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Orthopaedic surgeons and the medical device industry: The threat to scientific integrity and the public trust

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Orthopaedic Surgeons and the Medical Device Industry

The Threat to Scientific Integrity and the Public Trust

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The purpose of this article is to relate recent actions by the United States Department of Justice, the Institute of Medicine, the Association of American Medical Colleges (AAMC), and others to the specific challenges confronting the specialty of orthopaedic surgery. Further, it strives to reconcile the duty and value propositions associated with the orthopaedic surgeon-medical device company relationship, with the persistent risks that are attendant to that relationship, and to develop a new path—one that strives to restore the integrity of scientific investigation and day-to-day clinical decision making, while providing justification for future physician-industry interaction. To consider the topic in perspective, it is interesting to assess the origins of the current model of physician-industry interaction as they relate specifically to the issues currently confronting the specialty of orthopaedic surgery.

In 1980, novel legislation in the field of intellectual property, the Bayh-Dole Act, for the first time allowed universities and nonprofit organizations to replace the government as the principal beneficiaries of commercial development resulting from basic-science and clinical research. In essence, the act transferred the ownership of discoveries made with the help of

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federal research grants to the universities and small businesses where those discoveries were made. On the face of it, the Bayh-Dole Act made sense. Convinced that government ownership had deterred the development of incentives necessary to promote innovation and had severely inhibited productivity, supporters saw the act as a remedy for the depressed American economy in the 1970s. The goal of the act was specific—to address the concern that American firms were not using academic research efficiently for commercialization—and it intended to remedy that shortcoming by facilitating patenting and licensing by U.S. universities of inventions from federally funded research. If successful, it could help to usher in a new era of innovation in America. It was an interesting concept—one that supporters claim led to a very positive chain of events and to years of U.S. leadership in a variety of fields. The pharmaceutical and medical device industries led the way, dramatically increasing licenses and patents in the years that followed the adoption of the legislation.

For the medical profession, the result was, according to one observer, a modern alchemy, where "... ivory towers were being turned into gold and society was benefiting from hundreds of novel treatments introduced for a host of diseases."[1] While that view may have been accurate for a time, a series of increasing concerns developed over the years following passage of the Bayh-Dole Act. In what has been termed one of the most serious unintended consequences of a major piece of legislation, physician scientists and their universities evolved gradually from noble, highly trusted institutions into something closer to venture capital firms[1]. The increase in substantial financial conflicts of interest between clinical investigators and industry rose to such a remarkable level that, by 2007, a large percentage of physicians[2] and almost two-thirds of the department chairs in America[3,4] had important personal relationships with industry, serving as consultants, members of scientific advisory boards, and paid speakers. With regard to the integrity of decision making, however, the resultant risks were slow to be appreciated.

Only recently have academic medical centers and professional societies begun to address, in a systematic way, the core issue—the temptation of physicians to deviate from their professional obligations for economic or other personal gain[2,3,5,6]. Gradually, it became clear that the presence of self-interest associated with sponsored research substantially distorts how individuals make choices—in the clinic, in the classroom, and in the laboratory. Very recently, leaders of some professional societies and academic medical centers have taken on the challenge of determining how scientific objectivity can be maintained in the face of potentially compromising relationships ensuing from grants, royalties, and equity holdings provided to individual investigators and to academic institutions[7-14].

Despite some early efforts at self-regulation, the complications associated with the industry-physician partnership became so severe in the early 2000s that the Department of Justice entered criminal conspiracy complaints against five orthopaedic medical device companies, alleging violations of the Federal Anti-Kickback Statute. The government accused the companies of "using consulting agreements with orthopedic surgeons as inducements to use a particular company's artificial hip and knee reconstruction and replacement products."[15] Furthermore, the investigation revealed that it was common practice across America, from the late 1990s through 2006, for physicians, who performed work of little or no value, to be rewarded with consulting contracts, lavish trips and other perquisites[15]. In addition, it found that physician consultants failed to disclose the existence of their relationships to the centers where the surgeries were performed and to the patients who were under their care.

Compliance in the Wake of the "Big Five" Nonprosecution and Deferred Prosecution Agreements

In 2007, Zimmer, DePuy Orthopaedics, Biomet, Smith and Nephew, and Stryker Orthopaedics (a division of Howmedica Osteonics) were identified by the U.S. Department of Justice as providing improper financial incentives to orthopaedic surgeons to induce their selection of hip and knee devices. To avoid criminal prosecution, these companies entered into nonprosecution and deferred prosecution agreements pursuant to which they agreed to eighteen months of federal monitoring to ensure their implementation of corporate compliance procedures. Because these companies together account for nearly 95% of the market for hip and knee surgical implants[16], this innovative prosecutorial arrangement sought to change the way an entire industry did business.

Alleged violations of the Federal Anti-Kickback Statute[17] were the basis of this unprecedented industry-wide enforcement effort. The companies had been accused of providing financial inducements to orthopaedic surgeons through consulting agreements and direct financial perquisites. At the crux of these allegations was the underlying conflict of interest that the Anti-Kickback Statute is designed to prevent: the conflict between what is in the surgeon's financial interest and what is in the best interest of the patient.

