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**American Orthopaedic Association
Orthopaedic Institute of Medicine**

**Report from
the Task Force on
Surgeon-Industry Relationships
in the Discipline of Orthopaedic Surgery**

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EXECUTIVE SUMMARY

It is the obligation of every physician to put the best interest of the patient above all other considerations. Patients seeking care from orthopaedic surgeons are often vulnerable; their clarity, judgment, and decision-making capacity are skewed by pain and suffering. The invasive nature of surgery—combined with the urgent and potentially life-threatening nature of many orthopaedic conditions—requires an unwavering commitment from the surgeon to maintain the centrality of the patient's welfare in decision-making and justify the patient's trust.¹ The challenge facing the discipline of orthopaedic surgery, and the profession of medicine in general, is to sustain the undeniable value of surgeon innovation, research, and teaching in collaboration with the biopharmaceutical and device industry (industry) while eliminating gratuitous relationships that are inappropriate, can skew professional judgments and increase cost to the health-care system without adding value, and, most important, can undermine public trust in the discipline and in the medical profession more broadly.

Recognizing the need for guidance that is unique to the discipline of orthopaedic surgery, the American Orthopaedic Association (AOA) established a Task Force on Orthopaedic Surgeon-Industry Relationships in 2010 under the aegis of its Orthopaedic Institute of Medicine (OIOM). The purpose of the Task Force was to assemble a diverse group of individuals with different perspectives to discuss and explore, in an unbiased manner, the critical topic of industry relations with orthopaedic surgeons.

The OIOM Task Force recognizes that a financial conflict of interest exists in the discipline of orthopaedic surgery. Orthopaedic surgeons are uniquely qualified to inform product development, which ultimately provides more and better options for patient care. Relationships with industry are valuable and productive when they are ethical, transparent, and managed appropriately. Positive change can be accomplished through a thorough examination of current relationships with industry and elimination of those that are gratuitous in nature; a reaffirmation of altruism and other core values of medical professionalism; a recommitment to ethical standards of conduct; and a repeated emphasis of these values and standards in all phases of orthopaedic education.

The OIOM Task Force has put forth in this document many recommendations and considerations that are designed to protect the core values of the discipline of orthopaedic

surgery and underscore the need to reaffirm and strengthen professionalism and integrity among its members along the entire arc of their careers. The sixteen specific recommendations emphasized in this report are viewed as the next steps in moving the discipline of orthopaedic surgery closer to the goal of maximizing relationships with industry that are respectful of the values of both partners and patients and are beneficial to patients, while eliminating those relationships that are gratuitous and entered into primarily to generate physician revenue.

The OIOM believes it appropriate and timely to provide leadership to the orthopaedic discipline regarding the increasing prevalence of orthopaedists' relationships with industry, which have been driven by extraordinary advancements in science and technology and their translation into new and improved orthopaedic devices and instrumentation. Ironically, industry is dependent on the orthopaedic community for the optimization of products, device instrumentation, and techniques, and for their utilization and subsequent promotion to the orthopaedic community. The discipline of orthopaedic surgery must maintain its autonomy and self-regulate by educating its trainees and young professionals in the core values and principles of the profession, as well as in the science, technology, and art of the discipline by insisting on lifelong learning and personal assessment throughout their professional lives, and by making certain that they retain the freedom to care for the sick and infirm according to their best professional judgment and existing best evidence. Failure to regulate ourselves will inevitably lead to increasingly intrusive external regulation. Most important, the OIOM avers that the self-regulation called for is the right thing to do for the patient.

Orthopaedic Institute of Medicine
Surgeon-Industry Relationships in Orthopaedic Surgery

Recommendations
1. Orthopaedic surgeons need to understand the distinction between industry relationships that are gratuitous, self-indulgent, and potentially corruptive, and those that are designed to advance the discipline and improve the treatment and care of patients.
2. Orthopaedic surgeons should refrain from establishing the former classes of vendor relationships and serve as exemplary role models for future generations of orthopaedic surgeons. This type of training should begin in medical school and residency programs.
3. Payment for consulting with industry—by providing advice, expertise, or other services in the context of product development—should be fee-for-service or hourly consulting fees based on fair market value and well-defined contractual obligations with prespecified timelines and deliverables.
4. Orthopaedic surgeons involved in institutional purchasing decisions must disclose all relationships with industry and recuse themselves from decision-making in which they or their immediate family members may profit financially or otherwise benefit.
5. Orthopaedic surgeons involved in successful product development activities in which genuine intellectual property (IP) is transferred and royalties are paid must make sure that neither they nor their partners profit further from their patients; surgeons in leadership positions must never demand that others use their products.
6. Investigator-initiated grants for “weak” research projects (i.e., not contributing meaningfully to the literature) may be incentives or rewards for prescribing or purchasing influence; these are inappropriate relationships.
7. Orthopaedic surgeons should only participate in research that meaningfully contributes to the professional literature; is adequately powered to examine clinically important endpoints; and has a study design, operational structure, and oversight mechanism to minimize bias and ensure patient safety. The analysis and reporting of research data must be independent of industry influence, particularly if the research is industry-funded.
8. Participation in speaker’s bureaus should be avoided.
9. Authorship should conform to International Committee of Medical Journal Editors (ICMJE) guidelines. The use of ghostwriters is always unacceptable.
10. The Accreditation Council for Graduate Medical Education (ACGME) should explore the feasibility of developing a standardized core curriculum for inculcating professionalism and ethics in graduate medical education (GME) programs.
11. Industry makes important contributions to building research and education capacity at universities; these relationships must be premised on the charitable and educational uses to which a university may put a tax-subsidized industry gift and not to any corporate or product endorsement.
12. Funds from industry for residency, fellowship, and other training programs should be distributed through unbiased, independent, third-party organizations or through the central administration of the institution. Residency and fellowship training programs should stop accepting individual-focused grants from companies and require companies to submit funding through either of the aforementioned approaches.
13. Reliance on prescription drug samples should be eliminated. Industry should increase access to patient assistance programs to make medications more affordable to patients.
14. Device companies are encouraged to support research in multicenter networks to improve transparency and objectivity. These studies may include the establishment of registries.
15. Industry funds should not be used to develop clinical practice guidelines. When forming guideline committees, individual and composite numbers of financial ties to industry should be evaluated and minimized to avoid actual or perceived industry influence on the resultant guidelines.
16. Professional societies should systematically measure and publicly report the percentage of industry support received for their operating budgets; set goals for progressively reducing industry support to 25% or less (with no more than 5% coming from an individual donor company); and develop explicit policies to manage industry support and disclosure practices, including formation of conflict of interest committees. A central disclosure repository for all orthopaedic professional societies should be implemented, rather than having each organization use its own separate disclosure database.

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PROLOGUE

It is the obligation of every physician to put the best interest of the patient above all other considerations. This concept of altruism, the fundamental tenet of medicine, dates back to Socrates, Plato, and Aristotle.² Pellegrino described medicine as neither a science nor an art, but a practice that gives rise to ethical axioms, which if violated, also violate the good of medicine.²

Patients seeking care from orthopaedic surgeons are often vulnerable; their clarity, judgment, and decision-making capacity are skewed by pain and suffering. The invasive nature of surgery combined with the urgent and potentially life-threatening nature of many orthopaedic conditions requires a commitment from the surgeon to maintain the patient's welfare central in decision-making and requires extraordinary trust from the patient.¹ Shared decision-making is encouraged in the patient-physician relationship, and the surgeon is obligated to inform patients of all of their options and the potential implications of treatment decisions in a manner that allows them to make the best decisions for their individual situation. Typically, patients participate in treatment decisions by choosing their surgeon, engaging in discussions about therapeutic options, and providing informed consent; however, they ultimately relegate control and power to the surgeon and the surgical team.¹ Because patients can refuse treatment, they generally accept ownership of treatment decisions, particularly if the surgeon provides justification.^{1,3} Patients trust that their physician will provide them with objective information and that any recommendations will be made in their best interest, knowing their individual circumstances and goals regarding the outcomes of treatment.³ In addition, the rapidly changing field of orthopaedic surgery complicates the patient's ability to develop any expertise and therefore be fully informed of their orthopaedic treatment options.

The development of new devices and implants in the field of orthopaedic surgery relies heavily on input from the surgeons who implant the devices. The involvement of surgeons in product design and development is somewhat unique to the surgical fields of medicine. This model has proven successful with the development of the total hip replacement by Professor Sir John Charnley in 1962, which revolutionized the field of orthopaedic surgery and the care of patients with orthopaedic conditions.⁴ The biomedical device industry, with revenues of nearly \$30 billion per year globally, has flourished from this collaboration. Hundreds of new devices and implants

are marketed in the U.S. annually; many with only a 5 to 10 year life cycle.⁵ This short life cycle is attributed to replacement by new and improved products rather than the occurrence of safety issues.⁵ The collaborative relationship between orthopaedic surgeons and industry, particularly the device industry, is a necessary and mutually beneficial relationship with the potential for great advances in patient care and medical technology; however, in this relationship there is also the opportunity for conflict of interest to erode beneficence and the integrity of the patient-physician relationship. Once the product is approved by the regulatory authorities and marketed, orthopaedists are free not only to use them on their own patients but also to recommend their use to other surgeons. This situation sets up the potential for abuse, in part because a lack of solid evidence comparing devices precludes drawing informed conclusions about which devices are optimal.⁶

In recent decades, the discipline of orthopaedic surgery has evolved into one that relies on device implantation as a means to improve patient quality of life. Prior to 1970, most orthopaedic interventions consisted of nonoperative treatment and surgical procedures that did not involve total joint replacement devices. In the ensuing decades, numerous technologic breakthroughs resulted in the development of hip and knee implants that have dramatically improved the quality of life for millions of patients. Total hip replacement has been termed the “operation of the century.”⁷

Orthopaedic surgeons practicing in subspecialties such as joint reconstruction, trauma, spine surgery, and sports medicine routinely place implants in most of their patients who require surgical intervention. Essentially all of the initial breakthroughs in improving care through the use of orthopaedic implants have been developed by surgeons. For example, modern fracture fixation devices were largely developed by a group of Swiss surgeons with contributions from German and Russian surgeons. Industry was enlisted in these efforts primarily to manufacture and distribute the devices, but the vision that led to these breakthroughs that have advanced the discipline to its current state came largely from innovative surgeons who sought to improve the quality of care for patients.

More recently, the surgeon-industry relationship has evolved from the past model. In many cases, this relationship appears to prioritize influence over surgeon decision-making rather than improving the quality of devices in the marketplace. The challenge facing the discipline of orthopaedic surgery is maintaining the undeniable value of surgeon innovation, research, and

teaching in collaboration with industry while eliminating gratuitous relationships that are inappropriate, undermine the public trust, and have the potential to increase costs to the health-care system without adding value.

