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U.S. Senate Special Committee on Aging Hearing on "Examining the Relationships between the Medical Device Industry and Physicians" February 27, 2008

Mr. Chairman, Senator Smith, and members of the Committee, I am pleased to testify in front of you today on behalf of Zimmer, as this panel examines the relationships between the medical device industry and physicians. Your Committee has taken a real leadership role in examining this important issue, and it is a privilege to be able to provide our Company's insight as part of the information you are gathering in this area.

Zimmer was founded more than 80 years ago and is a worldwide leader in designing, developing, manufacturing, and marketing orthopaedic reconstructive and other medical products. More than 7,500 Zimmer employees are at work today all around the world, and their commitment is to provide effective, innovative solutions to relieve the pain of arthritis, other debilitating musculoskeletal conditions, and traumatic injuries experienced by millions of patients, and to restore their mobility and productivity. Our hip and knee joint replacement systems and our wide range of other products and services make us valuable contributors to healthcare systems in over 100 countries, and it is that global perspective I hope to bring to the Committee today.

The world of medical devices is on the threshold of change. In the near future, our aging population will create a surge in demand for innovative products that meet clinical needs. A dramatic increase in the prevalence of arthritis, obesity, and other chronic conditions, combined with the ongoing incidence of debilitating acute conditions, will significantly increase the need for joint replacement and other medical technologies that maintain quality of life and productivity.

As a leader in the medical device industry, Zimmer is focused on how to meet the profound needs of an aging population at a time when the rise of these chronic conditions and the ongoing burden of acute conditions will drive healthcare consumption and productivity losses to unprecedented levels. We believe it is essential to understand and address what it will take for our Company and our industry to meet the needs of the patients of the future and the healthcare systems that serve them.

The subject of this hearing – the relationships between physicians and the medical device industry – warrants some historical context at the outset before we detail how our Company is responding to the challenges these relationships present, and why we are supporting the Physician Payments Sunshine legislation co-sponsored by Chairman Kohl.

The medical device industry has transformed patients' lives through a rare combination of clinical knowledge and engineering, bringing the insights of highly

skilled physicians who work directly with patients together with the technical knowledge of engineers who design and build safe and effective devices.

This collaboration has been the heart of a product development model that continues to identify and address profound unmet patient needs. Because physician skill level is a key driver of successful patient outcomes, physician training on the safe and effective use of today's complex products and procedures has also been central to the significant benefit patients have experienced with medical devices. We note that the federal government recognizes the importance of collaboration in our industry and is focusing its efforts not on eliminating collaboration, but rather on determining models for appropriate and necessary collaboration.

Over the years, as devices and procedures expanded in number, complexity, and impact, so too did the industry's investment in the collaboration that made them possible. Expansion in collaboration increased consulting relationships between industry and physicians, so that physicians could be paid for their intellectual property contributions as well as the services they provided while developing products and conducting the physician training necessary for successful patient outcomes.

Collaboration with physicians will always be important to clinically meaningful innovation in medical technology. In this industry, the same physician we rely on as a consultant to develop or train on the safe and effective use of our products may also select products for patients. Despite what were then regarded by industry as

proper and adequate programs to manage and control these circumstances, with hindsight it now appears that as industry expanded to meet patient needs the use of physician consultants may have been excessive at times. Such excesses fostered a degree of mistrust of the industry and physicians and invited the understandable scrutiny of the government and other stakeholders.

The historical model for collaborative relationships requires change to inspire confidence and trust, while preserving the best of the collaboration that drives innovation and advances effective patient care.

In April 2003, the Department of Health and Human Services' Office of the Inspector General issued voluntary compliance guidance to pharmaceutical manufacturers, to help them prevent healthcare fraud and abuse by promoting a high level of ethical and lawful corporate conduct. In January 2004, a new Code of Ethics on Interactions with Healthcare Professionals, developed by our industry association, the Advanced Medical Technology Association, became effective.

Zimmer's continuous consideration of our own compliance standards, combined with these measures taken by OIG and AdvaMed, prompted us to re-evaluate thoroughly our model for the management of conflicts of interest that may result from collaboration. This re-evaluation, which we started in 2003, led to the implementation of our enhanced Corporate Compliance Program in 2005. Now, as we build upon that foundation, we are applying further discipline to ensure we align collaboration strictly

with necessity and aggressively reduce the risk of actual, potential, or perceived conflicts of interest.

As the Committee is aware, in September 2007, Zimmer and the four other leading U.S. orthopaedic companies signed agreements with the federal government to resolve a Department of Justice investigation that began in March 2005, pertaining to past consulting arrangements with healthcare professionals.

Under the terms of the resolution, Zimmer entered into a Deferred Prosecution Agreement, without admitting any liability. We agreed to pay a civil monetary sum and to be subject to oversight for 18 months by a federally appointed monitor. The government granted Zimmer a civil release and agreed not to pursue any criminal charges against our Company if we comply with the Deferred Prosecution Agreement. Further, the U.S. Attorney's office acknowledged that the agreement does not allege that our Company's conduct adversely affected patient health or patient care.