The nonprosecution and deferred prosecution agreements have now ended, successfully marking a new era for the orthopaedic device industry. As the federal monitor for Smith and Nephew, one of us (D.S.) personally observed the important compliance improvements and industry transformation achieved by this process throughout 2007 to 2009. The strict compliance measures mandated by the nonprosecution and deferred prosecution agreements in areas of (1) determination of the need for health-care professional consultants, (2) payments to health-care professional consultants, (3) disclosure and transparency

regarding financial arrangements with health-care professionals, and (4) compliance training and hotline reporting have all fostered an industry-wide culture of improved compliance and accountability. Of course, whether the industry will continue on this positive path remains to be seen, but the structural sea changes have occurred and corporate policies are in place to ensure continued success.

Although the nonprosecution and deferred prosecution agreements process explicitly applied directly to only the companies, the unacceptable transactions and relationships that were the subject of the federal proceeding always involved two parties: a company and a professional. Now with the expiration of the nonprosecution and deferred prosecution agreements, the health-care professional side of the arrangement will continue to be addressed. It is certain that public scrutiny is far from over because, as stated by David Rothman, PhD, professor at Columbia University and president of Columbia University's Institute on Medicine as a Profession, "the rules of the game have changed."[18] The Department of Health and Human Services Office of Inspector General will expand enforcement efforts by targeting individual orthopaedic physicians who are as culpable as medical device companies for entering into illegal arrangements[18], and these expanded enforcement efforts will likely result in negative public perception as to the professional side of the subject relationships. Now that device manufacturers have been identified and their compliance practices have substantially improved, there is a new challenge to counter any negative public view and build on the progress achieved within the past eighteen months. To do this, it is imperative that physicians adopt and follow the strictest policies and codes of ethics regarding their interactions with the industry to avoid both actual and apparent conflicts of interest.

Inappropriate interactions between physicians and the medical device and pharmaceutical industries have threatened scientific integrity and diminished the public trust. While much progress has been achieved, in this environment of welcome scrutiny and awareness—where a hotline report can result in a full investigation or whistle-blower suit—physicians must be increasingly sensitive to public perception and be proactive in their approach to compliance to avoid suspicion and to maintain the integrity of the profession and its relationship with patients and its work products. This requires adherence to the most stringent codes of ethics and conflict-of-interest policies, particularly those that aim to avoid the appearance of impropriety by placing reasonable restraints on physician-industry interactions.

Throughout the deferred prosecution agreement process, a number of hotline reports concerning medical device company interactions with health-care professionals were received. They ranged from allegations of nepotism to the providing of a free boat, expensive meals, basketball tickets, and a day of pheasant shooting. While it may be argued that these kinds of activities are *de minimis* and could not possibly result in any inducement to use a certain product, such an argument appears to be at odds with current opinion.

Several recent studies have demonstrated that offerings such as free lunches, subsidized trips, and even small gifts may influence a surgeon's medical judgment[19]. Physicians themselves have cited these studies and have proposed the adoption of much stricter limitations on interactions with the pharmaceutical and medical device industries. For instance, on April 2, 2009, a group of physicians issued a special communication in the *Journal of the American Medical Association* that, in part, advised medical associations to move toward a complete ban on industry funding[20]. The reasoning for this stringent and progressive proposal is that current policies are not adequately detailed to prevent real or apparent undue influence or bias and that lack of strong uniform controls threatens to undermine the reputation of the profession.

The movement to adopt more stringent policies is in direct response to increasing public concern over physician conflicts of interest caused by industry ties and is consistent with an overall trend to further regulate and control physician-industry interactions. The AAMC has recommended strict conflict-of-interest policies that place limitations on faculty-industry relationships[21]. Institutions such as Johns Hopkins[22] and Partners HealthCare[23] (a system that consists of Harvard-affiliated facilities such as Massachusetts General Hospital and Brigham and Women's Hospital) have recently announced more stringent conflict-of-interest policies that restrict physician-industry ties. There have also been recent legislative initiatives such as a Massachusetts law requiring pharmaceutical and device manufacturers to adhere to a strict marketing code of conduct[24]; the Massachusetts law also mandates disclosure of information related to pharmaceutical and device manufacturers' financial arrangements with health-care professionals, as does a recently announced policy of the Stanford University School of Medicine[25] and a recently proposed federal law[26].

Stringent policies such as those suggested in the *Journal of the American Medical Association* proposal and advanced in other recent initiatives establish bright-line rules to avoid both actual and perceived conflicts of interest and, ultimately, allegations of illegality. Courts have widely held that, regardless of best intentions, if merely even one purpose of an arrangement is to induce federal health-care program referrals, the Anti-Kickback Statute is violated[27-30]. The determination of intent or purpose is highly subjective; what is a kickback to one may not be a kickback to another. Without strict rules that seek to avoid appearances of impropriety, it is difficult to consistently determine the boundaries of acceptability in physician-industry interactions, particularly in areas such as the provision of gifts,

entertainment, meals, and hospitality; the existence or extent of inducement to use a particular product will depend on the circumstances and individuals involved.

To address the inherent subjectivity regarding physician-industry interactions and overcome the public stigma, physicians should adopt the approach taken in the *Journal of the American Medical Association* proposal and other recent initiatives to adhere to the strictest codes of ethics and conflict-of-interest policies. The revised AdvaMed (Advanced Medical Technology Association) Code of Ethics on Interactions with Health Care Professionals[31] serves as a useful standard that aims to avoid negative perceptions. For example, its recommendations include (1) placing a blanket prohibition on the provision of entertainment (including activities such as theater, sporting events, and hunting); (2) setting forth stricter limitations on the provision of meals in terms of purpose and setting or location; and (3) prohibiting gifts, other than the occasional provision of items that benefit patients or serve a genuine educational function and—except for medical textbooks or anatomical models used for educational purposes—have a fair market value of less than $100; notably, unlike the previous AdvaMed Code, the revised Code does not permit any type of noneducational branded promotional item, even if such an item is of minimal value and related to the health-care professional's work or for the benefit of patients (such as pens, notepads, and mugs).

