GUIDE TO THE

ETHICAL PRACTICE of ORTHOPAEDIC SURGERY

4th edition - 2003

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Foreword

The ethical practice of orthopaedic surgery is a matter of utmost importance to all orthopaedic surgeons. The Academy first adopted its *Code of Ethics for Orthopaedic Surgeons* in 1988 and its *Principles of Medical Ethics in Orthopaedic Surgery* in 1991. These have been revised several times, based upon comments from the Fellowship and other orthopaedic organizations. The Board of Directors, upon the recommendation of the Ethics Committee, adopted *Medical Professionalism in the New Millennium: A Physician Charter* in 2002.

This booklet, *A Guide to the Ethical Practice of Orthopaedic Surgery* (4th edition, 2003), deals with these documents and how they can and should be used. *The Principles of Medical Ethics and Professionalism in Orthopaedic Surgery, Code of Medical Ethics and Professionalism for Orthopaedic Surgeons*, and *Medical Professionalism in the New Millennium: A Physician Charter* provide standards of conduct that define the essentials of honorable behavior for the orthopaedic surgeon.

Developed by the Academy's Committee on Ethics, this booklet includes these documents as well as a number of the Academy's official Opinions on Ethics and Professionalism and various Position and Advisory Statements that involve ethical issues.

I urge each of you to take an opportunity to review and understand this *Guide to Ethical Practice of Orthopaedic Surgery (4th ed.)*. Please use this book, discuss it with your colleagues, and retain it in your personal files for future reference.

Sincerely,

/s/ James H. Herndon, MD
President
Board of Directors

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Introduction

Ethics is the discipline dealing with principles or moral values that govern relationships between and among individuals. It defines what one physician ought to do.

The Principles of Medical Ethics and Professionalism in Orthopaedic Surgery (*Principles*), *Code of Medical Ethics and Professionalism for Orthopaedic Surgeons* (*Code*) of the American Academy of Orthopaedic Surgeons (Academy) and *Medical Professionalism in the Millennium: A Physician Charter (Physician Charter)* provide standards of conduct that define the essentials of honorable behavior for the orthopaedic surgeon. They are **aspirational**. The basic tenet of these documents is that, within orthopaedic surgery, the orthopaedic surgeon must develop and maintain a deeply ingrained moral commitment to the patient's best interests. This basic tenet is articulated in several ways within the *Principles, Code,* and *Physician Charter.*

Orthopaedic surgeons may be obliged to comply with several standards of conduct. *The Principles of Medical Ethics and Professionalism in Orthopaedic Surgery,* the *Code of Medical Ethics and Professionalism for Orthopaedic Surgeons*, and *Medical Professionalism in the New Millennium: A Physician Charter* specifically recognize several:

- Legal standards and constraints;
- Personal standards relating to the care of orthopaedic patients as viewed by most orthopaedic surgeons; and
- Organizational and societal standards of conduct.

At times, these standards appear to be in conflict, and when there is a conflict, the legal standards and constraints will by necessity prevail. For example, physician advertising is legal, though distasteful to some. Nevertheless, professional ethical codes must conform to the standards within the law. Thus, the Academy's *Principles of Medical Ethics and Professionalism in Orthopaedic Surgery* and the *Code of Medical Ethics and Professionalism for Orthopaedic Surgeons* permit truthful advertising but prohibit an orthopaedic surgeon from publicizing him or herself "through any medium or form of public communication in an untruthful, misleading or deceptive manner." These concepts are explored in greater detail in the Opinions on Ethics and Professionalism on Advertising by Orthopaedic Surgeons.

Underlying the Academy's *Principles of Medical Ethics and Professionalism, Code of Medical Ethics and Professionalism* and *Medical Professionalism in the New Millennium: A Physician Charter* are critical professional values (e.g., compassion, respect for the patient, and honesty) and the integrity to commit one's professional life to them. These values and integrity form the foundation for an ethical career in orthopaedic surgery.

General Information

A. Genesis

In 1988, the Academy adopted its first *Code of Ethics* in response to numerous requests from its members. The Academy's first *Code of Ethics* was developed by a task force through an exhaustive two year review process.

When the Board of Directors adopted the *Code of Ethics*, it also established a permanent Academy Committee on Ethics. This Committee, which reports directly to the Board of Directors, is charged with reviewing and suggesting revisions of the Code when appropriate and with offering general interpretations of the *Code*. The Board of Directors amended the Code of Ethics in 1991, 1995, 2001 and 2002, based upon recommendations made by the Committee on Ethics.

In 1991, the Board of Directors adopted *The Principles of Medical Ethics in Orthopaedic Surgery*. Created upon recommendation of several Academy committees and developed by the Committee on Ethics, these ten Principles represent a distillation of the most important aspects of the *Code* in a simple one-page document. The *Principles* were amended in 1995 and 2002.

In 2002, the Board of Directors, upon the recommendation of the Ethics Committee, adopted *Medical Professionalism in the New Millennium: A Physician Charter (Physician Charter).* It also revised the name of the *Principles of Ethics* and the *Code of Ethics* to include the already-in-existence concept of professionalism which they embrace.

B. Purpose

The Academy's *Principles* and *Code* and the *Physician Charter* call for a standard of behavior for orthopaedic surgeons that is **aspirational**, that is, above the minimal standards established by the law. The goal of these documents is to ensure that patients receive the highest quality orthopaedic care available.

The Academy believes that the education of orthopaedic surgeons regarding ethics is one of the most important mechanisms to promote the needs and concerns of individual orthopaedic patients. The development of these documents regarding ethics has provided the Academy, its committees, and many orthopaedic surgeons and orthopaedists-in-training with an opportunity for thought and inquiry concerning ethics in orthopaedic surgery.

C. Opinions on Ethics and Professionalism

As part of the Academy's educational efforts regarding ethics, the Board of Directors has charged the Committee on Ethics with developing Opinions on Ethics and Professionalism, amplifying *the Principles of Medical Ethics and*

Professionalism and the *Code of Medical Ethics and Professionalism* and *Medical Professionalism in the New Millennium: A Physician Charter* and applying them to practical situations. These Opinions are available to orthopaedic surgeons and the public through the Academy's on-line and fax-on-demand services, and generally are published in the AAOS *Bulletin* upon adoption.

D. Challenges or Complaints by Fellows About Other Fellows

Under the Bylaws of the Academy and Academy policy, a Fellow may challenge or complain about the activities of another Fellow by writing to the Chair of the National Membership Committee. These complaints may often involve alleged unethical behavior. A complaint should be written with sufficient detail to enable the Chair of the National Membership Committee to determine the best handling of the issue. The Chair of the National Membership Committee might refer the matter to the appropriate Regional Membership Committee. The National Membership Committee might also meet with the Fellow who is alleged to have acted unethically or otherwise inappropriately if the initial investigations shows that probable cause exists.

In the course of its investigation, the National Membership Committee may use the Committee on Ethics as a resource panel. The National Membership Committee may request specific ethical advice in the course of its investigation regarding individual applicants, members or Fellows. The Committee on Ethics reviews the information presented to it by the Membership Committee and offers a non-binding opinion to the Membership Committee regarding whether the alleged behavior of the individual was ethical. The Committee on Ethics does not conduct independent investigations nor does it offer opinions on complaints filed by one Fellow against another directly to either of the individuals.

After a full investigation, the National Membership Committee recommends an action to the Board of Directors regarding the challenge or complaint and any other matters that had been referred to it (see Article VIII of the Bylaws).

E. Complaints by Patients Regarding Orthopaedic Surgeons

The Academy occasionally has received complaints by patients regarding orthopaedic surgeons and their office staffs. These complaints often deal with poor treatment in the surgeon's waiting room, rudeness on the part of the orthopaedic surgeon or the staff, and billing issues. Some deal with quality of orthopaedic care provided.

The Academy does not directly handle complaints by orthopaedic patients. It communicates with the patient, urging the patient to discuss the situation with his or her physician or the county or metropolitan medical society where the alleged matter occurred. In addition, when appropriate, and unless specifically prohibited by the patient, the complaint will be shared with the orthopaedic surgeon about whom the complaint has been filed. The Academy will encourage him or her to contact the patient about the concern.

F. Limited Role of the Academy

Most problems in the practice of orthopaedic surgery are not appropriate for consideration by the Academy, even if they have ethical components. In general, ethical disputes between orthopaedic surgeons should be brought to the Academy's attention only after genuine attempts at problem-solving have occurred between the parties at a local level. In addition, some problems clearly present overriding legal issues (such as malpractice of fraud), which should be handled by legal authorities. Other disputes present issues of institutional management, which can better be dealt with by hospital medical staffs or by the managed care organization, or present primarily commercial disputes between parties, in which any "ethical" issue is secondary.

The Academy cannot ensure that ethical conduct will always occur. The Academy lacks both the resources and the legal authority to be an omnipresent "police officer" for all activities of orthopaedic surgeons. To provide guidance to it Fellows or members, the Academy's Committee on Ethics issues Opinions on Ethics and Professionalism that interpret the Academy's *Principles* and *Code*, and *Physician Charter*. These advisory opinions outline what the Academy views as an ethical course of conduct in particular circumstances.

G. Other Avenues to Redress Complaints

1. Obligation to Report Unethical or Illegal Conduct

One of the more frustrating experiences for dedicated orthopaedic surgeons is to observe what they believe is clearly unethical or illegal conduct by colleagues, without a clear method for resolving the issue. The *Principles* provides that "the orthopaedic surgeon should maintain a reputation for truth and honesty with patients and colleagues, and should strive to expose through the appropriate review process those physicians who are deficient in character or competence or who engage in fraud or deception." In addition, the Academy's *Code* provides that

> "Within legal and other constraints, if the orthopaedic surgeon has a reasonable basis for believing that another orthopaedic surgeon 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 the duly-constituted peer review authorities 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."

A distinguishing feature of orthopaedic surgery is that most orthopaedic surgeons have committed themselves to standards of conduct that are higher than the legal minimum and more demanding than the morals of the marketplace. Naturally, when other orthopaedic surgeons appear to violate these norms, it is distressing to those who do not. More importantly, when patients may have been deceived or harmed or when laws may have been violated, orthopaedic surgeons have an obligation to take some sort of action. This is particularly true in situations in which the orthopaedic surgeon has information unavailable to the patient or others, so that if he or she takes no action, it is likely that no one will. Yet, the orthopaedic surgeon wishing to act faces limitations of the process.

2. Limited Role of the Academy

As discussed previously, for several reasons the Academy has a very limited role in complaints brought by orthopaedic surgeons against other orthopaedic surgeons:

- If an orthopaedic surgeon is concerned about the conduct of an orthopaedic surgeon who is not a member of the Academy, the Academy will have no jurisdiction over the matter. The Academy's ethical guidelines officially cover only Academy Fellows and members.

- The Academy's *Principles* and *Code*, and the *Physician Charter* are directed primarily to ensuring that orthopaedic patients receive the highest quality care available; they do not deal with all possible subjects or professional activities or misconduct. When the conduct of an orthopaedic surgeon lies outside of the subjects dealt with in the *Principles* or the *Code* or when it involves relations with other physicians, these documents may or may not have provisions that apply.

- Because of the Academy's limited resources, it cannot "police" all orthopaedic conduct. Thus, if a complaint is basically about allegedly incompetent surgery, the hospital or court of law—not the Academy—is often far better to resolve the matter. If criminal activity (e.g., the diversion of controlled substances) is involved, the criminal justice authorities are better able to deal with the matter. If billing fraud is involved, a federal agency is authorized to act far more effectively than the Academy. Although these cases have ethical dimensions, they are not primarily ethical, but rather legal and institutional management problems.

- While the Academy has interest in such issues as corporate conduct affecting orthopaedic surgery and disagreements among orthopaedic surgeons, the *Principles, Code,* and *Physician Charter* provide little guidance on how best to *a*ddress these Issues.

In cases that do not raise issues that are primarily ethical, the Academy encourages those who wish to file a complaint to seek assistance either from other competent organizations with jurisdiction over the matter or from the appropriate government agency or agencies.

3. Possible Legal Risks to the Orthopaedic Surgeon Who Brings a Complaint

A practical question many orthopaedic surgeons ask is: "Can I get myself in legal trouble for reporting misconduct?" Unfortunately, the answer is yes. However, one must distinguish the legal risk of being found liable from the risk of being sued unsuccessfully. Even if an orthopaedic surgeon has an unassailable legal position, the reality is that in some instances he or she may be sued for reporting misconduct. Laws vary from jurisdiction to jurisdiction. A reporting physician should be familiar with the applicable laws of the state in which the alleged misconduct occurred and when possible, seek local counsel before reporting suspected misconduct.

If sued, can an orthopaedic surgeon be held liable for reporting misconduct? The basic legal rules are:

- One cannot be held liable for acting in good faith and for reporting on a reasonable basis suspected misconduct to a government authority; one must be acting in "good faith," that is, genuinely for the purpose of protecting the public and not simply to harass or harm a competitor; and

- There may be fewer protections afforded if the orthopaedic surgeon goes to a private body (a hospital or managed care organization) rather than a public agency (state medical or licensure agency). Often, the reporting physician (particularly if in economic competition with the physician who allegedly has committed misconduct) and the private body are charged with conspiring to limit the livelihood of the physician in question. However, again, if the reporting is one in "good faith," the risk to the reporting orthopaedic surgeon should be diminished.

The Academy makes every effort to handle confidentially complaints about Fellows. The name of the communicant is not revealed to others without the express consent of the complaining Fellow or until it is required to be made known under legal due process requirements. This is necessary if the Academy's National Membership Committee finds "probable cause" that a problem exists and begins the process for disciplining the Academy member.

4. Other Avenues for Specific Issues

The following offers alternative avenues that physicians might consider when particular, fairly frequently occurring issues arise.

False or Deceptive Advertising

At the federal level, the Federal Trade Commission (FTC) is the federal agency best able to investigate charges of false and deceptive advertising. The principal statute enforced by the FTC forbids all deceptive acts or practices in interstate commerce, including misleading advertisements. If one believes in good faith that an advertisement substantially misrepresents credentials or fees or the success or nature of the procedures performed by an orthopaedic surgeon or by other health professionals, a letter may be submitted to the FTC requesting that it investigate. The FTC will review the material submitted and then determine whether a full investigation is warranted.

If the false advertisement was disseminated through the U.S. mail, then the U.S. Postal Service may also be contacted. The Postal Service has the power to halt the use of the U.S. mails for fraudulent purposes. Generally, the Postal Service will handle cases involving physicians only if the advertised product or service seems fraudulent. In such a situation, the Postal Service has very powerful enforcement tools. Should one believe that an orthopaedic surgeon is using the mail as part of a scheme to defraud consumers, the nearest postal inspector may also be called.

Finally, if the false statements relate to a drug or device, the U.S. Food and Drug Administration (FDA) may have jurisdiction. However, the FDA's authority over physician conduct is limited because of a provision of the law stipulating that the FDA may not regulate the "practice of medicine." The FDA generally does not act against physicians who make false claims concerning drugs or devices manufactured by others.

Several states have enacted laws specifically directed at false or misleading advertisements by physicians. In these states, the State Attorney General may have authority to regulate deceptive advertisements.

Fraudulent Billing

Medicare The U.S. Department of Health and Human Services (DHHS) routinely investigates allegations of Medicare fraud and abuse. If an orthopaedic surgeon learns of cases where a physician or other health professional is fraudulently billing patients covered by Medicare, he or she can notify the Inspector General of DHHS by calling 800/368-5779. DHHS also maintains ten regional offices for investigating allegations of Medicare fraud; the nearest local office can also be contacted. In addition, because Medicare fraud is a criminal offense, the United States Attorney for the district is empowered to investigate allegations of Medicare fraud. If an orthopaedic surgeon feels he or she has been unjustly accused of fraud and wishes to dispute the allegations, the Academy recommends contacting his or her state medical society for attorney referrals.

Medicaid Sometimes the complaint concerns patients covered by Medicaid rather than Medicare. In that situation, one can contact the State Attorney General of the state where the fraud occurred. Most states have established special Medicaid fraud control units, usually in the State Attorney General's office.

Fraud on Third-Party Payers State and local law enforcement officials also investigate fraud. If an orthopaedic surgeon believes that a health professional has committed fraud, regardless of whether Medicare or Medicaid funds are involved, he or she may notify the State Attorney General, the county prosecutor or the district attorney. In addition, state insurance commissioners also investigate complaints.

False Claims or Services State Licensure boards may have jurisdiction over false claims or services. Many state statutes provide that a physician's license can be suspended or revoked for submitting bills for services not actually provided.

Substandard Patient Care

A number of institutions address problems of deficient medical care. In cases of gross incompetence, state boards of medicine or licensure should be notified. The boards have the power to act, but only if they are notified of quality-of-care problems will the nature and frequency of such problems become known so that they can be corrected.

County or metropolitan medical societies sometimes receive complaints that a physician has not provided adequate care. However, these groups typically only settle disputes between patients and physician who have voluntarily agreed to submit the problem or complaint for resolution. County or metropolitan medical societies often lack the fact-finding tools or the enforcement powers necessary to resolve difficult issues relating to the quality of care.

The quality assurance or peer review committees of most hospitals and many managed care organizations are empowered to investigate and adjudicate allegations of the provision of inadequate medical care. In addition, peer review organizations in some states have even broader powers than hospital committees.

Unfair Commercial Practices

Federal law prohibits fraud and abuse associated with Medicare coverage or payments. This statute is very broad and prohibits the solicitation or receipt—or the offer of payment—of any remuneration in return for purchasing, leasing or ordering any Medicare-covered good or service. The courts have determined that those payments may be illegal even if the physician actually provides some services, if just one of the purposes of the arrangement is to stimulate additional referrals. An almost identical statue applies to Medicaid. Information that a health professional is receiving fees simply for referrals can be forwarded to the Office of the Inspector General of DHHS or to the local U.S. Attorney.

The states also have statutes regulating commercial relations. For example, states uniformly treat “kickbacks” and bribery as criminal offenses. Information regarding the seemingly unlawful exchange of money or services may be forwarded to the State Attorney General, the district attorney or county attorney, or other appropriate law enforcement body—or to a state board of medicine or licensure, some of which have authority over commercial relationships.

PRINCIPLES OF MEDICAL ETHICS AND PROFESSIONALISM IN ORTHOPAEDIC SURGERY

The following *Principles of Medical Ethics and Professionalism in Orthopaedic Surgery* have been adopted by the Board of Directors of the American Academy of Orthopaedic Surgeons. They are not laws, but rather standards of conduct that define the essentials of honorable behavior for the orthopaedic surgeon.

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.

II. **Integrity.** The orthopaedic surgeon should maintain a reputation for truth and honesty with patients and colleagues, and should strive to expose through the appropriate review process those physicians who are deficient in character or competence or who engage in fraud or deception.

III. **Legalities and Honor.** The orthopaedic surgeon must obey the law, uphold the dignity and honor of the profession, and accept the profession's self-imposed discipline. The orthopaedic surgeon also has a responsibility to seek changes in legal requirements that are contrary to the best interest of the patient.

IV. **Conflicts of Interest.** The practice of medicine inherently presents potential conflicts of interest. Wherever 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 a conflict of interest cannot be resolved, the orthopaedic surgeon should notify the patient of his or her intention to withdraw from the care of the patient.

V. **Confidentiality.** The orthopaedic surgeon should respect the rights of patients, of colleagues, and of other health professionals and must safeguard patient confidences within the constraints of the law.

VI. **Medical Knowledge.** The orthopaedic surgeon continually must strive to maintain and improve medical knowledge and to make relevant information available to patients, colleagues, and the public.

VII. **Cooperation.** Good relationships among physicians, nurses, and health care professionals are essential for good patient care. The orthopaedic surgeon should promote the development of an expert health care team that will work together harmoniously to provide optimal patient care.

VIII. **Remuneration.** Remuneration for orthopaedic services should be commensurate with the services rendered. Orthopaedic surgeons should deliver high quality, cost-effective care without discrimination.

IX. **Publicity.** The orthopaedic surgeon should not publicize himself or herself through any medium or form of public communication in an untruthful, misleading, or deceptive manner.

X. **Societal Responsibility.** The orthopaedic surgeon has a responsibility not only to the individual patient, to colleagues and orthopaedic surgeons-in-training, but also to society as a whole. Activities that have the purpose of improving the health and well-being of the patient and/or the community in a cost-effective way deserve the interest, support, and participation of the orthopaedic surgeon.

Adopted October 1991
Revised December 1995
Revised May 2002

CODE OF MEDICAL ETHICS AND PROFESSIONALISM FOR ORTHOPAEDIC SURGEONS

PREAMBLE

Concerns for the patient's welfare and the appropriate behavior of the physician are a part of the heritage of medicine originating with the Code of Hammurabi, a code of ethics dating from 2000 B.C. Guidelines for ethical behavior must address the demands of contemporary orthopaedic practice. The American Academy of Orthopaedic Surgeons (Academy) developed The *Principles of Medical Ethics and Professionalism in Orthopaedic Surgery* and the *Code of Medical Ethics and Professionalism for Orthopaedic Surgeons* primarily for the benefit of our patients and to serve as a guide to conduct in the physician-patient relationship. These documents are, in part, derived from the *Current Opinion of the Council on Ethical and Judicial Affairs of the American Medical Association (AMA)*. Since the AMA document is necessarily broad, the Academy documents are directed to concerns of specific interest to orthopaedic surgeons. Orthopaedic surgeons are encouraged to refer to the *Current Opinion of the Council on Ethical and Judicial Affairs of the AMA* for guidance if the particular ethical matter at issue is not addressed in the Academy's *Principles of Medical Ethics and Professionalism in Orthopaedic Surgery* and *Code of Medical Ethics and Professionalism for Orthopaedic Surgeons*

The Academy's *Principles of Medical Ethics and Professionalism in Orthopaedic Surgery* and *Code of Medical Ethics and Professionalism for Orthopaedic Surgeons* provide standards of conduct that define the essentials of honorable behavior for the orthopaedic surgeon. The *Principles of Medical Ethics and Professionalism in Orthopaedic Surgery* and *Code of Medical Ethics and Professionalism for Orthopaedic Surgeons,* while taking into account the legal requirements of medical practice, call for and espouse a standard of behavior that is higher than that required by the law.

