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REPLY TO THE LETTER TO THE EDITOR

Conflict of Interest? What conflict of interest?

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Dear Editor

Conflicts of interest are common among orthopedic professionals who provide public healthcare service, and who also directly interact with the orthopedic industry for receiving any form of monetary or in-kind compensation. Interactions with industry can be manifold: industry funded research projects (mostly product related); consulting for industry proprietary R&D projects; any form of contractual assignment of intellectual property for inventors; holding private stock or options to private stock; being a clinical study investigator for a personal honorarium or for the hospital/department being paid "good" money for engaging in such studies; being invited to educational events significantly sponsored or organized by a single or few industry partner(s); sales based royalty payments to professionals or to institutions primarily governed by doctors; research or clinical fellow positions paid by industry at clinical sites using their products; any other form of monetary or in-kind value in gifts, for a not further specified purpose, transferred from industry to doctors.

The above listed interactions all have in common that the orthopedic professional will gain money personally and/or for his institution, or that he will gain visibility/publicity furthering his professional career, and that this gain somewhat depends on the success of one or multiple product(s) that the medical professional directly or indirectly promotes or endorses with his activities. As such, they constitute potential conflicts of interest. The fundamental problem is not that individuals are entering into such potential conflicts of interest, because, particularly as academically motivated professionals, it is almost impossible not to do so. To have such a potential conflict of interest, per se, is neither right nor wrong. The problem, however, is that professionals fail to be transparent about conflicts of interest, which is definitely wrong.

The proposal to engage with the industry is attractive, particularly for academically minded professionals. While public funding for musculoskeletal research and education is gradually eroding, the orthopedic industry, willingly and opportunely, engages to fill this void. Applications to the industry for receiving research or educational support are much less scrutinized than applications submitted to highly competitive peer-reviewed public funding programs. Clinicians working long hours for providing public healthcare service have difficulty in succeeding in such competitive programs that are equally drawn on by full-time researchers. The peer pressure of like-minded clinicians is high, so it is all too understandable, and at this level equally opportune, that academicians resort to industry money as opposed to money granted by public funding agencies.

The prestige that comes along with getting money from outside the university, regardless of the source, to further university-based education and research, equally benefits the supported individual and the hosting academic institution. Universities in fact demand from individuals wanting to climb the academic ladder that they demonstrate the ability to attract extramural funding. In fact, academia drives young clinicians to aggressively seek extramural funding. The problem is that somewhere along the path of their professional careers, individuals start having double roles as clinician scientists and members of an academic institution, and also as independent professionals engaged directly with the industry and perhaps become private

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investors or even entrepreneurs. Although many academic institutions want its faculty to have industry contracts, even personal ones, reviewed and approved by the institution, others are quite lax about interposing themselves between the academician and the industry.

North American universities typically encourage basic scientists and engineers to engage in private consulting or entrepreneurism, because they see this as a form of translational research and ultimately value generation for the university through commercialization of basic research ideas. The main difference between basic researchers/engineers and clinician scientists engaging in technology transfer, however, is that the latter potentially become the customers of their own research ideas.

Surgeons and interventional radiologists frequently implant medical devices or use disposable procedure kits, and as such are the target of industry sales forces. Industry relies much on medical professionals to describe the need for new products, later to validate new products in formal (regulatory) clinical studies and ultimately to use them in their clinical practice. As a result, medical professionals can be the supplier, gatekeeper and customer to the industry at the same time. This vertical integration of business relationships creates an oligopoly.

With a similar result, the merger and acquisition strategy of the medical device industry starting in the nineties has rationalized away midsized players, and today only few big players are left in the market. The result is a very tightly knit, intimate relationship that few leading professionals maintain with the medical device industry. If the same individual is an inventor, co-developer or author of new devices and/or procedures, later being a clinical investigator for this product and ultimately becoming a significant clinical user and promoter of the product at scientific and educational meetings, perhaps have even financial benefits directly linked to product sales, the potential conflicts of interests are pre-programmed.

