

Australian Orthopaedic Association
Position Statement on
Interaction with Medical Industry
2009



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Introductory statement

This Position Statement applies to all members of the Australian Orthopaedic Association (AOA), including Fellows, Associates, Affiliates and Registrar Affiliates.

The primary focus of the orthopaedic profession is to provide excellence in patient care, with compassion and respect.

AOA expects the highest qualities of professionalism, integrity, ethical behaviour and standards of its members.

AOA recognises that collaborative relationships between members and industry (refer Addendum 1) are important in advancing and improving patient care.

While AOA recognises that its members may pursue academic and commercial ventures, members must be mindful of their professional responsibilities and the potential for such ventures to cause conflicts of interest with patient care. A conflict of interest is considered to exist when professional judgment concerning the wellbeing of the patient has a reasonable chance of being influenced by other interests of the member. (Refer Addendum 2)

1 AOA Members' Responsibilities to the Patient

All members must act in a patient's best interest when recommending or using medical devices. Members' recommendations must be unencumbered by commercial persuasion that may influence their judgment towards a patient's treatment options.

Members must declare to the patient or their representative any potential conflict of interest associated with their care. Such a declaration must enable the patient to make an informed decision about their care.

2 AOA Members' Commercial Responsibilities

A member must disclose to colleagues, institutions, and other affected entities, any financial interest in a medical device or a procedure if the member or an institution with which they are associated, has received or will receive any direct or indirect payment of a financial or other benefit from the inventor or manufacturer of the medical device or procedure.

A member must not accept any form of personal promotion or advertising from industry.

A member must not seek gifts from industry.

Members must not receive any gifts, money or other benefits from industry exceeding an individual value of AU\$50.

A member must not accept any direct or indirect financial inducement from industry for utilising a particular implant or for switching from one manufacturer's product to another.

AOA recognises that a genuine commercial relationship may exist between a member and industry and that a payment to, or a subsidy of, the member may be appropriate in certain circumstances. Any such payment or subsidy should conform to an AOA-approved process. (Refer Addendum 3)

- A member may enter into a bona fide consultancy (including the evaluation of a product or development of a new product), provided it is covered by a contract in writing as per Addendum 3.

- The learning of new surgical techniques (demonstrated by an expert in the field in their institution) or the review of new implants or devices with on-site education may provide the added benefit of educating a large number of attendees per session and offer important insights into the function of ancillary staff and institutional protocols. In these circumstances, reimbursement for expenses may be appropriate.

Reimbursement should be limited to expenses that are strictly necessary and able to withstand public scrutiny. In no case should honoraria or reimbursement for leave from paid employment to attend a course be accepted. In addition, attending a course and learning techniques must not require or imply that the member should subsequently use the products or services provided by the particular commercial organisation.

A member who has influence in selecting medical devices or services for an institution or group shall, prior to the commencement of any such selection process, disclose any relationship with industry to their colleagues, any institution with which they are associated and any other related entities.

3 Educational Meetings

AOA recognises the collaborative role of industry in the education of members.

Support for AOA meetings will only be accepted from a company that has subscribed to an industry code of conduct. (Refer Addendum 5)

Industry donations received for an AOA conference or meeting convening body, to help lower the costs of the meeting, are acceptable, provided donations are publicly acknowledged. The convening body must ultimately determine the location, curriculum, faculty and educational methods of the conference or meeting, not industry.

In certain circumstances a payment or subsidy to a member or conference organiser may be appropriate.

If a member is part of the faculty (refer Addendum 4) or the organising committee, when recompense (in the form of a payment, subsidy or otherwise) is received, such recompense should be limited to expenses that are deemed appropriate and able to withstand public scrutiny.

A member must not accept financial, or 'in kind' support from industry:

- (i) to attend educational meetings (educational dinners at reasonable cost excepted);
- (i) to attend industry-related functions with no educational value; or
- (ii) for or on behalf of any person who does not have a bona fide professional interest in the information being shared at the meeting.

4 Presentations and Publications

A member must acknowledge industry support in any publication or presentation of research results, accompanied by a declaration of the potential conflict of interest.