Orthopaedic surgeons should recognize that they are role models for orthopaedic surgeons-in-training and other health care professionals and should by their deeds and actions comply with the Academy's *Principles of Medical Ethics and Professionalism in Orthopaedic Surgery* and *Code of Medical Ethics and Professionalism for Orthopaedic Surgeons.*

I. The Physician-Patient Relationship

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.

I. B. The physician-patient relationship has a contractual basis and is based on confidentiality, trust, and honesty. Both the patient and the orthopaedic surgeon are free to enter or discontinue the relationship within any existing constraints of a contract with a third party. An orthopaedic surgeon has an obligation to render care only for those conditions that he or she is competent to treat. The orthopaedist shall not decline to accept patients solely on the basis of race, color, gender, sexual orientation, religion, or national origin or on any basis that would constitute illegal discrimination.

I. C. The orthopaedic surgeon may choose whom he or she will serve. An orthopaedic surgeon should render services to the best of his or her ability. Having undertaken the care of a patient, the orthopaedic surgeon may not neglect that person. Unless discharged by the patient, the orthopaedic surgeon may discontinue service only after giving adequate notice to the patient so that the patient can secure alternative care.

Managed care agreements may contain provisions which alter the method by which patients are discharged. If the enrollment of a physician or patient is discontinued in a managed care plan, the physician will have an ethical responsibility to assist the patient in obtaining follow-up care. In this instance, the physician will be responsible to provide medically necessary care for the patient until appropriate referrals can be arranged.

I. D. When obtaining informed consent for treatment, the orthopaedic surgeon is obligated to present to the patient or to the person responsible for the patient, in understandable terms, pertinent medical facts and recommendations consistent with good medical practice. Such information should include alternative modes of treatment, the objectives, risk and possible complications of such treatment, and the complications and consequences of no treatment.

II. Personnel Conduct

II. A. The orthopaedic surgeon should maintain a reputation for truth and honesty. In all professional conduct, the orthopaedic surgeon is expected to provide competent and compassionate patient care, exercise appropriate respect for other health care professionals, and maintain the patient's best interests as paramount.

II. B. The orthopaedic surgeon should conduct himself or herself morally and ethically, so as to merit the confidence of patients entrusted to the orthopaedic surgeon's care, rendering to each a full measure of service and devotion.

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.

II. D. Because of the orthopaedic surgeon's responsibility for the patient's life and future welfare, substance abuse is a special threat that must be recognized and stopped. The orthopaedic surgeon must avoid substance abuse and, when necessary, seek rehabilitation. It is ethical for an orthopaedic surgeon to take actions to encourage colleagues who are chemically dependent to seek rehabilitation.

III. Conflicts of Interest

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.

III. B. If the orthopaedic surgeon has a financial or ownership interest in a durable medical goods provider, imaging center, surgery center or other health care facility where the orthopaedic surgeon's financial interest is not immediately obvious, the orthopaedic surgeon must disclose this interest to the patient. The orthopaedic surgeon has an

obligation to know the applicable laws regarding physician ownership, compensation and control of these services and facilities.

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.

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.

III. E. Except when inconsistent with applicable law, orthopaedic surgeons have a right to dispense medication, assistive devices, orthopaedic appliances, and similar related patient-care items, and to provide facilities and render services as long as their doing so provides a convenience or an accommodation to the patient without taking financial advantage of the patient. Ultimately, the patient must have the choice of accepting the dispensed medication or patient-care items or obtaining them outside the physician's office.

IV. Maintenance of Competence

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.

V. Relationships With Orthopaedic Surgeons, Nurses, and Allied Health Personnel

V. A. Good relationship among physicians, nurses, and other health care professionals are essential for good patient care. The orthopaedic surgeon should promote the development of an expert health care team that will work together harmoniously to provide optimal patient care.

V. B. The professional conduct of the orthopaedic surgeon will be scrutinized by local professional associations, hospital(s), managed care organization(s), peer review committees, and state medical and/or licensing boards. These groups deserve the participation and cooperation of orthopaedic surgeons.

V. C. Orthopaedic surgeons are frequently called upon to provide expert medical testimony in courts of law. In providing testimony, the orthopaedic surgeon should exercise extreme caution to ensure that the testimony provided is non-partisan, scientifically correct, and clinically accurate. The orthopaedic surgeon should not testify concerning matters about which the orthopaedic surgeon is not knowledgeable. It is unethical for an orthopaedic surgeon to accept compensation that is contingent upon the outcome of litigation.

VI. Relationship to the Public

VI. A. The orthopaedic surgeon should not publicize himself or herself through any medium or form of public communication in an untruthful, misleading, or deceptive manner. Competition between and among surgeons and other health care practitioners is ethical and acceptable.

VI. B. Professional fees should be commensurate with the services provided. It is unethical for orthopaedic surgeons to bill individually for services that are properly considered a part of the "global service" package where defined, i.e., services that are a necessary part of the surgical procedure. It is unethical for orthopaedic surgeons to submit billing codes that reflect higher levels of service or complexity than those that were actually required. It is unethical for orthopaedic surgeons to charge for services not provided.

VI. C. Physicians should be encouraged to devote some time and work to provide care for individuals who have no means of paying.

VI. D. The orthopaedic surgeon may enter into a contractual relationship with a group, a prepaid practice plan, or a hospital. The physician has an obligation to serve as the patient's advocate and to ensure that the patient's welfare remains the paramount concern.

VII. General Principles of Care

VII. A. An orthopaedic surgeon should practice only within the scope of his or her personal education, training, and experience. If an orthopaedic surgeon contracts to provide comprehensive musculoskeletal care, then he or she has the obligation to ensure that appropriate care is provided in areas outside of his or her personal expertise.

VII. B. It is unethical to prescribe, provide, or seek compensation for unnecessary services or not to provide services that are medically necessary. It is unethical to prescribe controlled substances when they are not medically indicated. It is also unethical to prescribe substances for the sole purpose of enhancing athletic performance.

VII. C. The orthopaedic surgeon should not perform a surgical operation under circumstances in which the responsibility for diagnosis or care of the patient is delegated to another who is not qualified to undertake it.

VII. D. When a patient submits a proper request for records, the patient is entitled to a copy of such records as they pertain to that patient individually. Charges should be commensurate with the services provided to reproduce the medical records. Certain correspondence from insurance carriers or attorneys may call for conclusions on the part of the orthopaedic surgeon. As such, a reasonable fee for professional services is permissible.

VIII. Research and Academic Responsibilities

VIII. A. All research and academic activities must be conducted under conditions of full compliance with ethical, institutional, and government guidelines. Patients participating in research programs must have given full informed consent and retain the right to withdraw from the research protocol at any time.

VIII. B. Orthopaedic surgeons should not claim as their own intellectual property that which is not theirs. Plagiarism or the use of others' work without attribution is unethical.

VIII. C. The principal investigator of a scientific research project or clinical research project is responsible for proposing, designing, and reporting the research. The principal investigator may delegate portions of the work to other individuals, but this does not relieve the principal investigator of the responsibility for work conducted by the other individuals.

VIII. D. The principal investigator or senior author of a scientific report is responsible for ensuring that appropriate credit is given for contributions to the research described.

IX. Community Responsibility

IX. A. The honored ideals of the medical profession imply that the responsibility of the orthopaedic surgeon extends not only to the individual but also to society as a whole. Activities that have the purpose of improving the health and well being of the patient and/or the community in a cost-effective way deserve the interest, support, and participation of the orthopaedic surgeon.

Adopted October 1988
Revised October 1991
Revised December 1995
Revised February 2001
Revised May 2002

MEDICAL PROFESSIONALISM IN THE NEW MILLENNIUM: A PHYSICIAN CHARTER

Project of the ABIM Foundation, ACP-ASIM Foundation, and European Federation of Internal Medicine*

[Note: The Board of Directors of the American Academy of Orthopaedic Surgeons adopted this statement on "Medical Professionalism in the New Millennium: A Physician Charter" as Academy policy during its meeting on May 17, 2002.]

Physicians today are experiencing frustration as changes in the health care delivery systems in virtually all industrialized countries threaten the very nature and values of medical professionalism. Meetings among the European Federation of Internal Medicine, The American College of Physician-American Society of Internal Medicine (ACP-ASIM), and the American Board of Internal Medicine (ABIM) have confirmed that physician views on professionalism are similar in quite diverse systems of health care delivery. We share the view that medicine's commitment to the patient is being challenged by external forces of change within our societies.

Recently, voices from many countries have begun calling for a renewed sense of professionalism, one that is activist in reforming health care systems. Responding to this challenge, the European Federation of Internal Medicine, the ACP-ASIM Foundation, and the ABIM Foundation combined efforts to launch the Medical Professionalism Project (www.professionalism.org) in late 1999. These three organizations designated members to develop a "charter" to encompass a set of principles to which all medical professionals can and should aspire. The charter supports physicians' efforts to ensure that the health care systems and the physicians working within them remain committed both to patient welfare and to the basic tenets to be applicable to different cultures and political systems.

PREAMBLE

Professionalism is the basis of medicine's contract with society. It demands placing the interests of patients above those of the physician, setting and maintaining standards of competence and integrity, and providing expert advice to society on matters of health. The principles and responsibilities of medical professionalism must be clearly understood by both the profession and society. Essential to this contract is public trust in physicians, which depends on the integrity of both individual physicians and the whole profession.

At present, the medical profession is confronted by an explosion of technology, changing market forces, problems in health care delivery, bioterrorism, and globalization. As a result, physicians find it increasingly difficult to meet their responsibilities to patients and society. In these circumstances, reaffirming the fundamental and universal principles and values of medical professionalism, which remain ideals to be pursued by all physicians, becomes all the more important.

The medical profession everywhere is embedded in diverse cultures and national traditions, but its members share the role of healer, which has roots extending back to Hippocrates. Indeed, the medical profession must contend with complicated political, legal, and market forces. Moreover, there are wide variations in medical delivery and practice through which any general principles may be expressed in both complex and subtle ways. Despite these differences, common themes emerge and form the basis of this charter in the form of three fundamental principles and as a set of definitive professional responsibilities.

FUNDAMENTAL PRINCIPLES

Principle of primacy of patient welfare. The principle is based on a dedication to serving the interest of the patient. Altruism contributes to the trust that is central to the physician-patient relationship. Market forces, societal pressures, and administrative exigencies must not compromise this principle.

Principle of patient autonomy. Physicians must have respect for patient autonomy. Physicians must be honest with their patients and empower them to make informed decisions about their treatment. Patients' decisions about their care must be paramount, as long as those decisions are in keeping with ethical practice and do not lead to demands for inappropriate care.

Principle of social justice. The medical profession must promote justice in the health care system, including the fair distribution of health care resources. Physicians should work actively to eliminate discrimination in health care, whether based on race, gender, socioeconomic status, ethnicity, religion, or any other social category.

A SET OF PROFESSIONAL RESPONSIBILITIES

Commitment to professional competence. Physicians must be committed to lifelong learning and be responsible for maintaining the medical knowledge and clinical and team skills necessary for the provision of quality care. More broadly, the profession as a whole must strive to see that all of its members are competent and must ensure that appropriate mechanisms are available for physicians to accomplish this goal.

Commitment to honesty with patients. Physicians must ensure that patients are completely and honesty informed before the patient has consented to treatment and after treatment has occurred. This expectation does not mean that patients should be involved in every minute decision about medical care; rather, they must be empowered to decide on the course of therapy. Physicians should also acknowledge that in health care, medical errors that injure patients do sometime occur. Whenever patients are injured as a consequence of medical care, patient should be informed promptly because failure to do so seriously compromises patient and societal trust. Reporting and analyzing medical mistakes provide the basis for appropriate prevention and improvement strategies and for appropriate compensation to injured parties.

Commitment to patient confidentiality. Earning the trust and confidence of patients requires that appropriate confidentiality safeguards be applied to disclosure of patient information. This commitment extends to discussions with persons acting on a patient's behalf when obtaining the patient's own consent is not feasible. Fulfilling the commitment to confidentiality is more pressing now than ever before, given the widespread use of electronic information systems for compiling patient data and an increasing availability of genetic information. Physicians recognize, however, that their commitment to patient confidentiality must occasionally yield to overriding considerations in the public interest (for example, when patients endanger others).

Commitment to maintaining appropriate relations with patients. Given the inherent vulnerability and dependency of patients, certain relationships between physicians and patients must be avoided. In particular, physicians should never exploit patients for any sexual advantage, personal financial gain, or other private purpose.

Commitment to improving quality of care. Physicians must be dedicated to continuous improvement in the quality of health care. This commitment entails not only maintaining clinical competence but also working collaboratively with other professionals to reduce medical error, increase patient safety, minimize overuse of health care resources, and optimize the outcomes of care. Physicians must actively participate in the development of better measures of quality of care and the application of quality measures to assess routinely the performance of all individuals, institutions, and systems responsible for health care delivery. Physicians, both individually and through their professional associations, must take responsibility for assisting in the creation and implementation of mechanisms designed to encourage continuous improvement in the quality of care.

Commitment to improving access to care. Medical professionalism demands that the objective of all health care systems be the availability of a uniform and adequate standard care. Physicians must individually and collectively strive to reduce barriers to equitable health care. Within each system, the physician should work to eliminate barriers to access based on education, laws, finances, geography, and social discrimination. A commitment to equity entails the promotion of public health and preventive medicine, as well as public advocacy on the part of each physician, without concern for the self-interest of the physician or the profession.

Commitment to a just distribution of finite resources. While meeting the needs of individual patients, physicians are required to provide health care that is based on the wise and cost-effective management of limited clinical resources. They should be committed to working with other physicians, hospitals, and payers to develop

guidelines for cost-effective care. The physician's professional responsibility for appropriate allocation of resources requires scrupulous avoidance of superfluous tests and procedures. The provision of unnecessary services not only exposes one's patients to avoidable harm and expense but also diminishes the resources available for others.

Commitment to scientific knowledge. Much of medicine's contract with society is based on the integrity and appropriate use of scientific knowledge and technology. Physicians have a duty to uphold scientific standards, to promote research, and to create new knowledge and ensure its appropriate use. The profession is responsible for the integrity of this knowledge, which is based on scientific evidence and physician experience.

Commitment to maintaining trust by managing conflicts of interest. Medical professionals and their organizations have many opportunities to compromise their professional responsibilities by pursuing private gain or personal advantage. Such compromises are especially threatening in the pursuit of personal or organizational interactions with for-profit industries, including medical equipment manufacturers, insurance companies, and pharmaceutical firms. Physicians have an obligation to recognize, disclose to the general public, and deal with conflicts of interest that arise in the course of their professional duties and activities. Relationships between industry and opinion leaders should be disclosed, especially when the latter determine the criteria for conducting and reporting clinical trials, writing editorials or therapeutic guidelines, or serving as editors of scientific journals.

Commitment to professional responsibilities. As members of a profession, physicians are expected to work collaboratively to maximize patient care, be respectful of one another, and participate in the processes of self-regulation, including remediation and discipline of members who have failed to meet professional standards. The profession should also define and organize the educational and standard-setting process for current and future members. Physicians have both individual and collective obligations to participate in these processes. These obligations include engaging in internal assessment and accepting external scrutiny of all aspects of their professional performance.

SUMMARY

The practice of medicine in the modern era is beset with unprecedented challenges in virtually all cultures and societies. These challenges center on increasing disparities among the legitimate needs of patients, the available resources to meet those needs, the increasing dependence on market forces to transform health care systems, and the temptation for physicians to forsake their traditional commitment to the primacy of patients' interests. To maintain the fidelity of medicine's social contract during this turbulent time, we believe that physicians must reaffirm their active dedication to the principles of professionalism, which entails not only their personal commitment to the welfare of their patients but also collective efforts to improve the health care system for the welfare of society. This Charter on Medical Professionalism is intended to encourage such dedication and to promote an action agenda for the profession of medicine that is universal in scope and purpose.

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Opinions on Ethics and Professionalism

Advertising by Orthopaedic Surgeons

Issues raised

What parameters exist to guide orthopaedic surgeons regarding advertising?

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

"IX. The orthopaedic surgeon should not publicize himself or herself through any medium or form of public communication in an untruthful, misleading, or deceptive manner."

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

"I.D. When obtaining informed consent for treatment, the orthopaedic surgeon is obligated to present to the patient or to the person responsible for the patient, in understandable terms, pertinent medical facts and recommendations consistent with good medical practice. Such information should include alternative modes of treatment, the objectives, risks and possible complications of such treatment, and the complications and consequences of no treatment."

II. A. The orthopaedic surgeon should maintain a reputation for truth and honesty. In all professional conduct, the orthopaedic surgeon is expected to provide competent and compassionate patient care, exercise appropriate respect for other health care professionals, and maintain the patient's best interests as paramount.

"VI.A. The orthopaedic surgeon should not publicize himself or herself through any medium or form of public communication in an untruthful, misleading, or deceptive manner. Competition between and among surgeons and other health care practitioners is ethical and acceptable."

Other references

American Medical Association, *Current Opinions* of the Council of Ethical and Judicial Affairs:

Section 5.01 ("Advertising and HMOs")
Section 5.02 ("Advertising and Publicity")

Legal analysis

Federal and state antitrust laws prohibit medical associations like the Academy from impeding physicians who use truthful advertising. The reason for this prohibition is to preserve and promote a free and open market by enabling physicians to disseminate information about their services to patients. Policy makers at the federal and state level believe that truthful advertising may assist patients in making better informed judgments and choices.

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Although truthful advertising has substantial legal protections, physician advertising that is not truthful is not protected by federal or state antitrust laws nor is it protected from state regulation by the First Amendment. In fact, physician advertising that is false, deceptive, or misleading within the meaning of Section 5 of the Federal Trade Commission (FTC) Act is illegal. [15 U.S.C. Sect. 45]. The FTC has the authority to sue physicians who disseminate false or deceptive advertising. In addition, the FTC may enjoin them from further dissemination of misleading advertisements, and under some circumstances, may levy fines. Furthermore, physicians who violate an FTC order which prohibits the dissemination of false or deceptive advertising are subject to substantial fines.

In addition, many state consumer protection laws and medical practice acts prohibit false or deceptive physician advertising. These laws generally empower state attorneys general to sue physicians who engage in false advertising for fines or to enjoin further illegal activity. State medical licensure boards often have the authority to discipline physicians who engage in false advertising. In addition, patients who have been injured by false or misleading physician advertising may be able to sue the physician involved for damages under consumer protection statutes or common law fraud claims.

Ethical analysis

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. This principle of ethical conduct is buttressed by its enforcement in law.

A successful physician-patient relationship is based on trust. The patient trusts that the physician has the appropriate training and skills, will listen to the patient's complaints and symptoms, and will advise the patient accurately and objectively about the alternative courses of treatment. It is essential to this relationship that the patient have confidence that the physician is honest and is not manipulating the information presented for any purpose. Because the patient is often in a relatively uninformed position, patients usually assume that the physician is telling them all they need to know and that what they are told is accurate. Consequently, patients are especially at risk for untruthful, misleading or deceptive advertising.

For this reason, false and deceptive advertising by physicians destroys the trust relationship between the physician and patient which is essential to quality medical care. A physician's misrepresentation may harm patients by making them less likely to seek out treatments they need or vulnerable to accepting treatments that are not essential.

The FTC has developed four general rules to determine whether physician advertisements are truthful and not false, deceptive or misleading. The four rules are:

1. Advertisements should be accurate and not contain explicit false claims or misrepresentations of material fact. Generally, a false claim or a misrepresentation of fact would be material if it would be likely to affect the behavior or actions of an ordinary and prudent person regarding a physician or physician service.

2. Advertisements should not contain material implied false claims or implied misrepresentations of material fact. An advertisement that does not contain direct

false claims or misrepresentations should not by implication create false or unjustified expectations about the physician or physician services being publicized. An implied false claim or misrepresentation would be material if it would be likely to affect the behavior of an ordinary and prudent person towards a physician or physician service.

3. There should be no omissions of material fact from advertisements. In advertisements, disclosures of information are necessary where omission would make the advertisement as a whole misleading to an ordinary and prudent person or an average member of the audience to whom it is directed.

4. Physicians should be able to substantiate material claims and personal representations made in an advertisement.

The ultimate question of whether an advertisement is truthful can be determined by addressing whether all four of these rules of truthful advertising have been followed in the development and dissemination of the advertisement.

Specific issues

- *Endorsements and Pictures*

Endorsements and pictures are sometimes used to represent the benefits of specific orthopaedic services, such as the degree of relief, recovery, or other benefits that may be attained if the services are used. The primary concern raised by endorsements and pictures is whether they communicate benefits of orthopaedic services that are representative of the benefits ordinarily attained by the average patient. If they communicate a degree of relief or recovery that is exceptional or otherwise not representative of the average patient, they may mislead patients into having unjustified medical expectations about the orthopaedic services advertised.

- *Claims: "Painless"*

The degree of comfort, ease, or pain involved in the provision of an orthopaedic service is difficult to measure by objective standards. How these factors are experienced by an individual is subjective and varies from patient to patient. Therefore, claims or representations about the degree of comfort, care or lack of pain involved in an orthopaedic service may be difficult to substantiate and may be misleading if not used with care.

Statements that an orthopaedic procedure does not cause pain or is painless raise concerns if the services advertised are invasive. It is highly unlikely that an invasive orthopaedic procedure will not cause some degree of pain.