Physicians should strongly consider adopting even stricter policies, such as a complete prohibition on the acceptance of industry gifts regardless of purpose or value. In addition, although it would not appear to be prohibited under the AdvaMed Code for a health-care professional to attend a baseball game with a sales representative if the health-care professional is paying his or her own way, it may be regarded as inappropriate by others. To avoid any perception of impropriety, these kinds of situations should be avoided.

The orthopaedic device industry has made considerable progress toward instilling a commitment to compliance; however, the public perception of the integrity of the profession is still at risk, and there is a long way to go to elevate the industry's reputation.

The Duty Proposition: How Financial Entanglements Can Blur the Distinction Between Trade and Profession

Guided by the Department of Justice, industry has made progress over the past few years toward managing conflicts effectively. Many surgeons, on the other hand, continue to defend a culture of entitlement and exception[32], a defense that is increasingly ineffective against a public perception of greedy doctors perpetuated by the lay press. Headlines of major newspapers highlight financial payments from industry to physicians, without a balanced explanation of context[33]. Public trust has been eroded further by headlines linking profit motives to the provision of care. For instance, an article entitled "An Operation to Ease Back Pain Bolsters the Bottom Line, Too" states that "in the absence of better data, critics in the field point to a different reason for the fusion operation's fast rise: money."[33] Another article quotes a patient who warned, "When an orthopedist says you need surgery and you are in terrible pain, you assume he is right. . . . Think long and hard."[34] It has become increasingly clear that, in the context of financial conflicts, damaged perception matters more than nuanced reality.

At its core, the clinical relationship of physician and patient is a reciprocal "clinical fidelity."[35] Patients share sensitive information with their doctors, rely on advice provided, and comply with treatments recommended. In exchange, they expect undivided loyalty from their physicians. In a vulnerable state of sickness, patients yearn to believe that their doctors are caring professionals—practitioners who maintain their patients' well-being ahead of conflicting self-interest and the interest of any other party[35]. In an era when orthopaedic surgeons earn more by performing surgery than by treating patients nonoperatively, the choice of providing advice to patients regarding surgery compared with the act of performing the procedure constitutes a fundamental conflict. Yet, solutions that call for the separation of the decision-making process from the surgery itself are not feasible[36-38]. A more appropriate outcome would have physicians reengage in medicine as a profession, not as a trade—a goal that is facilitated by distancing patient-care decisions, as much as possible, from extraneous financial arrangements[39].

Tainted Science

Industry funding in orthopaedics is strongly associated with favorable outcomes, even for the scientific gold standard of randomized clinical trials. Results are favorable to the implant manufacturer in 73% of industry-sponsored studies compared with 44% of independent studies[40] (odds ratio, 3.3; 95% confidence interval, 2.4 to 4.5) for spine implants; 93% and 37%, respectively, for hip implants; and 75% and 20% for knee implants[41]. A pattern of results favorable to the study sponsor is also observed more generally in biomedical research. Structured reviews of published studies have shown a results bias favoring the sponsor, with an odds ratio of 8.0 (95% confidence interval, 1.1 to 53.2) for studies funded by drug manufacturers, 3.6 (95% confidence interval, 2.6 to 4.9) for studies funded by biomedical suppliers, and 5.3 (95% confidence interval, 2.0 to 14.4) for studies funded by for-profit organizations[42].

True innovation deserves to be rewarded. The long process from concept to prototype, to investigational device, to device approval, and to the delivery of the device to the marketplace depends on the personal drive and sacrifice of the inventor and the risk borne by the sponsor. Federal granting

TABLE I Conflict of Interest

Ethical or Professional Interest	Self-Interest
Recommending tests or procedures	Performing the same tests or procedures
Recommending participation in a clinical trial	Being paid for referring patients to a clinical trial
Support for research	Further funding only if positive results
Writing prescriptions for drugs	Being courted by the company
Using a specific product	Receiving gifts or being paid by the company

agencies and foundations rarely support the process. Successful innovation deserves financial reward limited by market valuation rather than arbitrary thresholds. The problem is that true innovation is rare.

A report by the National Institute for Healthcare Management Research and Educational Foundation analyzed 1035 new drug applications approved by the U.S. Food and Drug Administration between 1989 and 2000[43]. Of those drugs, 361 (35%) had a new active ingredient, but 674 (65%) had an active ingredient that was already marketed; 558 (54%) offered the ingredient in a different dosage route of administration or a combination with other drugs; and 116 (11%) had the identical product already available. The average price of a new version was twice the price of the older version. Device innovation may be even more rare—with proliferation of "me too" products flooding the market with each new device approval.

Myths and False Beliefs

Social science research has provided important principles related to financial conflicts of interest. We are all subject to self-serving bias[44]. When individuals have a stake in the outcome, they tend to weigh arguments differently than if the outcome is independent of personal gain[45].

