

## BOA Code of Ethics: Interaction with the Medical Industry.

### Disclosure of conflicts of interest.

#### Introduction

The primary focus of the Orthopaedic profession is to provide excellence in patient care and the BOA expects its members to maintain the highest standards of professionalism, integrity, and ethical behaviour.

It is recognised that collaboration between clinicians and industry is important in advancing and improving patient care. Industry often supports the development of new technologies, research, innovation and the continuing education of orthopaedic surgeons. It is clear in all commercial relationships that promotional expenditure and sponsorship can be used to influence the behaviour of individuals and it is in the interests of clinicians and the medical industry to ensure that this does not occur and that the relationship is totally transparent to outside inspection.

The UK Government has given specific advice upon the place of promotional expenditure and sponsorship in guidance issued relating to the new Bribery Act which came into force in April 2011. The guidance suggests that “reasonable and proportionate promotional expenditure which seeks to improve the image of a commercial organisation, better to present products or services, or establish cordial relations, is recognised as an established and important part of doing business.” The act does not seek to criminalise normal and reasonable hospitality. Hospitality is unlikely to breach the Act if it is reasonable and proportionate, has a bona fide business purpose and is not intended to inappropriately influence an individual.

#### Conflicts of Interest

The practice of medicine inherently presents potential conflicts of interest. There is nothing intrinsically unethical in finding oneself in a position of conflict of interest, however the conflict must be recognised and managed appropriately. When conflicts arise the interests of patients, whose ethical treatment is the primary focus of the orthopaedic profession, should always be placed above secondary gains.

Surgeons have an obligation to disclose any conflicts to patients, colleagues and/or the public. They must strive to resolve any interest by maintaining a professional relationship with patients and always acting in their best interest.

#### Relationship with Industry

A conflict of interest arises when a clinician, or an immediate family member, has a direct or indirect **financial arrangement, positional interest** or other relationship with industry, which could be perceived as influencing the clinician’s obligation to act in the best interest of patients.

A **financial arrangement** includes, but is not limited to:

- Compensation for employment
- Compensation from patients' referral pattern
- Paid Consultancy, advisory board service etc.
- Share ownership or options
- Intellectual property rights (patents, copyrights, trademarks, licensing agreements, royalty arrangements)
- Paid expert opinion
- Honoraria, speaker's fees
- Gifts
- Travel, meals, hospitality

A **positional interest** occurs when the clinicians or his/her family member has any form of relationship with a company with which the clinician has or is considering a transaction or arrangement.

### **Responsibility of the Surgeon to the patient**

Clinicians must always act in the best interest of patients when recommending or using medical devices. Any potential conflict of interest associated with a patient's care must be declared to the patient, or to their representative, to allow them to make an informed decision about their care. Reasonable treatment alternatives or the further opinion of a clinician with no conflict of interest should be offered to ensure the most appropriate care is provided. If a conflict cannot be resolved satisfactorily, the clinician should consider notifying the patient of their intention to withdraw from the relationship.

Clinicians with a financial or ownership interest in a medical goods provider, image centre, surgery centre, or other health care facility must declare their financial interest to patients - especially if their financial interest is not immediately obvious.

### **Commercial responsibilities of the BOA member**

Clinicians should not:

- Accept any form of personal promotion or advertising from industry
- Seek gifts, money or other benefits from industry exceeding an individual value of £20
- Accept any direct or indirect financial inducement from industry for using a particular implant or for switching from one manufacturer's product to another.

### **Commercial relationship with industry.**

The BOA recognises that a genuine commercial relationship may exist between a member and industry. When a formal commercial relationship does exist,

payment to, or subsidy of, the member may be appropriate in the circumstances defined below:

### Consultancy

It is essential to establish a legal contract in advance. Compensation should be appropriate for the work done and at the level that reflects the market value.

The contract should include the following evidence:

- documentation of an actual need for the service
- proof at the time of completion of the contract, that the service has been provided
- evidence that reimbursement for consulting services is consistent with a fair market value
- reimbursement should not be based on the volume or value of business the clinician generates by means of the members 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
- where the consultancy involves a research project, the principal investigator shall ensure that the relevant results are submitted for publication in a peer-reviewed journal with no bias or influence from funding sources regardless of positive or negative findings.

### Royalties

Clinicians who receive material benefit from the use of a medical device or product should not accept payments such as royalties or the like from the use of that product on their own patients, or patients who have treatment at an institution where the clinician has had influence over procurement decisions. This will normally include the clinician's home institution. It is acceptable to receive royalties or the like when products are used outside the clinician's home institution.

### Disclosure

Wherever possible a clinician who has a financial interest in any device or procedure should remove him/herself from influencing any purchasing decision of the affiliated institution. When this is not possible a clinician 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 and details of any sponsored, educational non-CME event they have attended (vide infra), prior to the commencement of any such selection process. A clinician should make a similar disclosure if he/she requests a medical device or service for use in his/her own practice.

Clinicians must disclose to colleagues, institutions and other affected entities, any financial interest in a medical device or procedure if the clinic or institution with which they are affiliated, has received, or will receive any direct or indirect payment of a financial or other benefit from the invention or manufacture of the medical device or procedure.

## Research

Formal collaboration with industry should always be for sound, ethical research with local peer review and/or ethics committee approval. Finders fees and related schemes are not acceptable. Questions concerning the probity of research arrangements are best dealt with by full disclosure and by accessing ethics review board expertise.