Recent instances of failure to disclose or inadequate disclosure and management of financial ties between industry and physicians have heightened general awareness of conflicts of interest in medicine and raised serious questions about medical professionalism.⁸⁻¹⁰ Industry does indeed serve an important role in the advancement of medicine through its investments in research and development, but its primary mission, to increase market share and shareholder value, differs fundamentally from that of the medical profession. Collaborating with the medical community to improve profitability is legitimate from a business point of view. The potential for conflict arises in the medical profession because of the unique role that physicians play with respect to their patients, in all medical disciplines, but perhaps especially so in the surgical disciplines where patients regularly entrust their life and functional capabilities to their surgeons. Accordingly, financial ties between physicians and industry that are secret or incompletely disclosed and may reasonably be deemed inappropriate, abuse public trust and raise uncertainties about the altruism and objectivity of the medical profession. This lack of transparency can call into question a physician's ability to make a decision in the best interest of the patient, as well as challenge the validity of published research. Not exempt from this scrutiny are the academic health and science systems (AHASs; these are also referred to as academic health centers [AHCs]) and professional medical societies that provide leadership, education, and standards of care through the development and promulgation of clinical practice guidelines.

The OIOM believes it appropriate and timely to provide leadership to the orthopaedic profession concerning the growing influence of industry in shaping orthopaedic practice. Ironically, this industry is dependent on the orthopaedic community for technology innovation; for optimum refinement of products, device instrumentation, and techniques; and for their utilization and subsequent promotion to the medical community. The added costs of new technologies increase patient and payer scrutiny of the relationships between the orthopaedic profession and the device manufacturers. In orthopaedists' dual roles as utilizers and promoters of new products, patients, payers, and the public at large would like to believe that professional decisions are being made on the basis of professional experience, scientific evidence, and cost effectiveness, not because orthopaedists have income streams that depend on their use of particular products. Consequently, the perception of financial conflicts of interest between those

who produce the devices for profit and those who not only utilize but also play key roles in disseminating the devices understandably raises concerns of distortions of professional judgment due to the substantial financial rewards to both parties.

The OIOM affirms at the outset that the primary responsibility for avoiding corrosive financial conflicts of interest; for protecting the independence and integrity of professional judgments, decisions, and actions; and for assuring that legitimate, even necessary, interactions with industry are transparent, ethical, and capable of withstanding severe scrutiny rests on individual orthopaedic surgeons, the discipline of orthopaedic surgery, and orthopaedic surgery professional societies.

INTRODUCTION

As defined by the Institute of Medicine, conflicts of interest are “circumstances that create a risk that professional judgments or actions regarding a primary interest will be unduly influenced by a secondary interest.”⁸ It is very important to understand that a conflict of interest is a *set of circumstances* and *not* a judgment about the character of an individual. The Institute of Medicine describes primary interests as those that promote and protect “the integrity of research, the quality of medical education, and the welfare of patients” and secondary interests as those which “may include not only financial gain but also the desire for professional advancement, recognition for personal achievement, and favors to friends and family or to students and colleagues.”⁸

Nonfinancial conflicts of interest are ubiquitous in professional life, cannot be eliminated, and are generally managed by professional standards and codes of conduct. Thus, policies aimed at controlling conflicts of interest “typically focus on financial gain as this aspect is relatively more objective, fungible, and quantifiable.”⁸ Financial conflicts of interest in general are typically more visible and subject to more control through statutes, regulations, and policies.

Financial conflicts of interest, and their sometimes disastrous consequences, have become far better understood by the public during the first decade of the 21st century. The appearance of a conflict of interest in matters affecting decisions that the public—including patients, taxpayers, or public policy makers—cannot make on its own but must rely on the advice of presumed experts from the relevant disciplines is always troubling, and even more so when the conflict has not been disclosed and is only later discovered.

Today's physicians do not enjoy the same level of trust that the profession once held. This may be attributed in part to adverse publicity surrounding incidents where physicians have failed to distinguish between legitimate interactions with industry that are in the interest of advancing science, technology, and patient benefit, and interactions driven primarily by the prospect of personal gain. It is necessary to keep in mind that the primary mission of these (indeed all) companies is to increase value for their shareholders, and using physicians to increase their sales volume and market share, and rewarding physicians well for their participation, is legitimate from a business point of view. The conflict arises in the medical profession because of the unique role that physicians play with respect to their patients, in all medical disciplines, but perhaps especially so in the surgical disciplines where patients regularly entrust their lives and their functional capabilities to their surgeons. Accordingly, physicians should not allow themselves to be used as "salespersons" for personal financial gain, and this is certainly true for orthopaedists.

Within the profession of medicine, orthopaedic surgery needs to do a better job self-regulating and assuring transparency so that integrity, trust, and the respect of the public is preserved, especially regarding close interactions with industry in furthering research and development. Also of concern are industry representatives who provide necessary technical support in delivering patient care.

Existing guidance on managing conflicts of interest has been published,^{8,11-14} however, the orthopaedic leadership finds that these existing guidelines do not fully meet the unique needs of orthopaedic surgery. By necessity, orthopaedic surgery is a discipline that collaborates extensively with industry in the development, improvement, and refinement of orthopaedic devices; the instrumentation and techniques needed to safely implant these devices; and the education of practicing surgeons on new techniques involving these devices. Simply put, companies cannot produce devices without clinical input and surgeons cannot manufacture devices.

Professional orthopaedic societies face unique challenges in managing industry relationships because they receive financial support from industry through charitable donations or corporate sponsorship of conferences/meetings, exhibit hall rental space, journal advertising, research grants, and funding of educational activities. For example, industry support for scientific

meetings, educational conferences, or research society meetings is often solicited by event organizers, primarily as sponsors or to rent exhibit hall space, and this is considered an acceptable interaction with industry. However, to protect the integrity of these programs, industry support may be accepted only if there is no expectation of industry influence, e.g., industry has no role in the selection or implementation of programs or speakers, and exhibit space is physically separate from meeting space.

AHASs have also been challenged by their relationships with industry and are adopting stringent new policies that will enable them to steer a course between advancing their professional missions that are furthered by beneficial relationships with industry, while avoiding relationships that conflict with professionalism in education, research, and patient care. The new institutional policies attempt to distinguish interactions that are essential to translate scientific discoveries into beneficial products from those that are gratuitous and undermine the tenets of medical professionalism.

Medical device companies are successful when they develop products that are superior, from a medical and/or cost-effective perspective, to those available on the market. This success is increased by rapid innovation, successful marketing strategies, and high volume product utilization. Regarding new technology and device innovations, the expectation of the American public that “new is always better” may, at times, be inconsistent with the accumulated evidence on the safety, efficacy, and comparative cost-effectiveness of existing products, as demonstrated by high-quality transparent research. With too few evidenced-based studies about these devices, many uncertainties remain around the issue of which devices and implants are optimal.⁶ Orthopaedic surgeons should caution patients when the safety and efficacy of a new technique or device is not fully known. Conversely, some orthopaedic surgeons may choose to continue to use their own outdated devices when newer or superior devices are available.⁶

As professionals, surgeons must always make choices that are in the best interest of their patients rather than those that are driven by their own self-interest. It is the goal of the medical community to provide to every patient the benefits of the most appropriate and effective therapy. When surgery is the preferred treatment, a surgeon must provide patients with as much current information as is available so that patients may make informed decisions that are in their best interest. To that end, the discipline of orthopaedic surgery must maintain its autonomy and self-regulate by educating its trainees and young professionals in the core values and principles of

the profession as well as in the science, technology, and art of the discipline, by insisting on life-long learning and personal assessment throughout their professional lives, and by making certain that they retain the freedom to care for the sick and infirm according to their best professional judgment and existing best evidence. Failure to self-regulate will lead to increasingly greater external regulation as demonstrated by events in the United Kingdom, where many of the privileges of self-regulation have been withdrawn by society because of medicine's failures.¹⁵ In the United States, the interventions of the Department of Justice can be seen as a response to the failure of self-regulation in the discipline of orthopaedic surgery.^{9,10}

GOALS

Recognizing the need for guidance that is unique to the discipline of orthopaedic surgery, the AOA established a Task Force on Orthopaedic Surgeon-Industry Relationships in 2010 under the aegis of its OIOM. The purpose of the Task Force was to assemble a diverse group of individuals with different perspectives to discuss and explore, in an unbiased manner, the critical topic of industry relations with orthopaedic surgeons, particularly, those that occur in AHASs and professional societies. The Task Force—comprised of experts in government, academic health-care administration and leadership, medical education, law, and clinical orthopaedic practice, including individuals with device development expertise from both the surgeon and industry perspectives—was charged with examining relationships with industry, identifying those that beneficially impact the field of orthopaedic surgery, and developing recommendations for managing these relationships.

The goals of the Task Force were to:

1. Identify and examine surgeon-industry relationships.
 - a. Define the various relationships between the biopharmaceutical and device industries (industry) and both the orthopaedic surgeons in AHASs and in hospitals and the professional organizations and societies representing orthopaedic surgeons (societies).
 - b. Examine these relationships critically and differentiate those that are essential to improving orthopaedic practice and science from those that are gratuitous and give rise to financial conflicts of interest that undermine professionalism and patient trust.
2. Determine the prevailing attitudes among current orthopaedic surgeons in residency and fellowship programs regarding the issues of industry relations in order to understand better the magnitude of the challenge that faces the discipline.

3. Develop guidance for individual orthopaedic surgeons, AHASs, departments of orthopaedic surgery, hospitals, and professional orthopaedic societies to eliminate gratuitous relationships with industry and ensure that those that optimize patient care and advance the discipline are conducted ethically and transparently.
4. Develop recommendations and next steps.

For the purpose of this Task Force study, conflict of interest is focused primarily on financial conflicts associated with relationships with the biopharmaceutical and medical device industries. Such relationships can be either direct, through financial support of organizational activities, or indirect, often through covert influence on decision-makers and educators in professional societies or clinical practice settings. The Task Force also focused on surgeon-industry relationships in the context of orthopaedic surgeons who are primarily engaged in private practice or employed in AHASs.

The Task Force has studied the many types of relationships that exist between surgeons and industry and identified conflicts of interest that can result from these relationships and their potential to affect, or reasonably appear to affect, the independence of a surgeon's judgment. Particular attention was paid to the recent criminal investigation undertaken by the U.S. government regarding the relationships of the discipline of orthopaedic surgery to orthopaedic device manufacturers, resulting in the imposition of deferred prosecution agreements with the manufacturers.^{9,10}

The Task Force reviewed and discussed the pertinent literature and policies addressing the relationships between industry and the medical profession, with particular attention to guidance provided by the Institute of Medicine,⁸ American Academy of Orthopaedic Surgeons' Standards of Professionalism,¹¹ the Council for Medical Specialty Societies,¹² Pew Prescription Project,¹³ and the Accreditation Council for Continuing Medical Education (ACCME).¹⁴ Policies from the University of Rochester,¹⁶ Yale University,¹⁷ and Washington University at St. Louis¹⁸ were also consulted.

