

Patient Discussion Guide

This discussion guide is intended to provide you with important facts and information to facilitate discussions with your patients, and to help you answer any questions that you may receive from your patients concerning a settlement announced by the Department of Justice with five medical device manufacturers of artificial hips and knee joints.

Why is this financial information posted on the websites of these five companies?

Suggested Answer:

As part of their agreements with the U.S. Attorney of New Jersey (United States Department of Justice or DOJ), five orthopaedic hip and knee manufacturers were required to post the names of physicians with whom they have financial relationships and the amount of money such physicians received on their respective company websites. The agreements with the companies result from an investigation into the relationships between orthopaedic surgeons and the companies. The DOJ asserts that the posting of the dollar amount of the financial relationship between the surgeon and the company will improve transparency regarding these relationships.

On October 31, the company websites listed the name and amount of compensation that each physician received during 2007. At the end of November, a second series of lists will be released by these same companies detailing the names of physicians that received in-kind contributions for things like meals and travel.

It's important to remember that the appearance of a physician's name on any disclosure filing referenced above indicates only that he or she has received compensation from the manufacturer. It is not an indication that any doctor on the list has broken the law or violated professional standards.

Why would a doctor ever take money from implant manufacturers?

Suggested Answer:

The relationships between physicians and device manufacturers have led to many significant developments that have benefitted millions of patients. These include:

- Improvements in prosthetic materials that make joint replacements last longer.
- Design enhancements that provide better hip and knee mobility and more normal joint function.
- Advances in prosthetic joint instrumentation that enable surgery to be done through less-invasive ways, which accelerates surgical recovery and minimizes muscle damage.

- Use of integrated computer-assisted surgery technology that improves reliability for total joint replacements.
- *[The treatment that individual physicians may be providing to your patient may also benefit from these kinds of partnerships. If so, you may wish to reference the patient's treatment as well.]*

In many of these cases, physicians have assisted medical device manufacturers with specialized knowledge and expertise, for which they have received compensation.

What different kinds of financial relationships do doctors have with implant manufacturers?

Suggested Answer:

First, it's important to understand that not all physicians have financial relationships with implant manufacturers. In fact, we believe that a majority of orthopaedic surgeons do not.

For those doctors who have relationships with implant manufacturers, there are a number of different types of relationships with implant manufacturers that result in compensation, including providing consulting advice, conducting research, developing new products and educating fellow orthopaedic surgeons and the public.

These arrangements have led to a number of important breakthroughs and developments that have helped millions of patients.

If these relationships are commonplace, what did these implant manufacturers do that was wrong and that led to the settlements?

Suggested Answer:

The U.S. Attorney that led the investigation was concerned that some of the payments made by the implant manufacturers to a limited number of physicians were improper.

As an orthopaedic physician, I can tell you that this is an issue our profession takes extremely seriously. Our professional society, the American Academy of Orthopaedic Surgeons (AAOS) holds its members to extremely high ethical standards to ensure that even the appearance of a conflict of interest does not jeopardize the trust that patients place in our doctors.

I belong to the AAOS, and for the past two decades we have discussed and considered carefully the appropriate relationships between orthopaedic surgeons and implant manufacturers. In 2007, we adopted Standards of Professionalism on Orthopaedist-Industry Conflicts of Interest that require orthopaedic surgeon



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members to identify and disclose potential conflicts of interest to their patients, the public, and colleagues. These Standards also clearly articulate how and under what circumstances our members may work with and be compensated by industry, as well as the penalties for member noncompliance with the AAOS policy.

Have you personally taken money from implant manufacturers?

Recognizing that the facts, circumstances and contractual provisions governing the relationships between certain member-physicians and medical device manufacturers, are unique and confidential, the AAOS cannot provide members with individualized counsel on how to respond except to advise you:

- *To be truthful and factually accurate in your answers to patients;*
- *To stress that Code of Medical Ethics and Professionalism for Orthopaedic Surgeons (Section III. C.) requires AAOS members to disclose potential conflicts of interests to patients: the relevant section of the Code states:*

“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.”