- *Claims: "Safe" or "Effective"*

General representations about the safety or effectiveness of specific orthopaedic services should not be misleading. Such representations may cause a layperson to lack appreciation for the nature of any risks or adverse effects associated with the orthopaedic procedure, even if the likelihood that adverse effects may occur is low. More specific representations can also cause concerns. For example, a statement that an orthopaedic surgeon has cured or successfully

treated a large number of cases involving a particular serious ailment is deceptive if it implies a certainty of result and creates unjustified and misleading expectations in prospective patients.

Representations about the safety or effectiveness of orthopaedic services should be substantiated with sound scientific support, such as peer reviewed publications in medical literature or other authoritative sources of scientific information. Such claims should not contradict or be inconsistent with conclusions reached by authoritative federal agencies, such as the National Institutes of Health, the Centers for Medicare and Medicaid Services, the Food and Drug Administration or others, unless such a contradiction or inconsistency can be substantiated with sound scientific evidence.

Simply using a phrase such as "safe" is likely to deceive prospective patients by implying an absolute or binary ("safe" versus "unsafe") standard, when in fact the "safety" of an orthopaedic procedure is necessarily a qualified concept. The failure to qualify the claim is particularly objectionable since a variety of phrases could easily be employed to communicate the safety/risk relationship (e.g. "relatively safe," "safe for most patients," or "among the safer types of orthopaedic surgery").

- *Claims: "Cure"*

Use of the term "cure" with reference to a problem is often deceptive. To "cure" a condition means to alter the circumstances so that the condition no longer exists and will not recur. In order not to be misleading, the term "cure" should almost always be further explained and qualified to give the patient an accurate understanding of his/her prospects for improvement.

- *Claims: Physician Qualifications*

Orthopaedic surgeon qualifications include education, training, and other indicators of status or achievement within the profession. The lay public does not have a good understanding about what various qualifications represent. Most patients will assume that physician qualifications in an advertisement indicate training, knowledge, expertise, and competence with respect to the services being advertised. That assumption is likely because patients will conclude that qualifications are listed in an advertisement to substantiate the orthopaedic surgeon's ability to perform the services being advertised. It is possible for patients to be misled if the qualifications listed imply a level of education or training which the orthopaedic surgeon did not receive; if they imply a degree of scrutiny of the orthopaedic surgeon's knowledge, training and competence that did not in fact occur; if they imply a qualification which the orthopaedic surgeon does not have; if the qualifications are inaccurately listed; or if the qualifications do not indicate education, training, knowledge, expertise, or competence with respect to the services being advertised.

- *Claims: "World Famous," "Top Surgeon," "Pioneer"*

Only a small fraction of all orthopaedic surgeons can justifiably claim to be "world-famous." These may include some orthopaedic surgeons who are editors of major journals, who have authored widely used texts, or who have made major, original contributions to medical techniques. However, it is the very elusiveness of measures of "fame" which makes invoking them in trying to lure patients misleading. Merely traveling extensively, presenting addresses at professional meetings or treating patients from abroad does not mean that an orthopaedic surgeon is "world-famous." To so indicate is to use the inherent imprecision of the concept of fame to mislead patients. There can be little question that such claims are employed in order to

give patients the impression that the orthopaedic surgeon meets some objective, high level of competence, skill or recognition - which probably does not exist with respect to the advertiser. The same is true of advertising oneself as a “top orthopaedic surgeon.”

Saying that one has “pioneered advances in orthopaedic surgery” is also deceptive. Such a phrase connotes a major breakthrough, not a minor alteration or refinement of conventional procedures. Simply being one of many “investigators” for a type of orthopaedic prosthesis, using one piece of equipment, or using a slightly refined surgical procedure does not justify use of the term “pioneer.” Since all orthopaedic surgery requires some degree of innovation, an orthopaedic surgeon cannot meaningfully claim to be an originator or developer of a technique or product simply because he or she has modified what existed before in some minor way.

- *Claims: Fees and Costs*

Orthopaedic surgeons may advertise truthful information about fees and costs. However, statements about fee information can be misleading if they do not fairly inform the public about the costs likely to be incurred when patronizing the advertised physician. For example, the description of any service for which a fee or a range of fees is advertised must not be deceptive or misleading, and the statement should also indicate whether there may be additional fees for related services that are commonly required when the advertised service is obtained.

Opinions on Ethics and Professionalism

Care and Treatment of the Medically Underserved

Issue raised

What are the orthopaedic surgeon's obligations to care and/or treat the medically underserved, i.e., patients who do not have insurance and who are unable to pay for such services?

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

"X. **Societal Responsibility.** The orthopaedic surgeon has a responsibility not only to the individual patient, to colleagues and orthopaedic surgeons-in-training, but also to society as a whole. Activities that have the purpose of improving the health and well-being of the patient and/or the community in a cost-effective way deserve the interest, support and participation of the orthopaedic surgeon."

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

"I.B. The physician-patient relationship has a contractual basis and is based on confidentiality, trust and honesty. Both the patient and the orthopaedic surgeon are free to enter or discontinue the relationship within any existing constraints of a contract with a third party. An orthopaedist has an obligation to render care only for those conditions that he or she is competent to treat. The orthopaedist shall not decline to accept patients solely on the basis of race, color, gender, sexual orientation, religion or national origin or on any basis that would constitute illegal discrimination."

"I.C. The orthopaedic surgeon may choose whom he or she will serve. An orthopaedic surgeon should render services to the best of his or her ability. Having undertaken the care of a patient, the orthopaedic surgeon may not neglect that person. Unless discharged by the patient, the orthopaedic surgeon may discontinue services only after giving adequate notice to the patient so that the patient can secure alternative care. Managed care agreements may contain provisions which alter the method by which patients are discharged. If the enrollment of a physician or patient is discontinued in a managed care plan, the physician will have an ethical responsibility to assist the patient in obtaining follow-up care. In this instance, the physician will be responsible to provide medically necessary care for the patient until appropriate referrals can be arranged."

"VI.C. Physicians should be encouraged to devote some time and work to provide care for individuals who have no means of paying."

"IX.A. The honored ideals of the medical profession imply that the responsibility of the orthopaedic surgeon extends not only to the individual but also to society as a

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whole. Activities that have the purpose of improving the health and well-being of the patient and/or the community in a cost-effective way deserve the interest, support, and participation of the orthopaedic surgeon."

Other references

American Academy of Orthopaedic Surgeons, Position Statement on Health Care Coverage for Children at Risk, September, 1997.

American Medical Association, *Current Opinions* of the Council on Ethical and Judicial Affairs,

Section 2.095 ("The Provision of Adequate Health Care")
Section 9.065 ("Caring for the Poor")

American Medical Association Council on Ethical and Judicial Affairs, "Caring for the Poor," JAMA, 269: 2533-2537 (1992).

Background

A significant portion of the citizens in the United States have inadequate access to medical care.[i] According to a 1992 study, 17 percent of Americans had inadequate access to physicians, reflected in such factors as premature death and disability caused by controllable illnesses and high rates of infant and child mortality.[ii] A 1996 study by researchers in the Harvard School of Public Health found that 37 million Americans (31 percent) were without health insurance or had difficulty getting or paying for medical care at some time during 1995.[iii]

Since 1988, the number of *uninsured* persons in the United States has increased steadily each year. The non-elderly uninsured population grew from 33.5 million in 1988 to nearly 40 million in 1994, the year of the most recent national estimate.[iv]

The number of American under age 65 with private insurance who are *underinsured* is estimated to be between 25 to 48 million, or ten to twenty percent of the population. These figures are 50% larger than analogous figures for 1987 and may be growing, since employers are offering less generous health insurance policies than in the past.[v] In addition, the percentage of Americans with employer-sponsored health insurance is decreasing; nearly 6% fewer American under age 65 had such insurance in 1995 than in 1988. [iv]

While a lack of insurance or underinsurance do not necessarily result in reduced access to medical care, it clearly has an impact. People who are uninsured report up to 47% fewer visits to physicians and fewer hospitalizations than those who have insurance, even though they are in worse health.[vi]

The lack of access to health care in the United States is disproportionately distributed throughout the population. Well over half of U.S. population living under the poverty level are women and children. One in seven children in the United States is without health insurance. This is nearly one-fourth of the total uninsured population. When compared to the insured, they are four times more likely to report needing, but not

receiving health care.[vii] In addition, strong differences in access to and utilization of health care persist for various racial and ethnic groups.[viii] The lack of access to health care, particularly primary and preventative health care, has pronounced consequences both for the health care system and for society in general.

In addition, as the health care environment changes, there has been tendency by many Managed Care Organization (MCOs) not to cover those without insurance or those who are underinsured.

Ethical Considerations

I. Obligation of Individual Physicians To Treat the Medically Underserved

Organized medicine has long recognized that the individual physician has an ethical obligation to treat the medically underserved. For example, the first *Code of Ethics* of the American Medical Association (AMA) in 1847 provided that "to individuals in indigent circumstances, professional services should be cheerfully and freely accorded."[ix] More recently, in 1993, the AMA Council on Ethical and Judicial Affairs stated that medical professionals should reaffirm their responsibility for making health care available to the needy.[vi]

Each physician has a moral and ethical obligation to care for the medically underserved. The objective of the medical professional is to care for the sick, to treat the ill without regard for who they may be, what their diseases are or whether they can pay. While reimbursement may follow, the pursuit of material gain is not the primary end of the medical profession.

The obligation of individual physicians to help care for the medically underserved is based in the concept of professionalism, including its pursuit of moral ideals such as justice and beneficence. By drawing on the physician's mercy, compassion and empathy, charity care strengthens the bond between physician and patient that have often been weakened by increased commercialization of medicine. Providing care to patients without expectation of payment reaffirms the primacy of medicine as a helping profession.

Although physicians provide considerable charity care, improvements can and should occur. For example, in 1996, the AMA House of Delegates recognized a growing need for voluntary physician efforts to care for the uninsured in an era of increased fiscal constraint in both public and private sector programs.[x] While most physicians provide free or reduced fee care within their practices, in 1993 as many as one-quarter to one-third failed to provide services to the medically underserved.[vi]

What Care Individual Physicians and Orthopaedic Surgeons Are Providing

In 1994, the AMA reported that 68% of all practicing physicians provided some free or reduced fee care, and devoted an average of 12% of their

II. Obligation of Society and the Medical Profession To Treat the Medically Underserved

The duty to care for the medically underserved rests not only with individual physicians, but also with society and the medical profession as a whole. The policies of the Academy make improved access to medical care a clear priority. Since 1992, the Academy has publicly supported universal, affordable health care available to all. In its response to health care reform, the Academy stated that this country "must provide an essential and universally accepted health package for all Americans, regardless of ability to pay. This health care package must include a basic level of high quality health services, including musculoskeletal services.[xiii] In 1992, the Academy also stated that the medically underserved should be covered through "an expansion of the federal-state health care financing system.[xiii]

What Services the AMA and Medical Societies Are Providing?

A survey conducted by the AMA in 1997 found that 29 state or metropolitan medical societies conducted programs to arrange for the provision of free care by participating physicians in the state or area. In addition, 36 state or metropolitan medical societies sponsored or participated in free clinics to serve the medically underserved.[x]

Recommendation of the AMA Council on Ethical and Judicial Affairs

In 1993, the Council of Ethical and Judicial Affairs of the AMA adopted a guideline regarding the obligation of society and the medical profession to treat the medically underserved. The Academy generally endorses the guideline and has revised it as appears below:

> **The American Academy of Orthopaedic Surgeons and state and local medical societies should help society meet its obligations to provide health care services to the medically underserved. By working together in providing care for little or no compensation, by volunteering at local free clinics and/or by participating in active professional organizations and their affiliated alliances, orthopaedic surgeons and other physicians can be directly involved in and can encourage the provision of coordinated quality care for the medically underserved.**

work time, 7.2 hours per week, to caring for the medically underserved, up from 6.5 hours per week in 1990.[x]

According to *Orthopaedic Practice in the United States: 1996/7,*[xi] approximately ten percent of the care provided by orthopaedic surgeons is uncompensated or is paid by the Medicaid program. Four percent of the care is entirely uncompensated.[xi] In the most recent Orthopaedic Census Survey that specifically dealt with the issue of orthopaedic surgeon's providing uncompensated care, the Academy found:

- Eighty-one percent of orthopaedic surgeons regularly provide care for patient from whom they neither expect nor receive compensation (including charity care clinics);

- Orthopaedic surgeons provide, on average, 37 professional hours per month on uncompensated care or where compensation is Medicaid or other reduced payment. This includes 9.1 hours where compensation is neither expected nor received; 13.3 hours where compensation is expected but not received; and 14.8 hours where compensation is Medicaid or similar reduced payment; and

- Sixty percent of orthopaedic surgeons indicate they are providing more uncompensated or reduced compensated care than they were five years ago. The average increase in hours per month indicated was 31 percent.[xii]

Recommendation of the AMA Council on Ethical and Judicial Affairs

In 1993, the Council on Ethical and Judicial Affairs of the AMA adopted a guideline regarding the individual physician's obligation to treat the medically underserved. The Academy generally endorses this guideline and has revised it as appears below:

> **Caring for the medically underserved should be a normal part of each physician's overall service to patients. Although the measure of what constitutes an appropriate contribution may vary with circumstances such as community characteristics and geographical location, orthopaedic surgeons should work to ensure that the needs of the medically underserved in their communities are met. Since a large number of the medically underserved are children, the orthopaedic surgeon has a special obligation to treat them without discrimination based on the ability to pay.**
>
> **Orthopaedic surgeons should devote their energy, knowledge, and prestige to designing and lobbying at all levels to better programs to provide care for the medically underserved.**

[i] Bodenheimer T., *Underinsurance in America*; New England Journal of Medicine*,* 1992: 227, 274-278.

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[iii] Pear R., *Health Costs Post Problems For Millions, A Study Finds,* New York Times (10/23/96)

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[v] Short PF and Banthin JS, *New estimates of the underinsured younger than 65 years,* JAMA*,* 174: 1302-1306 (1995)

[vi] American Medical Association, Council on Ethical and Judicial Affairs, Section 9.065, *Caring for the Poor,* found in JAMA, 263 (19): 2533-2537 (1993)

[vii] Donelan K, Biendon RJ, Hill CA, Hoffman C, Rowland D, Frankel M, and Altman D, *Whatever Happened to the Health Insurance Crisis in the United States?* JAMA, 276 (16): 1346-1350 (1996)

[viii] American Medical Association, *Report #50 of the Board of Trustees: Racial and Ethnic Disparities in Health Care* (December 1995)

[ix] Lundberg GD, *National Health Care Reform; Answers of Inevitability is Upon Us,* JAMA, 265: 2565-2567 (1991)

[x] American Medical Association, Council on Medical Service, *Report #14*: *Physician Initiatives for Care of the Low-Income Uninsured* (June 1997)

[xi] American Academy of Orthopaedic Surgery, *Orthopaedic Practice in the United States, 1996-97,* 13

[xii] American Academy of Orthopaedic Surgeons, *AAOS Orthopaedic Physician Census,* Supplemental Form A, 1992, 25

[xiii] American Academy of Orthopaedic Surgeons, *Position Statement on Principles of Health Care Reform* (1992)

Opinions on Ethics and Professionalism

Continuing Medical Education

Issue raised

What are the standards of continuing medical education to which orthopaedic surgeons should subscribe?

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

"VI. The orthopaedic surgeon continually must strive to maintain and improve medical knowledge and to make relevant information available to patients, colleagues, and the public."

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

"IV.A. The orthopaedic surgeon continually must 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 relevant continuing medical educational activities."

Other references

American Medical Association, *Principles of Medical Ethics*, Article V. "A physician shall continue to study, apply and advance scientific knowledge, make relevant information available to patients, colleagues, and the public, obtain consultation, and use the talents of other health professionals when indicated."

Background

Every orthopaedic surgeon has an ethical and professional obligation to stay abreast of the developing knowledge in the musculoskeletal sciences. The contract that exists between surgeon and patient, and between the profession and society, requires the acceptance of this obligation. The rate of growth of scientific knowledge and clinical experience in our specialty place an extraordinary responsibility on each orthopaedic surgeon to maintain his or her knowledge base.

The American Academy of Orthopaedic Surgeons believes that a lifelong commitment to continuing medical education is essential for orthopaedic surgeons. This commitment is essential if orthopaedic surgeons, as professionals, are to fulfill their commitment to provide high quality health care. The choice of educational methods or experience is the responsibility of individual orthopaedic surgeons. The Academy places no specific requirements on its Fellows in terms of areas or types of instruction, minimum number of hours of education during a particular time period, or preferred providers of education programs.

For additional information, contact Richard N. Peterson at (847) 384-4048
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Recommendations

The Academy believes that each orthopaedic surgeon must develop his or her own approach to knowledge maintenance in an organized and explicit manner to assure that it addresses content in all areas in which care is provided. To do this requires:

- A self-generated practice audit to determine the types of conditions, procedures, complications, etc. which comprise one's practice experience, and to assess the results of treatment provided.

- A periodic self-assessment evaluation which addresses the knowledge and content areas relevant to the individual's practice.

- The development of a personal education plan, to include study in identified areas of deficiency, and the subsequent scheduling of educational activities to fulfill the goals developed in the education plan.

As an organization devoted to the education of orthopaedic surgeons and others, the Academy makes available current authoritative and evaluative educational materials to enhance orthopaedic knowledge and to facilitate the provision of improved patient care. The Academy's commitment to education is enduring and substantive. Every orthopaedist should make a similar commitment to excellence.

For additional information, contact Richard N. Peterson at (847) 384-4048

Opinions on Ethics and Professionalism

Ethics in Health Research in Orthopaedic Surgery

Issue raised

What are the general ethical issues involved in the conduct of health research in orthopaedic surgery?

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

"II. The orthopaedic surgeon should maintain a reputation for truth and honesty with patients and colleagues, and should strive to expose through the appropriate review process those physicians who are deficient in character or competence or who engage in fraud or deception."

"VI. The orthopaedic surgeon continually must strive to maintain and improve medical knowledge and to make relevant information available to patients, colleagues, and the public."

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

"III.C. When an orthopaedic surgeon receives anything of value, including royalties, from a manufacturer, the orthopaedic surgeon must disclose this fact to the patient. It is unethical for the orthopaedic surgeon to receive compensation (excluding royalties) from a manufacturer for using a particular device or medication. Reimbursement for administrative costs in conducting or participating in a scientifically sound research trial is acceptable."

"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."

"IV.A. The orthopaedic surgeon continually must 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 . . ."

"VIII.A. All research and academic activities must be conducted under the conditions of full compliance with ethical, institutional, and government guidelines. Patients participating in research programs must have given full informed consent and retain the right to withdraw from the research protocol at any time."

"VIII.B. Orthopaedic surgeons should not claim as their own intellectual property that which is not theirs. Plagiarism or the use of others' work without attribution is unethical."

"VIII.C. The principal investigator of a scientific research project or clinical research project is responsible for proposing, designing, and reporting the research. The principal investigator may delegate portions of the work to other individuals, but this does not relieve the principal investigator of the responsibility for work conducted by other individuals."

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"VIII.D. The principal investigator or senior author of a scientific report is responsible for ensuring that appropriate credit is given for contributions to the research described."

Other references

American Academy of Orthopaedic Surgeons, Position Statement on Animals in Biomedical Research, October, 1994.

American Academy of Orthopaedic Surgeons, Policy on Authorship, February, 1993.

Association of American Medical Colleges, "Framework for Institutional Policies and Procedures to Deal With Fraud in Research," November, 1988.

Association of American Medical Colleges, "Beyond the Framework: Institutional Considerations in Managing Allegations of Misconduct in Research," September, 1992.

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American Medical Association, *Principles of Medical Ethics,* "Article V. A physician shall continue to study, apply and advance scientific knowledge, make relevant information available to patients, colleagues, and the public, obtain consultation, and use the talents of other health professionals when indicated."

American Medical Association, *Current Opinions* of the Council on Ethical and Judicial Affairs,

Section 2.07 ("Clinical Investigation")
Section 8.031 ("Conflicts of Interest: Biomedical Research")
Section 9.08 ("New Medical Procedures")
Section 9.09 ("Patents for Surgical and Diagnostic Instrument")
Section 9.095 ("Patenting of Medical Procedures")

American Medical Association, *Reports* of the Council on Ethical and Judicial Affairs,

Report 24, "Scientific Fraud and Misrepresentation," December, 1989.

Report 25, "Conflicts of Interest in Biomedical Research," December, 1989.

J.A. Buckwalter, "Medical Researchers Must Be Ethical," *AAOS Bulletin*, July, 1990.

Council for International/Organizations of Medical Sciences, *International Ethical Guidelines for Biomedical Research Involving Human Subjects,* 1993.

Definitions

Orthopaedic surgeons conduct research in a number of areas. "Health research" is considered to be the universe of research dealing with health care-related matters. Health research encompasses various types of research, including clinical research (defined by the AMA as "a part of a systematic program competently designed, under accepted standards of scientific research, to produce data that are scientifically valid and significant"), outcome studies research, psychosocial research, and demographic and economic studies. In this Opinion on Ethics and Professionalism, unless otherwise noted, the broad term "health research" will be used.

Ethical considerations

According to the Academy's Opinion on Ethics and Professionalism regarding Continuing Medical Education, upon completion of orthopaedic residencies (or fellowships), orthopaedic surgeons assume an ethical and professional obligation to stay abreast of developing knowledge in the musculoskeletal sciences. Many orthopaedic surgeons have chosen to go beyond this basic obligation to assist in the advancement of musculoskeletal knowledge and in its dissemination.

