

# United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510-6200

October 16, 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. I have also been examining the safety and cost of 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.

Recently, several articles in *The New York Times* reported that Medtronic warned doctors to stop using a potentially faulty wire attached to your heart defibrillators.<sup>1</sup> This defect has caused malfunctions in hundreds of patients and may have contributed to five deaths. What I find troubling is that Medtronic took months to stop the sales of the faulty lead, even though the problem had been reported in a peer-reviewed journal months prior.<sup>2</sup> This study found over 500 complaints of adverse events with this particular lead that were reported in the FDA's MAUDE data between September 2004 and January 2007.

Certainly this data was also available to executives at Medtronic. However, Medtronic took no apparent action to inform doctors and patients of the potential risks. Meanwhile, it was reported by the *Chicago Tribune* that Medtronic launched a \$100 million marketing campaign in January to advertise its heart defibrillators, some of which used the faulty leads.<sup>3</sup>

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<sup>1</sup> *The New York Times*, "Patients Warned as Maker Halts Sales of Heart Implants," October 15, 2007.

<sup>2</sup> Heart Rhythm Society, "Early failure of a small-diameter high-voltage implantable cardioverter-defibrillator lead," Vol 4, No 7 (July 2007): pp. 892-6 (Epub April 10, 2007). ..

<sup>3</sup> *Chicago Tribune*, "Medical ads aim straight for the heart," January 23, 2007.

Accordingly, I would appreciate your company briefing my staff on why it took Medtronic months to respond to problems with its defibrillator lead.

Thank you in advance for your continued cooperation in this matter and please contact Angela Choy or Paul Thacker no later than October 31, 2007, at (202) 224-4515 to set up a briefing.

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