- *To stress that the AAOS Standards of Professionalism dealing with Orthopaedist-Industry Conflicts of Interest require AAOS members to identify and disclose potential conflicts of interest to their patients, the public, and colleagues. These Standards also clearly articulate how and under what circumstances our members may work with and be compensated by industry, as well as the penalties for member noncompliance with the AAOS policy. A copy is attached to this patient discussion guide. Feel free to share it with your patients.*

**STANDARDS OF PROFESSIONALISM (SOPs)
OF THE
AMERICAN ASSOCIATION OF ORTHOPAEDIC SURGEONS®**

ORTHOPAEDIST-INDUSTRY CONFLICTS OF INTEREST

(Adopted April 18, 2007)

Adopted April 18, 2007, but the enforcement of these SOPs will begin with acts occurring on or after January 1, 2008. This will allow the AAOS to conduct an educational program for the Fellowship regarding these SOPs prior to their enforcement.

The primary focus of the orthopaedic profession is care of the patient. As part of their lifetime commitment to patients, orthopaedic surgeons must maintain specialized knowledge and skills through participation in continuing medical education programs, seminars, and professional meetings. Often, these professional functions are sponsored by the community of medical device manufacturers, pharmaceutical companies, and other businesses who play an important role supporting continuing medical education (CME) events and the development of new technologies that contribute to the on-going patient-physician relationship. This collaborative effort ensures that patients have the best surgical outcomes through the invention and testing of new technology, research and evaluation of existing technology, and continued education of orthopaedic surgeons.

Cooperative relationships between orthopaedic surgeons and industry benefit patients. Orthopaedic surgeons are best qualified to provide innovative ideas and feedback, conduct research trials, serve on scientific advisory boards, and 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.

Orthopaedic surgeons must be mindful of potential conflicts of interest with patient care in pursuing academic and commercial ventures. A conflict of interest exists when professional judgment concerning the well being of the patient has a reasonable chance of being influenced by other interests of the physician. The self-interest of the physician may be financial in nature. The competing interests may involve fame and notoriety for the physician or time for the physician or the physician's family. When such conflicts exist, there is concern that care decisions may not be in the best interests of the patient. Disclosure of a conflict of interest is required in communications to patients, the public and colleagues. The benefit to the patient must be the primary goal and must not be compromised. Orthopaedic

surgeons, like all physicians, have an ethical obligation to present themselves and the services they provide to patients in a clear and accurate manner.

When faced with a potential conflict of interest that cannot be resolved, an orthopaedic surgeon should consult with colleagues or an institutional ethics committee to determine whether there is an actual or potential conflict of interest and how to address it.

For purposes of these Standards of Professionalism, “industry” includes pharmaceutical, biomaterial, and device manufacturers.

For purposes of these Standards of Professionalism, “CME events” refer to educational events that meet the requirements of and have been approved by the Accreditation Council for Continuing Medical Education (ACCME). Further, it is understood that attendance at a CME event shall mean that the orthopaedic surgeon is attending and is not an instructor at that CME event.

For purposes of these Standards of Professionalism, a conflict of interest occurs when an orthopaedic surgeon 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 orthopaedic surgeon’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;
- Paid consultancy, advisory board service, etc.;
- Stock ownership or options;
- Intellectual property rights (patents, copyrights, trademarks, licensing agreements, and royalty arrangements);
- Paid expert testimony;
- Honoraria, speakers’ fees;
- Gifts;
- Travel; and
- Meals and hospitality

A “positional interest” occurs when an orthopaedic surgeon or family member is an 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.

Some states have enacted legislation regarding relationships between physicians and industry. When the law supersedes these Standards of Professionalism, AAOS Fellows and Members are expected to follow the law.



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These Standards of Professionalism draw from the aspirational *Code of Medical Ethics and Professionalism for Orthopaedic Surgeons* that appears in bold italics. The statements that follow the **aspirational** Code establish the **mandatory** minimum standards of acceptable conduct for orthopaedic surgeons when engaged in relationships with industry. Violations of these minimum standards may serve as grounds for a formal complaint to and action by the AAOS as outlined in the AAOS Bylaws Article VIII.

The Standards of Professionalism on Orthopaedist-Industry Conflicts of Interest apply to all AAOS Fellows and Members. Only an AAOS Fellow or Member may file complaints of an alleged violation of these Standards of Professionalism regarding another AAOS Fellow or Member.

Aspirational: AAOS 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.

Mandatory Standards:

1. An orthopaedic surgeon shall, while caring for and treating a patient, regard his or her responsibility to the patient as paramount.
2. An orthopaedic surgeon shall prescribe drugs, devices, and other treatments primarily on the basis of medical considerations and patient needs, regardless of any direct or indirect interests in or benefit from industry.