Orthopaedic surgeons who conduct health research have special ethical responsibilities. They must accept responsibility for ethical conduct in their own scientific work and should help support high standards of ethical conduct in the scientific community. Failing to do so may impede or delay progress in learning about the musculoskeletal sciences and will damage the credibility of all health researchers, thereby harming not only the research community, but also the greater orthopaedic community and the patients whose care depends on the results of research.

The Academy believes the ethical tenets described below constitute reasonable guidelines to assist health researchers in orthopaedics. These guidelines include the following:

The purpose of health research: Health research should be designed and conducted to develop new or confirmatory knowledge that promotes health, prevents diseases and injuries and improves diagnosis and treatment of diseases and injuries. If the research involves human subjects, it is appropriate only when the potential risks to the patient are reasonable in relation to the potential benefits to the patient and the importance of the knowledge which reasonably might be gained.

Examples of unethical conduct:

- Designing and conducting research with the primary purpose of discerning methods of causing injury, illness or suffering;
- Designing or conducting research that is repetitious or redundant with the primary intent of advancing individuals or specific groups financially or professionally;
- Designing or conducting research that is not intended to produce new or confirmatory information that is valid or significant; and
- Purposefully stating, reporting or misinterpreting (by omission or commission) data to arrive at a pre-determined theory or opinion.

Support of sponsorship of research: The majority of financial support for health research comes from the federal government. Although support by industry for biomedical research has risen sharply in recent years, it still represents a small portion of the total external funding received by research universities.

For many years, health researchers perceived that commercial support of research was inappropriate because of the potentially biased results which might occur. However, this position has softened significantly since many major medical developments have resulted from research funded by private sources. Furthermore, industry support of health research, particularly biotechnology research, has become substantial in recent years.

There are three parties, with distinct interests, concerned with the corporate funding of health research: (1) the individual researcher; (2) the research institution; (3) the corporation funding the research. The interrelationships among these groups may vary substantially.

In the most frequent type of relationship, the funding corporation develops a Request for Proposal (RFP) or presents a research protocol to the researcher and funds the researcher for carrying out the protocol.[i] This essentially creates a fee-for-service arrangement. Assuming that basic rules for scientific propriety are followed, this constitutes an appropriate remunerative relationship. In this relationship, it may be undesirable for the individual researcher to deal with or negotiate with the corporation funding the research. Consequently, research institutions often have created a structure whereby funded research arrangements can be negotiated in a manner that is satisfactory to all parties. Generally, the Office of the Vice-President for Research or the Dean for Research has experience and background information which provide for effective negotiation.

A second type of relationship involves the researcher submitting an unsolicited research proposal directly to the funding corporation.[1] The researcher would benefit by obtaining funds for needed equipment and supplies and the funding corporation would benefit by the possibility of expanding its market potential for a given product. This arrangement also may be viewed as ethically appropriate and mutually beneficial, assuming the proper conduct of science ensues and full disclosure is maintained.

A third type of relationship involves truly cooperative projects.[1] Often, these types of relationships are enacted in the setting of a clinical trial. Numerous advantages exist for the researcher, the research institution, and the funding corporation for the development of cooperative programs between medicine and industry. Full disclosure is essential to the success of this type of venture.

Ethical problems may arise when the researcher or the research institution have a direct financial interest in the research program. For example, researchers may hold stock or stock options in the funding corporation that manufactures the product or they may have other profit-sharing arrangements with the company. These financial interests may compromise (or give the impression of compromising) the objectivity of the researchers and cause them to downplay or suppress negative data while exaggerating favorable data. Such economic incentives may also introduce subtle biases into the way research is conducted, analyzed or reported.

The Academy believes that guidelines for circumstances in which researchers face economic conflicts of interest may be determined in reference to two ethical principles:

- A researcher ethically may share the economic rewards of his or her efforts. If a drug, device, or other product becomes financially remunerative, the researcher may receive profits that reasonably resulted from his or her contribution. The Academy's *Code of Medical Ethics and Professionalism for Orthopaedic Surgeons* explicitly permits an orthopaedic surgeon to receive royalties. However, the researcher ethically may not ethically reap profits that are not justified by the value of his or her actual efforts.

- Potential sources of bias in research should be eliminated, particularly where there is a direct relationship between a researcher's personal interests and potential outcomes of the research.

Several conclusions result by applying these two ethical principles. Once the researcher becomes involved in a research project for the funding corporation or knows that he or she might become involved in the research, he or she ethically cannot buy or sell the funding corporation's stock until the involvement ends and the results of the research are publicly disseminated. As long as the researcher is involved in research on the funding corporation's product, he or she has the potential to derive profits that stem from inside information, rather than from individual effort.

Researchers may serve as consultants or may be retained to lecture on behalf of the funding corporation. However, the researcher's remuneration ethically must be commensurate with his or her actual efforts on behalf of the funding corporation.

Safeguards may be necessary to protect against the appearance of impropriety, even when ethically permissible relationships among the researcher, research institution and the funding corporation exist. Full disclosure presents the best mechanism to address doubts about the propriety of a research arrangement. Researchers should disclose all ties to corporations whose products they are investigating. For example, the researcher's participation in educational activities supported by the corporation; participation in other research projects funded by the corporation; and consulting arrangements with corporation must be disclosed to the research institution, to the funding corporation, to audiences who hear the research results and to journals that publish the results of the research.

Example of unethical conduct:

- Knowingly negotiating for more funding than is appropriate to support the project and related institutional and departmental overhead costs;

- A researcher's selling or purchasing stock in a company whose orthopaedic device is being tested by that orthopaedic surgeon-researcher;

- A researcher's receiving financial incentives to alter data;

- A researcher's receiving excessive remuneration by the funding corporation for evaluating that corporation's products;

- A failure to disclose research or consulting arrangements with the funding corporation when reporting about research on devices manufactured by that corporation.

Use of research resources: Resources allocated by governmental agencies (federal, state or local), industry or philanthropic organizations for the performance of specific research should be used only for that purpose unless the granting agency gives specific permission for reallocation of the resources.

Example of unethical conduct:

- Using resources provided by any organization for the direct financial benefit or personal use of the investigators.

Use of animals in research: The Academy believes that the appropriate and humane use of animals in research is justified to enhance the quality of life of both humans and animals. Animals should be used in research only when there are no suitable alternatives. Research projects should be designed to use the minimal number of animals possible in a manner that avoids abuse of the animals and maintains appropriate standards of animal care. Researchers should conduct animal research only with the approval of the institution's Animal Care and Use Committee and in compliance with all applicable regulations and standards. [*See also* AAOS Position Statement on Animals in Biomedical Research.]

Examples of unethical conduct:

- Using methods that cause animals unnecessary discomfort;
- Failing to maintain appropriate standards of animal care;
- Using excessive numbers of animals to perform experiments;
- Using inappropriate animal models; and
- Using animals when other methods of conducting the research would be scientifically valid, e.g., computer simulations, tissue culture or mathematical models.

Use of human subjects in research: The *Statement of Principles* of the American College of Surgeons provides "[t]he progress in medical care through research depends on informed partnership between patients and physicians in the development of new drugs and treatment methods. It is recognized that certain advances in the knowledge of treatment of disease can only be learned by properly conducted clinical trials during which the results of varying treatments recommended by individual doctors are carefully compared."

Human subjects should be used in health research only when there is no reasonable alternative. Human subjects should never be exposed to unnecessary risk, embarrassment or expense and should fully understand the purpose of the research and if their participation may benefit them (a therapeutic experiment) or is intended primarily to benefit future patients (a nontherapeutic experiment). The selection criteria of human subjects must be objective and reasonable.

Human subjects should provide **voluntary informed consent** before being included in a prospective study and should be allowed to decline to continue participation in a research program at any time without compromising of their medical care. Paragraph VIII.A. of the Academy's *Code of Medical Ethics and Professionalism for Orthopaedic Surgeons* provides that "[p]atients participating in research programs must have given full informed consent and retain the right to withdraw from the research protocol at any time." To ensure full informed consent, three elements must exist:

(1) The orthopaedic surgeon must explain to the patient in terms the patient can understand the proposed treatment, its likely effect on the patient, and purpose of the research. Orthopaedic surgeons must provide at least the degree of information that is required by applicable state and federal law, which will include at a minimum information on the purpose of the research, its potential side effects, alternatives and risks of the proposed treatment as well as the method, purpose, conditions of participation and the opportunity to withdraw from the research protocol without penalty.

(2) The patient's consent must be knowing. The orthopaedic surgeon must believe reasonably that the patient has understood the basic information and has engaged in rational decision-making in deciding to participate in the research; and

(3) The patient's consent must be voluntary. The orthopaedic surgeon must believe that the patient's consent is free from undue or overbearing influences, e.g., fear of the loss of care or medical benefits if the patient declines to participate.

Human subjects participating in clinical research programs should receive the care and treatment that is in their best interest and be assured that the potential benefit of the research outweighs the risks. Researchers should conduct human subject research only with the approval of the research institution's Institutional Review Board (IRB) (and for other required review committees) and in compliance with all applicable regulations and standards. This review and approval mechanism ensures that there is informed consent, that the rights of patients are respected, and that patients participating in the research protocol are treated with the same concern and devotion as other patients.

Examples of unethical conduct:

- Failing to disclose risks;
- Exposing patients who are participating in the research protocol to unnecessary risks;
- Failing to obtain voluntary, fully informed consent of adult patients or to obtain the substituted consent of the patient's legally authorized representative when the patient lacks the legal capacity to consent (e.g., is a minor);
- Causing human subjects unnecessary embarrassment;
- Causing human subjects unnecessary expense;
- Manipulating human subject cohorts with selected medical problems or results of treatment with the intent of proving the investigator's bias or to promote a given treatment or medical device; and
- Directly or indirectly coercing human subjects to participate in the research protocol.

Responsibility of the research institution: The ultimate responsibility for the ethical conduct of research resides within the institution in which the health research is conducted and/or with the Primary Investigator (PI). Research institutions should assure that rigorous scientific standards are upheld by each of their faculty, staff, and students and should extend these standards to all reports, publications, and databases produced by the institution. All medical schools and research institutions should

implement guidelines for a review process for dealing with allegations of scientific misconduct, which include appropriate due process protections for those alleged to have committed scientific misconduct. In addition, the research institution must be capable of and committed to implementing effective procedures for examining allegations of scientific misconduct.

Examples of unethical conduct:

- The research institution's failing to maintain guidelines for dealing with allegations of scientific misconduct or fraud;
- The research institution's failing to inform and educate staff and students of institutional guidelines for dealing with allegations of scientific misconduct or fraud; and
- The research institution's failing to implement and enforce institutional guidelines for dealing with allegations of scientific misconduct or fraud.

Responsibilities of the Principal Investigator (PI): The Principal Investigator (PI) of a health research project is responsible for proposing, designing and reporting the research. In addition, the PI is usually accountable for dispensing project funds. Paragraph VIII.C. of the Academy's *Code of Medical Ethics and Professionalism for Orthopaedic Surgeons* provides that "the Principal Investigator may delegate portions of the work to other individuals, but this does not relieve the Principal Investigator of responsibility for work conducted by other individuals."

Examples of unethical conduct:

- The Principal Investigator's failing to participate in and supervise the design or conduct or a research project;
- The Principal Investigator's failing to adequately supervise those conducting the project; and
- The Principal Investigator's failing to critically review the results and verify the accuracy of reports.

Reporting results of research: The results of research should be described in timely, objective, accurate, complete reports and potential conflicts of interest should be identified. Specifically, Paragraph III.D. of the Academy's *Code of Medical Ethics and Professionalism for Orthopaedic Surgeons* provides that when reporting on clinical research or experience with a given device or procedure, orthopaedic researchers have a ethical obligation to "disclose any financial interest in that procedure or device if the researcher or any institution with which that researcher is connected has received anything of value from its inventor or manufacturer."

Examples of unethical conduct:

- Failing to provide timely, accurate reports;
- Failing to report unfavorable results;
- Providing reports that do not contain a sufficient and accurate methodology to replicate the experiments or references to where such information might be obtained;

- Falsifying reports;
- Fabricating results;
- Reporting results of uncertain or minimal significance unless clearly stated as such;
- Preparing multiple partial reports or duplicate reports of the same work to increase apparent productivity of the investigators; and
- Failing to identify potential conflicts of interest including possible financial benefits to the investigators from research reports.

Authorship and credit for scientific work: The Principal Investigator of a research study is responsible for insuring that articles describing the research include appropriate credit for individuals contributing importantly to the research. The Academy has endorsed *The New England Journal of Medicine*'s policy on authorship. It provides that authorship of research articles should be limited to individuals who have made substantial contributions in fulfilling each of the following conditions: (1) conception and design, or analysis and interpretation of data; (2) drafting the article or revising it critically for intellectual content; and (3) final approval of the version to be published.[2] Similarly, the authorship policy of *The Journal of bone and Joint Surgery* states that "[I]t is to be clearly understood that each author has participated in the design of the study, contributed to the collection of data, participated in the writing of the manuscript, and assumes full responsibility for the content of the manuscript."[3] In addition, sources of financial and technical support and individuals who provide important materials and information should be acknowledged.

Examples of unethical conduct:

- Failing to credit co-workers; individuals who have designed the project or who have interpreted the data; individuals or agencies that have provided resources to fund the project; or individuals or groups that have previously performed similar research, if such research is valid and appropriate;
- Failing to credit sources of quotations;
- Plagiarizing or using others' work without attribution;
- Failing to review and credit relevant previous publications; and
- Including as authors individuals who did not make substantial contributions to the work.

Copyrights and royalties: Most research institutions maintain an intellectual property policy which encourages controlled entrepreneurial activity by research faculty. A typical structure for managing these matters involves the research institution's Committee on Intellectual Property (or similarly named group), which serves in a capacity advisory to the administrative officer overseeing the policy. These intellectual property policies have many variations peculiar to the particular institution, but in general determine distribution of rewards for researchers for developing new products and authors for writing and publishing articles and books.

Typically, the patent to devices created and the copyright to articles written belong to the Principal Investigator or his or her research institution or funding corporations. The ownership of patents, the allocation of revenues, copyright and other intellectual property interests among Principal Investigators, the research institution and the funding corporations and other important issues should be made clear either in standing policies of the research institution or in clear contracts executed before the commercial support is received. The rewards of commercialization should be fairly allocated.

It is ethically acceptable for a Principal Investigator to receive royalties from a funding corporation for using a particular device or medication the researcher has developed. However, it is unethical for an orthopaedic surgeon-Principal Investigator to commit to *always* use a particular product in which he or she developed and for which the researcher receives royalties.

Examples of unethical conduct:

- The Principal Investigator's agreeing to always use a device he or she developed.

Research records: Accurate and complete records of research data should be maintained until there has been sufficient time for critical review. The time will vary with the type of research, but five years after publication is sufficient for most work.

Example of unethical conduct:

- Failing to maintain accurate complete records of research activity so that replication of the work or verification of the results is difficult or impossible.

Scientific errors; contradictory results and inability to replicate results: If errors in the proposal, conduct or reporting of research are identified, the Principal Investigator has an ethical obligation to report such errors. If the Principal Investigator or other investigators repeat an experiment and obtain results that contradict the initial report or they are unable to replicate the experiment, the contradictions or inability to replicate an experiment should be reported. If the long-term results of a health research project differ from the initial reported results, the differences should be reported. Scientific publications have a responsibility to publish reports of scientific errors, contradictory results, and failures to replicate previously reported research.

Examples of unethical conduct:

- Failing to report any significant scientific error;
- Failing to report work that contradicts previously reported data or conclusions;
- Failing to report late adverse outcomes for techniques or devices which were introduced with favorable initial experience;
- Failing to report difficulties in replicating or verifying previous findings; and
- A scientific publication's failing to publish reports of scientific errors, contradictory results, and failure to replicate previously reported research.

Obligation to report scientific misconduct (versus differences in methods, interpretation and judgment): Orthopaedic surgeons have an ethical obligation to report scientific misconduct in research if they become aware of it. A spectrum of activities constitute scientific misconduct, ranging from duplicate publication at the lower end to fraud and plagiarism at the upper end. The U.S. Public Health Service (PHS) and the National Science Foundation (NSF) broadly define "scientific misconduct" to include research fraud (including plagiarism, deception, falsification and/or fabrication of scientific data) as well as "other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting or reporting research."

However, while it is clear that unequivocal scientific misconduct must be reported, members of the health research community have a concurrent responsibility to attempt to distinguish between honest error and scientific misconduct. Orthopaedic surgeons must also respect differences in scientific methods and analysis, interpretation and judgment about data.

Examples of unethical conduct:

- Failing to identify and report unequivocal instances of scientific misconduct;
- Personally attacking, verbally or in writing, other investigators, based upon differences in methods, analysis, interpretation, judgment or opinion;
- Attempting to discredit or intimidate other investigators because of differences in methods, investigation or interpretation of data;
- Attempting to restrict funding or research, publication or presentation of data because of differences in interpretation; and
- Making accusations of scientific misconduct when honest error may be as likely.

Recommendations

The American Academy of Orthopaedic Surgeons urges orthopaedic surgeons who participate in health research to review and adopt these ethical tenets, which have been developed by the Academy's Committee on Ethics and Council on Research and Scientific Affairs. These tenets provide a flexible, ethical framework for the conduct and the publication of research results.

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[i] AMA Council on Ethical and Judicial Affairs, *Report 25*: Conflicts of Interest in Biomedical Research, 1990; 1-20.

[2] "Instructions for Authors," *JAMA*, 276(1): 19-23, July 3, 1996

[3] "Instructions for Authors," *JBJS*, 78-A (10): 2, October, 1996

Opinions on Ethics and Professionalism

Gifts and the Orthopaedic Surgeon's Relationship with Industry

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?

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

"I. 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, Section 8.061 (Gifts to Physicians from Industry) of the *Current Opinions* of the Council on Ethical and Judicial Affairs.

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

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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 and professionalism in orthopaedic surgery. 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 Academy 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 and be able to withstand public scrutiny.

Guidelines

To avoid acceptance of inappropriate gifts or other financial support, the American Academy of Orthopaedic Surgeons 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 that the orthopaedic surgeon use the products or services provided by that particular industry.

3. **Social Functions.**
   Although the Academy is generally opposed to social events sponsored by industry, social functions supported by industry in combination with significant continuing medical education events are 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.

   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, whether or not CME credits are provided, may be of educational value and improve patient care. Orthopaedic surgeons are responsible for insuring that the decision to accept subsidies from industry is in the best interest of their patients. The Academy 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. **Consultant Expenses and Honoraria.**
   It is appropriate for consultants to industry who provide genuine services to receive reasonable compensation and to accept reimbursement for reasonable travel, lodging and meal expenses. Token consulting or advisory arrangements cannot be used to justify compensating orthopaedic surgeons for their time, travel, lodging or other out-of-pocket expenses.

8. **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.

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

Opinions on Ethics and Professionalism

The Orthopaedic Surgeon in the Managed Care Setting

Issue raised

What ethical parameters exist for orthopaedic surgeons treating patients in a managed care setting?

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

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

"I. B. The physician-patient relationship has a contractual basis and is based on confidentiality, trust, and honesty. Both the patient and the orthopaedic surgeon are free to enter or discontinue the relationship within any existing constraints of a contract with a third party. An orthopaedist has an obligation to render care only for those conditions that he or she is competent to treat..."

"I. C. The orthopaedic surgeon may choose whom he or she will serve. An orthopaedic surgeon should render services to the best of his or her ability. Having undertaken the care of a patient, the orthopaedic surgeon may not neglect that person. Unless discharged by the patient, the orthopaedic surgeon may discontinue services only after giving adequate notice to the patient so that the patient can secure alternative care. Managed care agreements may contain provisions which alter the method by which patients are discharged. If the enrollment of a physician or patient is discontinued in a managed care plan, the physician will have an ethical responsibility to assist the patient in obtaining follow-up care. In this instance, the physician will be responsible to provide medically necessary care for the patient until appropriate referrals can be arranged."

"II.C. …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 organization 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."

"VI. D. The orthopaedic surgeon may enter into a contractual relationship with a group, a prepaid practice plan, or a hospital. The physician has an obligation to serve as the patient's advocate and to ensure that the patient's welfare remains the paramount concern."

Other references

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Principles of Medical Ethics and Professionalism in Orthopaedic Surgery, Article I, “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.”

American Medical Association, *Current Opinions* of the Council on Ethical and Judicial Affairs,

Opinion 4.04 (“Economic Incentives and Levels of Care”)
Opinion 8.021 ("Ethical Obligations of Medical Directors")
Opinion 8.051 ("Conflict of Interest Under Capitation")
Opinion 8.052 ("Negotiating Discounts for Specialty Care")
Opinion 8.11 ("Neglect of Patient")
Opinion 8.115 ("Termination of the Physician-Patient Relationship")
Opinion 8.13 ("Managed Care")
Opinion 8.132 ("Referral of Patients: Disclosure of Limitations")
Opinion 8.135 ("Managed Care Cost Containment Involving Prescription Drugs")
Opinion 8.137 ("Restrictions on Disclosure in Managed Care Contracts")
Opinion 9.031 ("Reporting Impaired, Incompetent or Unethical Colleagues")

Definitions and Background

Managed care is a system for delivering health care that was designed with the goal of providing efficient, cost-effective, quality care through a variety of managed care organizations (“MCOs”). In this Opinion on Ethics and Professionalism, MCOs are defined as organizations that provide specified medical services to an enrolled population. MCOs employ or contract with a limited number of approved physicians. Patients covered by MCOs must use one of these approved physicians unless there is an “opt-out” or point of service option. Similarly, MCOs may enter into agreements with particular hospitals and other facilities. Patients enrolled in MCOs must go to an approved facility for inpatient or outpatient care for their services to be covered.

