



## ***Position Statement on Physician and Industry Relations***

The North American Spine Society (NASS) is a multidisciplinary medical organization dedicated to fostering the highest quality, evidence-based and ethical spine care by promoting education, research and advocacy. NASS is comprised of more than 6,200 members from several disciplines including orthopedic surgery, neurosurgery, physiatry, neurology, radiology, anesthesiology, research, physical therapy and other spine care professionals.

Professional relationships between physicians and the medical device and pharmaceutical industry are essential to the development of new technologies and medical advancement. These relationships do not in any way reflect negatively on the character of an individual or of the industry as a whole. The purpose of disclosure in the physician-industry relationship is to encourage transparency in situations in which there is even the potential for bias. Disclosure is not intended to evaluate whether or not bias exists. The establishment of uniform disclosure requirements frees the individual from having to decide which relationships might influence decision-making and which might be irrelevant. NASS and other Professional Medical Associations (PMAs) have made great strides to provide uniform procedures for disclosure of these relationships so the possibility for confusion or misrepresentation is minimized.

### **Industry Funding of Medical Research and Products**

Pharmaceutical and medical device manufacturers provide funding for medical research, which is an avenue for the creation and testing of new products designed to meet patient treatment needs. For the purposes of this document, vendors of pharmaceuticals and devices, biologics and spine-related products are defined as 'industry.' Many forms of interaction between industry and professional organizations potentially contribute to the advancement of medical science and/or improvement of patient care and concurrently raise the issue of conflict of interest (COI). These include:

- Advancement of Medical Technology: The development of medical technology and improvement of existing products requires collaboration between industry and physicians. Many PMAs support medical research through assignment of grants, which come from funds donated by industry to the Society. Other medical research is conducted with direct funding by industry of physicians and health care providers who are faculty at academic institutions and/or in private practice.
- Safe and Effective Use of Medical Technology: The safe and effective use of medical technology may require that the industry offer physicians and other health care providers appropriate instruction, education, training, service and technical support. The Food and Drug Administration and/or companies may also require this type of training as a condition of use.
- Education: Both Continuing Medical Education (CME) and non-CME events have come under increased scrutiny due to the perception of bias. Accreditation Council for Continuing Medical Education (ACCME) guidelines must be followed for CME related events; however, non-CME events may be viewed as commercial in nature, and provide an opportunity for marketing that may result in perception of unprofessional relationships.

## Transparency of Funding and the Recent Evolution of Policy in Conflict of Interest (COI) Activity

In September of 2007, five orthopedic hip and knee implant companies—Zimmer, DePuy Orthopaedics, Smith & Nephew, Biomet and Stryker Orthopaedics—reached a settlement with the US Department of Justice (DOJ), concluding an 18-month investigation into whether those companies violated the federal anti-kickback statute. The criminal complaint accused Zimmer, DePuy, Smith & Nephew and Biomet of using consulting agreements with orthopedic surgeons to improperly promote the use of a joint replacement device (Stryker cooperated with the investigation earlier than the other companies and entered into a different settlement with the DOJ). Under the terms of the agreement, each company was ordered to conduct a needs assessment to determine the reasonable needs for educational consulting services and new product development consultants. For all new consulting agreements, physicians interacting with these companies must disclose their financial relationships to their patients and the companies must disclose each consultant's name and what they have been paid on the company's website.<sup>1</sup>

In December of 2009, then-Senate Finance Committee Ranking Member Charles Grassley (R-IA) wrote NASS and 32 other medical groups requesting information on the nature of industry funding received by each group from 2006 to 2009. Specifically, the Finance Committee requested the names of any companies which had provided the organization funding and the total amount of that funding. The Committee also requested a detailing of policies relating to the acceptance of industry funding and disclosure requirements for top executives and board members. This request was spurred by the DOJ settlement referenced above as well as press accounts highlighting the lack of transparency in relationships between industry and some nonprofit organizations. NASS fully complied with Senator Grassley's request in January of 2010. The 10-page response detailed NASS' policies on industry funding and disclosure and listed disclosures for members of the then-current NASS Board of Directors.<sup>2</sup>

The Patient Protection and Affordable Care Act, which was signed into law on March 23, 2010, includes the Physician Payment Sunshine provision which was originally introduced in the 111<sup>th</sup> congress as S. 301 by Senators Charles Grassley (R-IA) and Herb Kohl (D-WI). While the provision does not limit financial relationships, it requires all US manufacturers of drug, device, biologics and medical supplies covered under Medicare, Medicaid or SCHIP to report payments on an annual basis to the department of Health and Human Services (HHS), which will post the information on a public website.

The provision requires disclosure of payments—whether cash or in-kind transfers—to all covered recipients including: compensation; food, entertainment or gifts; travel; consulting fees; honoraria; research funding or grants; education or conference funding; stocks or stock options; ownership or investment interest; royalties or licenses; charitable contributions; and any other transfer of value as described by the secretary.

The law exempts educational material provided for the benefit of patients, rebates and discounts, loans of covered devices, items provided under warranty, dividend or investment interests in a publicly-traded security or mutual fund, and payments made to a physician who is a patient, or an employee of the reporting company. In addition, the law exempts payments less than \$10 until the aggregate annual total per company, per covered recipient, reaches \$100, at which point all payments (retroactively) must be disclosed. Prescription drug and device samples are also exempted.

States are prohibited from collecting the same information required to be reported under this section. States may continue to collect other types of data *not* captured or excluded from reporting (with the exception of *de minimis* and threshold limits), as well as data for public health purposes or legal proceedings.

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<sup>1</sup> Piechocki, M. "Five Orthopedic Device Companies Reach Settlement with DOJ for Investigation into Consulting Practices." [Ortho Super Site](#). 28 September 2007.