In all presentations acknowledgement of any industry support and a declaration of conflict of interest or otherwise must be made at the commencement of that presentation.

Abstracts submitted for all educational meetings must include acknowledgement of industry support and potential conflict of interest for inclusion in the abstracts.

5 Orthopaedic Fellowships

All fellowships of three months' duration or longer and supervised by members should be registered with and accredited by AOA.

Industry support for fellowships should be funded through a third party to ensure 'arm's-length' administration. Such third parties may include: the AOA Fellowship Fund, universities, research institutions and foundations, philanthropic associations, public and private hospitals or other organisations associated with the provision of health care.

To assist with compliance, the AOA Fellowship Fund can accept industry support for fellowships that are accredited by AOA, as an alternative to other suitable third parties (as convenient) or where no alternative appropriate administrative third party is readily available.

All donations by industry must be publicly acknowledged.

No fellowship should bear an industry sponsor's name.

Contributions to the AOA Fellowship Fund will only be accepted from a company that has subscribed to an industry code of practice. (Refer Addendum 5)

6 Orthopaedic Trainees (Registrar Affiliates)

All orthopaedic trainees, training, research and education are covered by this Position Statement.

7 Compliance

Matters of non-compliance with this Position Statement will be handled in accordance with clause 10 of AOA's Constitution (www.aoa.org.au).

Addenda

Addendum 1 – Definition of 'Industry'

For the purposes of this Position Statement, 'industry' is defined as suppliers of medical devices, including implants or other therapeutic goods.

Addendum 2 – Definition of 'Conflicts of Interest'

For purposes of this Position Statement, a conflict of interest occurs when a member or an immediate family member has, directly or indirectly, a financial interest or positional interest or other relationship with industry that could be perceived as influencing the member's obligation to act in the best interest of the patient.

A 'financial interest', 'financial arrangement', 'financial inducement' or 'financial support' includes, but is not limited to:

- Compensation from employment;
- Compensation from patient referral pattern;
- Paid consultancy, advisory board service, etc;
- Share ownership or options;
- Intellectual property rights (patents, copyrights, trademarks, licensing agreements, and royalty arrangements);
- Paid expert opinion;
- Honoraria, speakers' fees;
- Gifts;
- Travel; and
- Meals and hospitality.

A 'positional interest' occurs when an orthopaedic surgeon or family member is an owner, officer, director, trustee, editorial board member, consultant, or employee of a company with which the orthopaedic surgeon has or is considering a transaction or arrangement.

Addendum 3 – Bona Fide Consultancy Arrangements

A member shall enter into consulting agreements with industry, only when such arrangements are established in advance and in writing to include evidence of the following:

- Documentation of an actual need for the service;
- A need to provide some proof at the time of completion of the contract, that the service has been provided;
- Evidence that reimbursement for consulting services is consistent with fair market value;
- Reimbursement should not be based on the volume or value of business he or she generates, by means of the member's own surgical practice;
- Where the consultancy agreement includes a research project that involves human or animal experimentation the research project must be approved by a research ethics committee; (refer Addendum 6)
- Where the consultancy involves a research project, a member who is the principal investigator shall use his or her best efforts to ensure at the completion of the study that relevant research results are reported and reported truthfully and honestly with no bias or influence from funding sources, regardless of positive or negative findings.

Addendum 4 – Definition of 'Faculty'

For the purposes of this Position Statement, 'faculty' is defined as a speaker at a conference or meeting.

Chairmen of educational sessions per se, are not considered faculty.

Addendum 5 – Industry Codes of Conduct

The Medical Technology Association of Australia Code of Practice is an acceptable benchmark of an industry code.