MCOs typically establish certain guidelines and procedures to prevent unnecessary expenditures and to ensure quality care. These measures may include pre-admission certification, concurrent review, discharge planning, independent peer review, case management and expanded quality assurance and utilization review.

By participating in managed care arrangements, both the physician and the patient typically sign written contracts with the MCO that may place constraints on both the physician and the patient’s choices. Hence the implied “contract” of the traditional physician-patient relationship is altered by the constraints of the MCO. Established physician-patient relationships may be interrupted. This may place a strain on established ethical principles such as the physician’s freedom to accept or reject a patient, refer the patient to a colleague of one’s choice, provide the treatment he or she prefers, discuss some alternative treatments that may not be provided in the MCO, etc. The withholding of information from patients based on the requirements of the MCO (i.e., a "gag rule") is unethical and has been ruled illegal in many states. Additionally, the efficiency of prompt treatment may be hampered by additional utilization review, mandatory second opinion and peer review processes.

Not every specific instance can be addressed in this Opinion on Ethics and Professionalism, but the following guidelines may be of assistance in resolving ethical dilemmas.

Ethical considerations

1. **Prior to joining a managed care organization (MCO), the orthopaedic surgeon should be fully familiar with the MCO's utilization guidelines and reimbursement policies to ultimately ensure that the patient's welfare remains the paramount concern. (*Code of Medical Ethics and Professionalism for Orthopaedic Surgeons*, Paragraph VI.D).**

   By understanding all of the guidelines and policies prior to joining the MCO, the orthopaedic surgeon will be able to provide care for patients and should not be surprised by any unknown aspects of the MCO. Specifically, the orthopaedic surgeon should not be disappointed by the MCO's use of utilization guidelines to evaluate his/her diagnosis and treatment of patients. In addition, the orthopaedic surgeon will receive remuneration for his/her services in an amount he/she has knowledge of prior to providing those services. By understanding all of these aspects of the MCO, the orthopaedic surgeon can concentrate on patient care and work in a constructive manner within the MCO.

2. **In a managed care setting, as in all medical situations, the orthopaedic surgeon has a legal and ethical obligation to "ensure that the patient's welfare remains the paramount concern." (*Code of Medical Ethics and Professionalism for Orthopaedic Surgeons*, Paragraph VI. D.)**

   In all that physicians do, they should act in the best interests of their patients. The orthopaedic surgeon should advocate for medically necessary patient care. As managed care plans proliferate, it is possible that orthopaedic surgeons who contract with MCOs may encounter subtle or direct incentives to reduce the level of medically necessary care provided to enrolled patients.

   It is possible that health insurance enrollment agreements between the patient and the MCO may limit the services that an orthopaedic surgeon may provide without additional cost to that patient. The MCO has the obligation to inform its enrollees regarding the terms and conditions of their coverage; if the MCO limits medical services which the physician may provide, the MCO has the obligation to inform the enrolled patient of these limitations. The enrolled patient has the obligation to understand what is covered by his or her managed care plan. However, the orthopaedic surgeon should be aware that some patients do not understand the terms and conditions of their health insurance enrollment agreements. The physician has the obligation to inform the patient of the diagnosis and the patient's treatment options and, if required by the physician's service agreement with the MCO, to certify that the medical services proposed are medically necessary.

   A situation may occur in which an orthopaedic surgeon believes care is medically necessary for an enrolled patient and the MCO does not authorize it. The orthopaedic surgeon should inform the enrolled patient of this circumstance so that he or she might appeal through the MCO's appellate process. The orthopaedic surgeon has an obligation to provide medical information to assist in the enrolled patient's appeal and to participate in a more active role, if necessary. If the MCO's appeal mechanism has been used and the MCO's utilization review committee, upon review, does not determine that the proposed care is medically necessary, the orthopaedic surgeon should document this decision in the medical record.

It is ethical for the orthopaedic surgeon to "enter into a contractual relationship with a group, a prepaid practice plan, or a hospital." (*Code of Medical Ethics and Professionalism for Orthopaedic Surgeons,* Paragraph VI. D.) The service agreement between the physician and the MCO must allow the orthopaedic surgeon to act in a manner which is ethical and which is in the best interest of the enrolled patient.

The orthopaedic surgeon should understand the services he or she will be required to provide under his or her service agreement with the MCO. It is unethical for the physician to enter into an agreement with the MCO that prohibits the provision of medically necessary care.

3. **Having joined the managed care organization, the orthopaedic surgeon should interact in a professional manner, so that the patient's psychological and physical welfare continues to remain of paramount concern (*Code of Medical Ethics and Professionalism for Orthopaedic Surgeons*, Paragraph VI.D).**

   The orthopaedic surgeon should remember that patients who are being treated for a medical illness are physically and psychologically susceptible to unprofessional comments from their physician. While it is reasonable for the orthopaedic surgeon to explain to his/her patients the diagnostic and treatment limitations of the MCO, criticizing the MCO in front of the patient does not help the patient feel comfortable in a time of stress. Furthermore, such open criticism may weaken the doctor-patient relationship. While physicians are tempted to use patients as allies to improve managed care scenarios, in reality, when physicians attempt to do so in the physician-patient treating relationship, it is usually unsuccessful and frustrating to the patient.

   A more appropriate way for the orthopaedic surgeon to deal with utilization or treatment issues regarding a particular patient is to go directly to the MCO's Medical Director or Administrator and voice concerns that a particular aspect of the utilization process is not providing adequate care for this patient.

   More effective changes in MCO policies can occur if the orthopaedic surgeon works within the system. If such change is not likely to occur, the orthopaedic surgeon should rise above the conflict and maintain a professional approach to the problem.
   The orthopaedic surgeon has an ethical obligation to educate the MCO and its employees about musculoskeletal patient care. If done in a professional way, this is often very beneficial to the MCO and the care that its physicians provide patients. Such general education should include educating other health care professionals and include an appreciation for research projects related to outcome and other topics.

   Ultimately, if negotiations with the MCO do not affect reasonable changes, then it is reasonable for the orthopaedic surgeon to consider resigning from the MCO rather than continuing to be in a state of conflict.

   If a conflict does exist between the physician's opinion and the MCO's opinion, the physician should remember that the patient's welfare is of paramount importance.

4. **It is ethical for the orthopaedic surgeon to consider cost as one factor in determining appropriateness of care (*Code of Medical Ethics and Professionalism for Orthopaedic Surgeons*, Paragraph IX.A).**

   The orthopaedic surgeon has the ethical responsibility to consider the health of the public, particularly with regard to allocation of medical resources in society. Therefore, it is ethically appropriate for the orthopaedic surgeon to consider cost as one factor in choosing between equivalent but alternative forms of treatment, particularly in those cases with multiple treatment options.

   Receiving a financial return for services can encourage some physicians to over treat. Conversely, a system that uses a capitated reimbursement plan may encourage physicians to under treat. The orthopaedic surgeon's personal economic consideration should not influence his/her decision-making in patient care.

5. **The orthopaedic surgeon has the legal and ethical responsibility to practice only within the scope of his or her personal education, training and experience (*Code of Medical Ethics and Professionalism for Orthopaedic Surgeons*, Paragraph VII.A).**

   The MCO should allow the orthopaedic surgeon to practice within the scope of his or her education, training and experience. If the physician enters into an agreement with an MCO to provide a broad spectrum of care that he/she is not adequately trained to provide, the physician should look elsewhere for appropriate alternate care within the MCO or elsewhere to treat the patient. The orthopaedic surgeon's service agreement with the MCO should include a mechanism to allow appropriate referrals to other physicians.

6. **Having undertaken the care of the patient, the orthopaedic surgeon has a legal and ethical responsibility to continue providing appropriate patient care within limits established by the MCO (*Code of Medical Ethics and Professionalism for Orthopaedic Surgeons*, Paragraph, I.C).**

   The relationship between the orthopaedic surgeon and the patient is the central focus of all ethical concerns. Consequently, a difficult situation is created when care for a patient in a MCO is interrupted either by the patient's change in insurance or by a change in the physician's service agreement with the MCO. If the patient is no longer qualified to be treated in the MCO, there should be provisions regarding transferring of care such that the orthopaedic surgeon can complete the patient's current treatment program with the least interruption.

   Prior to the lapsing of the physician's service agreement with the MCO, the orthopaedic surgeon should give adequate written notice to the patient regarding the termination of the relationship and attempt to minimize disruption in the transfer of the care of the patient to another physician. The orthopaedic surgeon should make available the patient's medical records upon request.

7. **The orthopaedic surgeon has the ethical obligation to report recognized unethical activities of gatekeepers, specialists and other health care professionals (*Code of Medical Ethics and Professionalism for Orthopaedic Surgeons*, Paragraph II.C).**

If the MCO utilizes a gatekeeper who declines to refer and enroll patients for medically appropriate care or who refers and enrolls patients inappropriately, substandard care may result. Although the primary responsibility for monitoring the performance of the physicians within the MCO rests with the MCO itself, the orthopaedic surgeon, as part of the MCO, should report unethical and/or substandard patient care. It is important for the orthopaedic surgeon to carefully weigh the advantages and disadvantages of involving the patient in discussions of the activities of other physicians that the orthopaedic surgeon feels are unethical.

8. The orthopaedic surgeon has the ethical obligation to educate managed care organizations and their employees and agents about musculoskeletal concerns. (*Code of Medical Ethics and Professionalism for Orthopaedic Surgeons*, Paragraph IX.)

The *Code of Medical Ethics and Professionalism for Orthopaedic Surgeons* provides that "[t]he honored ideals of the medical professional imply that the responsibility of the orthopaedic surgeon extends not only to the individual but also to society as a whole." (*Code of Medical Ethics and Professionalism for Orthopaedic Surgeons*, Paragraph IX.) Individuals and society will both benefit when orthopaedic surgeons discuss with MCOs, their employees, affiliated physicians and other health care professionals their unique concerns about the musculoskeletal system and its care. This may enhance the quality of care being provided by MCOs. This discussion might also emphasize the need for managed care systems to support the education of health care professionals and the conduct of research, for without either the quality of musculoskeletal care, and indeed all medical care, will be diminished over the long term.

Opinions on Ethics and Professionalism

Medical and Surgical Procedure Patents

Issue raised

Is it unethical for an orthopaedic surgeon to patent a medical and/or surgical procedure?

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

"VI. Medical Knowledge. The orthopaedic surgeon continually must strive to maintain and improve medical knowledge and to make relevant information available to patients, colleagues, and the public."

"X. Societal Responsibility. The orthopaedic surgeon has a responsibility not only to the individual patient, to colleagues and orthopaedic surgeons-in-training, but also to society as a whole. Activities that have the purpose of improving the health and well-being of the patient and/or the community in a cost-effective way deserve the interest, support, and participation of the orthopaedic surgeon."

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

"IV. A. The orthopaedic surgeon must continually 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..."

Other References

U.S. Constitution, Art. 1, Section 8, cl. 8. Congress has the power to "promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."

35 U.S.C. §101. Any "new or useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof" may be patented.

American Medical Association, Section 9.095 ("Patenting of Medical Procedures") of the *Current Opinions* of the Council on Ethical and Judicial Affairs.

American Medical Association, *Report* of the Council on Ethical and Judicial Affairs, "*Patenting of Medical Procedures*," June 1995.

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Background

For more than a century, medical and surgical methods and processes for diagnosing and treating disease were not considered patentable. In 1952, Congress amended the patent law, adding to the list of subject matter which could be patented "new and useful processes." At the time, the clear legislative intent was to codify existing policy, not change it. Regardless of this intent, since 1952, the U.S. Patent and Trademark Office ("PTO") has routinely issued method or process patents for purely medical and surgical procedures not associated with any drug or medical device (hereinafter referred to as "Medical Procedure Patents"). In fact, the PTO has estimated that as many as 100 medical procedure patents are issued every month. Until recently, such patents were rarely enforced. However, over the past decade, the holders of some of these Medical Procedure Patents actively have sought to enforce them, and in recent years, the number of Medical Procedure Patents has dramatically increased.

Ethical Issues

The patients who we serve are assured a higher quality of care if innovations in medicine and surgery are openly discussed and disseminated by physicians and other health care professionals. Medical Procedure Patents may inhibit these discussions on both legal and financial grounds. In addition, orthopaedic surgeons have an obligation to support and participate in cost-effective musculoskeletal care. Medical Procedure Patents potentially may increase the costs of new procedures and devices, as the "inventor" would be entitled to compensation over and above the on-going accepted cost of the new procedure or device.

The training of orthopaedists-in-training and continuing medical education for practicing orthopaedic surgeons are based on the free sharing and passing on of knowledge, methods, and procedures. Since it would be in the patent holder's interest to keep an "invention" a secret until the patent is granted, Medical Procedure Patents may discourage orthopaedic surgeons from openly sharing developing medical information. In addition, the enforcement of Medical Procedure Patents is a strong disincentive for orthopaedic surgeons to share the results of their professional experiences and/or independent discoveries of similar existing methods with their colleagues, since this sharing may identify themselves as a potential target for infringement suits. Thus, the granting of Medical Procedure Patents may undermine the process of peer review, evaluation, and critical appraisal of medical innovation within orthopaedics.

If the PTO continues to grant Medical Procedure Patents, medical education similarly may be compromised. Medical schools, medical societies (including the Academy) and other entities providing medical education might either be prohibited from teaching certain patented procedures or would be required to pay a licensing fee to the inventor before teaching a course that includes the patented method. The cost of medical education would also increase if medical schools were required to pay royalties to patent holders to teach patented surgical and medical techniques.

In addition, Medical Procedure Patents may unreasonably interfere with the practice of medicine and the physician-patient relationship. Enforcing such Medical Procedure Patents may compromise patient confidentiality since all procedures will have to be recorded. Also, patients may be denied access to certain procedures, or their choice of physicians may be restricted to only those doctors who are paying royalties to the original "inventor" of the process. Granting

Medical Procedure Patents may adversely affect the quality of care, impede medical technology, and contribute to the increasing cost of health care.

Medical Procedure Patents may impede the advancement of medicine, curtail academic access, compromise peer review, place unreasonable limits on the research community, directly interfere with the education of new physicians, and interfere with the physician-patient relationship and the quality of medical care provided to the patient. Under these circumstances, the patenting of "pure" medical procedures or techniques would be unethical.

Legal and Other Issues

The consensus in the medical community is that no medical process is really new. Every method innovation is largely based on "prior art." Every advancement in medicine builds on existing knowledge. Sufficient "prior art" exists in almost every instance where the PTO has granted a Medical Procedure Patent. Seen in this light, the PTO should not have granted these patents. Also, a real possibility exists of expensive litigation over whether a Medical Procedure Patent should have been granted in the first place. Such litigation has already occurred in this country and serves to increase the cost of health care generally.

The PTO has neither the staff nor the expertise to identify "prior art." Moreover, most medical methods and procedures have not been patented, and consequently, the PTO is ill-equipped to determine whether a process is new. In most instances, these medical and surgical processes have existed for years, and have been transferred from teacher to student through practice seminars, actual "hands-on" training, and through the medical literature.

Legislation

In October, 1996, President Clinton signed into law legislation involving Medical Procedure Patents. The legislation permanently precludes the filing of infringement suits against physicians and other medical practitioners for the performance of "medical activities" that would otherwise violate patents on medical or surgical procedures. A "medical activity" is broadly defined to include the performance of a medical or surgical procedure on a human body, organ or cadaver or on an animal used in medical research. The Act does not apply to patents issued before October, 1996 and it does not affect enforcement of biotechnology patents, patents on drugs or devices or patents on new uses of drugs or other compositions of matter.

Recommendations

Consistent with the *Principles* and *Code of Medical Ethics and Professionalism for Orthopaedic Surgeons,* the American Academy of Orthopaedic Surgeons believes that it is unethical for orthopaedic surgeons to seek, secure, or enforce patents on medical or surgical procedures.

The granting of Medical Procedure Patents may pose a serious threat to medical advancement, medical education, and patient care, as well as contribute to the spiraling costs of health care. Furthermore, the Academy believes that the granting of Medical Procedure Patents conflicts with the Academy's mission of fostering and assuring the highest quality and most cost-effective musculoskeletal health care.

Opinions on Ethics and Professionalism

Reporting of Suspected Abuse or Neglect of Children, Disabled Adults or the Elderly

Issues raised

What is the orthopaedic surgeon's obligation to report suspected cases of abuse or neglect of children, disabled adults or the elderly?

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

"I. 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."

"III. The orthopaedic surgeon must respect the law, uphold the dignity and honor of the profession, and accept its self-imposed discipline. The orthopaedic surgeon also has a responsibility to seek changes in legal requirements that are contrary to the best interest of the patient."

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."

"II.B. The orthopaedic surgeon should conduct himself or herself morally and ethically, so as to merit the confidence of patients entrusted to the orthopaedic surgeon's care, rendering to each a full measure of service and devotion."

"II.C. The orthopaedic surgeon should observe all laws, uphold the dignity and honor of the profession, and accept its self-imposed discipline . . ."

"III.A. The practice of medicine inherently presents potential conflicts of interest. Whenever a conflict of interest arises, it must be resolved in the best interest of 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."

Other references

American Medical Association, *Current Opinions* of the Council on Ethical and Judicial Affairs,

Section 1.02 ("The Relation of Law and Ethics")
Section 2.02 ("Abuse of Children, Elderly Persons and Others at Risk"

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Background

Much has been written in recent years regarding an apparent epidemic of child abuse in the United States. A 1992 study by the National Committee for Prevention of Child Abuse showed that nearly three million children in the United States were reported as suspected victims that year. However, fewer than half those reports were found to merit further investigation.[I] The study found poor children were at the greatest risk, but owing to insufficient public funds, only about two-thirds of the families in which abuse or neglect was confirmed received help.[1]

It is impossible to determine whether the number of alleged child abuse victims is inflated with false allegations or under represents activity that is often kept secret. One widely cited figure comes from a 1985 survey showing that one in four women has suffered childhood sexual abuse.[I] In this survey, "Childhood" was defined as any time through age 18, and "abuse" was defined to include everything from a single glimpse of a flasher to forced intercourse. Studies limited to girls under 14, defining "abuse" as sexual contact with a man at least five years older, have shown a fairly consistent, rate of sexual abuse of 10 to 12 percent since the 1940s.[1]

In 1989, a U.S. congressional committee investigated the abuse and neglect of the elderly in the United States and found it to be a "national tragedy."[2] Elderly abuse may take forms, including physical, sexual, and psychological abuse as well as verbal abuse, financial exploitation and/or neglect by a caregiver. A 1989 congressional study indicates that one of every 25 Americans over age 65 suffers from some serious form of abuse, neglect or exploitation.[2] In addition, in Illinois, an Elder Abuse Demonstration Program conducted from 1985-1987 made similar findings.[2]

In 1993, a national poll found that 34 percent of adults in the United States report having witnessed a man beating his wife or girlfriend and that 14 percent of women report that a husband or boyfriend has been violent with them.[3] Studies suggest that as many as 30 percent of women treated in emergency departments (EDs) have injuries or symptoms related to physical abuse.[4] A U.S. Public Health Service national objective for the year 2000 is for at least 90 percent of hospital EDs to have protocols for routinely identifying, treating, and referring victims of sexual assault and spouse abuse (objective 7.12). In addition, in 1992, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) started to recommend that accredited EDs have policies, procedures, and education in place to guide staff in the treatment of battered adults.

Legal considerations

In response to the U.S. Child Abuse Prevention and Treatment Act of 1974, virtually every state has adopted legislation that requires physicians and others in authority to report suspected cases of child abuse. In addition, a number of states have enacted legislation requiring or permitting, without legal penalty, the reporting of elder and other abuse. While the provisions of these state statutes vary, most provide a specific immunity from suit when physicians and other health care workers report suspected cases as required or permitted under the law, even if the information is obtained in the course of a treating relationship protected under the physician-patient privilege.

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Illinois law is illustrative. In 1975, Illinois adopted the Abused and Neglected Child Reporting Act. The act requires physicians, school teachers and others to immediately report to the State Department of Children and Family Services a child known to them in their professional capacities who might be abused or neglected. In addition, a person required to report under the act and the medical examiner or coroner must contact the state if the child is suspected to have died as a result of abuse of neglect. A failure to report suspected child abuse or neglect will subject the physician to state disciplinary proceedings.

In 1988, Illinois adopted the Elder Abuse and Neglect Act. It provides for the permissive (not mandatory) reporting of alleged elder abuse to the State Department on Aging. The act provides that any person wishing to make a report of alleged or suspected abuse of a person 60 years of age or older will be immune from liability or professional disciplinary action on account of making the report, despite the laws of confidentiality in Illinois which would otherwise apply.

In most states, no specific laws exist that protect physicians or others who report cases of suspected abuse or neglect of adults who are disabled but who are unable to protect themselves under existing legal systems. The law presumes that once one has reached the age of majority (usually 18), one can make his or her own independent decisions and might file appropriate legal actions against those who abuse them. For example, an adult spouse who has been abused may notify the appropriate legal authorities to obtain a protective order or otherwise to stop the abusive acts. However, if the physician believes the disabled adult is being abused and is truly incapable of making his or her own decisions to report, the physician may obtain a court order to permit the reporting.

Most health care institutions have adopted policies implementing these or similar state statutes. As members of the medical staff, orthopaedic surgeons have an obligation to adhere to their institution's policies and procedures (and if they are inappropriate, to work to get them changed).

Ethical considerations

State statutes that require, or that permit without penalty, the reporting of cases of suspected abuse or neglect of children, disabled adults or elderly persons may create an ethical dilemma for some orthopaedic surgeons. The parties involved, both the suspected offenders and the victims, may plead with the orthopaedic surgeon to keep the matter confidential and not to disclose or report it for investigation by public authorities. The orthopaedist, by training, will often choose to maintain as strictly confidential all information, including information about alleged abuse or neglect, obtained in the course of medical treatment.