<sup>2</sup> Grassley, Charles. Senate Finance Committee Letter, December 2009. Print.

For each failure to report, fines of up to \$10,000 will be applied, not to exceed \$150,000 annually. For each knowing failure to report, fines of up to \$100,000 will be applied, not to exceed \$1,000,000 annually.<sup>3</sup>

### **NASS Actions on COI**

Because relationships between industry and physicians are under increased scrutiny, PMAs recently began to implement transparency and leadership divestment policies that extended beyond the traditional disclosure of relationships associated with CME and research publication. Over the past several years, NASS has set forth a robust participant disclosure and leadership divestment plan to ensure that industry relationships with NASS, its leadership and its members are fully transparent and that these relationships do not influence the work of the organization or its leadership. NASS, as a leader in this area, was the first to require all participants in any NASS activity—including those who serve in committee and leadership positions within the Society, speakers and authors on NASS publications—to disclose any industry relationship with an estimated value greater than \$100 in the previous calendar year. Disclosure must be made to NASS in actual estimated dollar amounts. This includes:

- any remuneration from or relationship with a company (example: stock ownership, stock options, stock warrants, royalties, consulting fees, loans from the sponsor, speaking arrangements)
- receiving gifts from a company (example: endowments, equipment, biomaterials, discretionary funds, support of office or research staff, support of training such as fellowships, sponsorship of trips, other sponsorships)
- holding office in a company (example: board of directors, scientific advisory board, other office) or in another PMA

As a leader in the field on the issue of physician and industry relationships, NASS worked with other PMAs to establish and promote federal regulations and laws that require disclosure. In addition to providing a detailed response to Senator Grassley's December 2009 letter, NASS has consistently communicated its position on industry relations and support for congressional action, such as early iterations of Sunshine Act legislation that has led to increased transparency of relationships between physicians and industry. In March 2008, NASS responded to an inquiry by Senate Special Committee on Aging Chairman Herb Kohl (D-WI). The letter, which followed a hearing on conflicts and consultant payments in the medical device industry, provided detailed information on NASS' disclosure policy for participants in NASS activities, discussed ongoing efforts to educate members on their ethical obligations and discussed additional efforts to strengthen NASS's current Conflict of Interest Disclosure Policy.<sup>4</sup> NASS also worked with congressional leaders on several iterations of the Physician Payment Sunshine Act and supported its inclusion of the final version in PPACA.

Additionally, NASS as an organization does not organize or provide speakers to commercial events sponsored by industry, and neither NASS as an organization nor those in leadership positions can act in any official capacity relative to an industry-sponsored course. Those in leadership positions may accept speaking invitations only for educational events hosted by government bodies, public groups, other not-for-profits (a not-for-profit foundation created as an arm of a corporation would *not* be acceptable), insurance carriers/third-party payors and other limited CME-accredited activities with "gray areas" to be reviewed in advance by NASS' Conflict of Interest Review Panel (COIRP).

### **NASS Position**

NASS has been at the forefront of providing members and participants in its activities with ethical guidelines for relationships with industry. NASS has taken great strides to ensure that the relationship between the pharmaceutical and device industry and NASS members, especially those leading the organization, is fully transparent. NASS continues

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<sup>3</sup> Physician Payments Sunshine Provisions in Health Care Reform. Pew Prescription Project. March 23, 2010.

<sup>4</sup> Faciszewski, Thomas. Letter. March 2008. Print.

to hold its members to the highest standards and believes that physicians and PMAs should be concerned about any source of funding that may create a real or perceived bias should the funding be accepted.

NASS is dedicated to educating its members, promoting quality spine care for patients and recognizes that in the setting of limited federal research funding and the need to test biomedical devices, some types of relationships between physicians and industry are necessary for medicine to advance.

In pursuing its mission, NASS administration and members collaborate with device manufacturers as inventors, scientific advisors and consultants. In the interest of avoiding conflicts of interest with respect to patient care, adherence to ethical standards by all parties that participate in this collaborative effort is essential and mandatory.

According to NASS policy:

- Members of the Board of Directors and committees are required to disclose all COI. Disclosure of the nature of the relationship requires the inclusion of relationships with family and significant others.
- Those with leadership and committee positions within the society, those who teach at NASS-sponsored CME and other educational activities, and authors of all NASS publications must abide by NASS disclosure policy. There must also be disclosure of relationships of spouses, de facto spouses, dependent and adult children, siblings, parents, other family members, trusts, organizations or other related enterprises over which the individual exercises an interest. However, there is no requirement for disclosure as a condition for membership.
- Divestment for the purposes of NASS leadership requires the elimination of most relationships with medical industry. NASS members in higher levels of leadership are required to divest completely, while members in less influential positions are required to divest proportionately less.
- Physicians who have funding with industry or other sources during their practice, research or scientific presentations must declare the funding they receive but are not subject to any further restrictions.
- PMAs themselves generally reject industry funding from certain categories and accept it from other categories. NASS accepts industry funding in the categories of certain advertising such as print ads, exhibit booth fees and in the form of unrestricted funds for research grants.

NASS, through several letters sent to Congress, voiced its support for Physician Payment Sunshine provisions that were included in the Patient Protection and Affordable Care Act. NASS believes the provision will strengthen transparency in the medical profession and uphold the ethical standards that NASS and the medical profession have in place to govern the interactions between physicians and the pharmaceutical and medical device industries.

NASS continually reevaluates its requirements for disclosure at both the individual and organizational levels and updates its policies to address changes in the field. Additionally, NASS will continue to work with Congress and federal agencies overseeing health care issues to ensure that regulations and laws are in line with evolutions in the field.

**Approved by the NASS Board of Directors, June 2011.**