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. 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.

### 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.**
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<td>The full report is available with the online version of this article as a data supplement at jbjs.org.</td>
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| 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. |

Note: Members of the task force include G. Paul DeRosa, MD; Peter Angelos, MD, PhD; Robert L. Barrack, MD; Jonathan P. Braman, MD; Robert M. Califf, MD; Nancy M. Cummings, MD; Edward N. Hanley, Jr., MD; David M. Hyman, JD; David Korn, MD; Stephen J. Peoples, VMD, MS; E. Anthony Rankin, MD; C. McCollister Evarts, MD; and Susan Roberts, PhD.