Children who have been seriously injured, allegedly by their parents, may attempt to protect their parents by saying that the injuries were caused by an accident. The reason may stem from the natural parent-child relationship or fear of further punishment. In addition, elderly patients who have been physically maltreated may be concerned that disclosure of what has occurred might lead to further (and possibly more drastic) maltreatment by those responsible.

However, despite the expressed wishes of the child, the disabled adult or elderly person not to report, the orthopaedic surgeon has both a legal and ethical obligation to comply with state mandatory reporting statutes and with institutional policies. Further, if an orthopaedic surgeon fails to comply with the state statutes and institutional policies requiring reporting of suspected

cases of abuse or neglect, he or she may anticipate that the victims could receive more severe abuse that may result in permanent bodily, brain injury or even death.

The orthopaedic surgeon's ethical and legal obligations to comply with statutory reporting requirements are clearly stated in the Academy's *Principles of Medical Ethics and Professionalism in Orthopaedic Surgery* (Article III) and the *Code of Medical Ethics and Professionalism for Orthopaedic Surgeons* (Paragraph II.C). In addition, the ethical obligation of the orthopaedic surgeon to report suspected cases of abuse or neglect of children, disabled adults or the elderly may exceed the statutory legal requirement.

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Opinions on Ethics and Professionalism

Second or Additional Medical Opinions in Orthopaedic Surgery

Issues raised

What are the ethical obligations involved in relationships between orthopaedic surgeons with respect to providing second or additional medical opinions? What different types of second or additional medical opinions exist?

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

"**I. B.** The physician-patient relationship has a contractual basis and is based on confidentiality, trust, and honesty. Both the patient and the orthopaedic surgeon are free to enter or discontinue the relationship within any existing constraints of a contract with a third party ...."

"**I. C.** The orthopaedic surgeon may choose whom he or she will serve. An orthopaedic surgeon should render services to the best of his or her ability. Having undertaken the care of a patient, the orthopaedic surgeon may not neglect that person. Unless discharged by the patient, the orthopaedic surgeon may discontinue services only after giving adequate notice to the patient so that the patient can secure alternative care."

VII. D. When a patient submits a proper request for records, the patient is entitled to a copy of such records as they pertain to that patient individually. Charges should be commensurate with the services provided to reproduce the medical records."

Other references

Principles of Medical Ethics and Professionalism in Orthopaedic Surgery, Article I. "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."

Code of Medical Ethics and Professionalism for Orthopaedic Surgeons, Article VII.A. "An orthopaedic surgeon should practice only within the scope of his or her education, training and experience."

American Medical Association, *Current Opinions* of the Council on Ethical and Judicial Affairs,

Section 3.04 ("Referral of Patients")
Section 7.01 ("Records of Physicians: Availability of Information to Other Physicians")
Section 7.02 ("Record of Physicians: Information and Patients")
Section 8.12 ("Patient Information")

Background

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Patients ultimately control their own personal health care decisions. While some patients may choose to limit their control of choice by enrolling in managed care organizations, all patients have the option to obtain health care services from whomever they wish. The physician assumes a contractual obligation in undertaking the care of a patient; the patient, the ultimate purchaser, owns and has a right to participate in all decisions in this contract.

Many patients find medical decision-making difficult, particularly regarding advanced medical technology. For this reason and economic pressures to contain costs, the process of seeking a "second opinion" from another physician has developed. While patients have independently sought second or additional opinions to confirm medical decisions in the past, the frequency of seeking additional medical opinions has skyrocketed in the past decade. Indeed, some patients now seek the opinions of multiple physicians, a practice called "doctor shopping," as a matter of course. In today's environment, there is an undercurrent of skepticism and distrust that encourages the solicitation of additional medical opinions. To compound this, confusion exists about the medical decision-making process in the lay and health care communities. Second or additional medical opinions sometimes have produced anxiety, frustration, anger, and intimidation in patients and physicians alike.

Many questions concerning the ethics of seeking and providing second or additional medical opinions have been raised. Some actions have resulted in accusations of impropriety and unethical behavior. While unethical behavior has occasionally occurred, many times the conflict has arisen from a lack of proper communication and mutual respect between the treating physician and the physician from whom the patient has sought additional information. This conflict raises the specter of "turf," greed, and dishonesty and, when aired in the public forum, does much to discredit the profession.

Definitions

Distinct types of interactions exist involving the gathering of additional medical opinions to which different ethical rules apply. They include:

- Consultations with a colleague, initiated by the treating physician, on behalf of and with the implicit consent of the patient, to gain additional diagnostic insight or confirmation in order to continue providing a comprehensive treatment plan for the patient;

- Referrals to a colleague, initiated by the treating physician, on behalf of and with the consent of the patient, to share the care of the patient in the performance of a specified service. A referral might be temporary or permanent; this decision should be made between the two physicians at the time of the referral.

- Transfers, initiated by the treating physician, to transfer all care of the patient to another physician. There are legal requirements for the treating physician in transferring a patient. The consent of the patient is required.

- Withdrawals, initiated by the treating physician, to discharge a patient from his or her care. There are legal requirements for the treating physician who is withdrawing services from a patient. In addition, the Academy's *Code of Medical Ethics and Professionalism for Orthopaedic Surgeons* provides that "unless

discharged by the patient, the orthopaedic surgeon may discontinue services only after giving adequate notice to the patient so that the patient can secure alternative care."

- Second opinions, initiated by a third party payer or the insurance company of the insured prior to giving authorization to the physician to perform the procedure. In most health insurance contracts, patients must comply with this requirement to receive the full benefit of their contract. The choice of which provider will provide the additional opinion is the sole decision of the insurer.

The patient may seek additional medical opinions by initiating a consultation with another physician concerning his or her care plan or by dismissing the treating physician and transferring all care to another health care professional. The patient's course of action is entirely within the patient's prerogative.

Ethical considerations

The patient has the ultimate decision-making authority in seeking second or additional medical opinions and referrals. Although the patient may choose to give up a certain degree of free choice by participating in managed care plans or by accepting insurance coverage with certain limitations, the choice of the options ultimately remains with the patient.

The American Academy of Orthopaedic Surgeons recommends that orthopaedic surgeons observe the following guidelines regarding second or additional medical opinions and referrals:

1. Any illegal action is unethical. For example, it would be illegal as well as unethical for the orthopaedic surgeon providing the second or additional medical opinion to slander the referring physician if the slanderous information is known or can be proven to be false.

2. In accepting a patient for consultation, it is ethical for the consulting orthopaedic surgeon to render an opinion and return the patient to the treating physician for continuing care. The consulting orthopaedic surgeon should communicate with the patient as well as the referring physician about the opinion.

   It is unethical for the consulting orthopaedic surgeon to solicit care of the patient. However, at the *sole* discretion of the patient, the patient ethically may choose to terminate his or her relationship with his or her treating physician and then enter into another treatment relationship with the consulting orthopaedic surgeon. It is not unethical for the consulting orthopaedic surgeon to accept the patient under these circumstances, although some orthopaedic surgeons choose not to accept the patient because of their personal view that a conflict of interest situation might be created.

3. When treating a patient referred by a colleague, the accepting orthopaedic surgeon ethically should return the patient to the referring physician after the index care has been rendered unless prior arrangements have been made

with consent of both the referring physician and the patient to transfer the patient's care permanently. In a referral, professional courtesy dictates that some type of direct communication be given to the referring physician.

4. In the specific case where orthopaedic surgeons agree to render "second" medical opinions for a third party who then directs patients to them, the assumption of that patient's care may be prohibited expressly by the terms of the physician's arrangement with the insurance company. If the patient independently is seeking an additional medical opinion, the orthopaedic surgeons may render an opinion and advise the patient of a proposed treatment plan, provided the contract permits such action. The physician must be aware of the provisions of his/her agreement with the third party.

5. As an extension of patient autonomy, patients have an ethical right to prompt and complete access to their medical record information unless the physician is bound by a contract with the patient's third party payer. As a corollary, orthopaedic surgeons who proffer second or additional medical opinions at the treating physician's or patient's request also have the right to complete access to this information. In general, the physician (or the physician's clinic or group practice) legally "owns" the patient's medical records that he or she maintains. However, this ownership is subject to the patient's right of privacy and, in legal proceedings, the doctor-patient privilege. It is also subject to the patients' right in most states to obtain copies of those records or to have copies transferred to another person.

   It is in the patient's best medical interests for orthopaedic surgeons to cooperate fully in sharing copies of a patient's medical records, including physician notes, prescriptions, charts, reports, laboratory results, technical information used to assess the patient's health condition, letters, photographs, x-rays, and diagnostic imaging. This is true whether the patient is referred by one orthopaedic surgeon to another for a consultation or if the patient elects to see another orthopaedic surgeon for continuing treatment.

6. The orthopaedic surgeon is bound legally and ethically to give his or her best medical opinion, regardless of whether the orthopaedist is the treating physician or the physician who is asked to render a second or additional medical opinion. The best interest of the patient should clearly remain the guiding principal. **Ultimately, patients independently may choose their treating physicians, request transfers of their care, and dismiss their physician at their own discretion**.

Opinions on Ethics and Professionalism

Sexual Harassment and Exploitation

Issues raised

What is sexual harassment? What should an orthopaedic surgeon do to help eliminate sexual harassment and exploitation?

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

"II. The orthopaedic surgeon should maintain a reputation for truth and honesty with patients and colleagues, and should strive to expose through the appropriate review process those physicians who are deficient in character or competence or who engage in fraud or deception."

"V. The orthopaedic surgeon should respect the rights of patients, of colleagues, and of other health professionals and must safeguard patient confidences within the constraints of the law."

"VII. Good relationships among physicians, nurses, and health care professionals are essential for good patient care. The orthopaedic surgeon should promote the development of an expert health care team that will work together harmoniously to provide optimal patient care."

"X. The orthopaedic surgeon has a responsibility not only to the individual patient, to colleagues and orthopaedic surgeons-in-training, but also to society as a whole. Activities that have the purpose of improving both the health and well-being of the individual and/or the community in a cost-effective way deserve the interest, support, and participation of the orthopaedic surgeon."

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

"II.A. The orthopaedic surgeon should maintain a reputation for truth and honesty. In all professional conduct, the orthopaedic surgeon is expected to provide competent and compassionate patient care, exercise appropriate respect for other health care professionals, and maintain the patient's best interests as paramount."

"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 another orthopaedic surgeon 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 the their professional and legal efforts to prevent the continuation of unethical or illegal conduct."

"V.A. Good relationships among physicians, nurses and other health care professionals are essential for good patient care. The orthopaedic surgeon should promote the development of an expert health care team that will work together harmoniously to provide optimal patient care."

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Other references

American Medical Association, *Current Opinions* of the Council on Ethical and Judicial Affairs, Section 3.08, "Sexual Harassment and Exploitation Between Medical Supervisors and Trainees." Updated June, 1994.

American Medical Association, *Reports* of the Council on Ethical and Judicial Affairs:

- "Sexual Harassment and Exploitation Between Medical Supervisors and Trainees," 1989; and
- "Reporting Impaired, Incompetent or Unethical Colleagues," 1992.

American Medical Association, "Guidelines for Establishing Sexual Harassment Prevention and Grievance Procedures," 1991.

Background

Sexual harassment involves two different situations: (1) unwelcome sexual advances and requests for sexual favors; and (2) the existence of a hostile or offensive work environment that may consist of verbal or physical conduct of a sexual nature (e.g., touching, vulgar humor, risqué remarks, pictures or photographs) or a general hostility towards individuals because of their gender. There need not be sexual advances to create a hostile or offensive work environment.

Examples of sexual harassment include inappropriate sexual advances; favoritism based upon gender, sexist jokes or slurs; the exchange of rewards for sexual favors; and malicious gossip or rumors. Sexual harassment also encompasses the use of sexist teaching materials, denied opportunities or poor evaluations because of gender, and punitive measures based upon the refusal of sexual advances.

In 1990, the American Medical Association sent a survey regarding sexual harassment and exploitation to the 130,000 female medical students, residents and physicians currently in practice in the United States. Nearly three-quarters of the 2,225 respondents said that they had experienced sexual harassment at some time in their career. Most encountered it during medical school and residency. More than 40% were harassed while in practice and some respondent's encountered sexual harassment in more than one setting. Colleagues and management staff were cited most often as the perpetrators of the harassment.

When asked, "If you did not report the incident, why not?" 977 (44%) of the survey respondents cited fear of negative impact and felt no action would have been taken. 760 (35%) felt no action would have been taken. Others said that no sexual harassment policy existed at their institution. Despite the low response rate in this survey, it is important to recognize that so many female physicians-in-training and physicians considered themselves to be targets of sexual harassment.

Legal considerations

During the past several years, the number of complaints of sexual harassment in the workplace has increased substantially as has the number of lawsuits alleging violations of state or federal law based on incidents of sexual harassment.

Legal claims of sexual harassment fall into two categories: “quid pro quo harassment,” whereby submission to or rejection of the sexual conduct is used as the basis for employment decisions; and “hostile environment harassment,” in which conduct is so pervasive that it unreasonably interferes with an individual’s job performance or creates an intimidating, hostile or offensive working environment.

Perceptions of what constitutes offensive behavior sometimes differ between men and women. Men generally are less inclined than women to view sexual teasing as harassment. Recently, courts have begun to adopt the “reasonable woman” test for sexual harassment, ruling that behavior was sexual harassment if a “reasonable woman” would view it as such.

In a case of alleged hostile environment sexual harassment, a plaintiff must prove that “the employer did not respond promptly and effectively when it was apprised of (or should have discovered) the harassment.” An internal investigation followed by appropriate disciplinary action, when warranted, has been held to constitute a proper response in a number of cases.

Employees, such as nurses and support staff, who are sexually harassed may also seek redress from the federal Equal Employment Opportunity Commission (EEOC) and its state counterparts. In the educational context, medical schools and medical trainees are often perceived as sharing an educational rather than an employment relationship. However, the EEOC has determined that interns and residents are sometimes considered to be employees of the medical schools that provide them with clinical training. As such, interns and residents may have the same legal standing as employees to file charges of sexual harassment and discrimination under Title VII of the Civil Rights Act of 1964. In addition, the Civil Rights Act of 1991 gives victims of sexual harassment, whether employees or physicians-in-training, the right to receive punitive damages of up to $300,000. Sexual harassment is also widely prohibited under state law.

Ethical considerations

By definition, conduct that would constitute sexual harassment is unethical. Patient care may be exposed to potential harm when orthopaedic surgeons have made unwelcome sexual advances towards other members of the health care team caring for the patient. Patient care may also be jeopardized in this circumstance by the creation of a sexually hostile or offensive work environment. Orthopaedic surgeons should ensure that their actions cannot be considered unwelcome sexual advances even by the most critical observer. They must also ensure that the nurturing and caring health care environment does not become sexually hostile or offensive by inappropriate communications, touching or sexual favoritism.

In the educational context, most ethicists believe that sexual harassment, broadly defined, occurs even in consensual sexual relationships between medical supervisors and trainees. These relationships raise ethical concerns because of inherent inequalities in the status and power that medical supervisors wield in relation to medical trainees. Whenever a sexual

relationship exists between a medical trainee and a supervisor who has professional responsibility for the trainee, the potential for sexual exploitation exists, despite the voluntary nature of the relationship. The supervisory role should be eliminated if the parties involved wish to pursue their relationship.

Policies dealing with sexual harassment and exploitation

The American Academy of Orthopaedic Surgeons urges orthopaedic surgeons to comply with institutional sexual harassment policies and to develop and enforce such policies (or the concepts underlying these policies) in their own offices. To be effective, sexual harassment policies should include a grievance procedure that is sensitive to the difficulties and potential repercussions experienced by those who report alleged sexual harassment or exploitation. These policies should also acknowledge that both men and women are subject to sexual harassment or exploitation from members of the same or opposite gender and that mechanisms for resolving inappropriate sexual conduct must be equally stringent in all cases. Sexual harassment policies should also assure the rights of both the accuser and the accused and, to the extent possible, should protect the confidentiality of all involved. Generally, an effective sexual harassment policy will include:

- A description of the types of conduct that constitute sexual harassment;
- A strong statement that sexual harassment is unethical and unlawful and that the institution/orthopaedic surgeon will not tolerate such behavior;
- A statement of an employee's right to complain about harassment without fear of retaliation;
- A requirement that supervisors and employees promptly report any sexually harassing conduct;
- A procedure for prompt, full and objective investigation of sexual harassment charges; and
- A statement that offenders will face disciplinary action and possible discharge.

In the educational context, a number of instances of sexual harassment and exploitation have been reported. Because of this, the AMA House of Delegates in 1989 adopted three recommendations dealing with sexual harassment, developed by the AMA's Council on Ethical and Judicial Affairs. They are:

- All medical training programs should develop and implement policies that address sexual harassment and exploitation between educators and medical trainees;
- Such sexual harassment policies should include a discussion of consensual sexual relationships; and
- Such sexual harassment policies should contain a grievance procedure, including a mechanism to assure that the rights of both trainees and educators to due process are rigorously observed.

Recommendations

The American Academy of Orthopaedic Surgeons urges orthopaedic surgeons to be aware of and sensitive to issues of sexual harassment and exploitation. Orthopaedic surgeons should conduct their activities professionally and should not jeopardize patient care through inappropriate sexual actions or comments. Policies should be implemented and followed to ensure that all members of the health care team may perform their professional duties without fear of sexual harassment or exploitation.

Opinions on Ethics and Professionalism

Sexual Misconduct in the Physician-Patient Relationship

Issue Raised

What obligations does an orthopaedic surgeon have regarding sexual misconduct in the physician-patient relationship?

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

"I. 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."

"II. The orthopaedic surgeon should maintain a reputation for truth and honesty with patients and colleagues, and should strive to expose through the appropriate review process those physicians who are deficient in character or competence or who engage in fraud or deception."

"V. The orthopaedic surgeon should respect the rights of patients, of colleagues, and of other health professionals and must safeguard patient confidences within the constraints of the law."

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."

"I.B. The physician-patient relationship has a contractual basis and is based on confidentiality, trust, and honesty. Both the patient and the orthopaedic surgeon are free to enter or discontinue the relationship within any existing constraints of a contract with a third party. An orthopaedist has an obligation to render care only for those conditions that he or she is competent to treat. The orthopaedist shall not decline to accept a patient solely on the basis of race, color, gender, sexual orientation, religion, or national origin or on any basis that would constitute illegal discrimination."

"II.B. The orthopaedic surgeon should conduct himself or herself morally and ethically, so as to merit the confidence of patients entrusted to the orthopaedic surgeon's care, rendering to each a full measure of service and devotion."

"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."

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Other references

American Medical Association, *Current Opinions* of the Council on Ethical and Judicial Affairs, Section 8.14, *"Sexual Misconduct in the Practice of Medicine."*

American Medical Association, *Reports* of the Council on Ethical and Judicial Affairs, Report 29, "Sexual Misconduct in the Practice of Medicine," January, 1991.

Johnson, SH: Judicial review of the disciplinary action for sexual misconduct in the practice of medicine, *JAMA*; 1993; 270: 1596-1600.

Background

Sexual contact between a physician and patient may occur in several circumstances: (1) the physician may become involved in personal relationships with patients that are concurrent with but independent of treatment; (2) some physicians may use their position to gain sexual access to their patients by representing sexual contact as part of care or treatment; (3) physicians may assault patients by engaging in sexual conduct with incompetent or unconscious patients. There seems to be little or no data indicating the prevalence of each type of sexual misconduct.

Although a number of studies have attempted to establish the incidence of physician-patient sexual contact, the actual prevalence of physician-patient contact cannot be determined with accuracy. What data exists is generally based on self-reporting by physicians.[1] Because of the stigma attached to physician sexual contact with patients and the professional repercussions which may result from admitting to such contact, most researchers believe that the occurrence of patient-physician sexual contact is grossly underreported. There is a small minority of physicians who have reported having sexual contact with their patients.[2] Studies of psychiatrists indicate that between 5-10 percent reported having sexual contact with patients.[1]

Data for all specialties are not available, but a 1976 study suggests that this percentage may be comparable for other specialties.[2] Research also indicates that the effects of physician-patient contact are almost universally negative or damaging to the patient.

There is a long-standing consensus within the medical profession that sexual contact or sexual relations between physicians and patients are unethical. Current ethical thought uniformly condemns sexual relations between patients and physicians. In addition, the laws of many states prohibit sexual contact between physicians and their patients. The ban on physician-patient sexual contact is based on the recognition that such contact jeopardizes patients' medical care.

Legal Considerations

Physicians engaged in sexual activity with patients may be subject to legal penalties for such conduct. Sexual conduct by physicians with their patients may generate civil damage actions against the physician for malpractice.[3] In addition, criminal prosecutions, either under general sexual assault statutes or under recently enacted more specific statutes, are possible.[4] Indeed, four states currently specifically classify sexual exploitation by a psychotherapist as sex offenses under criminal statutes. It is noteworthy that the statue in a least one state - Florida - specifies that consent of the patient cannot be used as a defense by a physician against charges of sexual misconduct.

Sexual activity of physicians with patients may also trigger licensure disciplinary action against the physician. Seven states have enacted licensure statutes that specifically provide for disciplinary action for sexual activity, and others address the issue of a physician's having sexual relations with a patient under the general categories of "unprofessional conduct" or "moral turpitude." The range of sanctions available to licensure boards provide greater flexibility in adjusting the penalty to fit the degree of violation. However, the effectiveness of the disciplinary system in handling improper sexual activity by physicians with patients or former patients has been criticized for failing to protect patients.[5]

Ethical Considerations

Patient consent

Several elements of the physician-patient relationship may combine to give the physician undue influence over his or her patient. Within the physician-patient relationship, the physician possesses considerable knowledge, expertise, and status. A patient is often most vulnerable, both physically and emotionally, when seeking medical care. When a physician acts in a way which is not to the patient's benefit, the relatively weak position of the patient makes it difficult for the patient to give meaningful consent on the part of the patient which has led researchers to compare physician-patient sexual contact to other sexually exploitive situations such as sexual assault and incest.