Aspirational: AAOS Code of Medical Ethics and Professionalism for Orthopaedic Surgeons, II. C.:

The orthopaedic surgeon should obey all laws, uphold the dignity and honor of the profession, and accept the profession's self-imposed discipline. Within legal and other constraints, if the orthopaedic surgeon has a reasonable basis for believing that a physician or other health care provider has been involved in any unethical or illegal activity, he or she should attempt to prevent the continuation of this activity by communicating with that person and/or identifying that person to a duly-constituted peer review authority or the appropriate regulatory agency. In addition, the orthopaedic surgeon should cooperate with peer review and other authorities in their professional and legal efforts to prevent the continuation of unethical or illegal conduct.

Mandatory Standard:



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3. An orthopaedic surgeon convicted of violating federal or state conflict of interest laws or regulations shall be subject to discipline under the AAOS Professional Compliance Program.

Aspirational: AAOS Code of Medical Ethics and Professionalism for Orthopaedic Surgeons, III.A.:

The practice of medicine inherently presents potential conflicts of interest. When a conflict of interest arises, it must be resolved in the best interest of the patient. The orthopaedic surgeon should exercise all reasonable alternatives to ensure that the most appropriate care is provided to the patient. If the conflict of interest cannot be resolved, the orthopaedic surgeon should notify the patient of his or her intention to withdraw from the relationship.

Mandatory Standards:

4. An orthopaedic surgeon shall, when treating a patient, resolve conflicts of interest in accordance with the best interest of the patient, respecting a patient's autonomy to make health care decisions.
5. An orthopaedic surgeon shall notify the patient of his or her intention to withdraw from the patient-physician relationship, in a manner consistent with state law, if a conflict of interest cannot be resolved in the best interest of the patient.

Aspirational: AAOS Code of Medical Ethics and Professionalism for Orthopaedic Surgeons, 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.

Mandatory Standards:

6. An orthopaedic surgeon shall decline subsidies or other financial support from industry, except that an orthopaedic surgeon may accept gifts having a fair market value of less than \$100, medical textbooks, or patient educational materials.

7. An orthopaedic surgeon who has influence in selecting a particular product or service for an entity shall disclose any relationship with industry to colleagues, the institution and other affected entities.
8. An orthopaedic surgeon shall disclose to the patient any financial arrangements with industry that relate to the patient's treatment, including the receipt of inventor royalties, stock options or paid consulting arrangements with industry.
9. An orthopaedic surgeon shall accept no direct financial inducements from industry for utilizing a particular implant or for switching from one manufacturer's product to another.
10. An orthopaedic surgeon 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;
 - Proof that the service was provided;
 - Evidence that physician reimbursement for consulting services is consistent with fair market value; and
 - Not based on the volume or value of business he or she generates.
11. An orthopaedic surgeon shall participate in or consult at only those meetings that are conducted in clinical, educational, or conference settings conducive to the effective exchange of information.

Aspirational: AAOS Code of Medical Ethics and Professionalism for Orthopaedic Surgeons, 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.

Mandatory Standards:

12. An orthopaedic surgeon shall accept no financial support from industry to attend industry-related social functions where there is no educational element.
13. An orthopaedic surgeon who is attending a CME event shall accept no industry financial support for attendance at a CME event. Residents and orthopaedists-in-training may accept an industry grant to attend a CME event if they are selected by their training institution or CME sponsor and the payment is made by the training program or CME sponsor. *Bona fide*



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faculty members at a CME event may accept industry-supported reasonable honoraria, travel expenses, lodging and meals from the conference sponsors.

14. An orthopaedic surgeon, when attending an industry-sponsored non-CME educational event, shall accept only tuition, travel and modest hospitality, including meals and receptions; the time and focus of the event must be for education or training.
15. An orthopaedic surgeon, when attending an industry-sponsored non-CME educational event, shall accept no financial support for meals, hospitality, travel, or other expenses for his or her guests or for any other person who does not have a *bona fide* professional interest in the information being shared at the meeting.

Aspirational: AAOS Code of Medical Ethics and Professionalism for Orthopaedic Surgeons, III.D.:

An orthopaedic surgeon reporting on clinical research or experience with a given procedure or device must disclose any financial interest in that procedure or device if the orthopaedic surgeon or any institution with which that orthopaedic surgeon is connected has received anything of value from its inventor or manufacturer.

Mandatory Standards:

16. An orthopaedic surgeon, when reporting on clinical research or experience with a given procedure or device, shall disclose any financial interest in that procedure or device if he or she or any institution with which he or she is connected has received anything of value from its inventor or manufacturer.
17. An orthopaedic surgeon who is the principal investigator shall make 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.