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Code of Ethics for Industry Interactions with NASS

Preamble- Goal and Scope

The North American Spine Society (NASS) is dedicated to educating its members and promoting quality spine care for patients. In pursuing its mission, NASS (administration) and its members (NASS membership) 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. Therefore, NASS has adopted the following mandatory Code of Conduct for itself and those entities conducting business with NASS, to ensure ethical business practices and responsible relationships between NASS and device or drug manufacturers, and their representatives. For the purposes of this document, vendors of devices, biologics, and spine-related products are defined as 'device manufacturers.'

There are many forms of interactions between 'device manufacturers' and professional organizations (NASS and its members) that 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 require collaboration between 'device manufacturers' and NASS' membership

Safe and Effective Use of Medical Technology: The safe and effective use of medical technology may require that the 'device manufacturers' offer NASS membership appropriate instruction, education, training, service and technical support. The FDA and/or companies may also require this type of training as a condition of use.

Research: NASS supports medical research through assignment of grants which come from funds donated by 'device manufacturers' to the Society . Other medical research is conducted with direct funding by 'device manufacturers' to members of NASS who are faculty at academic institutions and/or in private practice.

Education: Both CME and non-CME events have come under increased scrutiny, with questions regarding bias in the information provided. 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.

Adherence to this code is *required* by those commercial entities wishing to participate with NASS in corporate relationships.

I. 'Device manufacturers' Sponsored Product Training and Education (non-CME)

- i. NASS has a responsibility to ensure that its members have access to appropriate education and training. In the course of disseminating new technologies or alternate surgical procedures for previously used products, this may require that prior to use, the

- NASS member participates in training provided by 'device manufacturers', whether of their own accord, or under direction of regulatory agencies.
- ii. This type of non-CME education will usually require NASS members to act as faculty, in conjunction with company representatives. These presentations require full transparency and disclosure by participating faculty; including the type of relationship with the represented 'device manufacturer' and the financial value of that relationship to the individual.
 - iii. Payments to faculty should be at fair market value (FMV), and provided only in the context of a signed contract, designating the services provided by the faculty member (see IV). On a contractual basis only, reimbursement for airfare (coach), hotel stays and food (modest) may be provided.
 - iv. Programs or events often occur at centralized locations, necessitating out of town travel and may extend more than one day. Programs focused on the education and training in the safe and effective use of products should be conducted in clinical, educational, conference or other meeting facilities conducive to the effective transmission of knowledge. Programs requiring "hands on" training in medical procedures should be held at training facilities, medical institutions, laboratories or other appropriate facilities. Training staff should have the proper qualifications and expertise to conduct such training. Hospitality in the form of modest meals and receptions in connection with these events must be subordinate in time and focus to the educational or training purpose of the meeting.
 - v. Any remuneration going to non-faculty physicians who subsequently use the products being demonstrated may be grounds for investigation by the Department of Justice (DOJ). However, reimbursement of reasonable travel expenses may be allowed.
 - vi. 'Device manufacturers' may not pay for meals, hospitality, travel or other expenses for guests of NASS members in attendance, or any other person who does not have a *bona fide* professional interest in the information being shared at the meeting.

II. Supporting Third Party Educational Conferences (CME)

- i. To the extent that educational programs for physicians are supported by any commercial entity, including pharmaceutical, device, equipment, and service entities, the programs should be offered only by ACCME-accredited providers according to ACCME standards. ACCME guidelines for exhibits and commercial interactions should be followed.
- ii. Participating 'device manufacturers' interested in supporting NASS educational activities may contribute unrestricted funds (grants) to NASS for CME activities. All contributors to the CME fund will be acknowledged equally.
- iii. Compliance with the standards of ACCME, and appropriate content validation and hospitality (a.k.a. "food & beverage") as required by ACCME will be enforced.

III. Sales and Promotional Meetings

- i. It is appropriate for 'device manufacturers' to meet with NASS officers and committee members and other NASS members to discuss rules governing appropriate interactions between individual physicians and product development practices in the field; as well as determine educational needs of the membership or company representatives.
- ii. It is appropriate for 'device manufacturers' to pay for, and for NASS members to expect, only occasional modest meals and receptions conducive to the exchange of information.

