

Opinion on Ethics and Professionalism

The Orthopaedic Surgeon's Relationship with Industry

An AAOS Opinion on Ethics and Professionalism is an official AAOS statement dealing with an ethical issue, which offers aspirational advice on how an orthopaedic surgeon can best deal with a particular situation or circumstance. Developed through a consensus process by the AAOS Ethics Committee, an Opinion on Ethics and Professionalism is not a product of a systematic review. An AAOS Opinion on Ethics and Professionalism is adopted by a two-thirds vote of the AAOS Board of Directors present and voting.

Issue raised

Under what, if any, circumstances is it appropriate for orthopaedic surgeons to accept gifts or other financial support from industry, including pharmaceutical, biomaterial or device manufacturers, laboratories, durable medical equipment suppliers, or other vendors?

Discussion

Orthopaedic surgeons have long recognized the importance of continuing medical education in maintaining their professional skills. Both orthopaedists-in-training and practicing orthopaedic surgeons attend and participate in numerous continuing medical educational programs and seminars. Industry, including pharmaceutical, biomaterial and device manufacturers, has generously supported many of these beneficial programs.

For several years, there has been concern about industry making gifts to physicians. Some of these gifts that reflect customary marketing practices of industry may not be consistent with basic principles of medical ethics. The line is sometimes blurred between industry's providing funds for an actual continuing medical educational experience and providing funds to promote the use or purchase of a particular pharmaceutical, biomaterial or piece of orthopaedic equipment.

Generally, the American Academy of Orthopaedic Surgeons (AAOS) believes that it is acceptable for industry to provide financial and other support to orthopaedic surgeons if such support has significant educational value and has the purpose of improving patient care. All dealings between orthopaedic surgeons and industry should benefit the patient, be able to withstand public scrutiny, and comply with applicable laws.

Guidelines

To avoid acceptance of inappropriate gifts or other financial support, the AAOS recommends that orthopaedic surgeons observe the following guidelines:

1. Benefit to Patients.

The patient's best interest is paramount. Therefore, it is of utmost importance that any gift or other financial support accepted by an orthopaedic surgeon should primarily entail a benefit to his or her patient. A gift of any kind from industry should in no way influence the orthopaedic surgeon in determining the most appropriate treatment for his or her patient. It is only by strict adherence to this principle that the orthopaedic surgeon may maintain the patient's trust.

2. Gifts With Conditions Attached.

Orthopaedic surgeons should not accept gifts or other financial support with conditions attached. No gifts (including goods, meals, accommodations, meeting registrations, travel, etc. to attend educational meetings or learning new skills under the tutelage of an expert) should be accepted with the explicit or implicit requirement or expectation that the orthopaedic surgeon use the products or services provided by that particular industry.

3. Social Functions.

Although the AAOS is generally opposed to orthopaedic surgeons participating in social events sponsored by industry, social functions supported by industry in combination with significant continuing medical education events are sometimes acceptable. However, social functions supported by industry (e.g. dinners, tickets to sporting events or theater, golf outings, etc.) where there is no educational element should not be offered to nor accepted by orthopaedic surgeons.

4. Cash Gifts.

Cash gifts from industry to orthopaedic surgeons must not be offered nor accepted.

5. Continuing Medical Education (CME) Events.

a. Subsidies

Subsidies by industry to underwrite the costs of educational events where CME credits are provided can contribute to the improvement of patient care and are acceptable. A corporate subsidy received by the conference's sponsor is appropriate and acceptable so long as such support is publicly acknowledged and the location, curriculum, faculty, and educational methods of the conference or meeting are determined solely by the organization sponsoring the educational course, not industry. Direct industry reimbursement for an orthopaedic surgeon to attend an educational event is not appropriate.

b. Faculty Expenses and Honoraria for Continuing Medical Education Activities.

It is appropriate for faculty at educational events where CME credits are provided to accept reasonable honoraria and to accept reimbursement for reasonable travel, lodging and meal expenses from the conference's sponsor.

6. Other Educational Events.

Educational events sponsored by industry may be of educational value and improve patient care. Orthopaedic surgeons are responsible for ensuring that decisions to accept subsidies from industry are in the best interest of their patients. The AAOS believes a potential conflict of interest exists when an orthopaedic surgeon receives such subsidies.

Special circumstances may arise in which orthopaedic surgeons may be required to learn new surgical techniques demonstrated by an expert in the field in his/her institution or to review new implants or other devices on-site. On-site education provides the added benefit of educating a larger number of attendees per session and offers 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 time off to attend the course be offered or accepted. In addition, attending the course and learning the technique must not require or imply that the orthopaedic surgeon must subsequently use that technique.

7. Scholarships for Orthopaedic Surgeons-in-Training.

Scholarships or other special funds from industry to permit orthopaedic surgeons-in-training to attend continuing medical education conferences are appropriate as long as the selection of students, residents or fellows who will receive the funds is made by the orthopaedist-in-training's program director.

