

Disclosure Policy

Adopted by NASS Board of Directors: January 13, 2006
Revised October 2008, February 2009, March 2012

Purpose

NASS is a multidisciplinary medical organization dedicated to fostering the highest quality, evidence-based, and ethical spine care by promoting education, research, and advocacy. Our members strive for the highest standards of academic rigor, intellectual veracity and professionalism. To maintain the integrity of professional judgment of our members, volunteers and leaders, and to maintain public confidence, the society hereby adopts the following policy for the disclosure, management, and when indicated, divestment of financial conflicts of interest.

The society recognizes that professional relationships with industry are essential for development of new spinal technologies and medical advancement. These relationships do not in any way reflect negatively on the character of an individual or of industry. The goal of this policy is to establish uniform procedures for transparent disclosure of these relationships so the possibility for confusion or misrepresentation is minimized.

As professionals, we rely on the honor of our colleagues in matters of trust and disclosure. With regard to our professional obligations, even the appearance that any member, volunteer or leader is in a position where financial considerations potentially could influence his or her professional behavior is damaging. Accordingly, the intent of this policy is to encourage disclosure of situations in which there is even the potential for bias, without any implications regarding actual bias. The establishment of uniform disclosure requirements frees the individual from having to decide which relationships might influence his or her decision-making and which might be irrelevant.

It is further recognized that disclosure in and of itself is not an adequate remedy for conflicts, and may even in some cases serve to increase the potential harm (see AAMC, "The Science of Reciprocity"); even gifts as small as fountain pens and prescription pads have been proven to create a feeling of obligation in the recipient. The original disclosure policy adopted by the NASS Board of Directors in January, 2006 was intended to be and was always perceived as just the first step toward more transparency in the society.

Scope

In contrast to the original policy adopted in 2006, which was limited to disclosure of financial conflict of interest, the revised policy applies universally to include any activity, remunerative or non-financial, engaged in by a NASS member, which may have the potential of creating bias in the individual. This includes unpaid faculty positions at educational events directly supported by industry, unpaid service on a company's Scientific Advisory Board, and private investments in venture capital firms and start-ups that have no current value but hold the potential for future return on investment. The society recognizes that conflicts other than financial ones also exist, including friendship or animosity, the motivation for professional advancement through academic achievements, and competition for research and other grants. Indeed, conflicts of interest are an inescapable component of all human endeavors. These intrinsic conflicts associated with the practice of medicine are not the focus of this policy.

This disclosure policy applies to all participants in all NASS activities, including those who serve in committee and leadership positions within the society, speakers, and authors on NASS publications, including but not limited to The Spine Journal (TSJ), SpineLine, Contemporary Concepts and Clinical Guidelines.

Definitions

We apply the definition of a conflict of interest as a set of conditions in which professional judgment concerning a primary interest (such as the health of patients, the integrity of research, and the education of students, the public,

and other health care professionals) has the potential to be unduly influenced by a secondary interest (such as financial gain).¹

For this policy, company is defined as "a corporation... that carries on a commercial or industrial enterprise."² Company is further defined herein as an entity that produces or sells products or services to the spine market. We include in this definition companies that are in a development stage, that is, a company that devotes substantially all of its efforts to establishing a new business in which the principal operations either have not yet begun or have begun but without significant revenue.

Product is defined as "something that is distributed commercially for use or consumption." It is usually (1) tangible personal property; (2) the result of fabrication or processing; and (3) time that has passed through a chain of approval and commercial distribution before ultimate use or consumption.

Stock/security indicates an interest based on an investment in a common enterprise and includes any interest or instrument relating to finances, including a note, stock, treasury stock, bond, debenture, evidence of indebtedness, certificate of interest or participation in a profit sharing agreement. It is further defined to include private investments such as venture capital or investments in start-up companies which have undetermined future value potential. It does not include investments in publicly available stocks such as mutual funds.

Types of Relationships that Must be Disclosed

Required elements of disclosure include:

- 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) and
- holding office in a company (example: board of directors, scientific advisory board, other office) or in another professional medical association (PMA)
- any interest, ownership (regardless of percentage), or employment in device or biologic distributorship.

Classification of Relationships

Relationships that have taken place within the prior calendar year are to be held to a robust disclosure standard. NASS members participating in an activity should disclose all financial relationships that have occurred during the prior calendar year with an estimated value of greater than one hundred dollars (\$100), using the estimated dollar amount to the nearest one thousand dollars (\$1,000). The universal deadline for disclosure will be May 1, so that any income information required to complete the disclosure will have already been collected for tax purposes. However, in some cases the deadline for a disclosure for a CME activity will precede the May 1 deadline; in such cases, the education-imposed deadline will be in effect for participants in that activity. In the case of stock holdings, the relationships will be alternately classified in terms of "percentage of company" or "number of shares").

