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## **Ethics, Patient Interest Should Guide Physician, Industry Interactions—II**

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This is the second in a series of articles examining the relationship between healthcare companies and healthcare professionals. Yesterday, we reviewed the AAOS *Opinion on Ethics and Professionalism* and the proposed Orthopaedist-Industry Standards of Professionalism (SOPs); today we examine the Advanced Medical Technology Association (AdvaMed) *Code of Ethics on Interactions with Health Care Professionals*, which went into effect in January 2004. For more information about AdvaMed and the AdvaMed *Code*, visit the AdvaMed educational display, located in lobby C of the San Diego Convention Center.

### **AdvaMed Code**

AdvaMed represents more than 1,100 innovators and manufacturers of medical devices, diagnostic products and medical information systems. Its voluntary *Code of Ethics on Interactions with Health Care Professionals* can be found in its entirety on the AdvaMed Web site and at the AdvaMed educational display.

Upon release of the *Code*, AdvaMed president Pamela G. Bailey stated: “We are keeping pace with the most current thinking on manufacturers’ interactions with healthcare professionals who help develop and use lifesaving, life-improving medical innovations. This voluntary *Code* provides companies with information to facilitate ethical interactions with their partners in the healthcare community.”

In 2006, the AdvaMed Board voted to further encourage industry adoption of the *Code* by introducing an “AdvaMed *Code* logo.” Only device manufacturers that adopt compliance policies consistent with the *Code* and maintain a robust compliance infrastructure can use the logo.

Although compliance is voluntary, a 2005 survey of AdvaMed members found that more than half of the responding companies with ethical policies modified those policies to comply with the *Code*’s stricter requirements. About a quarter of responding companies had no prior ethical policy, but established one after the *Code* was introduced. Three out of four companies conduct regular training for employees, including sales representatives, marketing personnel, senior executives and general managers.

The AdvaMed *Code* discusses the following interactions between companies and healthcare professionals (including physicians) that advance medical science and/or improved patient care:

- **Advancement of medical technology.** Developing cutting edge medical technology and improving existing products are collaborative processes between healthcare companies

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and healthcare professionals.

- **Safe and effective use of medical technology.** The safe and effective use of sophisticated electronic, *in vitro* diagnostic, surgical or other medical technology often requires manufacturers to offer healthcare professionals appropriate instruction, education, training, service and technical support. Regulators may also require this type of training as a condition for product approval.
- **Research and education.** Industry support of *bona fide* medical research, education and enhancement of professional skills serves patient safety and increases access to new technology.

The AdvaMed *Code* also recognizes that there may be interactions between healthcare companies and healthcare professionals that are not specifically discussed in the *Code*. The *Code* highlights that all interactions between industry and healthcare professionals should follow “ethical business practices and socially responsible industry conduct and shall not use any unlawful inducement in order to sell, lease, recommend, or arrange for the sale, lease or prescription of ... products.”

### **Support for Education**

The AdvaMed *Code* distinguishes between company-provided product training and education and company support of third-party continuing medical education (CME) conferences, such as those sponsored by the AAOS and other professional societies. For AdvaMed member-sponsored education, companies may pay for reasonable travel and modest lodging costs incurred by the attending healthcare professional as well as modest meals and receptions in connection with these programs. The *Code* says that payment for the meals, hospitality, travel or other expenses of the healthcare professional’s guests or for any other person who does not have a *bona fide* professional interest in the information being shared at the meeting is inappropriate. The *Code* provides that AdvaMed members may support third-party CME conferences in the following ways:

- **Educational grants.** Members may make a grant directly to the conference sponsor or to a training program to allow medical students, residents, fellows and other healthcare professionals-in-training to attend educational meetings. The conference sponsor must be responsible for and control the selection of program content, faculty, educational methods and materials.
- **Modest meals and hospitality.** AdvaMed members may provide funding to conference sponsors to support conference meals and hospitality or they might provide meals and receptions themselves, but only in a manner consistent with the conference sponsor’s guidelines. Any meals, receptions and hospitality should be modest in value and

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subordinate to the purpose of the conference.

- **Faculty expenses.** AdvaMed members may make grants to conference sponsors for reasonable honoraria, travel, lodging and meals for conference faculty members.
- **Advertisement and demonstrations.** AdvaMed members may purchase advertisements and lease booth space for displays at third-party educational conferences.

The *Code* specifically addresses gifts to healthcare professionals, permitting such “gifts only if the gifts benefit patients or serve a genuine education function. Other than the gift of medical textbooks or anatomical models used for educational purposes, any gift from a[n AdvaMed] member should have a fair market value of less than \$100.”

The AdvaMed *Code* also discusses appropriate interactions between healthcare companies and healthcare professionals in sales and promotional meetings and regarding education about appropriate reimbursement for new medical technologies.

### **Consulting Arrangements**

Similar to the AAOS *Opinion on Ethics and Professionalism on the Orthopaedic Surgeon’s Relationship with Industry* and the proposed AAOS Orthopaedist-Industry SOPs, the AdvaMed *Code* also addresses the appropriate consulting arrangement between healthcare professionals and health care companies. In the section that follows, “Member” denotes an AdvaMed member company. The AdvaMed *Code* section on “Arrangements with Consultants” reads as follows:

“Many Health Care Professionals serve as consultants to Members, providing valuable *bona fide* consulting services, including research, participation on advisory boards, presentations at Member-sponsored training, and product collaboration. It is appropriate to pay Health Care Professionals reasonable compensation for performing these tasks. The following factors support the existence of a *bona fide* consulting agreement between Members and Health Care Professionals:

- Member consulting arrangements should be written, signed by the parties, and specify services to be provided.
- Compensation paid to consultants should be consistent with fair market value for the services provided.
- Consulting agreements should be entered into only where a legitimate need and purpose for the services is identified in advance.
- Selection of consultants should be on the basis of the consultant’s qualifications and expertise to address the identified purpose, and should not be on the basis of volume or value of business generated by the consultant.

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- The venue and circumstances for Member meetings with consultants should be appropriate to the subject matter of the consultation. These meeting should be conducted in clinical, educational, conference or other setting, including hotel or commercially available meeting facilities, conducive to the effective exchange of information.
- Member-sponsored hospitality that occurs in conjunction with a consultant meeting should be modest in value and should be subordinate in time and focus to the primary purpose of the meeting.
- Members may pay for reasonable and acutely expenses incurred by consultants in carrying out the subject of the consultant agreement, including reasonable and actual travel, modest meals, and lodging costs incurred by consultants attending meetings with, or on behalf of, Members.
- When a Member contracts with a consultant for research services, there should be a written research protocol.”

### **Summary**

There is increasing interest in the interactions between health care companies and health care 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 AAOS Orthopaedist-Industry SOPs and the AdvaMed *Code* 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](http://www.aaos.org/about/papers/ethics/code.asp)
- AdvaMed: [www.advamed.org/code\\_of\\_ethics.htm](http://www.advamed.org/code_of_ethics.htm)
- American Medical Association: [www.ama-assn.org/go/ethicalgifts](http://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/](http://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/03/050503FRCPPGPharmac.pdf](http://www.oig.hhs.gov/authorities/docs/03/050503FRCPPGPharmac.pdf)
- U.S. Food and Drug Administration Guidance for Industry, Industry-supported scientific and educational activities: [www.fda.gov/cder/guidance/isse.pdf](http://www.fda.gov/cder/guidance/isse.pdf)