After analyzing this information, the Task Force has concluded that equivocating about professional ethics is not providing the leadership necessary for this growing concern, and neither is passively following the standards set by other professions or by the medical technology industry. It is the discipline of orthopaedic surgery that must set the standard for

orthopaedists and their relationship with industry. Therefore, the Task Force developed specific guidelines that define and circumscribe the relationships with industry and that are essential for improving the quality of care to patients and other guidelines aimed at eliminating relationships that appear to be gratuitous and largely self-serving.

PRINCIPLES

The Task Force developed the following overarching principles to guide the discipline of orthopaedic surgery in navigating relationships with industry.

- I. **Professionalism and integrity.** An unwavering commitment to professionalism and integrity comprises the foundation for avoiding unethical relationships with industry and prioritizes the patients' needs as first and foremost.
- II. **Independence from industry influence.** Independence from undue industry influence is critical to the objective practice of medicine, leadership, education, and research.
- III. **Transparency.** Ethical and transparent collaborations between orthopaedist-inventors and industry are essential to facilitate the development of products that improve the care and well-being of patients. Transparency through full and timely disclosure of any and all related financial interests, and minimization or elimination of those that are conflicting, provides the necessary framework to protect the objectivity of clinical and research decisions made and educational content delivered. It is important to understand, however, that disclosure in itself does not cure a conflict, nor does it ensure that patients are sufficiently protected from biased recommendations, or students from biased educational or training content. Individuals should disclose all industry relationships and identify which of their financial relationships are related to their roles or functions.
- IV. **Active management of relationships with industry.** Identification and evaluation of individual relationships with industry, disclosures of relationships with industry, and active management of those that are conflicting are essential to minimizing, with the goal of eliminating, undue industry influence. Most AHASs and large teaching hospitals have mechanisms in place, such as conflict of interest committees and policies, for overseeing outside relationships and dealing with financial conflict of interest. For orthopaedic surgeons in small practice groups or hospitals, oversight and management functions are less standardized; the Task Force recommends that such groups develop, implement, and document policies and procedures for

managing financial conflict of interest (e.g., an external oversight committee or a designated individual). Managing and communicating expectations with industry is accomplished by defining the terms of the relationship to ensure the independence of professional choices, decisions, and actions.

The OIOM Task Force recommends the careful consideration of these principles to serve as a guide to the discipline. It is further recommended that these principles be incorporated into continuing medical education; resident education; basic, clinical, and translational research; the development of clinical practice guidelines; and the operating practices of orthopaedic societies. These principles should also inform specific relationships between the individual orthopaedic surgeon and industry, including the various roles that the orthopaedic surgeon undertakes while involved in clinical practice (Appendices A and B) and the question of the appropriateness of allowing health-care industry representatives in the operating room, a topic recently covered in *The Washington Post*.¹⁹ The recommendations herein are designed to protect the core values of the discipline of orthopaedic surgery with an emphasis on the need to reaffirm a commitment to professionalism and integrity among its members.

Survey of Residents and Emerging Leaders

Targeting future orthopaedic surgeons during medical school, residencies, and fellowships may present an opportunity to change the current culture of inappropriate surgeon-industry ties. Therefore, two surveys were conducted. At the 2010 annual meeting of the AOA (San Diego, CA), 119 orthopaedic surgery residents were surveyed to examine their perceptions of the relationships of orthopaedic surgeons with industry, especially in the context of their residency programs. Also in June 2010, the same survey was distributed electronically to 210 participants in the AOA's Emerging Leaders Program; 56 members responded to this survey.

Although the findings are limited in generalizability due to small sample size for both the resident (n=119) and the Emerging Leader population (n=56) and nonrandom samples, several key findings are noted. The majority of residents (71%, n=84) and Emerging Leaders (68%, n=38) replied that their residency program prepared them to ethically manage surgeon-industry relations. About one-third of the residents (39%, n=46) and Emerging Leaders (36%, n=20) surveyed felt that their role models and mentors were influenced by industry, underscoring the need for reform at all levels of the discipline of orthopaedic surgery.

Most residents (96%, n=112) and Emerging Leaders (89%, n=50) reported that industry had been involved in their orthopaedic education. Regarding continuing medical education, 88% of both residents (n=105) and Emerging Leaders (n=49) responded that industry should play a role in orthopaedic continuing medical education. Only 20% (n=23) of residents and 16% (n=9) of Emerging Leaders felt that gifts from industry (lunch, books, sponsored trips, research support, etc.) had influenced their behavior. Research has shown that gifts from industry, even those of modest value, create a need for reciprocity, which may impact treatment decisions.^{13,20,21}

The Task Force acknowledges the limitations of these data and the benefit that could have been gained from a more comprehensive survey that included community-based and academic orthopaedic surgeons and patients.

DISCUSSION

Excluding the independent inventor, most of the relationships between the orthopaedic surgeon and industry involve activities conducted, typically, as an aside to the surgeons' primary work responsibilities of patient care, teaching, or professional leadership (Appendix B). Care must be taken when maneuvering through these relationships to recognize conflicts of interest, set boundaries and clear expectations with industry, and function ethically and transparently so that conflicts of interest are minimized or avoided. Many of these relationships have the potential to benefit patient care and should not be regarded outright as improper. However, even slight deviations from professionalism and the ethical practice of medicine can transform these relationships into improper ones.

I. Professionalism and Integrity

Core tenets of professionalism and integrity form the foundation for avoiding unethical relationships with industry. In today's society, the orthopaedic surgeon can take on many roles beyond traditional clinical practice (Appendix B), thus raising the potential for conflict of interest. Functioning in one or more of these roles does not and should not automatically imply the existence of inappropriate relationships with industry. However, the potential for such relationships increases as roles overlap, particularly when industry relationships overlap with clinical practice.

Professionalism in medicine is an expectation, but also an ideal that lacks the specificity to exclude inappropriate relationships with industry.⁶ Medical professionalism should be based on the underlying assumption that gifts and financial entanglements, even minor ones, influence behavior and promote bias.⁶ Jerome Kassirer describes the following fundamental principles of professionalism: 1) financial considerations must never be allowed to compromise physicians' decisions about the care of individual patients or the safety of subjects involved in medical research; 2) because the integrity of scientific knowledge directly affects patient care, physicians' medical information must be free of bias generated by financial entanglements; 3) the profession must be accountable for ensuring that undue commercial influence does not make the cost of care so high that it excludes many from receiving it; and 4) we must aspire to the ideal of eliminating financial entanglements, but if physicians cannot or will not, we must have clear and enforceable methods that protect patients and have complete disclosures about the conflicts.⁶

Most surgeon-industry relationships offer the potential for patient benefit as these relationships often result in improvements in device design and use, accumulation of evidence to guide clinical decision-making and patient advocacy, and increases in the availability of surgeons who have access to high-quality training on specific devices and procedures. The individual surgeon may benefit from the relationship with industry through further education, personal satisfaction, prestige, and additional income. Industry benefits from the surgeon's expertise with product improvements, scientific credibility, and expert advice to guide strategic planning and marketing. These relationships are complex. The following underlying principles can be used to evaluate the legitimacy of surgeon-industry relationships.

Consulting fees are based on intellectual contribution and fair market value. Orthopaedic surgeons are uniquely qualified to provide insight and expertise for device development and instrumentation, and this may appeal to academicians and independent orthopaedic surgeons with expertise in a particular anatomic/therapeutic or mechanical/technical area. Orthopaedic surgeons consulting with industry by providing advice, expertise, or other consulting services typically in the context of product development should be paid fee-for-service or hourly consulting fees based on fair market value, and these arrangements must be contract-driven. In contrast, royalties are payments made by a licensee (e.g., industry) to the inventor who holds the patent (or to a bona fide contributor to the development of the product whose contribution has been thoroughly evaluated and documented) for the usage of an invention.

Purchasing decisions are unbiased and nonconflicted. Orthopaedic surgeons involved in institutional purchasing decisions must disclose all relationships with industry and recuse themselves from decision-making from which they may profit financially or otherwise benefit. Purchasing decisions should be based on a balance of optimal patient outcomes and cost and should meet the needs of the institution and the population served. Orthopaedists serving on gain-sharing and other purchasing committees must be nonconflicted, or if this is not possible, the conflicted surgeon should recuse himself/herself from participating in purchasing decisions in which there is a conflict.

Avoid combining volume-driven financial arrangements with clinical decision-making.

Orthopaedic surgeons must not enter into volume-driven arrangements with industry in the context of patient care. Some orthopaedic surgeons are engaging in cooperative buying in which groups of physicians profit by acquiring devices directly from manufacturers for the purpose of selling them to hospitals at a higher price; the hospitals, in turn, pass the inflated price along to insurance companies for reimbursement. Some hospitals designate individual suppliers as preferred providers of particular devices. In these buying arrangements, it is unclear whether the cost savings are purely profit for the buyer or if the cost savings are passed on to serve more beneficial needs. Both cooperative buying groups and preferred provider relationships remove choices for the patients and their physicians and, unlike gain sharing, may not focus primarily on improved patient outcomes. While these relationships may not be illegal, they are certainly unethical and run counter to the principles of integrity and professionalism. Incentivized patient care decisions such as choices or recommendations of therapy (e.g., braces, surgical implants, and hip and knee devices) constitute an inappropriate relationship with industry. Any relationship in which the surgeon is paid to use industry products or influence use by partners, departmental leaders, or health-care institutions is unacceptable and illegal. Patient care decisions should be based solely on the best interests of the patient and not on the benefit derived by the provider or institution.

Insist upon scientific integrity in research and publishing. Orthopaedic surgeons should strive to ensure scientific integrity when conducting research and publishing research findings by adhering to existing national and international guidance (e.g., Good Clinical Practice [GCP]²² and ICMJE Uniform Requirements for Manuscripts²³). Surgeons should participate only in research studies that meaningfully contribute to the existing literature; are adequately powered to examine clinically important endpoints; and have a study design, operational structure, and oversight mechanism to minimize bias and ensure patient safety. The analysis and reporting of

research data must be independent of industry influence. Independence and transparency in research is particularly important if the research is industry-funded. The Task Force supports the “rebuttable presumption,” as proposed by the Association of American Medical Colleges (AAMC), recommending that individuals who hold significant financial interests in research involving human subjects refrain from the conduct of such research absent [independent determination of] “compelling circumstances.”²⁴

The Task Force encourages scholarly relationships between surgeons and industry in which surgeons play an independent role in properly designed research studies (e.g., principal investigators and members of scientific advisory committees or data monitoring committees [DMCs]). These types of relationships ultimately improve patient outcomes, while independence and scientific integrity are maintained.

Companies eager to meet their business objectives may seek out orthopaedic surgeons as “thought-leaders” or “key opinion leaders” for various functions, many of whom will eventually serve the company through product promotion. Commonly, such individuals are enlisted as principal investigators in clinical studies and subsequent authors on the associated publication. All research initiatives should include the requirement of a final project report or manuscript that meets industry standards and is of sufficient quality for publication in a peer-reviewed journal with active participation of all authors in the study. Research initiatives lacking such rigor may be incentives or rewards for prescribing or purchasing influence; caution should be taken to avoid such relationships. Regardless of the role, payments made to the surgeon that are generous and disproportionate to the work required have marketing objectives designed for increasing sales. **All of these types of relationships are inappropriate and must cease.**

Gifts from industry are inappropriate. Orthopaedic surgeons should not accept items of value from industry through industry-supported “educational” activities (e.g., fishing trips, golf outings, meals, pens, books, bags, and golf balls) or business meetings (e.g., elaborate meals).