Frankly, it is a sort of self-created problem by the guild of leading clinicians, and also by most professional societies and academic institutions that do little to help untangle that closely knit relationship. As opportune as it is for the industry to maintain such relationships, they are equally opportune for individuals in the medical profession to improve their academic or professional status, sometimes to derive direct financial benefits from product sales, or also just to enjoy amenities that go along with joining industry-sponsored activities.

Medical societies do not have the human or financial resources to effectively act as gatekeepers between professionals and the industry. Often the boards of societies themselves are not at arm's length to persons involved in potential conflicts of interest, and therefore shy away from criticizing them. The large majority of academic institutions have written policies in place, stipulating rules for professional conduct related to private consulting work, conflicts of interest, ethics, human and animal research, etc. The problem is that few institutions actively check for violations of acceptable professional conduct. Individuals having already engaged in potentially unacceptable conduct will rarely come forward on their own. Co-workers, on the other hand, often feel intimidated to come forward to report concerns, because their professional careers are likely negatively affected by such moves.

For clarification, I do not think that it is unethical for clinician scientists to make considerable additional income from their own ideas that ultimately are beneficial to the patient and result in much earned commercial success. The problem only arises when the same individual produces research results, collects outcome data during mandated clinical studies and sets indications and directly or indirectly promotes in scientific and educational meetings the use of products. If the individual declares potential conflicts of interest in a proactive manner, possibly solutions could be found to cover certain key roles (e.g., principal investigator) with independent colleagues acting at arm's length (i.e., without any direct or indirect benefits).

However, it will never be possible to eliminate all potential conflicts of interest for medical professionals who maintain a regular relationship with the industry for either R&D activities, industry sponsored education or clinical trials. Laws can never replace personal responsibility, likewise policies will never replace professional ethics. Medical professionals, in general, should have high morals and be prepared to make informed and honest decisions that the general population, because they have not received the specific training, cannot. The medical professional's additional knowledge comes with authority and power that should never be used to put the patient at unjustified risks or create unilateral benefits to the doctor.

In the business world, directors of a public company throughout the year enjoy authority and power to make all relevant decisions, but at the fiscal year end their actions typically are reviewed by the general assembly of all shareholders, as well as by an auditor at arm's length, with specific training to review the company's books. If the director's past actions are approved, they receive a discharge. Employees and business partners do not participate in this annual review process. If directors, as holders of proprietary knowledge, abuse this knowledge to draw financial benefits from personal stock transactions, thereby putting regular shareholders at a disadvantage, they are, if others find out, criminally prosecuted for inside trading. Any stock transactions of the senior management are made public in quarterly SEC statements.

I wish orthopedic surgeons and the medical device industry would be that transparent for education and

clinical research. A fundamental problem is the dependency on money received by academic institutions and individuals from the industry for education and research purposes. Sponsoring for CME accredited educational events has to be received as an "unconditional educational grant", but is it really unconditional? I bet if the event would not be perceived helpful by the sponsor to market their products, they would not grant that money again in the following years. Or, imagine a laboratory study reporting unfavorable results for a specific device. The sponsor would not likely go back to that research laboratory to conduct another sponsored study.

Financial transaction for educational and research work administered by an academic institution would have to be truly at arm's length, for instance, paid into a pool and later distributed independently of the sponsor to academic institutions. Say one percent of gross product sales could go, like a tax, into this pool, with the dispersion administered by a diverse group of frequently changing, seasoned professionals. The academic output, as long as it is quality work, should not affect in any way the next financial input.

Furthermore, if academicians take part in product design and validation in clinical studies, their names should be made public in an easily accessible registry. The added visibility would automatically bring more responsibility to those clinicians engaging in product design. Lastly, the names of clinicians owning relevant numbers of shares in orthopedic companies with one or few products only, or receiving volume-based royalty for specific product sales, should equally be made public along with the associated product(s). Hereby, the actual monetary amounts would be less important than disclosing the relationship as such. More transparency is what will be required.