NASS members should further disclose relationships outside of the calendar year prior to disclosure which would reasonably be judged to have a direct relationship to the topic of the activity (as an example, an author should

disclose, during a paper presentation about a device, any grant funding received for research related to that device, regardless of when the relationship existed). Relationships that could reasonably be judged by an observer to be related to the topic at hand (be it a CME presentation, committee or Board discussion, or article in a publication) and which took place earlier than the calendar year prior to disclosure should be disclosed through general disclosure (i.e., estimated dollar amounts are encouraged but not required). The "estimated dollar amount" requirement is relaxed on relationship information older than the prior calendar year because of the difficulty in accessing and/or maintaining specific financial records for, for example, five years prior to a presentation.

NASS participants are required to disclose all relationships with industry, including relationships in negotiation. Relationships still in the negotiation phase will be classified with the same terminology, on the basis of estimated potential future value.

Persons with Interest Requiring Disclosure

The object of this policy is complete disclosure of financial arrangements between a company and participants in NASS activities. Participants in NASS activities include individuals presenting at NASS meetings and courses, audience members who make comments or ask questions during symposia or SIGs, authors for NASS publications such as The Spine Journal (TSJ), SpineLine, and Clinical Guidelines, NASS office holders, and individuals appointed to NASS committees and task forces. The relationships requiring disclosure include, but are not limited to, those involving these participants, their spouses, de facto spouses, children, siblings, parents, known holdings of all other family members, trusts, organizations or other related enterprises over which the individual exercises a controlling interest.

Process for Disclosure

Disclosure is provided through completion of an online Conflict of Interest Disclosure Module. Completion of this module is mandatory as part of acceptance of speaking engagements, abstracts, article authorships, or NASS official appointments to office, committee, board or other positions. Each author listed on a scientific presentation will be required to submit his or her individual disclosure. NASS office holders, committee members and board members will submit a disclosure form annually by May 1. Authors, abstract reviewers, moderators, and symposia participants for NASS Annual Meetings must adhere to deadlines set forth specific to those meetings. Additional, updated disclosure is required when substantive changes occur in their relationships in the interim.

This module is currently available on-line through the members-only section of the NASS Website, visit [My Account](#). Each member may update his or her form at any time throughout the year to keep it up to date.

Process for Reporting Disclosed Information

- Speakers, Faculty and Moderators. Disclosure will be acknowledged at the beginning of each presentation (invited presentation, abstract presentation, symposium, course or other speaking engagement) in a manner consistent with ACCME regulations. The disclosure for each author and speaker will also be listed in the program materials (handouts, final program, web content and other published materials). Disclosure must be submitted to NASS in the "estimated dollar amount" format listed above. NASS will classify the amount as a dollar range for disclosure purposes.
- Audience Members at CME Events. It should also be noted that audience members who volunteer questions or statements during symposia, SIGs, or other educational events should, before proceeding with their comments, disclose their own conflicts to the assembled group. Due to time constraints for

these individuals, those who are volunteering questions from the audience need only state conflicts which they deem to be relevant to the topic being discussed rather than engaging in the robust conflict offered by the invited faculty and speakers.

- Board Members. Each board member will ensure that his or her disclosure is updated on the online module prior to each meeting of the Board, and will abide by the NASS Policy on Conflict of Interest in Leadership. A printout of each board member's disclosure information will be included in the first tab of the board agenda book for each board meeting. Individuals with a conflict relative to the subject matter about to be discussed will be asked to immediately recuse themselves from the deliberation, unless they have special information of a technical nature that will help the board better understand the issue. In that case, the individual will be allowed to supply such information before recusing herself or himself from the deliberations. Recusal is defined as leaving the room in which the discussion is taking place, or disconnecting from the phone in the case of a telephone or video conference, for the portion of time during which the issue is discussed. Recused individuals will not vote or otherwise influence a decision in any matter related to the issue, and they may not witness the vote or be privy to the vote attribution. After the vote is recorded, the individual may be invited back into the room or call and will be apprised of only the final vote tallies. These individuals may then comment on the matter, but they may not alter the decision or request reconsideration. Disclosure information for the entire Board of Directors will be included in the password-protected members' section of the NASS website. Disclosure information for Board members as well as each year's Program Chairs will additionally be included in the Final Program for the Annual Meeting.
- Committee and Task Force Members. Each member will complete the Conflict of Interest Disclosure Module upon acceptance of appointment. The completed form will be made available to the chair of each committee or task force. If either the Chair or Council Director has questions regarding any portion of a new committee member's level of conflict, the chair or council director may petition the COI Review Panel for review and advice on the nature and management of such conflict. Prior to discussions at the committee level, disclosure will be updated by each individual relative to the topic being discussed, whether in person, via e-mail or on a conference call, and a document outlining disclosures sent out to the committee by the staff liaison. The recusal process shall be the same as in the Board protocol outlined above.

