides contributions for various educational activities. I would like to understand how the funding for these activities are determined and whether this funding is in any way tied to the marketing of Medtronic's products.

Another questionable form of medical product promotion appears to be in the area of Continuing Medical Education (CME). Drug companies pour about \$1 billion every year into CME. In April, the Finance Committee staff released a report finding that some educational courses have become veiled forms of advertising. As a result of information I have received, I am concerned that similar practices are now occurring in the device world. I understand that Medtronic sponsors educational courses at the Medical Education & Research Institute (MERI), and sponsors medical seminars that are organized by Broadwater, a CME company. I would like to learn more regarding how those courses are structured and how you ensure that the courses and seminars offered are independent and free of bias toward any particular device.

In light of these allegations and concerns, I request a briefing for my Committee staff about Medtronic's practices regarding payments and other transfers of value to physicians, and the effect these practices have on physician decision-making. Additionally, I would appreciate your response to allegations that Medtronic's practices of providing physicians with inordinately high consulting fees, free travel, and other perks distort decision-making among physicians and obscure the best interest of patients.

I also request that Medtronic provide responses to the following questions and requests for documents and records. Please respond by repeating the enumerated question, followed by the accompanying response.

For purposes of this letter, the phrase, "payment or other transfer of value" means any compensation, gift, honorarium, speaking fee, consulting fee, food, entertainment, gift, travel, discount, cash rebate, service, or other transfer of value.

1. Please provide the Committee with a list of all payments or other transfers of value made by Medtronic or its subsidiaries to outside organizations (hospitals, non profits, professional societies, private practices) involved in spinal surgery and/or treatment for spinal problems. For each payment or transfer, please include the date, amount, and reason for the payment or transfer. This request covers the period of January 2003 to the present.
2. Please provide the Committee with a list of all Key Opinion Leaders (KOLs) and any other thought leaders that have been identified by Medtronic regarding spinal surgery and/or treatment. This request covers the period of January 2003 to the present. Please include a list of all payments or other transfers of value made to KOLs. For each payment, list the name of the KOL/ thought leader amount of payment, date of payment, and reason for payment.

3. Please provide the Committee with a list of all payments or other transfers of value made to the following individuals: Lawrence G. Lenke, Jeffrey C. Wang, Behrooz A. Akbarnia, Thomas A. Zdeblick, Rick Delamarter, David Polly, Kevin Foley, Kenneth J. Burkus, Regis Haid, Rick Sasso, K. Daniel Riew, Steven Garfin, Choll W. Kim, Scott Boden and Stephen Papdopoulos. For each payment or transfer, please include the date, amount, and reason for the payment or transfer. This request covers the period of January 2000 to the present.
4. Please provide the Committee with a detailed account of all payments or other transfers of value made to MERI. For each payment or transfer, please include the date, amount, and reason for the payment or transfer. This request covers the period of January 2000 to the present.
5. Please provide the Committee with all records, documents, and communications between MERI and Medtronic. This request covers the period of January 2006 to the present.
6. Please provide the Committee with a detailed account of all payments or other transfers of value made to the medical communications company Broadwater, or any entity operating out of offices of Broadwater. Each payment should include the date of payment, amount of payment, and reason for payment. This request covers the period of January 2000 to the present.
7. Please provide the Committee with all records, documents, and communications between the medical communications company Broadwater and Medtronic. This request covers the period of January 2006 to the present.
8. Please provide a list of all current and former employees of MSD, to including the position of the employee and time in the position. This request covers the period of January 2000 to the present.
9. Please provide the Committee with all educational activity charitable contribution request forms that have been submitted to MSD since January 2003. Along with the forms, please provide supporting documentation from the person/organization making the request, as well as MSD documents that validate the approval/denial of the request.
10. Please explain the process currently in place that determines whether an educational activity charitable contribution request is approved or disapproved. Please provide the names and titles of all of the MSD employees involved in this process.

In cooperating with the Committee's review, no documents, records, data, or other information related to these matters, either directly or indirectly, shall be destroyed, modified, removed, or otherwise made inaccessible to the Committee. In addition, we would appreciate your identifying a Medtronic representative with whom we can discuss matters relating to your company as soon as possible.

I look forward to hearing from you by no later than October 3, 2007. All documents responsive to this request should be sent electronically, on a disc, in searchable PDF format to [Brian\\_Downey@finance-rep.senate.gov](mailto:Brian_Downey@finance-rep.senate.gov) and in accordance with the attached instructions and general definitions. If you have any questions, please do not hesitate to contact Chris Armstrong or Paul Thacker at (202) 224-4515.

Sincerely,

A handwritten signature in blue ink that reads "Chuck Grassley". The signature is written in a cursive, flowing style.

Charles E. Grassley  
Ranking Member

Attachment

## GENERAL INSTRUCTIONS

1. The terms “Medtronic Inc.” 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 “Medtronic Inc.” 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.