The first myth is that conflicts of interest are avoidable. Conflicts of interest are unavoidable. There are inherent conflicts between professional values and self-interest. Routine activities such as recommending tests or procedures have a conflict of interest if the recommending physician is also performing the same tests and procedures (Table I). Recommending participation in a clinical trial is often associated with being paid for referring patients to the trial. Support for research can be contingent on further funding only if positive results are produced. Writing prescriptions for drugs often leads to a courtship by the drug company. Using a specific product is often associated with receiving gifts or being paid by the company. These are intrinsic conflicts associated with medical practice. Unavoidable intrinsic conflicts include the desire to obtain noteworthy findings, the desire to publish in academic journals, the need to increase the number of research publications, and the ambition to advance a national reputation[46]. Faculty in academic centers often seek to advance their careers, vindicate intellectual biases, receive accolades from peers, and win research prizes. There is also satisfaction in being the first to fulfill the promise of a new procedure. These are some of the intrinsic unavoidable conflicts associated with research.

The second false belief is that bias is a deliberate choice. Bias is not a deliberate choice. Deliberate misrepresentation of data and findings is fraud[47]. Fraud is rare, but self-serving bias is pervasive. It affects individuals in their evaluations of themselves. Individuals often overestimate their own contribution to joint tasks[48]. The above-average effect, where more than half of the individuals rate themselves within the top 50%, has been identified in ethics discussions, managerial adeptness, productivity, and health administration. Success is often attributed to skill, and failure, to bad luck[48].

Individuals manifest different notions of fairness[49]. When working hard is compared with working long hours, the individuals who work more generally believe they should earn more and those who work less believe they should be paid equally[45].

The third false belief is that the biasing effects of gifts can be controlled. In a study of physicians, 76% believed strongly that drug advertisements and sales personnel were minimally important in influencing their prescribing habits, yet 49% changed their prescribing habits on the basis of drug promotions[50]. This discrepancy suggests either an unwillingness to admit in-

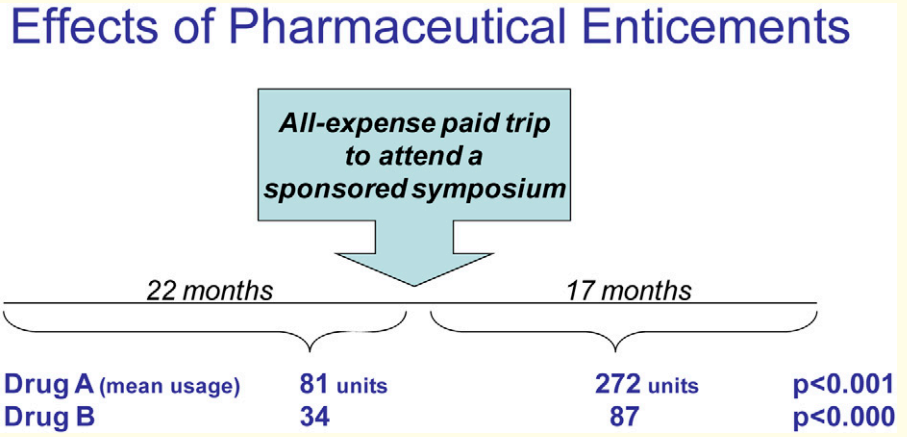

Fig. 1

Based on data presented in the study by Orlowski and Wateska[52].

fluence or a lack of awareness of influence.

The biasing effect is also prominent among physicians who attend sponsored lectures. After attending grand rounds sponsored by a drug company, the medical residents prescribed the company's drug favorably, with an odds ratio of 8.4 (95% confidence interval, 2.1 to 38.9)[51]. They also prescribed inappropriately, with an odds ratio of 7.8 (95% confidence interval, 1.6 to 45.5). There was no difference in drug choice between those who remembered the sponsor and those who did not.

Some physicians strongly believe that attending a sponsored symposium does not influence them. Recent findings of the effects of paid attendance at a conference have indicated, however, that the prescription of drugs increased from eighty-one units in the twenty-two months preceding a conference to 272 units in the seventeen months following the conference[52]. Study of another drug showed that prescriptions changed from thirty-four units in the preceding twenty-two months to eighty-seven units in the subsequent seventeen months (Fig. 1).

The fourth myth is that small gifts do not matter. Social science research has shown that what is considered inappropriate depends on the individual's perspective. In one study, 85% of medical students believed that it was inappropriate for a public official to accept a $50 gift from a contractor; however, only 46% of the medical students believed it was inappropriate for one of them to accept a $50 gift from a drug firm[53]. Nearly all (97%) of nurse practitioners thought it was inappropriate for a public official to accept a gift from a contractor, and most (64%) thought it was inappropriate for a medical student to accept a gift from a drug company. Only 30%, however, believed that it was inappropriate for a nurse practitioner to accept a $50 gift from a drug company[53].

Physicians and patients have different attitudes toward gifts. Patients are more likely than physicians to consider gifts as inappropriate and influential. Even small gifts, such as trips, dinners, pocket knives, lunches, mugs, drug samples, textbooks, pens, and videos, are more often considered inappropriate and influential by patients than by physicians (Table II)[54].

The fifth false belief is that bias is recognizable. Bias is difficult to recognize. In a survey of resident physicians, 61% stated that industry promotions and context did not influence their own prescribing, but only 16% believed that other physicians were similarly unaffected[55]. Every medical resident who considered lunches and pens inappropriate had accepted these gifts[55]. The difference shows inconsistency in physician attitudes of self compared with others.

The sixth false belief is that education reduces bias. Social science research has shown that awareness and knowledge about the biasing effect of gifts do not lead to a reduction in the effects of gifts[44,56].