Process for Review of Disclosures

NASS established, via a unanimous vote of the Board of Directors in May 2008, a Conflict of Interest Review Panel (COIRP) designed to facilitate the management of conflicts of interest. This committee will review disclosures of conflicts and establish policies for managing these conflicts. The committee will provide guidance to members on disclosure issues when requested for specific unclear situations,* advise the Professional Conduct & Ethics Committee (PCEC) regarding complaints related to incomplete disclosure, and vet potential NASS office bearers, especially in regards to specific types of relationships in accordance with the NASS Policy on Conflict of Interest in Leadership Positions.

***In some cases it may be difficult to assess a financial relationship and its concomitant potential conflicts. If an individual does not feel that he/she can adequately characterize the relationship, he/she will be referred to the COI Review Panel for guidance*

Security of Information

We recognize that financial disclosures contain sensitive information. Information supplied to NASS through the disclosure module in estimated dollar amounts will be viewed only by a limited number of NASS staff in the Education, Membership, and Ethics departments, who have signed Confidentiality Agreements regarding such

information. As stated in the revised Disclosure Policy, the information is stored on a password-protected, secure server. Once your information has been translated into ranges by staff, your disclosure in range format may be made available to the following parties: the audience of the CME activity at which you are presenting, the Committee/Task Force Chair (and appropriate Council Chair to which it reports) for the committee/task force on which you have volunteered to serve. In the case of questions regarding a volunteer or presenter's disclosure, the information may also be viewed by members of the Professional Conduct & Ethics Committee, the COI Review Panel, and/or the NASS Executive Committee. NOTE: Due to a recent Board of Directors ruling in October 2011, disclosure information—in range format—will begin to be made available to the general public beginning in early- to mid-2013. One may not "opt out" of having one's disclosure made publically available.

Process for Monitoring Compliance

The membership of NASS is bound by the bylaws of the association. Members who participate in NASS activities are expected to adhere to all codes and guidelines, including the rules set forth in the NASS Code of Ethics and the Disclosure Policy. If a member participant fails to live up to the obligations therein, it is incumbent upon the society and other society members to hold that individual accountable. In cases where an individual fails to disclose a significant relationship, it is an obligation of those members aware of the relationship to remind the forgetful individual of the obligation to disclose. If the failure persists, these members are obligated to report this failure to the COI Review Panel and/or Professional Conduct & Ethics Committee. The Professional Conduct & Ethics Committee may investigate the allegation, with the complainant (if one is not already in place) automatically defaulting to the secretary of the society as per current committee procedure. The committee will follow normal due process in its inquiry into the matter as outlined in the document "Procedural Guidelines of the Professional Conduct & Ethics Committee of the North American Spine Society." Failure to disclose a financial or other significant relationship with industry in accordance with this policy will be punishable according to NASS' Code of Ethics.

Waiver of Responsibility to Disclose

A member whose COI is the subject of pending litigation may apply directly to the Conflict of Interest Review Committee (COIRP) for a waiver of the responsibility to disclose. The information subject to the waiver—along with the reason for the litigation—must be disclosed to the COIRP so that they may make an informed decision as to whether to grant the waiver. Any waiver granted shall be for a period of one year from the date of issue or the final resolution of the litigation, whichever is shorter.

Sanctions for Violations

The Professional Conduct and Ethics Committee will recommend to the Board of Directors the discipline of members who neglect to disclose through the same methods already in place for other PCEC violations, including but not limited to one- or two-year suspensions of membership, membership expulsion, public letters of censure, and/or—in conjunction with the Education Council Chairs—barring the member from presenting at a specified number of future meetings.

References

1. Thompson DF. Understanding financial conflicts of interest. *N Engl J Med.* 1993;329:573-576.
2. Garner BA (ed). *Black's Law Dictionary*, 8th ed. Eagan, MN: West Publishing; 2004.