II. Independence from Industry Influence

The relationship between industry and the discipline of orthopaedic surgery has evolved over time. The interdependence has developed through necessity, mutual profitability, and innovation. Ensuring that this relationship is fair, balanced, and serves the best interest of the patient will involve challenges. However, it is the responsibility of the discipline of orthopaedic surgery to strive to end its overdependence on the supplementary income that it derives from

industry as opposed to requiring consistently improved performance of industry's products demonstrated in public ways, e.g., through comparative effectiveness research and postmarket surveillance studies. Individual orthopaedic surgeons must be ever vigilant to avoid industry influence, or the perception thereof, and orthopaedics as a discipline, must create an environment where industry influence in clinical decision-making is minimized or eliminated.

Foremost, orthopaedic surgeons should not profit from industry ties in their clinical decision-making. Surgeons involved in successful product development activities in which royalties are paid must make sure that neither they nor their partners profit further from their patients. Surgeons should insist upon contractual arrangements delineating these conditions. Under these provisions, surgeons can disclose to their patients that while they may advocate for the product based on their participation in its design, they will not profit financially from the decision to use it. Neither the institution nor the surgeon inventor should receive royalty payments for the use of the invention on their own patients. Surgeons profiting from product development should not be involved in institutional purchasing decisions.

Attention to professionalism and ethics should be emphasized and inculcated in all aspects of medical education and training. In orthopaedic fellowships and residencies, professionalism and ethics training, specific to the discipline of orthopaedic surgery, need to be evaluated and revised to meet the needs of today's practice environment. Societies can take the lead on efforts to strengthen professionalism and integrity through management of their research and educational efforts, particularly those emphasizing ethical behavior specific to the discipline and the importance of complete transparency of business relationships and financial gain with every patient.

For professional societies and for individual orthopaedic surgeons, industry support implies industry influence and must be avoided if the support carries industry influence into professional decision-making, whether in patient care, in conducting research, in training, or in teaching at any level. The perception of industry influence can often be managed if appropriate policies are implemented and full public disclosure is readily available.

For AHASs, new strengthened policies have been implemented in the leading centers and are spreading throughout the academic medical community. In many cases, these policies prohibit entire classes of relationships with industry and sharply reduce and strictly manage those that

remain acceptable. The Task Force commends these efforts and recommends **eliminating** all gratuitous relations with industry. At a minimum, all hospitals, not only academic institutions, should have policies governing physician disclosure to patients and to the public of any relationships, and have management plans overseen by independent parties such as conflict of interest committees.

Conflict of interest also exists when institutions receive financial benefit for employed or affiliated surgeons who have a relationship with industry, e.g., institutions receive a proportion of a surgeon's consulting agreement. Such relationships undermine the impartiality of the institutional oversight and create institutional conflict of interest. These arrangements should also be publically disclosed and appropriately and objectively managed by an independent third party.

Educational Activities

The Task Force has serious concerns about the future of medical education and its financing, as well as the future of medical research upon which academic medicine has become increasingly dependent. This has become even more concerning in the ongoing discussion about reductions in federal funding for GME. The Task Force acknowledges the important contributions that industry makes to building research and education capacity in certain areas and recommends that the contributions be premised on the charitable and educational uses to which a university may put a tax-subsidized industry gift and not to any corporate or product endorsement.

Continuing Medical Education (CME)

All program planning, including decisions about educational content and execution (e.g., speakers, topics, and venues), should be free of industry influence and must be in compliance with recently strengthened ACCME Standards for Commercial Support.¹⁴ Acknowledging the expertise available from industry, it may be acceptable for companies to nominate topics for consideration; however, decisions must be made on the basis of educational needs and program goals. In particular, the CME provider may not use commercial support to pay for travel, lodging, or other personal expenses of attendees (ACCME Standard 3.12).¹⁴

Non-CME Training Activities

Industry-sponsored product training provides an important resource for practicing surgeons, especially those outside of academia, and such product-specific training can be beneficial to patient safety. However, industry will typically maintain control over non-CME content to meet its business objectives. Societies must require non-CME informational/educational programs to be clearly distinguished from society-sponsored CME.²⁵ Training should be developed on the premise that a surgeon has decided to use a particular device based on evidence of successful outcomes prior to seeking out industry-sponsored training for the device. Industry should make its courses equally available to the high and low-volume surgeon for the benefit of all patients.

Programs providing training in the safe and effective use of medical products and devices should be selected based on their ability to meet learning needs. Industry-sponsored training should focus solely on educational activities and omit activities related to entertainment. Training personnel should have significant documented expertise in the safe and effective use of the product or device. Reimbursement of travel costs should be limited to instances where it is impractical to conduct training in reasonable proximity to the physician's place of practice.

Industry Funding of GME

Funds from industry to support residency and fellowship programs are acceptable as long as the funds are distributed through an intermediary to distance the donor (industry sponsor) from the recipient (training program leader and trainee), thereby disrupting the one-on-one relationship that engenders the feelings of reciprocity that can lead to financial conflicts of interest. In the discipline of orthopaedic surgery, third-party organizations have been developed to serve as intermediaries.

The AAMC recommends that industry funds be donated to the recipient institution's central administration (e.g., Office of the Dean or Hospital CEO) for distribution to the institution's training programs.²⁶ It is acceptable for companies donating funds directly to the central administration to designate the area of training to be supported (e.g., orthopaedics).

The Task Force recommends and encourages use of the third-party model for the funding of orthopaedic GME. However, some of the smaller companies are unwilling to fund GME using the hands-off, third-party model. Reform and consistency are needed throughout the discipline of orthopaedic surgery.

The flow of funds from a third-party organization can be either directly to the recipient department or through the central administration if required by the recipient institution; however, there must appropriate safeguards in place to preserve the third-party organization's designation of the specific program to be funded. To best serve the needs of orthopaedic GME, the Task Force believes that the third-party organization model is a more appropriate process for both maintaining interest in industry in funding GME and providing an appropriate mechanism to remove industry influence and conflict of interest, particularly since the third-party organization model can be integrated with the central administration pathway of funding recommended by the AAMC, if necessary.

In the discipline of orthopaedic surgery, there are currently three third-party organizations, without industry representation on their boards, developed to administer educational funds:

- The OMeGA Medical Grants Association was established in 2008 to ensure the continued financial support of orthopaedic residency and or fellowship programs.²⁷ OMeGA was founded by the AOA, but it is an independent legal entity that is nonconflicted and is not controlled by the AOA.
- The Orthopaedic Research and Education Foundation (OREF) was established in 1955 by leaders of the major professional organizations in orthopaedics, the AOA, the American Academy of Orthopaedic Surgeons, and the Orthopaedic Research Society as a means of supporting research and education that build the scientific base of clinical practice.²⁸
- The Center for Orthopaedic Trauma Advancement (COTA) was chartered in 2009 to serve as a nonconflicted intermediary and distributes unrestricted grants donated by industry to support fellowships and postgraduate education in orthopaedic trauma.²⁹ Funding is awarded by a competitive process based on the quality of the fellowship program.

These third-party administrators of funds are inherently reliant on industry to support the services they provide and therefore, must be clear in their role and service offerings. To remain unbiased, these independent organizations should not solicit or accept funding from industry for products or programs that they develop internally. Award decisions should be based on merit. Decisions should be made by independent review committees that may involve the third-party administrators. Committees should use clearly defined conflict of interest policies and associated transparency. No ties to faculty utilization of specific devices should be expected or

anticipated by industry sponsors or agreed to by the hospitals, residencies, or fellowships. Industry contact with residents and fellows involved in non-CME educational endeavors should be avoided. Any interactions between industry and residents and fellows must be disclosed to and approved by their residency and fellowship directors or orthopaedic chairs.

Increasingly, company-provided funds for fellowships are disappearing, leaving only the U.S. government to fund orthopaedic fellowships; this will lead to inadequate fellowship opportunities and a shortage of adequately prepared orthopaedic surgeons. Additionally, governmental funding of GME only covers a portion of the costs of training. Additional infrastructure costs (e.g., residency coordinators, book and journal funds, and research support) needed to run the residencies and fellowships are currently unfunded. These additional burdens on the academic orthopaedic system further limit the appeal of academics as a career and reduce the ability of academic orthopaedic surgeons to provide good educational opportunity to trainees. Reform is needed.

The Task Force encourages vendor companies to revisit this issue and consider ways to financially support fellowship education in an unbiased manner. In addition, the Task Force strongly encourages residency and fellowship training programs to stop requesting and accepting individual-focused grants from companies, but rather to require companies to provide funding through an independent, third-party organization or the central administration of AHASs for distribution. The Task Force recommends and encourages use of the third-party model for funding for all subspecialties of orthopaedic GME with no exceptions.

The Task Force considered whether it is appropriate for residents and fellows to receive industry-supported training on new devices and instrumentation without approval from their department chair. This issue becomes more complicated when considering that training could be conducted during the resident's or fellow's personal time. Given the lack of exposure to cadaver labs during training, the benefits of this type of activity were recognized. However, the Task Force concludes that industry representatives should not have direct access to residents or fellows without staff present. Attendance at a course should be at the discretion of the program director if he/she feels that the educational experience offered is not offered by the program and is in the best interests of patient care and the resident's or fellow's education. All funding should also run through the program director and/or institution and not between industry and the resident or fellow.

Clinical Practice Guidelines

The development of clinical practice guidelines, given their tremendous impact on patient care and medical costs, requires greater efforts to minimize bias and avoid industry influence. The OIOM Task Force agrees with sources reviewed for this discussion and is opposed to the acceptance of any industry funds for the development of clinical practice guidelines.^{8,11-14} When forming committees to develop clinical practice guidelines, individual and composite numbers of financial ties to industry should be evaluated and minimized to avoid actual or perceived industry influence on the resultant guidelines. Committee membership should be held to the most stringent conflict of interest standards with the ultimate goal of forming a committee with no ties to industry.¹³

Industry Funding of Research

Clinical trials, comparative effective research, and safety studies including patient registries are important components of the safe and effective evolution of patient care technology, the understanding of disease progression, and the making of informed risk-benefit decisions. Often, this research is industry-funded and may be subject to federal oversight through the U.S. Food and Drug Administration (FDA). Most of the leading AHASs have publication policies that make clear that research sponsors cannot infringe in any way on the academic freedom of faculty investigators. However, it is acknowledged that industry must maintain some level of control over the study to ensure that its purpose is being met and appropriate regulations and manufacturer responsibilities are upheld. Regarding publication, industry sponsors may be co-authors if they make legitimate contributions to the research, or they may be reviewers maintaining the right to review manuscripts for a specified, brief period of time, e.g., 30 days, prior to submission to ensure that proprietary information is not disclosed and devices and techniques are accurately characterized.