## Education

The BOA recognises the need for a collaborative role with industry for the education of its members.

### CME accredited educational events

In general, clinicians and their families should not accept industry funding, or other associated enticements, to attend CME accredited educational events, unless this is part of an established approved and openly declared fellowship or bursary programme.

### Industry organised meetings. Education about new techniques/products

Surgeons wishing to learn a new technique or how to use a new product, should not accept funding from industry unless attendance at the educational event is approved by their local hospital or department. The focus of the event must be education and only tuition, travel and reasonable hospitality can be accepted. In no case should honoraria be accepted – unless the surgeon is part of the faculty (see below).

If a member is part of the faculty or the organising committee, where a recompense in the form of payment, subsidy or otherwise is received, such recompense should be limited to appropriate expenses and payment consistent with fair market value for time dedicated to the meeting. At all times such payments must be able to withstand public scrutiny. Any such financial arrangement must be disclosed to meeting participants.

### CME accredited educational meetings organised by BOA members

Industry donations to a convening body organising an educational event to help lower the costs of the meeting are acceptable provided donations are publicly acknowledged in printed announcements. The convening body, not industry, must ultimately determine the location, curriculum, faculty and educational methods of the conference or meeting. They must at all times retain control over all aspects of the meeting.

## Presentations and publications

Clinicians 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 these acknowledgements and declarations of interest must be made at the beginning of the presentation.

Abstracts submitted for all educational meetings must include acknowledgements of industry support and any potential conflict of interest.

A list of the possible disclosures is given at the end of this document.

### **Orthopaedic Fellowships**

Industry support for UK Fellowships should be funded through a third-party. Such third parties may include the BOA, public and private hospitals, universities, research and educational institutions, philanthropic associations or other organisations associated with the provision of health care.

Residency/Fellowship Training Programmes can receive unrestricted industry grants or support for specific activities as long as there is full, transparent disclosure by the program of the sources of support through some local processes (e.g. on meeting materials, annual reports, website etc).

All donations by industry must be publicly acknowledged.

### **Orthopaedic Trainees/Fellows.**

The training, research and education of Orthopaedic surgeons of all grades are covered by this BOA position statement.

### **The Executive, Council and affiliated Committees of the British Orthopaedic Association.**

All clinicians or affiliated professionals, who are elected to posts within the BOA, or work within the organisation at the request of Council, must declare and register any potential conflicts of interest on an annual basis. There shall be a public record of these declarations on the BOA website.

At all BOA affiliated scientific meetings **one** of the following statements should be made on a slide at the beginning of each Presentation:

**DISCLOSURE:**

1. The author or one or more of the authors have received or will receive benefits for personal or professional use from a commercial party related directly or indirectly to the subject of this presentation.
2. The author or one or more of the authors have received or will receive benefits for personal or professional use from a commercial party related directly or indirectly to the subject of this presentation. In addition, benefits have been or will be directed to a research fund, foundation, educational institution, or other non-profit organisation with which one or more of the authors are associated.
3. Although none of the authors has received or will receive benefits for personal or professional use from a commercial party related directly or indirectly to the subject of this presentation, benefits have been or will be received but will be directed solely to a research fund, foundation, educational institution, or other non-profit organization with which one or more of the authors are associated.
4. No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this presentation.
5. The author or authors choose not to disclose whether any personal or non-personal pecuniary interest exists.

## **Declarations of Interests required by the BOA:**

### **Definitions:**

**A personal pecuniary interest** involves a personal payment. The main examples include the following.

- Any consultancy, directorship, royalty agreement, position in or work for a healthcare industry that attracts regular or occasional payments in cash or in kind.
- Any fee-paid work commissioned by a healthcare industry for which the individual is paid in cash or in kind.

**A non-personal pecuniary interest** involves payment or other benefit that benefits a department or organisation with which an individual is associated, but which is not received personally. The main examples include the following.

- The holding of a fellowship endowed by the healthcare industry.
- Any payment or other support by the health industry that does not convey any pecuniary or material benefit to an individual personally but that might benefit him or her. Examples include:
  - i) a grant from a company for the running of a unit or department with which a member is associated
  - ii) a grant or fellowship or other payment to sponsor a post or member of staff in the unit with which a member is associated
  - iii) the commissioning of research or other work by, or advice from, staff who work in a unit with which the member is associated

An individual covered by this Code is under no obligation to seek out knowledge of work done for, or on behalf of, the healthcare industry within the departments with which they are associated if the relationship is distant such that the member would not normally expect to be informed of that relationship.

**A personal family interest** relates to the personal interests of a family member and involves a current payment to the family member. The main examples include the following.

- Any consultancy, directorship, position in or work for a healthcare industry that attracts regular or occasional payments in cash or in kind.
- Any fee-paid work commissioned by a healthcare industry which is paid in cash or in kind.

# Declaration of Interests

I declare that I have read and understood the BOA's Code of Ethics on Declarations of Interests. I hereby declare the following interests in the healthcare industry according to the BOA's published code.

<b>Personal pecuniary interest</b>
Description (if you have no interests in this category, state 'None')
<b>Personal family interest (if you have no interests in this category, state 'None')</b>
Description
<b>Non-personal pecuniary interest (if you have no interests in this category, state 'None')</b>
Description

Draft AJT 3.4.2011