

United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510-6200

September 30, 2008

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 health care industry, including makers of medical devices, which receive hundreds of billions of taxpayer dollars every year for the care of Americans.

In carrying out this duty, I have been examining the substantial financial ties between the device industry and practicing physicians. I have also been examining the safety and cost of medical devices that are sold to the American public. As the largest medical device company in the United States, the practices of Medtronic Inc. (Medtronic) have a profound impact on American healthcare.

Last week, the *Wall Street Journal* (*WSJ*) reported on allegations of financial perks provided to doctors that included “entertainment at a Memphis strip club, trips to Alaska and patent royalties on inventions they played no part in.”^[1] I would appreciate your assistance in better understanding these allegations and would like to take this opportunity to lay out my specific concerns and questions.

First, I am glad to hear that Medtronic told the *WSJ* that the company is “committed to reform and transparency in the industry.” I also appreciate Medtronic’s important support for the Physician Payments Sunshine Act, which would require drug and device companies to make public their payments to physicians and bring greater transparency to medicine. However, until this legislation is enacted, the public will remain largely in the dark about such payments. As I am sure you are aware, some pharmaceutical companies have already taken the lead on this issue by voluntarily making public their payments to physicians. In the spirit of transparency, I hope that

^[1] David Armstrong, “Lawsuit Says Medtronic Gave Doctors Array of Perks,” *Wall Street Journal*, September 25, 2008.

Medtronic will consider making public its payments to physicians in the future and thereby show similar leadership in the device industry.

Second, according to *WSJ*, the lawsuits against Medtronic remain under seal. I would like to better understand the status of these lawsuits and the procedural process that has led to the current situation.

Third, the *WSJ* also reported allegations that one of the incentives Medtronic provided physicians was to include them on patents for medical devices and reward them with royalties, even though the physicians may not have contributed to the development of the product. Specifically, the article alleges that Medtronic “paid patent royalties to doctors who didn’t contribute novel ideas to products....” Allegations that a device company paid patent royalties to disguise kickbacks are serious, and I would appreciate your help in better understanding what practices led to these allegations and what has changed since that time.

Fourth, earlier this month the *WSJ* reported on problems with off-label use of Medtronic’s Infuse.^[2] Infuse is a bone graft replacement technology that uses a protein which creates bone. Specifically, it was reported that Medtronic gave payments to physicians, in the form of consulting agreements, as a means of increasing sales of Infuse. The allegations that Medtronic has been disguising these consulting agreements as inducements or kickbacks for physicians to use Infuse are equally troubling. Likewise, this is a practice that I would like to better understand and I would like to know what, if anything has changed since these reported events.

In light of the issues set forth above, I would also appreciate receiving both a briefing and written responses to the questions and requests addressed below. Please repeat the request and follow with the appropriate response. These questions are for the period of January 2003 to the present.

- 1) Has Medtronic considered, or is Medtronic currently planning on, publically disclosing payments to individual physicians? If so, please describe what type of information will be disclosed, when that disclosure will occur, and how the information will be made publically available.
- 2) Please provide the following information for all physicians with whom Medtronic has consulting agreements for Infuse.
 - a) name of physician;
 - b) copy of the consulting agreement;
 - c) date of payment(s);
 - d) the specific focus of their consulting agreement;
 - e) dates and descriptions of services performed by each physician pursuant to the consulting agreement;

^[2] David Armstrong, "Medtronic Product Linked to Surgery Problems," *Wall Street Journal*, September 4, 2008.

- f) the amount of payment(s); and
 - g) annual total of payments.
- 3) Please provide a list of all adverse events reported involving off-label use of Infuse.
- 4) Please provide any documents, receipts, emails, and records regarding a trip to Europe made by Dr. Jeffrey Wang and his family and paid for by Medtronic.

Thank you in advance for your continued cooperation in this matter and commitment to transparency. Please contact Paul Thacker or Chris Armstrong at (202) 224-4515 to set up a briefing, to include Medtronic General Counsel, Mr. Terry Carlson. All formal correspondence should be sent electronically in PDF format to Brian_Downey@finance-rep.senate.gov or via facsimile to (202) 228-2131 by no later than October 14, 2008.

Sincerely,



Charles E. Grassley
Ranking Member