For industry-sponsored research in AHASs, the publication policies of the AHASs must be respected; for research to be published in a leading medical or surgical journal, the ICMJE requirements regarding authorship, ghost writing, and financial conflicts of interest must be adhered to; and for research intended to support an application to the FDA, the agency's requirements must be followed. For research performed outside of AHASs by nonacademic orthopaedists, adherence to established guidance pertinent to the study design and indication is critical.

Conducting clinical studies involves adhering to protocol-specified procedures and appropriate regulatory guidance (e.g., GCP²²). For example, the conduct of prospective clinical trials requires a clinical research site with a minimum of a principal investigator (who takes on federally-mandated accountability with criminal penalties), a study coordinator or equivalent, legal support to interpret contracts, and financial support to manage budgets; in addition, a legally constituted institutional review board must be involved. Timelines are established with milestones that trigger investigator payments. These payments should be commensurate with the time and effort of the personnel and the materials required, including the professional effort of the principal investigator and co-investigators. Research is not unlike other aspects of medical care; payment for professional services in the area of research should be commensurate with the value of the work provided. Depending on the study design, conducting clinical studies may require considerable effort and resources over and above that of routine medical care.

Industry-sponsored investigator-initiated grants for research projects are commonly seen in orthopaedics. Often, these types of studies do not contribute substantially to the peer-reviewed literature and there may be incentives or rewards for prescribing or purchasing influence. Participation in investigator-initiated grants that result in studies unlikely to contribute significantly to the scientific literature should be avoided and discouraged at an institutional level. Industry-sponsored investigator-initiated grants are acceptable only: if the company has no influence over the analysis or presentation of the data; if the research objectives address legitimate research questions; and if the study results in a summary document of publishable quality in a peer-reviewed journal.

In industry-sponsored research designed to meet regulatory requirements for device approval or device safety or to further labeling or marketing claims, researchers from industry usually provide the expertise to develop the research protocol and seek input from the investigators. Principal investigators are therefore working collaboratively with industry but are also responsible for maintaining the scientific integrity of the research. Typically, the industry sponsor will own the data from its trials, however it is critical that PIs approve of the design and have unfettered access to the **primary data** and participate in the final decisions about how these data are to be analyzed, interpreted, and presented. It is important to note that clinical studies conducted to evaluate a new device's safety and effectiveness under an FDA-approved Investigational Device Exemption (IDE) are highly structured and regulated, with very significant

and critical oversight by the FDA. Since such studies involve the investment of millions of dollars by the sponsor (the product's manufacturer) to potentially gain regulatory approval to market that specific new device, it is recognized that decisions regarding the funding of such regulated studies are not appropriate for administration through independent, third-party research funding processes.

Decisions surrounding the design, conduct, interpretation, and communication of clinical trials are increasingly subject to review and oversight by data monitoring committees (DMCs), steering committees, or scientific advisory boards. These entities enhance the independence of the research by ensuring that the industry sponsor does not have undue control of the study.^{30,31}

AHASs play an important role in industry-sponsored research that is beneficial to society as they are increasingly becoming independent data coordinating centers for multiple trials as a means to increase the objectivity and credibility of research results. Decisions surrounding the distribution of some types of industry funds for research can be made by an independent committee or organization based on merit and peer review, and should be completely independent of the surgeon's relationship with the company (e.g., purchasing volume). When appropriate, research funds not intended for product regulatory approval requirements, such as comparative product outcomes studies, could be awarded through an independent, third-party process similar to that described for GME.

In AHASs, industry-provided research grants and contracts that flow through the institution's grants management administration are typically scrutinized and negotiated to ensure that there is no industry involvement that may infringe upon the academic freedom of the investigators. This oversight legitimizes these research awards and ensures that they contribute to general knowledge and result in scholarly accomplishment for the investigator and the institution that is desirable and important. However, such oversight is not typically available in nonacademic institutions.

Registries provide important safety and effectiveness data if conducted properly. Guidance for conducting patient registries has been recently supported by the Agency for Healthcare Research and Quality wherein a patient registry is defined as "an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that

serves one or more predetermined scientific, clinical, or policy purposes.”³² Oversight by an independent monitoring board is recommended.

Only through properly conducted research can the discipline systematically evaluate technology and obtain objective evidence to inform clinical decisions. Human clinical research requires that investigators have a command of specific professional, scientific, ethical, and regulatory knowledge; historically, orthopaedic surgery has invested little infrastructure to support research as an independent professional activity. Orthopaedic surgeons interested in research, but lacking the necessary research skills, are encouraged to seek additional training in research methods, regulatory standards, and operational procedures, as needed.

III. Transparency

In clinical practice, transparency can be accomplished by disclosing relevant relationships with industry to the patient, trainees, and colleagues in all oral or written communications about a particular product, and to the associated institution. One must be aware, however, that transparency does not cure a conflict of interest per se, particularly if the information is not readily accessible to patients.

Methods for capturing complete and full disclosure vary across organizations, ranging from forms that collect only the relationships deemed relevant by the reporter to requesting all relationships that would be captured by income tax reporting in an effort to obtain complete, monetary disclosure. Allowing the reporter to be the sole judge of “relevance” is increasingly recognized as inadequate, especially by the Inspector General of the Department of Health and Human Services. Requiring tax returns is unrealistic, since they may not adequately identify all industry ties and such an action would be regarded as grossly intrusive and an unacceptable invasion of an individual’s privacy. The Task Force is in favor of standardizing the process for collecting financial disclosures and conflict of interest information using a detailed and standardized data collection instrument.

Decisions concerning which relationships should be disclosed for a given role should be avoided. Instead, all relationships with industry should be self-disclosed, and those deemed relevant by the organization should be identified by the reporter. Individuals should be required to provide updates to the organization no less often than annually. Designated individuals or

committees should be formed to identify, monitor, and manage conflicts of interest in accordance with written institutional or organizational policies.

The newly mandated public databases of industry payments to physicians, like some existing in several states and that required by the Health Care Reform Act, are truly “game-changers” that must in time affect disclosure practices by providing a publicly accessible listing of all vendor payments to named individuals. The Task Force is in favor of the development of a central disclosure repository to be used by all orthopaedic organizations, rather than each organization developing its own separate disclosure database. Such a joint effort can be used to satisfy the Physician Payment Sunshine Provision legislation passed on March 22, 2010.³²

Potential conflicts of interest should be disclosed by the surgeon to the patient at the beginning of their relationship. Patients should not be expected to identify the conflicts by researching a database, website, or otherwise have the knowledge and skills to search for the information and interpret it. The information should be presented to the patient in an accessible and transparent manner. In the case of the financial conflicts, the dollar amount of the conflict is relevant and should be similarly disclosed.

Health-Care Industry Representatives in the Operating Room

Health-care industry representatives in the operating room are generally viewed by orthopaedic surgeons as important resources for optimizing their patients’ outcomes. The health-care industry representative provides product expertise and technical assistance to the scrub techs and nurses assisting the surgeon regarding the complex instrumentation used for certain orthopaedic procedures, particularly novel devices with which the surgical team may not have extensive experience. For example, implanting spine and total joints may require several trays of instruments to properly insert the device. The presence of industry representatives allows the surgeon to stay focused on the patient’s procedure and not the equipment. The benefit of their presence has not been studied. The OIOM survey of residents and Emerging Leaders found that over 95% (n=113 and 54, respectively) in each group believe that health-care industry representatives have a place in the operating room during cases; the specific type of case was not specified; however, only 47% (n=55) of residents and 14% (n=8) of Emerging Leaders felt that the patient should be informed through the informed consent process.

The Task Force acknowledges that patient and public education is needed in this area to clarify the benefits and offset the negative perceptions. Orthopaedic surgeons should be responsible for allowing health-care industry representatives in the operating room on a case-by-case basis. Orthopaedic surgeons must emphasize that the assistance of a health-care industry representative in the operating room is technical assistance and not a substitute for proper training.

Health-care industry representatives should have appropriate, standardized training and credentials, developed and implemented by an appropriate credentialing body, which currently does not exist. Efforts have been undertaken by the Association of periOperative Registered Nurses and others,³³ but this has yet to become consistently required and implemented across the health-care industry. The institution (hospital or surgical center) should monitor, manage, and document the health-care industry representative's credentials; this should not be the responsibility of the orthopaedic surgeon.

Precautions should be taken to ensure that health-care industry representatives are readily identified as such and not confused with licensed health-care professionals. For example, institutions should require that health-care industry representatives wear name tags and uniforms/scrubs of a different color from the colors worn by health-care providers so that health-care industry representatives are readily distinguished from health-care providers.

Orthopaedic surgeons must maintain the highest level of professionalism in all conversations and interactions with health-care industry representatives, with emphasis on maintaining the patient's privacy and respect. These interactions may occur in the operating room, or outside of the operating room in various activities, such as pre-operative planning conferences or Grand Rounds. Industry representatives should not be in the operating room before the patient is fully draped to ensure patient privacy.

Until a formal credentialing program is implemented, health-care industry representatives should be required to sign agreements attesting to standards of training and skills and ensuring the protection of patient privacy and confidentiality. This process should be managed by the institution, not by individual surgeons, divisions, or departments. Language should be included in the informed consent form that discloses the presence of a health-care industry representative in the operating room; it should also describe the rationale and function of the

individual. The language should be worded so that disclosure is made rather than patient consent requested.

The guidance developed in this document is intended to cover all health-care settings, from academic to rural. Health-care industry representatives may serve a different need in rural areas, where resources may be lacking compared to AHASs. In rural hospitals, certain cases may not be feasible without the product support offered by the health-care industry representative. Therefore, this issue should be discussed with patients as part of the consent process but should be viewed as disclosure rather than an optional consent item. Patients should be allowed to question the appropriateness or voice specific concerns. The surgeon should emphasize that the presence of the health-care industry representative is supportive and advisory, and that the representative is not directly involved in the procedure, is not a teacher to the professional surgical team, and is not present in the operating room to serve sales or marketing functions for her/his company.

An institution should provide disclosure in the patient's surgical informed consent form, as recommended by the institution's administrative and legal authorities. The following example may serve as a basis for developing this disclosure statement:

"Your doctor has requested the presence of a health-care industry representative during your procedure/operation. This person works for _____ (name of company), the manufacturer of the _____ (name of product) and is an expert on this product. The health-care industry representative will not be involved in the procedure directly; rather, he/she will be available for technical support regarding the product, if needed. Your surgeon feels that the health-care industry representative is a valuable resource to the surgical team and supports the surgical team's primary goal of ensuring your safety, privacy, and well-being."

Industry Support for Societies

Professional medical societies are expected to serve as independent and trustworthy sources of health-care information for education for its members and the public.³⁴ Therefore, they must review and carefully evaluate policies on the acceptance and disclosure of external funds and recognize the potential for bias and conflicts of interest.