Patients who seek medical care must be able to trust in the physician's dedication to their welfare in order for the physician-patient alliance to succeed. A physician who engages in sexual contact with a patient seriously compromises the patient's welfare. The patient's trust that the physician will work only for the patient's welfare is violated. Consequently, sexual contact and sexual relationships between physicians and their patients are uniformly considered to be unethical.

The orthopaedic surgeon's professional obligation to serve the needs of the patient means that his or her own needs cannot become a consideration in decisions about the patient's medical care. This is because consideration of the physician's needs or gratifications may interfere with efforts to address the needs of the patient. The emotional factors which accompany sexual involvement affect or obscure the physician's medical judgment, thus jeopardizing the patient's diagnosis or treatment.

Termination of the physician-patient relationship

Physicians and patients may be genuinely attracted to each other. However, any relationship in which a physician might take advantage of the patient's emotional or psychological vulnerability is unethical. Therefore, before initiating a dating, romantic, or sexual relationship with a patient, a physician's minimum duty is to properly terminate his or her professional relationship with the patient. In addition, physicians are advised to consult with a colleague before initiating a relationship with the former patient. Termination of the professional relationship would also be appropriate if a sexual or romantic attraction to (as opposed to actual contact with) a patient threatens to interfere with the judgment of the physician.

Even the termination of the physician-patient relationship does not totally eliminate the possibility that sexual contact between a physician and a former patient might be unethical. Sexual contact between a physician and a patient with whom professional relations have been terminated would be unethical if the sexual contact occurred as a result of the use or exploitation of trust, knowledge, influence or emotions derived from the former professional

relationship. The ethical propriety of a sexual relationship between a physician and a former patient depends substantially on the nature and context of the former relationship.

Reporting of sexual misconduct

Sexual misconduct is unlikely to be brought to the attention of the proper authorities by a patient because of the feelings of shame, humiliation, degradation, and self-blame.

The reporting of alleged sexual misconduct by one physician against other physicians is critically important in the case of sexual misconduct. Physicians are encouraged to report instances of sexual misconduct by their colleagues. Research on the reporting practices of physicians indicates that reluctance to report may involve concerns about confidentiality, either in the physician-patient relationship or among colleagues. In addition, because of the nature of sexual misconduct, most victims are rendered reluctant or unable to report the misconduct on their own. The Academy, in its *Principles of Medical Ethics and Professionalism in Orthopaedic Surgery*, provides that "[t]he orthopaedic surgeon should strive to expose through the appropriate review process those physicians who are deficient in character or competence or who engage in fraud or deception." Therefore, orthopaedic surgeons should be vigilant in exposing colleagues to appropriate review who allegedly have committed sexual misconduct.

The Academy and the AMA's Council on Ethical and Judicial Affairs believe that physicians who become aware of alleged sexual misconduct by a colleague should report the misconduct to the local medical society, the state licensing board or other appropriate authorities, except if the physician learns of the sexual misconduct while treating the offending physician.

AMA Council on Ethical and Judicial Affairs

In December, 1990, the AMA's Council on Ethical and Judicial Affairs released *Report 29* on "Sexual Misconduct in the Practice of Medicine." The *Report* concluded that:

1. A physician's sexual contact or romantic relationship with a current patient is unethical;
2. A physician's sexual contact or romantic relationship with a former patient are unethical if the physician uses or exploits trust, knowledge, emotions or influence derived from the previous professional relationship;
3. Medical training should include education on the issue of sexual attraction to patients and sexual misconduct at all levels;
4. Disciplinary bodies must be structured to deal effectively with physician sexual misconduct;
5. Physician's who learn of sexual misconduct by a colleague must report the misconduct to the local medical society, the state licensing board or other appropriate authorities. Exceptions to reporting may be made in order to protect patient welfare of the physician-patient privilege;
6. Many states have legal prohibitions against relationships between physicians and current or former patients.

Recommendations

The American Academy of Orthopaedic Surgeons condemns sexual misconduct by orthopaedic surgeons and other physicians. The Academy concurs with the December, 1990,

recommendations of the AMA's Council on Ethical and Judicial Affairs contained in Report 29 about "Sexual Misconduct in the Practice of Medicine." Orthopaedic surgeons who learn of the alleged sexual misconduct of a colleague have an obligation to report it to the local medical society, state licensing board or other authority. By taking this action, orthopaedic surgeons can help ensure that all patients are treated in a non-threatening, respectful manner.

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Position Statement

Anabolic Steroids to Enhance Athletic Performance

The American Academy of Orthopaedic Surgeons (AAOS) recognizes that although anabolic steroids may enhance athletic performance by increasing both the size and strength of athletes, their use can cause serious harmful physiological, pathological, and psychological effects.

The AAOS believes that anabolic steroids should not be used to enhance performance or appearance, and that they be banned from use in all sports programs. We recommend that sports-governing bodies make every effort to deter and to detect their use. When feasible, the relevant sports medicine bodies should implement aggressive drug testing programs to detect their use and impose harsh penalties for those athletes who use them and those individuals or institutions who facilitate their use.

The Code of Ethics for Orthopaedic Surgeons specifically addresses this issue. It provides in Paragraph VII.B:

". . . It is unethical to prescribe controlled substances when they are not medically indicated. It is also unethical to prescribe substances for the sole purpose of enhancing athletic performance."
Use of anabolic steroids has been associated with the following adverse effects: increased risk of benign and malignant tumors of the liver, testes, and prostate; increased risk of serious cardiovascular disease; impaired reproductive functioning in males and females which may be irreversible; tendon weakening and potential ruptures; irreversible closure of bone growth centers in adolescents; menstrual irregularity; and psychological dependence which may lead to withdrawal symptoms and depression upon the cessation of use. Major personality changes may occur, manifested by increasing aggressiveness and intensity which may lead to intense anti-social or psychotic behavior.

The use of performance-enhancing substances by athletes represents a most serious violation of ethical standards of organized sports activities at all levels, and should not be tolerated.
Recent legislation classifies anabolic steroids as controlled substances, and imposes restrictions on their distribution and use. The AAOS strongly supports law enforcement agencies in their efforts to enforce existing legislation to control the distribution and use of anabolic steroids.

Position Statement

Animals in Biomedical Research and Education

The American Academy of Orthopaedic Surgeons (AAOS) is committed to ensuring humane treatment of animal used for laboratory research or surgical education. Government agencies, accrediting agencies, and research institutions must monitor activities within the current laws and guidelines, and individual investigators must increase their sensitivity and discrimination in the use of animals for these purposes.

This position statement asserts that the appropriate use of animals in conducting biomedical and veterinary research and education is justified to enhance the quality of life for both humans and animals. Numerous medical advances, many of which today are taken for granted, were the results of research that required the use of animals. The development of insulin, for example, was critically dependent upon animal experimentation. The development of novel chemotherapeutics routinely requires such experimentation to establish efficacy and safety for use in humans and animals. Improvements in internal fixation of fractures, often life-threatening in animals, have also relied upon animal models of fracture repair.

The AAOS believes federal, state, accrediting agency, and local institutional guarantees and protections provide an appropriate framework for current animal research.

The Animal Welfare Act of 1966 as amended by the Food Security Act of 1985 (PL 99-198), the Health Research Extension Act of 1985 (PL 99-158), the National Institute of Health Guide for the Care and Use of Laboratory Animals (revised 1996), and the Public Education Health Service Policy on Humane Care and the use of Laboratory Animals by Awardee Institutions (revised 1985) provide excellent protections against the misuse or abuse of animals for research purposes. Additionally, the American Association for Accreditation of Laboratory Animal Care ensures that accredited care facilities meet reasonable and appropriate guidelines for the care of animals. Federal law requires each institution to have a local committee that reviews and assesses the appropriateness of all projects requiring animal experimentation. Peer review groups at granting institutions also provide another level of review of appropriate animal use and further protections. Appropriate use of these laws and guidelines will ensure that alternatives to animal experimentation have been first explored, that minimal numbers of animals and appropriate species have been chosen, that the experiments will answer meaningful questions, and that the animals are being treated in a caring and humane way.

The AAOS believes and encourages investigators employing experimental protocols involving laboratory animals to carefully consider the appropriateness and sensitivity of the protocols prior to choosing and using live animals.

The “3Rs” should be considered before investigators adopt an animal-based experimental protocol. **Replace** animal subjects with nonsentient organisms such cell or tissue cultures, or with an inanimate model such as a bench or computer simulation; **reduce** the number of sentient animal subjects by carefully designing and conducting experiments in a manner that produces reliable and statistically significant results, eliminating the need for repetitive confirmatory tests; or **refine** clinical protocols to reduce the incidence or severity of distress experienced by laboratory animals.

The above approaches, however, do and will continue to have common and particular inherent limitations. It is clear that cells and tissues in culture do not behave entirely like cells in the intact

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organism. It is also clear that bench and computer simulations do not always serve as sufficient proxies for "live" surgical intervention and that they must always be validated through some sort of animal or human behavior before they can achieve wide use.

Examples can be cited in which research studies depend on animal models because they permit in vivo study of the interaction of many tissue and organ systems:

> *The study of skeletal infection and pharmacal kinetics* - the interaction between antibiotics and infectious organisms can be quite different in a living animal and in a laboratory environment.
>
> *Fractures of long bone and soft tissue injury and repair* - the repair process involves many tissues and our current knowledge of these interactions is incomplete. Laboratory or experimental models do not provide the complex interactions required to adequately observe the repair process.

The AAOS believes research funds should be allocated within governmental and private research agencies to support the development of alternative approaches to animal research.

Current funding policies tend to favor biomedical research that addresses specific clinical problems, rather than research that develops and explores alternative experimental methods. Additional funding specifically aimed at developing alternative approaches to animal experimentation is warranted at this time. The AAOS has provided resources and continues to be supportive of these ongoing efforts.

The AAOS believes that animal models, in specific circumstances, can be used for surgical education and refinement of new surgical techniques.

Coronary bypass surgery and organ transplantation are two examples of numerous instances in which surgical techniques were developed and perfected in animals and later adopted as standard of care in humans. More recently, endoscopic technologies that have minimized the invasiveness and morbidity associated with open surgery were initially tested and refined using carefully selected animal models. The decision to use live animals for the development and improvement of surgical techniques should be done with caution and only after the proof of concept and feasibility of the procedures have been clearly established. Live animal models should be used for surgical education only when no other means for practical training are sufficient.

The AAOS believes current regulations, restrictions, and guidelines will need periodic review as alternative approaches evolve.

Alternative approaches to animal usage in research and education have changed significantly as they have become more refined and sophisticated, as their limitations have become known, and as new methods have become available. Additionally, increasingly refined, safe, and sophisticated human research has reduced the need for some animal experimentation. In fact, humans continue to be the most common species used for biomedical experimentation and medical education. Thus, current guidelines will need to be periodically updated in light of new methods and alternatives.

Position Statement

FAMILY VIOLENCE

Family violence is a major public health problem in the United States. It leads to physical and psychological disability, death and loss of productivity. It can perpetuate itself through successive generations and contributes to the escalating health care costs in this country. Family violence affects a significant proportion of the US population either as direct victims or as witnesses of abuse.[1]

Family violence constitutes a triad encompassing domestic violence ("intimate partner violence"), child abuse, and elder abuse. These problems can exist independently or in combination in the same household. Studies indicate that child abuse occurs in 33% to 77% of families in which there is abuse of adults.[2,3,4] Between 3.3 and 10 million children witness domestic violence each year.[5,6] Children whose mothers are abused may experience serious emotional distress and manifest severe behavioral problems as a result.[2,4]

Family violence is prevalent in our society. In 1999, there were 826,000 cases of documented child abuse or 11.8/1000 children. The highest rate of abuse was noted in those aged 0 to 3. There were 1100 deaths due to abuse and neglect or 1.62/100,000 children. Data indicates that 42.6%of these children were less than one year of age and 86.1% were less than six years of age.[7] It has been estimated that failure to diagnose an initial presentation of child abuse may result in a 30% to 50% chance of repeated abuse and a 5% to 10% chance of death.[8]

An estimated 2.5 million women and 1.6 million men are physically assaulted by an intimate partner annually in the United States. 30% of women and 37% of men receive medical care for their injuries.[9] A report based on statistics from a nationally representative sample of hospital emergency departments revealed that 36.8% of female patients and 4.5% of male patients who had been treated for violence-related injuries had been injured by current of former intimate partners.[10] Intimate partner violence can also result in complaints of chronic pain and somatizing disorders brought on by the stress of living in a violent environment.[11] Therefore, orthopaedic surgeons may be called upon to treat victims of family violence in both emergency and non-emergency settings. The number of patients presenting to the offices and clinics of orthopaedic surgeons is unknown and unstudied.

The National Center on Elder Abuse estimated that in 1996 there were 1 to 2 million elderly persons in this country who experienced abuse or neglect. Women made up 58% of victims. Two thirds of the perpetrators of abuse were family members who acted as caretakers.[12]

The American Academy of Orthopaedic Surgeons (AAOS) believes family violence, in the form of child abuse, adult domestic violence and elder abuse, is a major public health problem in the United States. The AAOS is committed to providing appropriate care to victims of family violence whether they present to an emergency department, orthopaedic office/clinic.

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Position Statement

Fee "Unbundling" and Uniform Definitions for Surgical Procedures

Trends indicate that global billing for surgical procedures will increase as the Medicare program adopts a physician fee schedule. The lack of uniform definitions for surgical procedures has led to confusion about what group of services, or global service package, should be considered part of a given procedure for billing and payment purposes. This confusion has resulted in fee "unbundling" by some surgeons. Fee "unbundling" occurs when the charge for a specific procedure remains the same, but one or more components of the procedure are separated from the global service package and given a separate, additional fee.

The American Academy of Orthopaedic Surgeons (AAOS) believes it is unethical for orthopaedic surgeons to separate from the global service package services which are a necessary part of the surgical procedure and to then bill individually for those services.

While the specific surgical methods used by different orthopaedic surgeons performing a given procedure may vary, the basic operative approach and sequence of events are typically similar enough to be included under a single global service package. The package should encompass all the steps which are necessary for the successful completion of the procedure, provided that complications do not arise which require the orthopaedic surgeon to add more demanding and time-consuming components to the procedure. Other procedures which are an integral part of the main operation should be considered as necessary adjuncts, not separate entities for which additional fees are justified. Only those services which represent procedures with clearly different indications should be billed and paid for separately.

The AAOS strongly encourages all third party payers, peer review organizations and others to adopt appropriate uniform payment policies regarding which services should be included in the global service package.

The lack of uniform definitions for surgical procedures has led some third party payers, peer review organizations, and others to adjust those components which are included in the global service package.

Through a consensus process and with nationwide input from orthopaedic surgeons, the AAOS has prepared a book containing intraoperative global service data for orthopaedic surgery; this model document fully incorporates the guidelines described in this Position Statement.

Position Statement

Firearms Violence

The American Academy of Orthopaedic Surgeons (AAOS) believes that death; injury and disability resulting from firearm violence must be reduced.

Firearm violence is a significant public health problem. The AAOS believes that the public should recognize the following information which outlines an epidemic of injury and death due to firearms.

- Firearms are involved in the deaths of more than 37,000 people each year, the second leading cause of injury-related death in the United States.
- Firearm deaths have increased 60 percent since 1968. During 1991, 5,356 young men and women under the age of 20 were killed by firearms, the leading cause of death for both African-American and Caucasian youth in America.
- Accidental shootings account for 5 percent of all firearm deaths in the United States each year. Youths in the home, under the age of 20, are involved in 84 percent of these cases. Firearm deaths involving children and adolescents have increased 143 percent between 1986 and 1992.
- The most common reason given for purchase of a gun is protection from crime; yet one study shows only two out of 398 firearm deaths in a home involved an intruder. Relatives and friends are 43 times more likely to die from a gun kept in the home for protection than is an intruder. Self-defense handgun shootings account for only 1.2 percent of homicides, according to the FBI.
- Medical costs for firearm violence surpass $4 billion yearly and total economic losses are estimated to exceed $14.5 billion each year. In 1993, the average estimated hospital cost of each firearm injury was more than $19,000.

The AAOS believes that most deaths and injuries due to firearms are preventable. The AAOS is committed to reducing death, injury and disability due to firearm violence through support of a comprehensive public health approach which includes the following:

Education, Prevention and Intervention

- Education of health professionals for the prevention, acute care and rehabilitation of firearm injuries.
- Public education programs designed to teach and encourage proper firearm use, lock and key storage and firearm safety.
- Supporting programs that educate patients and families about the dangers of firearms to children.
- Encouraging physicians to ask their patients about the presence of firearms in the home and encouraging proper storage to achieve a "childproof home."
- Scientific research, including social studies, aimed at identifying causes and solutions to the firearm problem.

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Data Collection and Trend Monitoring

- Accurate and objective data collection and trend monitoring of firearm injuries to enable the development of sound public policy.
- Public funding for a national firearm injury and fatality reporting system of the Centers for Disease Control and Prevention.

Public Policy Strategies

- Safety intervention strategies to control firearm possession and use by unsupervised youth under age 18.
- Implementation of proper licensing fees.
- Enactment of a required national waiting period that allows for an expanded police background check.
- Banning the sale or manufacture of firearms that are not detectable by ordinary security devices.
- Creating a long-term goal to eliminate specific categories of firearms that have little or no legitimate utility.
- Stricter enforcement of present local, state and federal laws and the imposition of mandatory penalties for crimes committed with firearms.
- Prohibiting the presence of firearms in hospitals except for law enforcement officials.
- Encouraging the American Hospital Association and the Joint Commission on Accreditation of Healthcare Organizations to develop guidelines and standards regarding hospital security issues.

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Position Statement

Health Care Coverage for Children At Risk

The American Academy of Orthopaedic Surgeons (AAOS) believes that health care coverage for all children is a mandatory investment in our nation's future.

Equitable access to health care is a social goal that has proved difficult to achieve in the U. S. The existence of substantial barriers in access to health care services for children is cause for particular concern. New initiatives are needed to address both financial and non-financial barriers to care for disenfranchised, "children at risk."[1,, 2]

The number of uninsured children in the U. S. has increased in the past decade. One in seven children is without health insurance. This is nearly one-fourth of the total uninsured population. When compared to the insured, they are four times more likely to report needing, but not receiving health care.[3]

Uninsured children are less likely to be immunized and less likely to receive care for acute and chronic illnesses, and injuries. As a result, many untreated, mild conditions become complicated, costly problems with sometimes permanent impairment.

Uninsured children are most likely to be in low-income, "working poor" families. Most are in two-parent families with at least one working parent.

A growing number of children lack health care coverage because their parents work in the service sector, are self-employed, or are in temporary jobs - most of which fail to offer health insurance. Large and small employers have also tightened their budgets to remain competitive, resulting in reduced benefit packages for employees.[4]

Children with insurance fare better, but they can also face obstacles in accessing appropriate health care.

The costs of anemia, child abuse, preventable injuries, developmental delays and unattended malnutrition are critical health care expenditures. They also fall heavily on society's ledger in the form of social services, education or correctional systems.[5]

The AAOS believes that the following principles should be the foundation of all children's health insurance programs:

1. **All children should receive timely, appropriate health care coverage.**
2. **Children should be viewed as a population with unique health care needs. They should not be treated uniformly as small adults.**
3. **Basic health care coverage for all children should include well-child care, early detection programs, and treatment of chronic conditions.**
4. **Health insurance programs must address children with special needs, including those with heart disease, asthma, epilepsy, juvenile diabetes, cerebral palsy, and many other chronic illnesses.**

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Too often insurance plans do not recognize children with special needs and they are denied coverage for appropriate outpatient services and assistive devices.

Children with special *musculoskeletal* needs include those with spina bifida, club foot, dysplastic hip, scoliosis, congenital deformities, spinal cord injury, infections of bones and joints, osteogenesis imperfecta, muscular dystrophy, limb deficiency, limb deformity, juvenile arthritis, and musculoskeletal trauma.

5. **The promotion of healthy lifestyles is critical for our nation's children, particularly adolescents.**

   Health problems that can be reduced through behavioral change must be addressed, including smoking, drug and alcohol use, violence, abuse and neglect.

6. **All health insurance programs for children should include these essential features:**

   Coverage for all children
   Pediatric guidelines specific to children's health problems. Adult guidelines should not be applied uniformly to children
   Program oversight to ensure that the funds accomplish what they are intended to accomplish
   Pediatric quality assurance criteria against which to measure and evaluate program achievements
   Education programs for the public, as well as health and medical professionals, on the unique health care requirements of children
   Health education and health promotion programs for parents and children that promote healthy lifestyles and quality of life for children

7. **Children's access to care must not be blocked by inadequate insurance or finances, nor by funding that is restricted to particular, or limited, diagnostic categories.**

   Among the most significant obstacles are financial barriers, including lack of adequate health insurance and inadequate funding for low-income children, and those with special health care needs. Other non-financial barriers arise due to the categorical nature for addressing children's health care needs.[6]

   The AAOS believes that additional measures must be taken to strengthen the public and private health care financing and delivery infrastructure in a manner that will ensure the highest quality of life for all children.

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Position Statement

Health Care Plan Accountability

Many major changes continue to take place in the way people purchase health insurance and receive medical care. The pressures to reduce health spending continue to be intense, and health plans and providers have become more aggressive in their cost containment activities. While many health plans have developed a number of effective techniques to achieve economy and maintain quality of care, others have not always achieved that balance.