TABLE II Attitudes of Patients and Physicians Toward Gifts*

	Inappropriate (%)		Influential (%)	
Gift	Patients	Physicians	Patients	Physicians
Trip	59	75	56	42
Dinner	47	33	48	24
Pocketknife	38	49	28	12
Lunch	23	10	29	12
Mug	23	18	31	8
Drug sample	22	26	42	55
Major textbook	20	29	38	10
Pen	19	4	31	8
Video	18	12	38	22
Small textbook	16	17	37	9

*Based on data in the study by Gibbons et al.[54].

Limits of Disclosure

Disclosure, as a method for managing conflicts, has limitations. An underlying fundamental problem, termed moral license, holds that, like confession, disclosure provides the surgeon investigator a feeling of absolution without cleansing the potentially tainted message[56]. Disclosure creates the false impression that biased advice is fair play. Professional medical associations often pay lip service to disclosure through unenforced and ineffective policies; members participating in the meetings frequently treat it casually as an obligatory burdensome step. Despite standards of professionalism established by the American Academy of Orthopaedic Surgeons (AAOS), the program for the 2007 Annual Meeting disclosed only 71.2% (245) of 344 payments reported by the five arthroplasty implant manufacturers on their web sites. While the AAOS program disclosures did not include dollar amounts, industry web sites provided more detailed information, indicating that forty-seven consultants were paid over $1 million a year[57-62]. Christopher J. Christie Jr., when he was U.S. Attorney for the District of New Jersey, stated frankly that the target would be shifted from industry squarely to the orthopaedic surgeon: "I've dealt with the supply issue, now I need to deal with the demand issue."[63] Legal action and external policing of this sort indicates how we and how our professional associations may have failed to protect the health of the public and the integrity of the profession.

In a concept described as anchoring, individuals have difficulty unlearning, ignoring, or suppressing the use of knowledge even if, subsequently, it becomes apparent that the data are inaccurate[56]. When evidence on which beliefs are made is discredited, the beliefs do not revert to their original state. They show the persistent effects of the discredited evidence. This phenomenon has been described as the "curse of knowledge" or the "failure of evidentiary discreditation."[56]

The Association of American Medical Colleges Recommendations

The AAMC published guidelines to facilitate the development of institutional policies related to financial conflicts[64,65]. The guidelines offer principles for examining and redesigning relationships with industry to conform to standards of medical professionalism. A report, issued in February 2008, entitled "Protecting Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI Policies in Human Subjects Research" called on all medical schools and major universities to develop and implement conflict-of-interest policies within two years[66].

While orthopaedic surgeons are required to work closely with the device industry for research and product innovation, industrial sponsorship of research differs from federal funding in several important ways. The subject of research in federal funding is typically fundamental science, whereas the subject for industry funding is product-based science. The application process for federal funding is complex compared with, typically, a simple one to two-page proposal for many industrial grants. The application review process is peer review for federal funding and business review for industry funding. The degree of difficulty in obtaining funding is different. Federal funding is competitive, and industry funding is typically noncompetitive. Response time to the funding application is prolonged in federal grants compared with a rapid review and response in industry support. The contact between the sponsor and researcher is rare in federal support, whereas it is frequent in industry support. The timing for accrual of research data is not typically specified in federal funding, whereas it can be discreetly specified in industry funding. Access to all research data for all study sites is usually not restricted in federal funding. Typically, it is very restricted in industry funding. The relationship between a sponsor and the study findings is disinterested for federal funding, whereas the sponsor is typically invested in the research outcomes for industry funding. Other factors include differences in protected time for researchers and investigators, salary support for investigators, and the ability to use funding for academic promotion or academic reputation.

Policies related to research activities have typically not addressed common relationships between investigators and sponsors. Investigators frequently report direct payments from industry, holding office in the company, or receiving gifts from sponsors. However, these types of activities are rarely addressed in institutional policies[64,65,67]. Our professional associations must develop methods of providing clinical context for device manufacturers while shielding individual patient-care decisions from undue commercial influence. Options include the development of scientific review processes for the distribution of industry research and education funds, the creation of registries to measure end results of implanted devices, and the provision of transparent taxation mechanisms to allow device manufacturers to sponsor the development of continuing education courses.

International Committee of Medical Journal Editors Recommendations

The International Committee of Medical Journal Editors (ICMJE) published uniform requirements for manuscripts submitted to biomedical journals[68]. These requirements are aimed to protect the integrity of the research process and the investigators. They require that the investigators retain access to all trial data, control all editorial and publication decisions, and fully disclose the role of the sponsor. ICMJE has advocated for a "'rebuttable presumption' standard by which an investigator is presumed to be ineligible to conduct human subjects research in which he or she has a significant financial interest, unless that investigator is uniquely qualified to do so,

TABLE III International Committee of Medical Journal Editors Uniform Disclosure Requirements for Potential Conflicts of Interest*

1. Board membership
2. Consultancy
3. Employment
4. Expert testimony
5. Gifts
6. Grants and/or grants pending
7. Honoraria
8. Payment for manuscript preparation
9. Patents (planned, pending, or issued)
10. Royalties
11. Payment for development of educational presentations including service on speakers' bureaus
12. Stock and/or stock options
13. Travel and/or accommodation expenses covered or reimbursed
14. Other (err on the side of full disclosure)

*According to Drazen et al.[71], disclosure applies to financial and nonfinancial relationships involving the author, institution, spouse or partner, and children under eighteen years of age. Any personal, professional, political, institutional, religious, or other associations that a reasonable reader would want to know in relation to the submitted work, including all sources of revenue and any entity that could broadly be considered relevant for the thirty-six months prior to submission of the work, and all relationships outside the thirty-six-month window that readers may want to know and could reasonably criticize an author for not disclosing. Public funding sources, such as the National Institutes of Health or the Medical Research Council, need not be disclosed.