Societies rely on industry support for their operating budgets and the complete elimination of industry support may diminish their effectiveness. The Task Force (with some members dissenting) does not support a complete elimination of industry support but agrees that societies should systematically measure and publicly report the percentage of industry support received, set goals for progressively reducing industry support (excluding revenue gained from journal advertising and exhibit hall space rental), further limit any single company from contributing more than 5% of their annual operating budget,^{13,35} and develop explicit policies to manage industry support and disclosure practices. Societal conflict of interest committees can be instrumental in this process.

Leadership of Professional Societies

The leadership of a professional society should always exemplify best practices in their relationships with industry. However, prohibiting any industry ties may limit the applicant pool and stifle the success of the society, especially in small subspecialty societies. Qualified individuals for leadership roles should expect to:

- 1) Provide full disclosure as a condition of acceptance of an application or nomination for a leadership role in a professional society.
- 2) Agree to have such disclosures publicly available on the society's website.
- 3) Disclose all relationships with industry and identify those deemed relevant to the individual's role in the organization.
- 4) Relinquish active, ongoing relationships while serving in the leadership position and refrain from initiating new relationships or activities. The Task Force recognizes that prior relationships that resulted in royalty payments for previously transferred IP are legal agreements between the surgeon and the company. These relationships may be ongoing while serving in the leadership role but must be disclosed, as described above, and managed.

IV. Active Management of Industry Relationships

Active management of disclosures and conflicts of interest among members of an organization is essential to minimize bias in decision-making, such as determining the use and distribution of industry funds for educational activities and research and institutional purchasing decisions. With any acceptance of industry funds comes the requirement of transparency and management of the expectations of industry support.

Of particular concern to the Task Force is the role of the orthopaedic surgeon as “product development consultant” and the potential for abuses in this relationship. The Task Force recognizes that collaborative relationships with industry are necessary to bring improvements to the market, and reasonable compensation for services is appropriate. However, abuses of these collaborative relationships resulting in exorbitant payments to surgeons, in some cases amounting to (illegal) kickbacks, has led to considerable scrutiny of the current compensation practices of surgeons.^{9,10}

Background: Purchasing vs. Licensing IP

Device companies will often purchase the patent for the IP from the surgeon who invents a device or consults on the development of a device, and in exchange, the company pays royalties to the surgeon inventor or consultant (Appendix C). Alternatively, the surgeon inventor/consultant may license the IP to the company for marketing and/or further development. Royalties are just one form of IP licensing compensation, which may be simple or complex. Licenses may involve straight fees and/or royalties. Licensing fees may be one-time payments to cover use of the IP for a specific period of time or annual fees for a specific number of years; some arrangements may be a combination of simple fees plus royalties.

The most important distinction between licensing and royalties is that royalties are sales volume dependent, providing higher value to the IP that is more successful in the market and lower value to the less useful or less popular IP based on market value. There is naturally more risk with market-based IP compensation (i.e., royalties based on sales) than simple licensing fee schemes but also more of a chance of a higher reward if the IP is very useful or provides a market advantage that is a commercial success.

The term for royalties should be limited and never extend to the life of the product. Many companies are now limiting the royalty payment terms to 5 to 7 years, occasionally with the option to renegotiate at the end of the term if there is a legitimate reason to do so (i.e., the IP is still relevant in the market). This reflects the typical life cycle of most orthopaedic implants and obviates the continued payment of royalties for IP that is no longer relevant in the market.

Royalties are paid to the surgeon as a specified percentage based on the volume of sales. Companies calculate and then pay the royalties based on their financial accounting of the relevant sales. Royalty recipients (i.e., the surgeon inventor/consultant) will often hire an outside

licensing management firm to periodically audit the company's financial records and calculations of royalty payments to ensure that the royalties have been calculated and paid according to the agreement.

The Appropriateness of Royalties: Patentable vs. Unpatentable Contributions

Lucrative and disproportionate payments to surgeons for product development activities, particularly if volume-based, can result in unnecessary surgical procedures for patients and increased health-care costs to patients, hospitals, and insurers, in addition to undermining trust in the medical profession.³⁶ Avoiding inappropriate product consultant relationships with industry requires personal and professional integrity from the surgeon and an unbiased assessment of the fair market value of surgeons' contributions by the company. With much to gain on both sides of this relationship, guidance is needed.

The simplest guideline for ensuring the appropriateness of royalty bearing contracts is to limit royalty payments to product development consultants or inventors who have made a bona fide contribution to the IP of a product that has been issued a patent. Arguments can be made that royalties are justified in the absence of a patent and defining a "bona fide" contribution to IP can be subject to interpretation and misuse. The guidelines in Table 1 should be considered when accepting royalties.

Table 1. Guidelines for the Appropriate Acceptance of Royalties (Adapted from Policies from the Washington University St. Louis School of Medicine¹⁸)

1. *Royalties should not be accepted unless they are for products or services sold by the company that embody the consultant's IP as defined in an issued patent, patent application, or copyright, or where the consultant has obtained a company attestation of his/her contribution of IP and its fair market value in terms of the royalty rate. A contractual agreement should provide for the specific and detailed identification of the IP for which the surgeon will be paid royalties by enumeration of the patent number, patent application serial number, or copyright registration number.*
2. *Royalty payments should not be accepted for performance of defined services (e.g., consulting, advisory, product review, etc.) provided to the company; royalties should be for only verifiable IP that the surgeon has contributed to specific products and services.*
3. *Royalty payments should not be accepted if they are based on a flat fee or structured as a minimum guaranteed amount.*
4. *Advances on royalty payments should not be accepted.*

5. *Royalty payments should never be accepted if they are based on the use or sales of products or services in the surgeon's institution or that of his/her partners or family members, if applicable.*
6. *The surgeon (inventor/consultant) should obtain and maintain records of royalty payments received, including the royalty rate and underlying sales figures.*

The Task Force prefers that all royalty payments be subject to patent. And, while this condition may be feasible for most physician-industry collaborations, in the field of orthopaedics it is recognized that many devices (e.g., many hip and knee devices) are not patented, even though many of these new devices represent substantial design improvements contributed by surgeon designers. In addition, it is not uncommon that the patent is issued years after the introduction of a device. Therefore, in some instances it may be acceptable to pay royalties for IP that is not supported by a patent. In these situations, as with patented products, it is important to document the specific contribution of the IP. For royalty bearing IP that is not the subject of a patent, patent application, or copyright, the surgeon should not receive royalties as any part of his/her compensation unless the company provides¹⁸ a written and detailed attestation that:

1. confirms that the surgeon has made a verifiable and valuable contribution of IP to the design and/or development of the royalty bearing product and describes that contribution, and
2. describes the process used and the findings from that process that the royalty rate being paid to the surgeon is consistent with the fair market value of such IP.

Royalty bearing agreements are contractual arrangements with prespecified royalty payment structures and predetermined royalty amounts; all are specified in advance of the issuance of the patent and are conditional on the issuance of a patent. If a patented IP does not result from product development activities, no royalties are paid, and there is typically no alternative compensation for the consultant's time. The consultant's product development agreement stipulates the terms (documentation, compensation/royalties, etc.) as well as the condition that any IP resulting from the project will be owned by the company (even though the consultant's name will appear on the patent).

Fee-for-Service Consulting

Orthopaedic surgeons may engage in consultancies with industry for the satisfaction of an intellectual and creative collaboration in the context of patient well-being and/or as an additional source of income. Fee-for-service consulting arrangements become more appealing if there is a risk that product development consulting will not result in a patent, or if the consultant has

concerns about the IP documentation requirements. Simple fee-for-service consulting arrangements (i.e., hourly compensation based on fair market value) stipulates that no royalty payments will be made and that the consultant has no claim to any IP developed. Payment is not based on sales volume.

Consultancies should be contract-driven, and contracts should delineate specific scope of services that are expected and the specific fair market value remuneration that will be provided in exchange (Table 2). Remuneration other than for deliverables specified in a written contract may properly be regarded as gifts or illegal kickbacks.³⁷ The contract should be negotiated to ensure that conflicts of interest will not develop that may infringe upon the surgeon's primary responsibilities to her/his patients, colleagues, and trainees.

Table 2. Minimal Set of Essential Elements for Consulting Contracts

1. *Contractual language stating that the consultant orthopaedic surgeon will not profit from his/her use of consultancy-related products in the context of patient care (i.e., consulting fees may not be based on the product(s) used in the individual surgeon's practice or that of his/her partners). Consultant compensation may never be based on company sales resulting from or related to a consultant's services (excluding genuine IP and royalty arrangements for use of the IP).*
2. *The scope of work is clearly identified and specific tasks and services are delineated.*
3. *A fair market value payment structure is specified and contingent upon completion of described tasks for that period and invoicing at stated intervals. Payment is not made until the service(s) has/have been provided and adequate procedures are in place to verify the delivery of the service(s). Fair market value of consulting fees varies in accordance with the subspecialty; however, ordinarily, payment should not exceed \$500 per hour, or \$3,000 for a presentation or lecture.¹⁸*
4. *Publication of data is addressed, if relevant.*
5. *Contract start and stop dates are specified. Contracts should be for only a period of one year with new contracts executed as appropriate on an annual basis. No contract should have automatic renewal language (i.e., "evergreen").*

Industry Sponsorship of Professional Conferences

Active management of sponsorship often comes into play when industry support is accepted by societies and used for conferences and other professional meetings. In return for sponsorship, acknowledgement of company support is generally expected. Recognition may take the form of the president of the organization acknowledging sponsors from the podium, signage in the

exhibit hall, or print in the program agenda. The Task Force agrees that acknowledging industry support is appropriate as an expression of gratitude and also facilitates transparency through public disclosure.

Journal Advertising and Industry Funding of Journal Supplements

Accepting funds from industry for journal advertising is an acceptable form of revenue for societies if the advertisements are clearly and easily distinguished from scientific articles. Care must be taken to avoid placement of advertisements in close proximity to relevant scientific articles. Societies should not accept industry funding for the development of journal supplements. However, following peer review and publication of supplements, it is acceptable for companies to purchase and distribute supplements as references for promotional materials.

Gifts, Meals, and Entertainment

In the context of conflicts of interest in medicine, gifts—including meals and entertainment—are items or services of value received gratuitously from industry and not in exchange for legitimate services.¹³ It is appropriate to accept modest meals if associated with business or educational activities. Companies interested in providing educational gifts should donate them directly to departments for distribution, rather than to individual residents or fellows. However, it is acknowledged that many AHASs are prohibiting the acceptance of any gifts from industry, altogether.

Authorship and Ghostwriting

Authorship decisions should be guided by the ICMJE recommendations that provide detailed criteria for authorship and contributorship²⁴ (Figure 1). Adherence to these guidelines, by definition, prohibits ghostwriting or authorship without qualifications. Public disclosure of the funding sources and personal financial relationships of the authors is expected and usually required by most journals.

