United States Senate

WASHINGTON, DC 20510

December 13, 2011

David Dvorak
Director, President, and CEO
Zimmer Holdings
345 East Main Street
Warsaw, IN 46580

Dear Mr. Dvorak:

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 Zimmer Holdings to deliver high-quality, safe and effective health care products. Patients who need joint replacements often struggle to find devices that effectively treat their pain and suffering. It is crucial that the Food and Drug Administration (FDA) and patients have access to up-to-date and accurate information on adverse events. Last year, questions arose in the media when Zimmer ended its relationship with a consultant, Dr. Richard Berger, who had notified the company that one of its knee implants, the NexGen CR-Flex, was failing prematurely. Dr. Berger had been a valued consultant for Zimmer and had received more than $8 million for designing products and training fellow surgeons over the previous decade. When he reported that the knee failed early in about 8-9 percent of his patients, Zimmer decided not to renew his consulting contract.

Such actions have been interpreted as having a chilling effect on scientific exchange and also undermine the confidence that consumers have in such products. Furthermore, the medical problems associated with implant design problems, such as revision surgery, 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 medical device post-marketing surveillance practices allow companies to recognize problems in a timely fashion, preventing expensive recalls later, and can also save lives and prevent unnecessary suffering. In order to understand better how your company conducts post-marketing surveillance and recalls, 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 devices made by Zimmer, or your subsidiaries. Do you provide each device a unique device identifier (UDI) or similar tracking mechanism?

2. Is Zimmer, or its subsidiaries, currently conducting any medical device post-market studies, and if so, did FDA require these studies?
    a. How often has Zimmer done such studies in the past?
    b. Has Zimmer 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?

4. How many individual complaints has your company received about the NexGen CR-Flex knee? Please also provide international data, where available. How many of these complaints did you report to FDA?
    a. How many removal surgeries have been done to date?
    b. How many of those patients have needed follow-up surgery, and how many surgeries are generally needed before removal is complete?

5. What failure-related costs are being reimbursed to NexGen CR-Flex knee patients and their insurers, including Medicare? What is your process for reimbursement?
    a. What is Zimmer's current assessment of the early failures that many knee patients experienced?

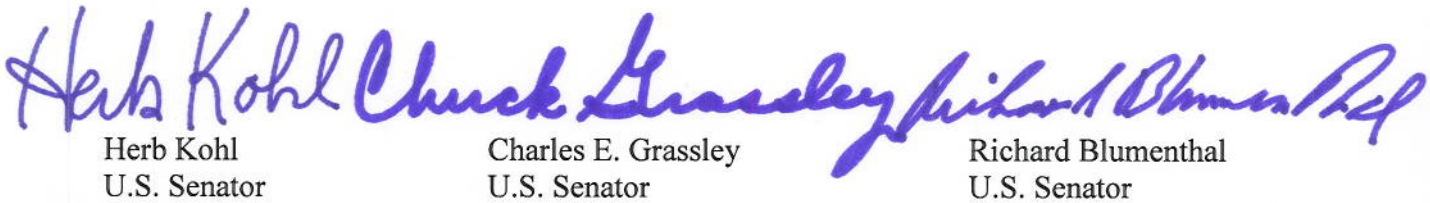
6. Please give an overview of how your company works with medical device registries, including the name of each registry and the purpose of the collaboration. When you work with foreign registries, how do you reconcile disparities in failure rates?

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 Zimmer 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, 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 "**Zimmer**" 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 "**Zimmer**" 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.