United States Senate

WASHINGTON, DC 20510

December 13, 2011

Omar Ishrak
Chairman and CEO
Medtronic
710 Medtronic Parkway
Minneapolis, MN 55432

Dear Mr. Ishrak:

As Chairman of the Senate Special Committee on Aging, Ranking Member of the Senate Judiciary Committee, and a member of the Senate Health, Education, Labor and Pensions Committee, we take seriously our responsibility to protect the interests of our nation's health care consumers. We are writing today to request information on how your company handles recalls and post-marketing surveillance of your products, two important tools for ensuring that only safe and effective medical devices remain in the marketplace.

All health care consumers in the United States depend on companies such as Medtronic to deliver high-quality, safe, and effective products. Recently, your company has experienced safety issues, such as with your spine product Infuse. A researcher at Stanford University School of Medicine found a higher risk of cancer associated with Infuse, and there have been allegations that researchers who received funds from Medtronic, sometimes millions of dollars, did not report negative findings from clinical trials. We are concerned that consumers, who have long relied on your products, are being adversely affected by these issues, both through the on-label and off-label use of the product. Complications arising from faulty medical devices can cause pain and suffering for patients and are costly for the manufacturer and the entire health care system.

As the Special Committee on Aging's recent oversight hearing detailed, effective post-marketing surveillance practices allow companies to recognize problems with medical devices in a timely fashion, preventing expensive recalls later, and can also save lives and prevent unnecessary suffering. We appreciate the briefing your company gave to the Special Committee on Aging staff some months ago on extensive developments in your post-market safety monitoring systems, but we have several follow-up questions related to enhancing the Food and Drug Administration's (FDA's) post-marketing surveillance and recall authorities and capabilities. In order to understand better how your company conducts post-marketing surveillance and recalls of medical devices, please respond to the following questions. The Attachment of this letter will specify in full detail what materials are to be included in response to this request.

1. Please outline the general systems and safeguards in place for monitoring medical devices made by Medtronic, or your subsidiaries. Do you provide each device a unique device identifier (UDI) or similar tracking mechanism?

2. Is Medtronic or its subsidiaries currently conducting any post-market medical device studies, and if so, did FDA require these studies?
    a. How often has Medtronic done such studies in the past?
    b. Has Medtronic ever failed to report such study results to FDA, and if so, did the agency take any action?

3. How does your company derive failure rates or rates of serious adverse events of medical devices? What is the current estimate of the serious adverse event rate of Infuse? Please give rates for both on-label and off-label usage.

4. How many individual complaints has your company received about Infuse to date? Please provide international data too, where available. How many of these complaints did you report to FDA? What percentage of these complaints were for off-label usage?

5. What failure-related costs are being reimbursed to Infuse patients and their insurers, including Medicare? What is your process for reimbursement?
    a. What is Medtronic's current assessment of the negative side effects of Infuse?

6. Please give an overview of how your company works with medical device registries, including the name of each registry and the purpose of the collaboration. When you work with foreign registries, how do you reconcile disparities in failure rates?

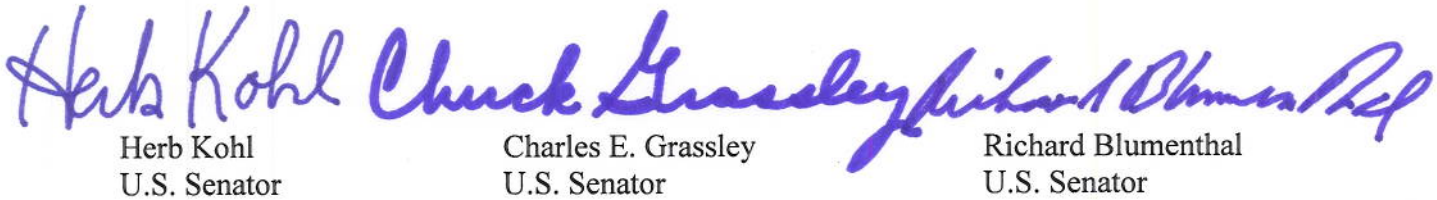
7. Do you require physicians who receive funds from your company to disclose those payments to their patients before the patients receive one of your medical devices? If not, why not?
    a. Does this policy vary by state and country where products are sold?

8. How does Medtronic apply lessons learned from past recalls to present and future recalls? For example, if there were problems communicating with patients in a recall, how does your company ensure that this does not happen in the future?

Please furnish this documentation by electronic mail, fax, or hand delivery, no later than close of business on January 23, 2012. Any questions concerning this request may be directed to Jack Mitchell or Sarah Molinoff of the Special Committee on Aging staff at (202) 224-5364, or Erika Smith of the Senate Judiciary Committee at (202) 224-5225. Thank you.

Any questions concerning this request may be directed to Jack Mitchell or Sarah Molinoff of the Special Committee on Aging staff at (202) 224-5364, Erika Smith of the Senate Judiciary Committee at (202) 224-5225 and Rachel Pryor of Senator Richard Blumenthal's staff at (202) 224-2823. Thank you.

Sincerely,



Herb Kohl
U.S. Senator

Charles E. Grassley
U.S. Senator

Richard Blumenthal
U.S. Senator

ATTACHMENT

GENERAL INSTRUCTIONS

1. The terms "**Medtronic**" and "your institute" 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**" 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. Each document produced shall be produced in a form that renders the document susceptible of copying.

7. 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.

8. 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.

9. 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.

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.