In this changing health care environment, the American Association of Orthopaedic Surgeons (AAOS) has consistently maintained that some federal patient protections are necessary to restore the physician-patient relationship, preserve the patient's choice of physician, and enhance access to specialty care. These protections include:

- **Access to a full range of medically necessary specialty care in-network.**
- **The ability to seek treatment out-of-network for a non-cost-prohibitive copayment.**
- **A prohibition on financial incentives that result in the withholding of care or denial of a referral.**
- **Comprehensive information provided to all enrollees and prospective enrollees that allow them to make an informed choice about plan coverage.**
- **A ban on "gag" clauses which prohibit physicians from discussing with patients their treatment options.**

Equally important, the AAOS believes that all health care plans must be held accountable for their actions, plan procedures and requirements, and coverage decisions that may adversely affect their enrollees.

Today, most health care plans in this country are exempt from state patient protection requirements and legal standards for negligence. Because federal law does not provide these protections for all health care plans, these plans have been able to avoid any accountability for decisions that detrimentally affect their enrollees.

Accordingly, the AAOS believes that there is a need for an immediate and appropriate federal remedy to rectify the current lack of plan accountability. The AAOS supports requiring every health care plan to provide for, or submit to, a binding expedited, independent external appeals mechanism or review for coverage decision-making and grievances against the plan.

Providing such a standard for participation for all health care plans in this country will ensure plan accountability, and afford the patient a timely independent resolution of their dispute with the coverage decisions of a health care plan.

For additional information, contact Kristin Glavin at (847) 384-4050 or glavin@aaos.org

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Advisory Statement

The Importance of Good Communication in the Physician-Patient Relationship

Good communication with patients has always been essential in orthopaedic practice. It is the *"cornerstone"* of the physician-patient relationship. Open, honest communication builds trust and promotes healing. It favorably impacts patient behavior, health outcomes, patient satisfaction, and often reduces the incidence of malpractice actions. For physicians, good communication with patients can also increase professional satisfaction, enhance community image, and provide a competitive economic advantage for the medical practice.

Increasing demands on orthopaedic surgeons in today's healthcare environment often leave less time to provide care to a greater number of patients. While time constraints can make it difficult to communicate as effectively as one would like, the quality of time spent with the patient remains very important. For this reason, effective *patient-focused communication skills* are essential. They can be applied quickly and effectively within the normal patient encounter.[1]

The American Academy of Orthopaedic Surgeons and the American Association of Orthopaedic Surgeons (AAOS) urge orthopaedic surgeons to use patient-focused communication skills during their direct patient encounters. These include:

- ***Showing empathy and respect***
- ***Listening attentively***
- ***Eliciting concerns and calming fears***
- ***Answering questions honestly***
- ***Informing and educating patients about treatment options and the course of care***
- ***Involving patients in decisions concerning their medical care***
- ***Demonstrating sensitivity to patients' cultural and ethnic diversity***

When time counts, it is the quality and not necessarily the quantity of physician-patient communication that is vital. To the patient, quality is often measured by how well the physician listens and acknowledges patient concerns. It is measured by how thoroughly the physician explains the diagnosis and treatment options, and how well the physician involves the patient in decisions concerning his or her care. These factors play an important part in the way patients perceive, recall, and evaluate their visits with the physician.[2]

AAOS believes that orthopaedic surgeons must place an emphasis on good communication with patients and the quality of the interaction, especially when time is limited.

Good communication between the orthopaedic surgeon and patient can be an effective risk management tool. While poor treatment outcome is one of the primary causes of malpractice actions, poor communication is also a factor in a majority of cases. Patients who sue often cite the failure of physicians to listen or the physician's unwillingness to answer questions. Patients who are well informed about treatment options, the course of care, expected outcomes, and possible complications are more satisfied patients, and are less likely to file malpractice claims.

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AAOS urges orthopaedic surgeons to provide information and education to their patients about treatment alternatives, and the course of care, especially expectations for surgical outcomes. Discussing the risks of surgery and possible complications, in a kind and compassionate manner, can create realistic expectations on the part of the patient, increase patient satisfaction, and minimize the risk of malpractice claims.[3]

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Position Statement

Improving America's Trauma Care System

The National Academy of Sciences has declared injury the nation's leading public health problem. It is the leading cause of death among people under age 45 and the fourth leading cause of death for all ages, with more than 93,500 fatalities annually. It is also the most expensive health problem, with an estimated 4 million years of productive work lost each year through death and disability. In 1990 alone, $173.8 billion in direct and indirect costs were incurred as a result of injury.

Despite these and other catastrophic effects, the nation's commitment to treating injury continues to wane. A lack of centralized planning, coupled with insufficient financing, has rendered our trauma care system wholly inadequate for a nation which prides itself on high quality health care.

The American Academy of Orthopaedic Surgeons (AAOS) believes our trauma care must be elevated to a level which ensures that each injured person has the greatest possible chance of survival and recovery.

To accomplish this, the AAOS endorses efforts to establish statewide and regional trauma care systems consisting of strategically located trauma centers designed according to widely accepted national guidelines. Overwhelming evidence indicates that these systems would save more lives and prevent more disabilities than today's haphazard distribution of state and local trauma centers, many of which are overly concentrated in large urban areas. Statewide and regional trauma care systems would assure that more injured patients have access to quality trauma care and would reduce the number of patients brought to hospitals which lack the resources to deal with injury.

The AAOS believes that the financial losses incurred by health care entities providing uncompensated trauma care must be eliminated.

According to conservative estimates, hospitals provided approximately $1 billion in uncompensated trauma care in 1988, representing 12 percent of all uncompensated care provided that year. Many hospitals are being forced to either withdraw from their area trauma care system or close altogether due to the financial difficulties of providing uncompensated trauma care.

Therefore, any concerted effort to improve our trauma care system must address the issue of health care for the uninsured. To this end, the AAOS reiterates that it is prepared to join with other medical organizations, civic groups, business and government to examine all options and to create a forum in which this issue can be addressed.

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Position Statement

Medical Error/Patient Safety Reporting Systems

A report released by the Institute of Medicine and several Congressional hearings have focused public attention on the need to improve patient safety and minimize medical errors. Proposals to achieve this objective include nationwide patient safety reporting systems.

The American Academy of Orthopaedic Surgeons (AAOS) is committed to ensuring patient safety and to decreasing medical errors.

Programs and initiatives of the AAOS directed towards reducing medical errors and improving patient safety to date include:

- A series of closed-claim professional liability insurance studies by the AAOS Committee on Professional Liability carried out since 1990 to determine common causes of orthopaedic error and resulting in the publication of the first and second editions of Managing Orthopaedic Malpractice Risk.

- The "Sign Your Site" initiative, which was developed as a result of a September 1997 AAOS task force study of preventable errors occurring in the operating room including surgery on the wrong site. The task force advised that surgery on the wrong site would rarely if ever occur when an awake and alert pre-operative patient and the surgeon mark the operative site immediately prior to surgery.

- A system of Continuous Quality Improvement, including clinical practice guidelines and performance measures, developed to improve quality and efficiency of care and focus on patient safety, which can be used to assist physicians in diagnosis and treatment decisions.

- Ongoing educational opportunities designed to educate orthopaedic surgeons in the best practice of orthopaedic care.

Medical error reporting should lead to improvements in patient safety. The AAOS believes the following principles are essential to ensure the success of a nationwide effort to reduce the number of medical errors:

- ***Public and private initiatives to ensure patient safety and reduce the number of medical errors should be encouraged through a non-punitive, cooperative environment.***

- ***Ensuring patient confidentiality and appropriate legal protection of all information involved in patient safety reporting systems is critical.***

- ***Patient access to their medical records should not be jeopardized by new initiatives.***

- ***Before instituting new reporting systems, federal and state governments should first determine, through supporting research, whether and how existing reporting programs as well as public and private initiatives have led to a reduction in medical errors.***

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The AAOS urges that the goal should be to prevent patient harm and minimize health systems errors. An important goal of any reporting system should be to foster open dialogue and reporting. Systems with punitive undertones would defeat an open dialogue.

To encourage maximum reporting, all information developed in connection with reporting systems, at all phases of reporting activity, should be privileged for purposes of federal and state judicial proceedings, both in civil matters and in administrative proceedings including discovery, subpoenas, testimony, and other forms of disclosure. The submission of information to reporting systems, or the sharing of information with third parties for the purpose of improving patient safety should not be construed as waiving any privilege of confidentiality recognized under state or federal law or established as part of a reporting system. All such information should be exempt from the Freedom of Information Act.

A federal law will be necessary to protect information under a national reporting system. Such federal law should not preempt state evidentiary laws that provide greater protection than federal law and should not interfere with the disclosure of information otherwise available including patients' access to their medical records. Health care professionals should be afforded full disclosure of peer review information related to their practices.

The AAOS encourages initial, scientifically sound research into reporting programs, including those mandated in approximately one-third of states, to determine whether and how they have led to a reduction in medical errors. Funding should be available to redesign systems based on research findings to prevent further errors. The costs to hospitals and other providers for implementing these systems should be considered. Research should not be disproportionately skewed to hospital-based errors but should target a broad range of practice settings.

Policies should encourage a constructive partnership between the federal government, hospitals, physicians, and other medical providers and personnel to initiate policies that can effectively decrease medical error in the United States. Federal government patient safety initiatives should involve a broad range of public and private organizations, including medical specialty societies, to continually advance efforts to improve patient safety.

The AAOS stands ready to work with a broad range of public and private agencies, including hospitals, medical professionals and others, to ensure safe patient practices. The AAOS has designated this initiative as a high priority in its' policies and advocacy.

Advisory Statement

Orthopaedic Medical Testimony

Orthopaedic surgeons are frequently called upon to provide orthopaedic medical testimony in legal or administrative proceedings. In some jurisdictions, criteria for medical witnesses may be inadequate and as a result, unqualified physicians may testify as orthopaedic expert witnesses. It is in the public interest that orthopaedic medical testimony be readily available and objective.

The Code of Medical Ethics and Professionalism of the American Academy of Orthopaedic Surgeons (AAOS) provides that:

> "Orthopaedic surgeons are frequently called upon to provide expert medical testimony in courts of law. In providing testimony, the orthopaedic surgeon should exercise extreme caution to ensure that the testimony provided is non-partisan, scientifically correct, and clinically accurate. The orthopaedic surgeon should not testify concerning matters about which the orthopaedic surgeon is not knowledgeable. It is unethical for an orthopaedic surgeon to accept compensation that is contingent upon the outcome of litigation."

The AAOS believes that, consistent with the Code of Medical Ethics and Professionalism and to limit uninformed and possibly misleading testimony, individuals providing orthopaedic medical testimony should be qualified for their role and should follow a clear and consistent set of ethical guidelines.

Orthopaedic Treating Physicians

As a citizen and a professional with special training and experience, the treating orthopaedic surgeon has an ethical and legal obligation to provide reasonably required factual or administrative testimony. If the orthopaedic surgeon's patient has a legal claim and requests his or her treating physician's assistance, the orthopaedic surgeon should furnish medical evidence, with the patient's consent, in order to secure the patient's legal rights. The orthopaedic treating physician has an ethical obligation to provide truthful, scientifically correct, and clinically accurate testimony and is entitled to reasonable compensation for the time spent to prepare and give testimony. A request for unreasonable compensation by the treating orthopaedic surgeon may be a de facto refusal to testify, and may be considered unethical. The treating orthopaedic surgeon may become an expert witness, but is not ethically bound to do so.

Orthopaedic Expert Witness: Qualifications

1. The orthopaedic expert witness should have a current, valid and unrestricted license to practice medicine in the state(s) in which he or she practices.

2. The orthopaedic expert witness should be a diplomat of or have satisfactorily completed the educational requirements of the American Board of Orthopaedic Surgery (or an orthopaedic surgery specialty board recognized by the American Board of Medical Specialties), as well as be qualified by clinical experience, education, or demonstrated competence in the subject of the case.

3. The orthopaedic expert witness should be familiar with the clinical practice, the applicable standard of care and the relevant facts and history of the case at the time of the incident.

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4. The orthopaedic expert witness should be engaged in the active practice and/or teaching of orthopaedic surgery or be able to demonstrate familiarity with present practices.

Orthopaedist Testimony: Guidelines for Behavior

1. The orthopaedist providing opinions and/or factual testimony should review and testify fairly and impartially and should not adopt an advocacy or partisan position.

2. The orthopaedic expert witness should be knowledgeable regarding concepts and practices relevant to commonly accepted standard(s) of care at the time of the incident. The attorney for the party who calls the orthopaedist should be informed of all favorable and unfavorable information developed in the orthopaedist's evaluation of the case.

3. The orthopaedic expert witness is obligated to state the basis of the testimony, to indicate if he or she is expressing a personal view, to state if this opinion differs from current commonly-accepted, evidence-based practice, and to acknowledge if differing opinions exist.

4. Compensation for providing testimony should be reasonable and commensurate with the time and effort required preparing for the deposition and appearing in court. It is unethical to link compensation to the outcome of the case.

5. The expert witness should be aware that failure to provide complete and truthful testimony may result in criminal prosecution for perjury, civil suits for negligence, and revocation or suspension of his or her professional license. Failure to maintain high ethical standards may result in censure, suspension, or expulsion from the American Association of Orthopaedic Surgeons and the American Academy of Orthopaedic Surgeons.

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Position Statement

Osteoporosis as a National Public Health Priority

A Joint Position Statement of the American Academy of Orthopaedic Surgeons and the National Osteoporosis Foundation

Osteoporosis is a widespread disease characterized by decreased bone mass and poor bone quality, which leads to increased numbers of fractures typically of the hip, spine and wrist. Osteoporosis is a global public health problem currently affecting more than 200 million people worldwide.[1]

The United States alone, 10 million already have the disease and 18 million are at risk, 80 percent of whom are women.[2] Although the incidence of osteoporotic fractures among African American and Hispanic women is less than that of Caucasian and Asian women, their risk is still significant. Each year, 1.5 million fractures are attributed to osteoporosis, including 350,000 hip fractures.[3,4] Seventy percent of those suffering from osteoporosis do not return to previous pre-injury status. The acute and long-term medical care expenses associated with these fractures costs the nation an estimated $10 billion - $18 billion.[4] Due to the dramatic growth of the elderly population and the rise in the incidence of fractures at earlier ages, osteoporosis has become a major public health problem of epidemic proportions.

Osteoporosis can be classified into two broad categories: primary and secondary osteoporosis.[5]

Primary osteoporosis is, by far, the most common form of the disease and includes:

- postmenopausal osteoporosis
- age-associated osteoporosis, previously termed senile osteoporosis, affecting a majority of individuals age 70 and older
- idiopathic osteoporosis affecting premenopausal women and middle-aged men

Secondary osteoporosis is a disease in which an identifiable agent or disease process causes loss of bone tissue and includes:

- inflammatory disorders
- disorders of bone marrow cellularity
- endocrine disorders of bone remodeling
- medication induced

Osteoporosis reflects the inadequate accumulation of bone during growth and maturation, excessive losses thereafter, or both. Although knowledge of the causes of osteoporosis is incomplete, genetic, endocrine and life style factors are contributory.[4] Since today's effective and safe treatments primarily preserve existing bone tissue, prevention, which involves maximizing maturational gains in bone density and minimizing post-maturity losses, emerges as the crucial current disease prevention strategy.[4]

The American Academy of Orthopaedic Surgeons (AAOS) and the National Osteoporosis Foundation believe that increased federal funding for research and education programs are essential to reduce the growth rate of osteoporotic fractures.

Based upon current scientific knowledge about osteoporosis, it is further believed such education programs should include information about:

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- risk factors associated with osteoporosis, including, insufficient calcium intake, sedentary lifestyle, smoking and excessive alcohol consumption. A family history of fractures, a small, slender body, fair skin and a Caucasian or Asian background can increase the risk of osteoporosis.
- early diagnosis of osteoporosis usually made by your doctor using a combination of a complete medical history and physical examination, skeletal X-rays, bone densitometry and specialized laboratory tests.
- the importance of adequate dietary intake of calcium, vitamin D and other nutrients, starting at an early age, especially young girls
- efficacy and safety of current estrogen and other hormone and estrogen antagonists (SERMs) to prevent and treat osteoporosis.
- efficacy and safety of bisphosphonates, calcitonin and evolving therapies to prevent and treat osteoporosis.
- sufficient exercise and activity.
- adverse effects of social behaviors such as using tobacco and alcohol
- fall prevention strategies and rehabilitation.

The care for patients with established osteoporosis should include: early diagnosis of potentially treatable secondary types of osteoporosis, protection against further bone loss by utilizing medications such as estrogen, SERMs, bisphosphonates and calcitonin, exercise and activity programs, and injury prevention strategies.

While there is much to be learned about the causes of osteoporosis, there is sufficient current knowledge to undertake therapeutic action today. Estrogen, bisphosphonates, intranasal calcitonin and SERMs provide a wide range of therapeutic choices for prevention and treatment of osteoporosis. Effective regimens that stimulate bone formation will require increased federal research support.

To minimize future predicted costs, morbidity, and mortality from increasing numbers of osteoporotic fractures in our rapidly aging population, the AAOS and the National Osteoporosis Foundation recommend that osteoporosis should become a national public health priority.[6] While current research demonstrates that pharmacological therapies can decrease the risk of fractures, new research is required to evaluate the role of each of our current therapies and to allow us to develop new therapeutic agents that can eliminate the underlying skeletal diseases.

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Advisory Statement

Physicians' Responsibilities in Regard to Violence

Violence is an enormous public health problem in the United States, both in terms of the number of lives touched, and lives lost, and in terms of the impact on the health care system. Violence in the context of this statement is defined as personal injury caused by intentional acts such as sexual abuse, abuse of children, spouses, or elderly persons, attacks related to the commission of a crime, or gang assaults. Approximately 20,000 deaths per year are attributed to intentional violence perpetrated by one person on another. Another 30,000 people die each year as a result of self-directed violence. In addition, almost 300,000 people are hospitalized every year as a result of intentional violence.

According to the U.S. Centers for Disease Control and Prevention, homicide and suicide are among the foremost causes of premature death in the United States. Together, they are the fourth leading cause of years of potential life lost to Americans under the age of 65.

Violence among family members has reached epidemic proportions. For example, more than 2 million cases of child abuse and neglect are reported annually. Between 2 and 4 million people are battered by their spouses each year. As much as 3 percent of the elderly population is abused each year. Violence is a disease with many etiologies, and the medical community is uniquely positioned to play an important role in reducing its prevalence and the pain and suffering that results. Because the incidence of violence continues to increase, it is imperative that physicians increase their efforts to curb this epidemic.
Unlike the child abuse movement where physicians have played a vital role, physicians have had minimal involvement in addressing other forms of family violence such as sexual abuse, domestic violence, and elder abuse. Yet, as they have in the area of child abuse, physicians can make significant contributions to the advancement of knowledge, practice, and policy in this vital area.

The American Academy of Orthopaedic Surgeons (AAOS) endorses the following principles and urges fellow members of the physician community to do likewise:

- **Physicians must become aware of and knowledgeable about the diagnosis and treatment of family violence, and should learn what resources are available in the community for referral of victims of violence.**

- **All physicians must become familiar with applicable abuse reporting laws and other legal requirements as well as appropriate procedures for dealing with and referring suspected cases of abuse.**

- **As members of multidisciplinary teams and/or community-wide coalitions, physicians can be helpful in educating other professional groups about the physical and mental health problems that result from family violence.**

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- **Physicians can play an important role by encouraging and participating in research on all forms of family violence.**

- **Physicians have a responsibility to make known their opinions about the laws, especially regarding those aspects that affect medical practice such as mandatory reporting, competency, professional judgment, patient self-determination, immunity, and liability.**

The AAOS joins the American Medical Association and other medical specialty societies in the support of the National Advisory Council on Family Violence.

The AAOS in October 1993 promulgated an "Opinion on Ethics" on the topic of "Reporting of Suspected Abuse or Neglect of Children, Disabled Adults or the Elderly." This Opinion may serve as additional guidance for the orthopaedic surgeon who encounters instances of family violence or neglect.

Portions of this statement have been adapted from the American Medical Association Report G, I-91.

Position Statement

The Scope Of Orthopaedic Practice In Managed Care Arrangements

In our rapidly changing practice environment, managed care organizations are establishing risk-sharing arrangements with providers for the management and delivery of musculoskeletal care. In some instances, orthopaedic surgeons are not able to contract for the provision of musculoskeletal care relating to certain anatomical areas, such as the foot and ankle. Instead, these contracts are being awarded to other types of providers. Thus, health care delivery systems are being created which deny patients with musculoskeletal problems access to the type of care which is most appropriate for their conditions.

The American Academy of Orthopaedic Surgeons (AAOS) opposes any arrangement in which orthopaedic surgeons are excluded from the provision of musculoskeletal care. We believe that this type of arrangement detracts from the overall continuity and quality of musculoskeletal care that we, as a specialty, are best qualified to delivery and which our patients need and deserve.

Orthopaedic surgeons are trained in the diagnosis and treatment of disorders affecting the bones, joints, and soft tissues of the entire spine, the upper extremities including the hand, and the lower extremities including the foot. Orthopaedic surgeons treat patients of all ages requiring acute and chronic care. They are trained in the cost-effective use and interpretation of laboratory and musculoskeletal imaging tests and procedures, the use of prostheses, orthoses and physical modalities as well as the appropriate referral to allied health care providers. By virtue of their medical background and training, orthopaedic surgeons can coordinate the resolution of musculoskeletal problems, including certain neurological and rheumatological conditions, in conjunction with primary care providers.

The AAOS further asserts that orthopaedic surgeons are by training, qualifying exams, and experience, preeminent providers of musculoskeletal care. The scope of practice for orthopaedic surgeons is broad and well defined and should be recognized as such.

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