Addendum 6 – References

The National Statement on Ethical Conduct in Human Research

http://www.nhmrc.gov.au/guidelines/ethics/human_research/index.htm

Australian Code of Practice for the Care and Use of Animals for Scientific Purposes

7th edition, 2004, NHMRC

<http://www.nhmrc.gov.au/publications/synopses/eA16syn.htm>

Standards of Professionalism (SOPs) of the American Academy of Orthopaedic Surgeons

<http://searchbt.aaos.org/btc/btclog.dll?QUERY=standards+of+professionalism&SCOPE=&LOGTYPE=Clic k&URL=http://www3.aaos.org/member/profcomp/sop.cfm>

AOA Code of Conduct

2006

http://www.aoa.org.au/AM/Template.cfm?Section=UPLOADED_FILES&Template=/CM/ContentDisplay.cfm&ContentID=4264

RACS Code of Conduct

<http://www.surgeons.org/AM/TemplateRedirect.cfm?template=/CM/ContentDisplay.cfm&ContentID=13132>

The Medical Technology Association of Australia and MTANZ Code of Practice

4th Edition, 1 October 2008

<http://www.miaa.org.au/pages/page90.asp>

Commonly Asked Questions During Consultation with Members on the Position Statement

Why is this Position Statement needed?

It was originally felt that comments on 'interaction with industry' could be included in a revised AOA Code of Conduct, targeted for 2009/10.

However, following events in the United States, with the Department of Justice requiring companies to put in place various compliance arrangements, it was necessary to develop a Position Statement in order to place in the public domain a strong statement that defines appropriate relationships between orthopaedic surgeons and medical device companies.

This Position Statement will remain a 'live' document, open to discussion/change as required, and it is anticipated that the Statement will ultimately be reincorporated into the AOA Code of Conduct.

This Statement is too prescriptive.

This Statement is not prescriptive enough.

The Working Group established by the Board of AOA to develop the Position Statement undertook extensive consultation with members, Branch Committees and the Subspecialty Groups. The Board carefully considered the Statement and the final version represents the culmination of this consultative process with members.

The document represents a pragmatic Statement that outlines standards of professionalism, integrity and ethics, while recognising that there are sound reasons for members to have appropriate relationships with industry that ultimately enhance patient care. It provides an appropriately robust framework without being unnecessarily prescriptive. It should be noted that the impact and efficacy of the Statement will be regularly reviewed.

'Members must not receive any gifts, money or other benefits from industry exceeding an individual value of \$50.' Why is this statement included?

AOA has a comprehensive complaints process available through the Professional Conduct and Standards Committee, as set out in clause 10 of the Constitution. This statement is included to avoid trivialisation and potential abuse of that process.

Are industry-sponsored and run meetings covered by this Statement?

AOA recognises the collaborative role of industry in the education of members and this is reflected in the CPD recognition of 'quality' industry meetings.

Members must not accept financial or 'in kind' support from industry to attend such meetings if they are not part of a contributing faculty or organising committee.

Educational dinners at reasonable cost are acceptable.

Fellowship names should include the sponsor's name.

The Statement specifies that 'no Fellowship should bear an industry sponsor's name'.

It is acceptable, however, to recognise a company that provides sponsorship, with the Statement requiring that 'all donations by industry must be publicly acknowledged'.

That is, although a fellowship should not be specifically named as a particular company's fellowship, the support of that company can and should be acknowledged. For example, 'The XYZ Orthopaedic Fellowship' is not acceptable but 'The Orthopaedic Fellowship, sponsored by XYZ' is acceptable.

A number of companies have indicated their support for this approach. It should also be noted that the MTAA Code of Practice requires member companies to provide funding for fellowships to an organisation (not an individual) and that the fellowship must be accredited by a professional association.

What about the arrangement some surgeons have with hospitals?

Industry has deliberately been defined in this document as 'suppliers of medical devices including implants or other therapeutic goods'.

It is considered that surgeons' commercial arrangements with hospitals fall within the domain of 'Informed Financial Consent', when a patient consents to treatment. This scenario will be addressed in the AOA Code of Conduct.

How will the AOA Fellowship Fund work and how will it be different from a company directly remunerating a fellow?

Many companies have involved reputable third parties (for example, universities or research foundations) to ensure arms-length administration. AOA has offered to provide such a service and act as a third party for support of a fellowship, where no alternative third party arrangement for support of the fellowship is available. While AOA encourages all orthopaedic fellowships to be AOA accredited, there is no compulsion for fellowship funding to be directed through AOA, but any fellowship funding that is, must be for an AOA accredited fellowship.