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Ethics, Patient Interest Should Guide Physician, Industry Interactions—

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In recent years, there have been extensive publicity and public on the relationship between pharmaceutical and medical device makers (industry) and individual physicians. Articles questioning some of these relationships have appeared in *The New York Times*, *The Wall Street Journal*, and the *Washington Post*. Further, in 2005, the U.S. Department of Justice began investigating certain consulting or professional service arrangements between orthopaedic surgeons and industry; this investigation is ongoing and as yet unresolved.

The American Academy of Orthopaedic Surgeons (AAOS) and the American Medical Association (AMA) have each provided guidance on the appropriate relationship between physicians and industry. The federal government, through the Food and Drug Administration and the Office of the Inspector General of the U.S. Department of Health and Human Services, has also offered its views. The Pharmaceutical Research and Manufacturers of America (PhRMA) released its *Code on Interactions with Health Care Professionals* in 2002 and the Advanced Medical Technology Association (AdvaMed) *Code of Ethics on Interactions with Health Care Professionals (Code)* went into effect in January 2004. In 2006, the AAOS developed proposed Standards of Professionalism (SOPs) on the Orthopaedist-Industry Conflicts of Interest, which will be considered at this Annual Meeting and voted on by the fellowship following the meeting.

Each of these statements expresses concern about appropriate interactions between healthcare companies and physicians. All recognize that this relationship is both critical and essential, but has also sometimes been abused, by physicians and industry alike. This series of articles will examine the current *AAOS Opinion on Ethics and Professionalism*, the proposed AAOS SOPs on Orthopaedist-Industry Conflicts of Interest, and the AdvaMed *Code of Ethics on Interactions with Health Care Professionals*.

AAOS Opinion on Ethics and Professionalism

The AAOS *Opinion on Ethics and Professionalism on the Orthopaedic Surgeon's Relationship with Industry (Opinion)* addresses the question of under what, if any, circumstances it is appropriate for orthopaedic surgeons to accept gifts or other financial support from industry. It is reprinted on pages 320-321 of the Annual Meeting Final Program and is accessible on the AAOS Web site. The general statement underlying the *Opinion* is:

“The AAOS believes that 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 and be able to withstand public scrutiny.”

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The *Opinion*, as revised in September 2005, provides nine clear guidelines to help orthopaedic surgeons avoid the acceptance of inappropriate gifts or other financial support. They include:

- **Benefit to patients:** Any gift or financial support accepted by the orthopaedic surgeon should primarily entail a benefit to the patient. A gift of any kind from industry should in no way influence the orthopaedic surgeon in determining the most appropriate treatment for a patient.
- **Gifts with conditions attached:** The orthopaedic surgeon should not accept gifts or other financial support with conditions attached. No gift or other financial support should be accepted if there is an explicit or implicit requirement that the orthopaedic surgeon use the product or services provided by that particular company.
- **Social functions:** Industry-supported social functions such as dinners or golf outings should not be offered to or accepted by the orthopaedic surgeon if there is no educational element involved.
- **Cash gifts:** Cash gifts from industry should not be offered to or accepted by the orthopaedic surgeon.
- **Continuing Medical Education (CME) events:** Industry subsidies underwriting the costs of CME events can contribute to the improvement of patient care and are acceptable. A corporate subsidy received by the event 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 sponsoring organization, not industry. Direct or indirect reimbursement by industry to an orthopaedic surgeon attending an educational event is not appropriate.
- **Other Educational, Non-CME events:** Industry-sponsored, non-CME educational events may be of educational value and improve patient care. Orthopaedic surgeons must insure that their decisions to accept industry subsidies are in their patients' best interests. The AAOS believes that such subsidies could create a potential conflict of interest. Special circumstances may require orthopaedic surgeons 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 courses can reach a larger number of attendees per session and offer important insights on the function of ancillary staff and institutional protocols. In these circumstances, reimbursement for expenses may be appropriate, provided it is limited only to necessary expenses and able to withstand public scrutiny. Honoraria or reimbursement for time off to attend the course should never be offered or accepted. In addition, attendance to learn a technique must not require or imply that the orthopaedic surgeon must subsequently use that technique.

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Consulting Arrangements

In 2005, the Ethics Committee developed an expanded provision on Consulting Arrangements in the *Opinion*, which was approved by the Board of Directors (BOD). This provision states:

“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 should be equal to fair market value.”

The Ethics Committee continues to monitor the environment and will recommend modifications of the *Opinion* as warranted.

Proposed SOPs on Orthopaedic–Industry Conflicts of Interest

Upon the request of AAOS members, the Board of Councilors (BOC) and Board of Specialty Societies (BOS/COMSS) authored new proposed SOPs on the Orthopaedist-Industry Conflicts of Interest (Orthopaedist-Industry SOPs) in 2006. They have been reviewed by the BOC, BOS, Ethics Committee, Committee on Professionalism, and BOD. These proposed SOPs will be considered at this Annual Meeting and will be voted on by the fellowship shortly afterwards.

The proposed SOPs establish mandatory minimum standards of acceptable conduct for orthopaedic surgeons who have relationships with industry. Violations of these minimum standards could serve as grounds for a formal complaint, and result in action regarding AAOS membership status by the BOD. To enable implementation of an extensive educational program on these SOPs and the appropriate relationship between orthopaedic surgeons and industry, the AAOS has recommended that enforcement of these SOPs, if adopted, begin with acts occurring on or after January 1, 2008.

The proposed Orthopaedist-Industry SOPs highlight the importance of cooperative relationships between orthopaedic surgeons and industry, while also being mindful of the

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potential real or perceived conflicts of interest involved in these relationships. The SOPs define these “conflicts of interest” broadly and establish 17 mandatory standards of compliance. These standards were drafted to be consistent with the provisions of the *AdvaMed Code*.

The full text of the Orthopaedist-Industry SOPs appeared in the December 2006 issue of the *AAOS Bulletin* and were included in the Official Meeting Notice sent to each fellow in January. They are also available on the AAOS Web site at:

www.aaos.org/News/Bulletin/dec06/fline1.asp

Summary

There is increasing interest in the interactions between healthcare companies and healthcare professionals, including physicians, as evidenced by recent articles in the media and the proliferation of voluntary codes governing these relationships. The *AAOS Opinion on Ethics and Professionalism*, the proposed Orthopaedist-Industry SOPs and the *AdvaMed Code* each acknowledge that the relationship between health care companies and health care professionals is critically important and may have significant educational value and improve patient care.

We strongly encourage orthopaedic surgeons, healthcare company representatives and others involved in medical education to read and understand the *AAOS Opinion on Ethics and Professionalism*, the proposed Orthopaedist-Industry SOPs, and the *AdvaMed Code* involving the complex and potentially challenging and rewarding relationships between healthcare companies and healthcare professionals.

Resources:

- AAOS: www.aaos.org/about/papers/ethics/code.asp
- AdvaMed: www.advamed.org/code_of_ethics.htm
- American Medical Association: www.ama-assn.org/go/ethicalgifts
- Pharmaceutical Research and Manufacturers Association (PhRMA) Code on Interactions with Healthcare Professionals:
www.phrma.org/code_on_interactions_with_healthcare_professionals/
- U.S Department of Health and Human Services, Department of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers – 68 Fed. Reg. 23731 (May 5, 2003): www.oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf
- U.S. Food and Drug Administration Guidance for Industry, Industry-supported scientific and educational activities: www.fda.gov/cder/guidance/isse.pdf