As part of the federal settlement, Zimmer also entered into a five-year Corporate Integrity Agreement with the OIG.

We are taking our obligations under the Deferred Prosecution and Corporate

Integrity Agreements extremely seriously and they are a top priority for our Company.

Zimmer welcomes the opportunity to share with this Committee today the progress we have made since signing these resolution agreements and especially our commitment to go beyond their requirements. We are dedicated to setting a new industry standard that we believe will meet the needs of both patients and the healthcare systems that serve them.

At the time of the settlement, the U.S. Attorney acknowledged that Zimmer's 2005 Corporate Compliance Program provided many of the requirements contained in the agreements the five companies entered into with the Department of Justice. Our new initiatives in the area of compliance further enhance our 2005 Program and exceed the requirements of those resolution agreements.

We believe these new compliance initiatives will allow us to continue to deliver industry-leading products of the highest quality backed by business practices that inspire confidence and trust. Ultimately, our goal is to ensure that patients benefit from innovations focused on their needs, and that everyone with a stake in quality healthcare can trust that physicians choose products based on what they believe is best for patients. For this reason, we now endeavor to prevent even the appearance of impropriety.

As a market leader, it makes sense to us that our leadership position should extend to include best practices in the areas of compliance and ethics. We believe these best practices are necessary to ensure a vibrant future for medical technology and for the patients our industry serves – creating principles and systems that drive greater

transparency, innovations that solve unmet patient needs, and value to the healthcare system over the long-term.

Our broader commitment includes fundamental changes in product development, marketing, surgeon training, educational and research funding, and transparency. We are currently finalizing the specific strategies that will comprise this broader plan.

Today I would like to share with the Committee a few examples of the changes we are putting in place while we continue to define and communicate the full scope of the program:

First, our sales and distribution teams and individuals with daily responsibility for sales support will have no involvement with physician consultants concerning the agreements we enter into with them, the services that the consultants provide for us, and the payments we make to them.

Second, we are reviewing our existing royalty-bearing hip and knee development agreements to ensure that they are consistent with the fair market value principles of our 2005 enhanced Corporate Compliance Program and the terms of our resolution agreements. We have initiated this process and are currently communicating with consultants who hold these royalty-bearing agreements.

Third, with respect to Zimmer's future funding of medical fellowships, residencies, and general educational programs, we plan to make cash donations to one or more appropriate, independent third-party institutions. These third-party institutions will choose the programs and applicants that will receive Zimmer funding globally. Zimmer will have no control or influence over the selection of the ultimate recipients of these funds. This approach makes it possible for Zimmer to continue to provide worthy support to the education of orthopaedic surgeons around the world, while eliminating any possibility for inappropriate influence.

Fourth, Zimmer's future charitable activities will include product donations to one or more appropriate, independent, global third-party charitable institutions. These institutions will determine the distribution and application of these donated products in areas of the world with great unmet medical need. Again, Zimmer will have no control over the distribution of these products and no influence over who receives them.

Finally, while the current AdvaMed Code of Ethics allows for certain educational, practice-related, or branded company gifts to healthcare professionals, Zimmer further restricted such gifts as part of our 2005 Corporate Compliance Program, and will now move to prohibit them altogether. In lieu of providing gifts to individual healthcare professionals, Zimmer may make cash donations to appropriate, independent third-party institutions that will then determine the dissemination of education-related items.

As we work to make these and other changes, and continually improve our Compliance Program, we will implement these improvements globally across our entire business, a commitment that also goes beyond the requirements of our resolution agreements. We will enhance our efforts to align all business units consistently throughout the world behind these best practices. We are pursuing these priorities with a commitment to ensure that when our products are chosen, it is because they are the best solution for patients. That is the sole basis upon which we want to compete, and the surest path forward to ensuring confidence and trust in our industry.

Given these commitments, we are strongly supportive of the Physician Payments Sunshine Act, introduced by Chairman Kohl and Senator Grassley, that aims to provide for the appropriate disclosure of relationships between medical technology companies and physicians. We believe that the goals of this legislation mirror the ideals of Zimmer and the medical device industry. Together, our collective goal is to ensure the highest quality care for patients.

Earlier this week, we sent a letter to Chairman Kohl, expressing our strong support for the Bill, and setting out our more detailed views on its provisions. I would appreciate if the letter could be made part of the record of this Hearing.

We acknowledge that initiating change is difficult. Nevertheless, we will carry these initiatives forward because we believe it is the right thing to do for our Company, our stockholders, and for the industry as a whole. Implementing these

enhancements will make it possible for us to focus entirely on what we do best, bringing to market products that enhance patients' lives.

Mr. Chairman, Senator Smith and members of the Committee, it has been a privilege to be able to outline the steps we are taking in this critically important area. As a company and as an industry leader, we believe our efforts demonstrate a firm commitment to a new standard for relationships between the medical device industry and physicians. We appreciate the Committee's consideration of our views as it exercises its important leadership on this issue.

I look forward to your questions.