Speaker's Bureaus

Industry-sponsored participation in speaker's bureaus, panels, or other educational programs can be a profitable activity for the orthopaedic physician, typically paying *at least* \$1,000 per speaking engagement plus expenses.⁶ Such fees are difficult to couch as fair market value. Fees that are not within accepted standards for physician compensation for time are unacceptable. All time spent should be adequately documented.

Figure 1. Criteria for Authorship: ICMJE Recommendations²¹

Authorship credit should be based on:

1. Substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data;
2. Drafting the article or revising it critically for important intellectual content; and
3. Final approval of the version to be published. Authors should meet conditions 1, 2, and 3.

The acquisition of funding, collection of data, or general supervision of the research group alone does not constitute authorship.

All persons designated as authors should qualify for authorship, and all those who qualify should be listed.

Each author should have participated sufficiently in the work to take public responsibility for the appropriate portions of the content.

Prescription Drug Samples

Prescription drug samples are very effective marketing tools for the pharmaceutical industry; many studies have shown that pharmaceutical drug samples influence prescribing behavior.³⁸⁻⁴¹ While it is commonly held that prescription drug samples serve as a safety net for uninsured and underinsured patients, a large nationally representative study reported that fewer than one-third of all prescription drug sample recipients were low-income; patients in the highest income category were most likely to have received free prescription drug samples.⁴² In addition, low-income uninsured patients were less likely to receive free prescription drug samples than patients with continuous health insurance. Prescription drug samples are distributed to patients without the benefit of a drug regimen review by a pharmacist and without the documentation required of prescriptions, as this is not required by law for distribution of prescription drug samples.⁴³

On the other hand, prescription drug samples that are routinely used in the practice of medicine, particularly in ambulatory, office-based settings, provide the ability to rapidly initiate therapy, save patients the cost of filling a full prescription when medication effectiveness in a particular patient is unknown, and provide medication to patients who cannot afford to fill a prescription. The Task Force recognizes that the practice of accepting samples generates an inherent conflict of interest for the physician; has the potential to impact patient safety; and spurs the use of new and expensive medications that have not been demonstrated to be in any way superior to older brands, some of which may even be generic. However, until all patients have adequate

health-care coverage, the judicious use of prescription drug samples can provide a benefit to patients. Although physicians are required to uphold the professionalism of the discipline, it is also the physicians' responsibility positively to impact patient care.

The Task Force recommends that prescription drug samples be delivered to and managed by an intermediary to distance the dispensing physician from the marketing influence of direct contact with drug salespersons. In addition, using a pharmacist, directly in an institution or indirectly through the use of a prescription or a hospital Pharmacy and Therapeutics Committee, allows for efficacy and safety checks, as well as an independent cost-benefit analysis, and is preferable to situations in which samples pass directly from sales representatives to doctors.⁴⁴ Finally, the Task Force is in favor of a movement away from reliance on prescription drug samples and recommends that the biopharmaceutical industry increase access to patient assistance programs to make medications more affordable to all patients.

RECOMMENDATIONS AND NEXT STEPS

The OIOM Task Force recommendations are designed to protect the core values of the discipline of orthopaedic surgery with an emphasis on the need to reaffirm and strengthen professionalism and integrity among its members. The Task Force has put forth many recommendations and considerations in this document but emphasizes the following as next steps in moving the discipline of orthopaedic surgery closer to the goal of maximizing beneficial relationships with industry and eliminating those that are gratuitous and entered into primarily to generate physician revenue.

1. Orthopaedic surgeons need to understand the distinction between industry relationships that are gratuitous, self-indulgent, and potentially corruptive, and those that are designed to advance the discipline and improve the treatment and care of patients.
2. Orthopaedic surgeons should refrain from maintaining the status quo and serve as exemplary role models for future generations of orthopaedic surgeons.
3. Orthopaedic surgeons consulting with industry by providing advice, expertise, or other services in the context of product development should be paid fee-for-service or hourly consulting fees based on fair market value and well-defined contractual obligations with prespecified timelines and deliverables.
4. Orthopaedic surgeons involved in institutional purchasing decisions must disclose all relationships with industry and recuse themselves from decision-making in which they or their immediate family members may profit financially or otherwise benefit.
5. Orthopaedic surgeons involved in successful product development activities in which genuine IP is transferred and royalties are paid for the use of the property must make sure that neither they nor their partners profit further from their patients. Surgeons in leadership positions must never demand that others use their specific products.
6. Scientific independence and integrity in research and publishing must be maintained. Investigator-initiated grants for “weak” research projects (i.e., not contributing meaningfully to the literature) may be incentives or rewards for prescribing or purchasing influence; these are inappropriate relationships.
7. Increased involvement in high-quality research is needed to build the evidence that underlies clinical decision-making. Orthopaedic surgeons should participate only in research studies that meaningfully contribute to the professional literature; are adequately powered to examine clinically important endpoints; and have a study design, operational structure, and oversight mechanism to minimize bias and ensure patient safety. The analysis and reporting of research data must be independent of industry

- influence. Independence and transparency are particularly important if the research is industry-funded.
8. Participating in speaker's bureaus should be avoided.
 9. Authorship should conform to ICMJE guidelines. The use of ghostwriters is an unacceptable practice.
 10. The ACGME should explore the feasibility of developing a standardized core curriculum for inculcating professionalism and ethics in GME programs.
 11. Industry makes important contributions to building research and education capacity at universities; these relationships must be premised on the charitable and educational uses to which a university may put a tax-subsidized industry gift, not to any corporate or product endorsement.
 12. Funds from industry for residency and fellowship programs and other training programs should be distributed through unbiased, independent, third-party organizations or through the central administration of the institution. Residency and fellowship training programs should stop accepting individual-focused grants from companies and require companies to submit funding through either of the aforementioned approaches.
 13. Reliance on prescription drug samples should be eliminated. Industry should increase access to patient assistance programs to make medications more affordable to patients.
 14. Industry is encouraged to support device research in multicenter networks to improve transparency and objectivity. These studies may include the establishment of registries.
 15. Industry funds should not be used to develop clinical practice guidelines. When forming committees to develop clinical practice guidelines, individuals without financial ties to relevant companies are strongly preferred. If such knowledgeable individuals cannot be identified, individual and composite numbers of financial ties to industry must be disclosed and should be evaluated and minimized to avoid actual or perceived industry influence on the resultant guidelines.
 16. Professional societies should systematically measure and publicly report the percentage of industry support received for their operating budgets; set goals for progressively reducing industry support with a goal to eliminate industry funding entirely; and develop explicit policies to manage industry support and disclosure practices, including the formation of conflict of interest committees. A central disclosure repository for all orthopaedic professional societies should be implemented, rather than having each organization use its own separate disclosure database.

In summary, the OIOM Task Force recognizes that conflicts of interest do exist in the discipline of orthopaedic surgery. And while the impact on patient care is uncertain, it is clear that industry has grown to expect some orthopaedic surgeons to facilitate their marketing objectives in exchange for monetary payments, income-earning opportunities, gifts, privileges, and prestige. Orthopaedic surgeons are uniquely qualified to inform product development, which ultimately provides more and better options for patient care. Relationships with industry are necessary, valuable, and productive when ethical, transparent, and managed appropriately with recognition of and respect for the very different values and missions of the profession and industry.

Preserving the status quo is unacceptable, and changes are needed. The discipline of orthopaedic surgery must aspire to reduce and eventually eliminate industry's financing of orthopaedic educational activities, gifts and meals, and the use of prescription drug samples. Positive change can be accomplished through a thorough examination of current relationships with industry combined with strengthened self-regulation, continuing reaffirmation of professionalism and ethical standards in practice and education, and adherence to the core principles of altruism and beneficence that lie at the heart of the medical profession.

APPENDICES

Appendix A. Types of Surgeon-Industry Interactions

Surgeon as Consultant	Surgeon as Researcher
<u>Essential</u> interactions improve patient outcomes and the advancement of patient care.	
- Independent inventor or product development consultant (with bona fide contribution to IP that is clearly documented) (Table 1). Typically paid with royalties or through a licensing arrangement for the usage of IP. Royalties are sales volume-based; companies must exclude payments for use by the inventor/consultant and his/her institution, partners, and family members, if applicable. - Fee-for-service consultant paid at fair market value for contributing to the design or use of a product. - Product testing consultant. - Educator of other surgeons. Surgeons must have complete editorial control over the content and materials presented, although a review by company representatives may be necessary to ensure regulatory compliance. Industry-prepared scripts are inappropriate. - Physicians allowing industry representatives in the operating room to provide technical assistance with products and to ensure that all instrumentation and product sizes and configurations necessary for the case(s) are available and understood by the staff. This practice should be discouraged in situations in which appropriately trained staff is available and no defined need is identified for the sales representative to be present in the operating room.	Investigator for: - Government-regulated studies. - Rigorously designed nonregulated studies, (e.g., health outcomes, comparative effectiveness, and patient registries). DMCs and scientific advisory boards can improve the integrity and objectivity of the study design, conduct, and interpretation. - Study team member such as medical monitor, DMC member, or clinical expert (e.g., radiographic reviewer).
<u>Non-essential</u> interactions are gratuitous and serve to benefit industry and/or surgeons.	
- Purely promotional activities utilizing a physician as salesperson are never acceptable and should be phased out. - Product development consultants who are paid royalties, licensing fees, or consultancy fees for inadequate contribution to the development of intellectual property (Table 1). May be viewed as buying favors.	- Company-sponsored studies that are unlikely to result in a product publishable in a peer-reviewed journal, either company-designed or investigator-initiated, and add no valid scientific information should be phased out. - Investigator-initiated studies must be rigorously designed, free from conflicts, and provide valid scientific information. - Funding that is unlikely to result in a product publishable in a peer-reviewed journal as well as any studies funded by company marketing or company commercial budgets should be

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	discouraged and phased out.
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Appendix B. Roles of Orthopaedic Surgeons Collaborating with Industry

Product Design and Development
Independent Inventor: Independently develops IP and licenses IP to the health-care industry. The inventor receives royalty payments and/or license fee for the use of the patent.
Product Development Consultant: Hired as a consultant to advise on product development. May be a member of company's product development team. The consultant may receive royalty payments (based on bona fide and documented contributions to IP). Royalties should only occur if the contribution is substantial and is based on clearly defined standards for the valuation of the contribution and documentation of the consultant's contributions. Fees must not be based on the consultant's volume of usage, as this creates an unmanageable conflict of interest and is a violation of medical ethics.
Product Development Fee-for-Service Consultant: Hired as a consultant member of a company's product development team. May also write surgical techniques and/or product brochures for new product(s). Following the product launch, he/she may convert to <i>Professional Education Fee-for-Service Consultant</i> (see below) to teach other surgeons about the use of the product. The surgeon is paid only fee-for-service consultant fees (at fair market value) plus expenses.
Research/Product Testing Fee-for-Service Consultant: Hired as a consultant to perform laboratory tests on materials or products. Usually a scientist/engineer, not a surgeon. Will only involve a surgeon if the individual also has appropriate engineering or other scientific expertise and/or manages a laboratory offering such testing services. Usually paid on a project basis; may occasionally involve fee-for-service.
Education/Marketing
Professional Education Fee-for-Service Consultant: Hired as a consultant to provide product-specific training to other surgeons at learning centers and cadaver labs; speak on personal surgical technique(s)/experience with product(s) in various venues such as dinner meetings and company scientific exhibits at professional meetings; and/or provide training on anatomy, surgical techniques, use of implants, and operating room protocol to company sales representatives. Paid fee-for-service consulting fees plus expenses.
Marketing Fee-for-Service Consultant: Hired as fee-for-service consultant to provide input for a company's marketing department, i.e., Voice of the Customer surveys, market demographics, market needs, opinions on or results of competitive products in the market, etc. May also write or help write product information brochures. Paid fee-for-service consulting fees (at fair market value) plus expenses.
Health-Care Delivery
Non-consultant Collaborator: Practicing orthopaedist who allows health-care industry representatives into the operating room; usually, these are sales representatives but they can include marketing or engineering personnel. Sales representatives are typically present in the operating room to provide support services (implant inventory, selection of appropriate implant, or technical product expertise). Other health-care industry representatives may be there to learn about procedures or how their product is working. Surgeons are not paid in this collaboration. The surgeon, operating room staff, or hospital may derive value from expertise. Patient care may benefit. Health-care representatives derive sales and relationship value; other industry visitors derive market and product knowledge and benefit. (In all these examples, patients must be informed.)

