



7075 Veterans Boulevard, Burr Ridge, IL 60527
Toll-free: (866) 960-6277 Phone: (630) 230-3600
Fax: (630) 230-3700 Web: www.spine.org

March 11, 2008

The Honorable Herb Kohl
Chairman, United States Senate Special Committee on Aging
Washington, DC 20510-6400
(202)224.5364

Re: North American Spine Society (NASS) Response to February 27, 2008 Hearing, “*Surgeons for Sale? Conflicts and Consultant Payments in the Medical Device Industry.*”

Dear Senator Kohl,

First, I would like to thank you for the leadership you have shown in further bringing to light the issue of financial conflicts of interest in the medical device industry. NASS appreciates being given the opportunity to comment on the record in relation to the hearing held on February 27. I hope that sharing NASS’ experience in dealing with these issues will be helpful to the Committee in your continuing efforts.

We first adopted our “Acceptance of Appointment and Covenant to Disclose” document, requiring all those in leadership or committee positions to disclose all conflicts before serving, in 1996. Promoting the highest ethical standards for spine physicians in every aspect of the society has been something of a passion among NASS leadership since 2001, when Stanley A. Herring, MD chose Ethics as the centerpiece of his NASS presidential efforts. From the creation of the Professional Conduct and Ethics Committee in 2002, to the implementation of a comprehensive disclosure policy in March 2006, to the current effort to expand and strengthen all of our existing policies, we have a legacy of providing spine professionals with strong, clear guidance on ethical practices.

We take this issue very seriously: NASS has implemented some of the most stringent obligations for disclosure among professional medical organizations. Participants in any NASS activity (educator, principle investigator, author, committee member, member of the Board of Directors or Executive Committee) are obligated to identify the entities with whom they have relationships and to specifically categorize remuneration, both by type and a designation of either “major” or “minor” (above or below \$10,000). This policy was adopted in March 2006 by an ad hoc Task Force specifically appointed by the Board, involving months of research into not only the nature of consulting relationships but the science of bias and the study of policies of other organizations such as the Mayo Clinic. It has more recently become apparent that more specific documentation of these relationships is needed, and the Professional Conduct & Ethics Committee is in the process of preparing specific recommendations regarding policy modifications for the Board of Directors, including more specificity in regard to remuneration amounts. We anticipate that our policy will continue to evolve over time as NASS, governmental agencies and commercial entities work collaboratively towards the common goal of transparency and accountability for the common good of patients, healthcare entities and society.

During the Aging Committee's hearing, Gregory E. Demske, Assistant Inspector general for Legal Affairs at the Office of the Inspector General of the Department of Health and Human Services, said, "Although most physicians believe that free lunches, subsidized trips or gifts have no effect on their medical judgment, the research has shown that these types of perquisites can affect, often unconsciously, how humans act." Mr. Demske's statement echoes the research presented by NASS member Sohail Mirza, MD at the 2007 NASS Annual Meeting in Austin, during the Ethics Symposium. We would be happy to provide you with a link and member password to access the video of this presentation—as well as the rest of the 2007 Ethics Symposium—on our website if you would like to view it in its entirety.

The future of medical innovation—including cures for diseases and conditions from which many of our patients suffer—is contingent upon collaboration between physicians and industry. The scarcity of medical research funding by government requires that funding arise from other sources. Products are developed specifically to improve patient outcomes, and physicians have a moral responsibility to ensure that products in development are thoroughly researched and tested. A recent study in the journal *Spine* evaluates the views of 245 patients given a one-page, eight-question survey in the waiting room of an orthopedic surgery clinic: "An overwhelming majority (94.3%) believed that the surgeon-industry relationship is beneficial to patients, and a majority (66.5%) of patients thought physicians should be compensated for this role."¹ In his analysis of this study, reviewer Paul M. Arnold MD, FACS observes, "It is also evident that there are 'extremes' in doctor-manufacturer relationships, and it is these abuses that seem to tarnish the vast majority of legitimate consulting deals. If surgeon-driven innovation is to continue, then open, honest, and transparent industry-physician relationships will be the only way for this to occur."