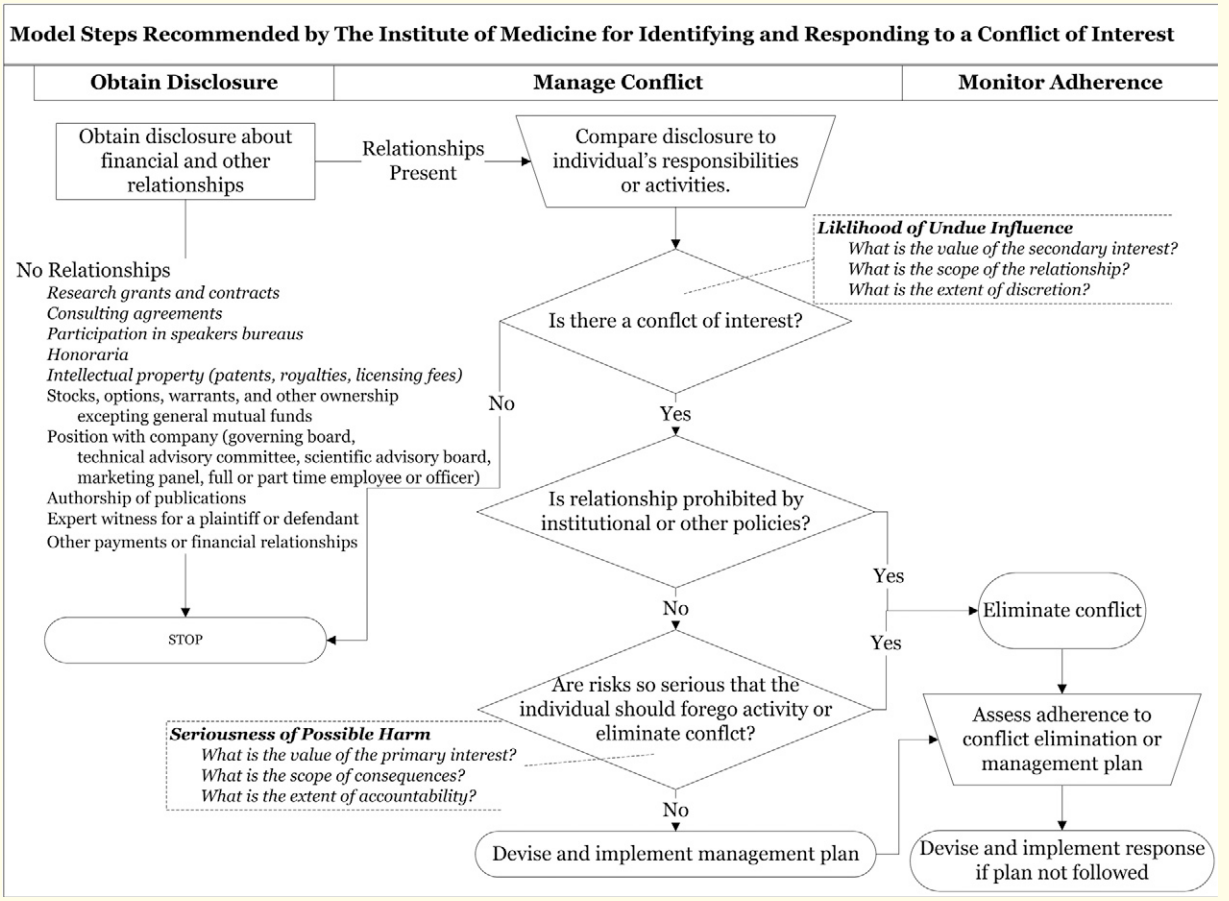

Fig. 2

Developed from recommendations in the Institute of Medicine 2009 report[75].

and even then, only under carefully monitored conditions."[69] The ICMJE has also introduced uniform requirements for disclosure[70-73]. While dollar amounts are not required, sponsors are identified for fourteen explicit categories of financial support (Table III)[70-72,74].

Institute of Medicine Recommendations

The Institute of Medicine published an extensive report on conflicts of interest in medicine[75]. The report provides detailed steps to disclose, manage, and monitor adherence to management of conflicts of interest (Fig. 2, Table IV).

The Value Proposition

Despite the shortcomings of the surgeon-medical device industry relationship noted in recent years, the value of the partnership, insofar as patient outcomes are concerned, is undeniable. In the early days of implant development, the intellectual contribution provided by the orthopaedic surgeon was more easily defined. Homer Stryker of Kalamazoo, Michigan, founded his own company, John Charnley developed his own hip arthroplasty implant and brought it to industry for commercialization, and the Association for the Study of Internal Fixation (AO/ASIF) developed a series of implants that were licensed to the Straumann Institute (Waldenburg, Switzerland) and distributed under the Synthes trademark. Initially, these implants were small in scope and were used by relatively few surgeons. Regulation of the commercial manufacture and distribution of the implants in the 1950s and 1960s was rudimentary. Few questioned the value of the partnerships in elevating the quality of care of patients with musculoskeletal disorders[76].

The maturation of the field over the last half century has presented both opportunities and, more recently, threats to the orthopaedic surgeon-industry partnership, especially with regard to orthopaedic implant design and distribution and to the education of professionals[2,76-78]. If it is accepted that the development of novel devices is beneficial, the process by which an orthopaedic surgeon may contribute to design and distribution requires explicit documentation.