- iii. Reasonable travel costs (coach airfare, hotel, meals) of attendees for demonstrations of non-portable equipment may be paid for or reimbursed, based on a *bona fide* contractual relationship that is already in place.

IV. Arrangements with Consultants

- i. Many NASS members serve as consultants or faculty to 'device manufacturers' and provide *bona fide* consulting services, including research, collaboration, participation on scientific advisory boards, presentations and 'device manufacturers'-sponsored training sessions.
- ii. Consulting in these situations should take place only with an explicit contract in place, with specific deliverables that are restricted to scientific issues.. The contract should define the deliverables and consulting fee rates at fair market value, and the term of the contract.
- iii. NASS members providing consulting as described above should adhere to the following:
 - a. Member consulting arrangements should be written, signed by the parties and specify all services to be provided.
 - b. Compensation paid to consultants should be consistent with fair market value for the services provided.
 - c. Consulting agreements should be entered into only where a legitimate need and purpose for the services is identified in advance.
 - d. Selection of consultants should be on the basis of the consultant's unique qualifications and expertise to address the identified purpose, and should not be on the basis of volume or value of business generated by the consultant.
 - e. The venue and circumstances for Member meetings with consultants should be appropriate to the subject matter of the consultation. These meetings should be conducted in clinical, educational, conference, or other settings, including hotel or other commercially available meeting facilities, conducive to the effective exchange of information.
 - f. 'Device manufacturer'-sponsored hospitality that occurs in conjunction with a consultant meeting should be modest in value and subordinate in time and focus to the primary purpose of the meeting.
 - g. 'Device manufacturers' may pay for reasonable and actual expenses incurred by consultants in carrying out the subject of the consulting arrangement, including reasonable and actual travel (coach airfare), modest meals and lodging costs incurred by consultants attending meetings with, or on behalf of, 'device manufacturers' provided that the intent to do so is included in the contractual agreement.
 - h. When a 'device manufacturer' contracts with a consultant for research services, there should be a written research protocol.
- iv. Modest gifts may be provided to NASS members only if the gifts benefit patients and/or serve a genuine educational function. Fair market value gifts should be less than \$100 – the exception being textbooks that provide medical education. Branded promotional items are prohibited. Gifts may not be given in the form of cash or cash equivalents.

V. Provision of Reimbursement and Other Economic Information

- i. Reimbursement information related to appropriate coverage, coding or billing of 'device manufacturers' or vendor products may be provided, only if and when that information has been reviewed and approved by the leadership of the NASS Medical and/or Surgical coding committees within the Advocacy Council..
- ii. Only accurate and responsible billing to Medicare and other payors will be supported by 'device manufacturers' and NASS membership.
- iii. NASS will collaborate with 'device manufacturers' to assist in the development of and promulgation of correct coding for new devices and/or methods of delivering previously developed products.

VI. Ghostwriting

- i. Ghostwriting of manuscripts is strictly forbidden. However, 'device manufacturers' scientific personnel may participate in the writing of and ultimately publication of articles related to specific products, including the results of IDE trials and post-market studies. These authors should be acknowledged properly in all written materials relative to manuscript preparation.
- ii. All authors must be acknowledged, including those who are employees of the 'device manufacturers' publishing the article. Primary authorship may only be attributed to affiliated investigators who actively participated in the study. All authors should disclose their level of involvement with development of any manuscript. Furthermore, authors must disclose their financial and/or other relationship with the 'device manufacturer'.
- iii. Authors who played no significant role in a study or review should not be named as authors. Failing to disclose "ghostwriters" may lead to the reader's assumption that the principal investigator was involved with writing the manuscript from the beginning.

VII. Sanctions

- i. 'Device manufacturers' and members who fail to abide by the rules set out in this document will be subject to sanctions.
- ii. Violations of these policies will be heard by the PCEC Committee. The recommendations for censure submitted to the BOD must be ratified by the BOD before they take effect. The BOD has the option to overrule a sanction recommendation for any reason.