In addition to continuing to revise and strengthen NASS' current Conflict of Interest Disclosure policy, we are also currently undertaking two projects related to ethics and industry relationships. The first is a Roundtable on Ethics in Spine Industry Relations, which will bring together leaders from device manufacturers of all sizes with NASS physician leadership and ethicists to collaborate on the creation of a new Code of Ethics for Industry that addresses such issues. Such a Code would apply to companies both large and small, as well as physicians (supplementing the existing Code of Ethics for members). Second, our Socioeconomic Affairs Council is hosting a forum for industry leaders and physicians, to discuss the socioeconomic issues and forces shaping spine care today. Part of the proposed curriculum for this forum will educate industry on how to participate in collaboration in numerous arenas—including coding, reimbursement issues, research, etc—while maintaining the highest degree of professionalism and ethics for both the manufacturers and the physicians involved. What we strive to do, instead, is to provide clear direction to both our members and to industry for how to collaborate with the highest degree of ethical behavior and professionalism.

The education of both physicians and industry is foremost in our strategy to encourage proper relationships. To that end, we have conducted General Session Ethics Symposia at our Annual Meeting for the past three years to educate our members on the proper way to collaborate with industry. In 2006, the symposia included an overview of the NY Times articles referenced in your hearing, and educated NASS members on the issues involved, including case studies and commentary from a professional ethicist, Wilton Bunch, MD. In 2007, the symposium provided an in-depth look at the moral, ethical and legal implications of relationships with the device industry, including research on the science of bias presented by Dr. Mirza; and a "pop quiz" using an audience response system, whereby audience members in this general session symposium were presented with scenarios for industry interaction and asked to judge whether the interaction was legal and—a higher bar—ethical. There was considerable confusion among a portion of the audience about where to draw the line to

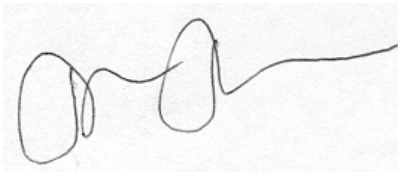
¹ Khan MH, Lee JY, Rihn JA, et al. "The Surgeon as a Consultant for Medical Device Manufacturers: What Do our Patients Think?" *Spine*. 2007;32(23):2616-2618.

maintain a completely ethical relationship. After responses were tabulated, Peter Winn, Assistant U.S. Attorney, Western District of Washington, gave his perspective on each case study. After Mr. Winn spoke, the audience voted again on whether they thought that each case was legal and ethical. Results clearly showed that audience members brought away from the symposium a measurable improvement in their acuity in judging the appropriateness of physician/industry relationships. This reveals that education is continually needed in this arena. At the end of the symposium, individual members clamored to ask questions of the panel about specific consulting arrangements that they had either seen or been approached to enter into: our members are hungry for guidance on how to conduct themselves, yet most medical schools, fellowships and residency programs omit education on this subject. This is a key role for professional societies.

While certainly the larger device manufacturers have been the subject of much of the recent attention, we feel it would be both unfair and unwise to require disclosure of relationships *only* from companies with revenues of over \$100 million. Start-ups should be held to just as high a standard as the larger, more established companies. If such disclosures are required from the start, as a company grows, it is more likely that good ethical practices will become part of the culture of that organization. It is a global culture of ethical behavior, industry-wide, that should be the ultimate goal.

We applaud the Senate Special Committee on Aging for inquiring into this important matter. We look forward to working with the Committee as you continue to examine this issue and would appreciate the opportunity to provide testimony at any future hearings on physician disclosure. Please do not hesitate to let us know if there is anything further we can do to assist you in your efforts.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Tom Faciszewski', with a long horizontal line extending to the right.

Thomas Faciszewski, MD
President, North American Spine Society