Intellectual Property and Patents

The criterion for royalty justification has come under question most recently with the Department of Justice investigation. It has been established that intellectual property must be transferred between the orthopaedic surgeon and the company in a design project if a royalty payment is to be made. Many

TABLE IV Recommendations by the Institute of Medicine*

General policy
1. Adopt and implement conflict-of-interest policies
2. Strengthen disclosure policies
3. Standardize disclosure content and formats
4. Create a national program for the reporting of company payments
Medical research
5. Restrict participation of researchers with conflicts of interest in research with human participants
Medical education
6. Reform relationships with industry in medical education
7. Provide education on conflict of interest
8. Reform financing system for continuing medical education
Medical practice
9. Reform financial relationships with industry for community physicians
10. Reform industry interactions with physicians
Clinical practice guidelines
11. Restrict industry funding and conflicts in clinical practice guideline development
12. Create incentives for reducing conflicts in clinical practice guideline development
Institutional conflict-of-interest policies
13. Create board-level responsibility for institutional conflicts of interest
14. Revise Public Health Service regulations to require policies on institutional conflicts of interest
Supporting organizations
15. Provide additional incentives for institutions to adopt and implement policies
16. Develop research agenda on conflict of interest

*Summarized from the Institute of Medicine report entitled ''Conflict of Interest in Medical Research, Education, and Practice.''[75]

consider the ownership of patents as the only true intellectual property. In law, however, patents, copyrights, trademarks, know-how, and trade secrets are all considered intellectual property. Moreover, one could contend that the involvement of surgical practitioners is helpful to the marketing of a device in that such involvement should ensure the teaching of appropriate indications. Only patents (considered true inventions), copyrights, and trademarks are granted exclusive rights protected by law. Know-how (the ability to execute specific tasks or to produce specific products [reducing an invention to practice]), however, is essential to the commercial success of many patented inventions. Only surgeons who have analyzed their results critically and have demonstrated an understanding of the process of the development of ideas to product development can add value to the process. This understanding cannot be thoroughly accomplished without extensive publication on the general topic (but not necessarily on the same implant or on the device being developed). Surgeon volume as the sole contribution is not an appropriate criterion for design team involvement.

Licensing

Intellectual property is often transferred or sold by its inventor through the process of licensing. In the typical license agreement, the inventor charges a royalty to the purchaser licensee for the right to utilize the inventor's intellectual property, which often includes related unprotected know-how as well as protected patents. The inventor often transfers the right for the licensee to pursue patents based on the inventor's know-how. Most licensees recognize that know-how is central to commercialization of an invention. The monitors of the companies involved in the Department of Justice investigation agreed with this interpretation and developed a fair value amount in terms of the percentage of product sales (royalty burden) that is appropriate for an orthopaedic implant.

Documentation of Work Effort

Another important feature of the value proposition that has been developed with regard to the royalty and consulting partnership is documentation of time, effort, and level of personal contribution to a project. The attorney mindset of billing for time spent on a project (which is now required in the surgeon-industry partnership) compared with the medical professional mindset of billing for a completed task, clinic visit, or operation—no matter how much time is required—can be culturally difficult for a medical professional. Many physicians are concerned about the potential for overbilling, whether it is related to time or to the potential to justify the time on the basis of overdocumentation. The adage that if it was not documented, it was not done is becoming an important standard for the orthopaedic surgeon who consults with industry. This process, however, should be easier for the surgeon to accept, as the same practice is being applied in the clinical setting, especially in cases in which the government is subsidizing care through Medicare. Fair market value for consulting time is dictated by outside sources, most recently the monitors in the case of the deferred prosecution and nonprosecution agreements of the Justice Department.

Finding a New Path for Orthopaedic Surgeons and Industry: Beyond Disclosure

All discussions of conflict of interest to date have hastened to enumerate the

"do nots" in physician relationships with industry[7,11,14]. Short of acknowledging the need to preserve a positive interaction between medicine and industry, however, none have sought to define the parameters that would characterize such a relationship. Such should also be our task.

In order to establish the new parameters of a constructive relationship with industry, one first acknowledges that a relationship is important, if not essential, but that the current iteration is flawed. The critical error lies in the too liberal assignment of value to casual, nonsubstantive interactions that surgeons have with device manufacturers. More holes in an acetabular shell, a 5° increase in the screw angle of a volar distal radial plate, or an additional cross-link between spinal rods do not necessarily constitute material product improvements worthy of compensation. Secondly, while some of the errors have been egregious, the demonization of any relationship with industry overshoots the mark and may lead to considerable harm in the long run. Some have proposed a "zero financial interest tolerance" for physicians in critical positions that relate to industry and provide potential for personal gain[20,79,80]. Elimination of individuals from important tasks and groups because they receive appropriate compensation for critical contributions handicaps the process and risks compromise of the quality of the final product. The contributions of those with such conflicts should be preserved by effective management of the relationship rather than by complete dismissal of the individual. Further, it is incumbent on our profession to repair any perception of disrepute insofar as industry relationships are concerned. Modifications in physician behavior are the requisite for a healthy physician-industry relationship, framed by the need to move beyond simple disclosure in protecting ourselves from the perils of conflicts of interest. In the words of David Korn, MD, "Disclosure is essential but not sufficient," in characterizing the relationship between medical professionals and industry[81].

