United States Senate
COMMITTEE ON FINANCE
WASHINGTON, DC 20510–6200

July 29, 2010

Via Electronic Transmission

David C. Dvorak
President and Chief Executive Officer
Zimmer Holdings Inc.
345 East Main Street
Warsaw, IN 46581

Dear Mr. Dvorak:

The United States Senate Committee on Finance (Committee) has jurisdiction over, among other things, the Medicare and Medicaid programs. As Ranking Member of the Committee, I have a responsibility to the more than 100 million Americans who receive health care coverage under these programs to oversee their proper administration and ensure that taxpayer dollars are appropriately spent on safe and effective medical devices. In carrying out this duty, I have also been examining various operations and activities of the device industry, including payments made to physicians for consulting activities, speaker bureaus, payments for Continuing Medical Education and conferences, and funding for research.

Over the last two years, several companies have taken important steps to meet the public's demand for transparency by disclosing their payments to physicians and organizations, such as patient groups and medical societies, voluntarily or as part of agreements with the Department of Justice (DOJ). As one of the requirements under the deferred prosecution agreement with DOJ, Zimmer Holdings, Inc. (Zimmer) has been posting on its website detailed information about the company's financial relationships with certain healthcare professionals since 2008.

I was troubled by last month's *New York Times* account of Zimmer's response to the allegations of safety concerns raised by two of its consultants. Specifically, *The New York Times* reported that one of the surgeons with whom Zimmer had a financial relationship, Dr. Richard Berger, raised concerns to the company a few years ago about the premature failure of a Zimmer knee, the NexGen CR-Flex.[1] According to the article, Dr. Berger was a long-time consultant for Zimmer—a financial relationship that spanned more a decade—with Dr. Berger receiving more than $8 million during that time frame. *The New York Times* also reported that a second Zimmer consultant, Dr. Lawrence Dorr, alerted other doctors that Zimmer's Durom hip device was failing a few years after they were implanted in patients. According to *The New York Times*, the two doctors were not alone in their concerns about the device failures. In both cases, however, Zimmer responded that it was the surgeons' technique, not the devices that were flawed.

[1] Barry Meier, "Surgeon vs. Knee Maker: Who's Rejecting Whom?" *The New York Times*, June 18, 2010.

Accordingly, I would appreciate your response to the following questions and requests for information by no later than August 12, 2010. In responding to this letter, please restate the enumerated question and follow with the appropriate response and documentation.

1) What process does Zimmer have in place to respond to allegations and concerns raised by its consultants or contractors regarding the safety of one of its products?

2) Since January 2008, how many Zimmer consultants or contractors have raised safety concerns or problems regarding Zimmer's products? For each product for which concerns or problems were reported, please include the following:

    a. The name and affiliation of the consultant or contractor and whether or not s/he is still a Zimmer consultant;
    b. The name of the product;
    c. The specific concern(s) or problem(s) reported to Zimmer;
    d. Whether or not the reports of safety concerns or problems led to product changes/modifications; and
    e. Whether or not the reports of safety concerns or problems led to product discontinuation.

3) Of the safety concerns or problems identified since January 2008, how many were refuted by Zimmer?

4) Although not required to track the long-term performance of its devices, does Zimmer voluntarily collect data on the performance of its hip and knee devices and other implantable devices? If so, how is that data collected? If not, has Zimmer considered putting in place a process for tracking and reviewing the performance of its devices?

Thank you in advance for your cooperation and assistance. Should you have any questions regarding this letter, please do not hesitate to contact Emilia DiSanto or Angela Choy at (202) 224-4515. Any formal correspondence should be sent electronically in PDF searchable format to Brian_Downey@finance-rep.senate.gov.

Sincerely,

Charles E. Grassley
Ranking Member