Appendix B (continued)

Research: Company-Sponsored Clinical Studies
Investigator, Regulated Studies: Participates as a clinical investigator in a company-sponsored government-regulated clinical study such as those required by the FDA for device approval and assessment of post-marketing safety. FDA-regulated studies for device approval IDE studies are usually prospective trials, with either concurrent or historical controls. Post-marketing safety studies are typically ongoing beyond the clinical trial phase, as they monitor long-term safety issues. The fee paid is usually based on fair market value for professional effort expended in the study and per patient costs incurred. The fee is usually based on the number of patients, study activities, and protocol and data reporting requirements at follow-up milestones or on an annual basis. Other study-related costs (IRB fees, labs, x-rays, etc.) are paid separately from study investigator compensation. Investigator, Nonregulated Studies: Participates as a clinical investigator in company-directed/company-sponsored nonregulated clinical study (post-marketing study; not to meet FDA regulatory needs). Can be any type of study, ranging from a randomized controlled trial to a patient registry or health outcomes study. Paid a consulting fee, usually hourly based on documented time, or paid similar to company-sponsored studies. Medical Monitor, Safety Officer, or Radiographic Reviewer: Participates in review/analysis of study data from a company-sponsored clinical study (may be either an FDA-regulated study or a nonregulated post-market study). Paid a consulting fee, usually hourly based on documented time.
Research: Investigator-Initiated Clinical Studies
Investigator: Includes any clinical study that is initiated, designed, and managed by a surgeon investigator/institution. Investigator-initiated studies are typically not FDA-regulated studies. The investigator or institution receives some or all financial support via a grant from a company. The study costs (i.e., IRB fees, labs, x-rays, etc.) are included in the overall cost of study.

Appendix C: Terminology (adapted from Gelberman et al. 2010⁴⁵)

IP: patents, trademarks, trade secrets, copyrights, know-how

Royalty payments: Royalties are the payments made to the owner of the IP (e.g., orthopaedic surgeon or her/his institution) by the person(s) (e.g., device company) who is/are licensed to commercialize the invention (or conduct further research and development). Royalties are quantified as a percentage of the product's sale price; this percentage can be influenced by other factors including industry-specific benchmarks, the IP's stage of development, and the relative bargaining positions of the licensor and the licensee.⁴⁶

Fair market value: determined by activity/contribution, based on natural market forces; should be determined by an objective third party.

Licensing: IP, if not sold to the end-user company where ownership is transferred, is typically licensed for use by the IP owner/inventor through a licensing agreement in which the owner/inventor receives a licensing fee or royalty payments for the right to utilize the inventor/owner's IP.

Appendix D. Conflict of Interest Statements

Orthopaedic Institute of Medicine
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Conflict of Interest Statements from the OIOM Council and Their Family Members. Note: All OIOM Council members reported “no” disclosures for family members.

OIOM Council Member's Name	Served as a director, officer, senior management position, or owner of any medical organization (hospital, surgery center, professional society, etc.)?	Served as a member of an editorial board of a medical journal?	Received royalties from a medical device or pharmaceutical company?	Been a member of a speaker's bureau or received an honorarium from a medical device or pharmaceutical company?	Served as a consultant for a medical device or pharmaceutical company?	Received research support from a medical device or pharmaceutical company?	Owned stock or stock options in a medical device or pharmaceutical company?
Mark Augusti	Yes. Smith & Nephew	No	No	No	No	No	Yes. Smith & Nephew
Joseph A. Buckwalter, MD	Yes. Board of Directors of the Musculoskeletal Transplant Foundation (a NFP society)	Yes. <i>Journal of Orthopaedic Research</i> and <i>The Journal of Bone and Joint Surgery</i> , American volume	No	No	Yes. Scientific consultant for ISTO and Carbylan Bioscience	No	No
Marc F. Swiontkowski MD	Yes. TRIA Orthopaedic Center	Yes. <i>The Journal of Bone and Joint Surgery</i> , American volume	No	No	Yes. Eli Lilly and Zimmer	No	No
Kristy L. Weber, MD	No	Yes. AAOS	No	No	No	No	No
C. McCollister	No	No	No	No	No	No	No

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OIOM Council Member's Name	Served as a director, officer, senior management position, or owner of any medical organization (hospital, surgery center, professional society, etc.)?	Served as a member of an editorial board of a medical journal?	Received royalties from a medical device or pharmaceutical company?	Been a member of a speaker's bureau or received an honorarium from a medical device or pharmaceutical company?	Served as a consultant for a medical device or pharmaceutical company?	Received research support from a medical device or pharmaceutical company?	Owned stock or stock options in a medical device or pharmaceutical company?
Evarts, MD							
Laura L. Forese, MD	Yes. Matthew Larson Foundation for Pediatric Brain Tumor Research and orthopaedic scientific research foundations. Both are 501(c)3 organizations that give away charitable donations.	No	No	No	No	No	No
Jeffrey N. Katz, MD	No	Yes. <i>The Journal of Bone and Joint Surgery</i> , American volume	No	No	No	No	No
Steven H. Stern, MD	No	No	No	No	No	No	No

Orthopaedic Institute of Medicine
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Conflict of Interest Statements from the OIOM Task Force on Surgeon-Industry Relationships and Their Family Members:
Disclosures for family members are indicated by italics; otherwise, Task Force members reported “no” for family members.

Task Force Member's Name	Served as a director, officer, senior management position, or owner of any medical organization (hospital, surgery center, professional society, etc.)?	Served as a member of an editorial board of a medical journal?	Received royalties from a medical device or pharmaceutical company?	Member of a speaker's bureau or received an honorarium from a medical device or pharmaceutical company?	Served as a consultant for a medical device or pharmaceutical company?	Received research support from a medical device or pharmaceutical company?	Owned stock or stock options in a medical device or pharmaceutical company?
Peter Angelos, MD, PhD	No	No	No	No	Yes. Olympus-Gyrus	No	No
Robert L. Barrack, MD	Yes. AOA (6/08-6/11, Finance Committee member), Knee Society (2011-2014, Treasurer), Hip Society (2011-2012, member-at-large), American Association of Hip and Knee Surgeons (2011, Program Subcommittee Chair member, Program	No	Yes. Smith & Nephew until 11/20/10 and Stryker	No	Yes. Stryker Orthopaedics, Hip and Knee component consultant (3/11 to present)	Yes. Smith & Nephew, Biomet, Biospace Med/EOS, Medical Compression Systems, Wright Medical	No

Orthopaedic Institute of Medicine
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Task Force Member's Name	Served as a director, officer, senior management position, or owner of any medical organization (hospital, surgery center, professional society, etc.)?	Served as a member of an editorial board of a medical journal?	Received royalties from a medical device or pharmaceutical company?	Member of a speaker's bureau or received an honorarium from a medical device or pharmaceutical company?	Served as a consultant for a medical device or pharmaceutical company?	Received research support from a medical device or pharmaceutical company?	Owned stock or stock options in a medical device or pharmaceutical company?
	Committee member, Education Committee member, Program Subcommittee member)						
Jonathan P. Braman, MD	No	Yes. <i>Techniques in Shoulder & Elbow Surgery, The Journal of Bone and Joint Surgery, Shoulder & Elbow Newsletter</i> editorial staff	No	No	No	No	No

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Task Force Member's Name	Served as a director, officer, senior management position, or owner of any medical organization (hospital, surgery center, professional society, etc.)?	Served as a member of an editorial board of a medical journal?	Received royalties from a medical device or pharmaceutical company?	Member of a speaker's bureau or received an honorarium from a medical device or pharmaceutical company?	Served as a consultant for a medical device or pharmaceutical company?	Received research support from a medical device or pharmaceutical company?	Owned stock or stock options in a medical device or pharmaceutical company?
Nancy M. Cummings, MD	Yes. President of The Forum, President-Elect of the Maine Medical Association	No	No	No	No	No	Yes. Cardio Solutions <i>Family Member: Cardio Solutions</i>
G. Paul DeRosa, MD	No	No	No	No	No	No	No
C. McCollister Evarts, MD	No	No	No	No	No	No	No
Edward N. Hanley, Jr., MD	No	Yes. Board of Trustees of <i>The Journal of Bone and Joint Surgery</i>	No	No	No	No	Yes. Medtronic
David M. Hyman, JD	No	No	No	No	No	No	No
David Korn, MD	No	No	No	No	No	No	No

Orthopaedic Institute of Medicine
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Task Force Member's Name	Served as a director, officer, senior management position, or owner of any medical organization (hospital, surgery center, professional society, etc.)?	Served as a member of an editorial board of a medical journal?	Received royalties from a medical device or pharmaceutical company?	Member of a speaker's bureau or received an honorarium from a medical device or pharmaceutical company?	Served as a consultant for a medical device or pharmaceutical company?	Received research support from a medical device or pharmaceutical company?	Owned stock or stock options in a medical device or pharmaceutical company?
Stephen J. Peoples, VMD, MS	No	No	No	No	Yes. Oscention Orthopedics, Lim, Schwartz Biomedical, Accelalox	No	Yes. Johnson & Johnson
E. Anthony Rankin, MD	Yes. Eastern Orthopaedic Association, American Joint Replacement Registry, OREF <u>Family Member:</u> <i>District of Columbia Board of Medicine - Dr. Marc Rankin</i>	Yes. Orthopaedics	No	No	No	No	No
Susan Roberts, PhD	No	No	No	No	Yes. Bayer HealthCare, DSMB; Lilly, DSMB	No	No

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