Components of a Healthy Physician-Industry Relationship

The futuristic approach to the constructive and ethically acceptable surgeon-industry relationship is predicated on four fundamental principles:

1. Complete Disclosure and Transparency of Conflicts

As has been articulated by some, a detailed and complete disclosure of financial and other substantive relationships is the starting point[81]. Specific dollar amounts received from industry for efforts related, directly or indirectly, to the matter at hand are disclosed[12,82,83]. This is most effectively accomplished on a web site in the public domain; indeed, most of the pertinent companies and an increasing number of universities already have such a policy. Objective reporting, such as income noted on U.S. Internal Revenue Service form 1099, should be the basis for such declarations. An unwillingness to disclose such relationships in this manner constitutes a basis for exclusion from any related position, task, or group. Moreover, surgical consent forms for an operation should disclose the existence of such surgeon-industry relationships to patients prior to the operative procedure being performed; some institutions have already adopted such a policy and standardized form. This provides a context within which every observer may judge the potential bias of each respective contributor when presenting at a meeting, publishing a paper, or participating in a group discussion.

2. Realistic Assessment of Actual Value Added

The material value of a surgeon-innovator's contribution is assessed by some dispassionate third party, a group comprising representative individuals from industry as well as a medical peer group. It is anticipated that there will be far fewer substantive compensable contributions as a result of this process. Likewise, it is assumed that this will be the cornerstone of a more credible, ethical, and consistent system of reward for surgeon designers.

3. Objective Third-Party Determination of "Fair Market Value"

As the term implies, market forces appropriately determine fair compensation for intellectual property transfer and consulting activity subsequent to a determination of real value added. It is expected that the royalty load for a given project varies within some range dependent on the magnitude and impact of each contribution and the relative success of the product in the marketplace. Similarly, natural market forces, overseen and approved by an objective third party, should govern hourly remuneration rates for consulting activities. This is contrasted with the current state, where a predetermined hourly rate for consulting activities and fixed percent of royalty load is set arbitrarily, independent of market forces, by regulators who themselves may be conflicted.

4. Removal of Linkage from Patient-Care Decision Making

Any conflict of interest, be it real or perceived, derives from the association of personal gain of the individual physician with the selection of a product which the physician participates in or even directs on behalf of the patient. Disclosure is no longer thought to confer immunity to being influenced[84]. If the role of the physician in the development process is to be preserved because he or she adds value, it then stands to reason that the triangle connecting the physician, the patient, and the vendor must be interrupted. The physician is either dissociated from the patient or from industry in this triangle; any role in device selection on behalf of the patient or the potential for personal gain by the physician (through reciprocity with the vendor) is eliminated. While at first blush the disconnection of the physician from the decision-making process for any individual patient appears contrary to the altruistic role of the physician, many health-care systems in the United States have already compromised the surgeon's ability to choose on behalf of the patient (e.g., by limiting implants to those supplied by certain vendors

chosen by the institution, most often based on favorable pricing considerations). Common practice currently precludes a royalty benefit to a designing surgeon based on patients cared for in the surgeon's home institution, but some would claim a serious conflict persists if the surgeon's payment remains correlated with the use of any specific implant. An alternative hybrid scenario might create a third-party-administered "innovator pool" that provides a reimbursement premium to surgeon-innovators whenever the procedure in question is performed, irrespective of which implant is used in any particular patient or which company manufactured it. Under such a system, the surgeon-designer is rewarded for participation in the product development process in a manner not connected with the use of any specific device in any particular patient. For example, the predetermined "royalty load" of a given device from each manufacturer might be paid to an independently governed fund rather than to any individual designing surgeon. The aggregate pool of royalty payments related to surgeon-designed devices would then be distributed to participating surgeon innovators on the basis of relevant metrics such as the time spent on projects and the success of the devices, rather than having payment linked to the success of any specific implant with which the surgeon may be involved. This approach would retain a more general incentive for the surgeon-innovator while separating the direct surgeon link to industry; it therefore also potentially preserves the physician role as agent in decision making for the individual patient. Likewise, the establishment of such a "medical device tax" could also perpetuate industry sponsorship of research and education, considering that the incentive for industry to continue its support of such activities is diminished by removal of its direct link to the surgeon who makes implant-purchasing decisions.

No matter how the surgeon-designer is removed from the conflict-of-interest triangle (e.g., eliminating the prospect of financial gain as was the case in the early history of implant development, or divorcing the physician-innovator from the process of device selection for any individual patient), there will be at least a temporary period when review of these situations by a dispassionate third party (an ethicist) will add considerable value in reassuring the public that the medical profession has adopted an ethical and transparent approach to relationships with industry. It is likely that there will be increasing demand for such individuals providing counsel to academic health centers in the years to come. Beyond the role of advisor, a principal function of such an individual might be to provide a binding review and adjudication of conflict-of-interest disclosure as well as a determination of the appropriate relationship structure between industry and physician-innovators as we move forward.

Whatever approach is adopted to raise our profession from the present quagmire must ensure ethical relationships between industry and the medical community and must restore the public trust in the treating physician as having the welfare of the patient as the principal motive. A thoughtful and reflective dialogue involving medicine, the lay public, and industry is essential. Elements of such a relationship include complete and full disclosure, a realistic assessment of value added, an independent determination of fair market value, and elimination of any linkage of the surgeon to either specific patient decision making or a relationship with industry that provides for personal gain. Amid all of this, we strive to protect the ethical interaction between medicine and industry that has fueled proper medical advances over the years. For all those who partake in the discussion, nothing less than genuine altruism will be required, as well as a clear and irrevocable understanding that what is past has passed and the future of all relationships with industry will look very different. Our choice is simple; we can elect to be part of the solution or a continuing part of the problem.

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