8. Consultant Expenses and Honoraria.

It is appropriate for consultants to industry who provide genuine services as faculty in educational events to receive reasonable compensation and to accept reimbursement for reasonable travel, lodging and meal expenses. Token or sham consulting or advisory arrangements, such as passive attendance at a meeting or being named to an advisory board for simply discussing a device without making any real contribution to product development or analysis, cannot be used to justify compensating orthopaedic surgeons for their time, travel, lodging or other out-of-pocket expenses.

9. Other Consulting Arrangements.

A symbiotic relationship exists between orthopaedic surgeons and industry. Orthopaedic surgeons are best qualified to provide innovative ideas and feedback, conduct research trials, serve on scientific advisory boards, and to serve as faculty to teach the use of new technology. Orthopaedic surgeons, in an effort to improve patient care, rely on industry to bring their creative ideas to fruition. A collaborative relationship between orthopaedic surgeons and industry is necessary to improve patient care, but must be carefully scrutinized to avoid pitfalls of improper inducements, whether real or perceived.

It is appropriate for consultants to industry who provide genuine services to receive reasonable compensation for their services. Such arrangements should be established in advance and in writing to include evidence of the following: 1.) Documentation of an actual need for the service. 2.) Proof that the service was provided; and 3.) Evidence that physician reimbursement for consulting services does not exceed fair market value.

Examples of inappropriate relationships between orthopaedic surgeons and industry include, but are not limited to: 1.) Receiving a consultant fee for simply attending a meeting; 2.) Receiving remuneration (i.e., anything of value, such as monetary payment, stock or other ownership interests, or investment opportunity) for using a particular implant; and 3.) Receiving consultant fees or other financial inducement for switching from one manufacturer's product to another.

10. Disclosure

- a. Fellows of the AAOS are encouraged to participate in the AAOS disclosure program. The AAOS Orthopaedic Disclosure Program serves as a central repository of all relevant commercial relationships for orthopaedic surgeons and other healthcare professionals involved in organizational governance, clinical practice guidelines (CPG) and appropriate use criteria (AUC) development, CME faculty or authors of enduring materials, editors-in-chief and editorial boards.
- b. Physicians should be honest, transparent and complete in reporting relationships with industry to their patients as appropriate, and to colleagues and learners in presentations and publications.
- c. Government regulations regarding reporting continually evolve. It behooves practitioners to stay current of prevailing rules and practices. For example, Physician Payment Sunshine Act, calls for increased reporting by drug and device manufacturers of certain gifts and payments they make to physicians. It is in the best interest of the physician to be aware of what is being reported under his/ her name as related to the Sunshine Act and other similar channels.

Proper collaborative relationships between orthopaedic surgeons and industry are critical for advancement and improvement in patient care. Such relationships allow industry to fulfill their goals to improve patient care and increase patient access to new products and also are beneficial to orthopaedic surgeons and their patients. Orthopaedic surgeons must continually strive to improve patient care through the development of new advances and methodology.

Orthopaedic surgeons should never lose sight of their primary ethical responsibility to provide competent, compassionate patient care, maintaining professionalism and objectivity at all times.

References:

Applicable provisions of the *Principles of Medical Ethics and Professionalism in Orthopaedic Surgery*

"I. **Physician-Patient Relationship.** The orthopaedic profession exists for the primary purpose of caring for the patient. The physician-patient relationship is the central focus of all ethical concerns. The orthopaedic surgeon should be dedicated to providing competent medical service with compassion and respect."

Applicable provisions of the *Code of Medical Ethics and Professionalism for Orthopaedic Surgeons*

"I. A. The orthopaedic profession exists for the primary purpose of caring for the patient. The physician-patient relationship is the central focus of all ethical concerns."

"III. C. When an orthopaedic surgeon receives anything of significant value from industry, a potential conflict exists which should be disclosed to the patient. When an orthopaedic surgeon receives inventor royalties from industry, the orthopaedic surgeon should disclose this fact to the patient if such royalties relate to the patient's treatment. It is unethical for an orthopaedic surgeon to receive compensation of any kind from industry for using a particular device or medication. Reimbursement for reasonable administrative costs in conducting or participating in a scientifically sound research clinical trial is acceptable."

"IV. A. The orthopaedic surgeon continually should strive to maintain and improve medical knowledge and skill and should make available to patients and colleagues the benefits of his or her professional attainments. Each orthopaedic surgeon should participate in continuing medical educational activities."

Other references:

American Medical Association Council on Ethical and Judicial Affairs: *Code of Medical Ethics*. Chicago, IL, 2014-2015 edition.

Opinion 8.061 – Gifts to Physicians from Industry. Issued June 2014 based on the report Amendment to E-8.061, Gifts to Physicians from Industry, adopted November 2013.

Australian Orthopaedic Association, "Orthopaedic Surgeons and Their Relationship with Industry," *Australian Orthopaedic Association Bulletin*, December 1997.

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