What We Really Think: The Device Industry in/with/against/versus/and Orthopaedics

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Over the last twenty years, the relationship between orthopaedic surgeons and the medical device industry has evolved considerably. The Advanced Medical Technology Association (AdvaMed) code was developed in 1993 to help guide relationships between the device industry and the surgeons using their products.[1] However, in 2007, the United States Department of Justice (DOJ) put this relationship under intense scrutiny and found that there were violations of federal anti-kickback laws in the dealings between industry and surgeons. The DOJ felt that physicians were being improperly incentivized to use certain products.[2] This discovery resulted in the five largest makers of orthopaedic implants being forced to enter into a deferred prosecution agreement (DPA),[3] and prompted a dramatic change of the terms by which industry and orthopaedic surgeons worked together. Preserving the best interest of the patient necessitated certain changes in the way these companies recruited and reimbursed surgeons for intellectual contributions, paid for continuing and graduate medical education (CME/GME), and demonstrated new products. Increasing transparency in the interactions of surgeons and industry and promoting adherence to high ethical standards was the primary goal of the new regulations; however, there have been other unanticipated consequences of the increased regulation as well.

In the course of this upheaval, the interaction between industry and residency training programs was substantially changed. Device companies had long been active in offering training courses to residents; this interest came under scrutiny in the eighteen months following the DPA - four of the companies were assigned a compliance monitor to oversee their spending. Three years later, however, in a 2010 review of the Orthopaedic Research and Education Foundation (OREF) and the Orthopaedic Medical Grants Association (OMeGA), two grants clearing houses for GME and CME training, one author found that approximately 25% of orthopaedic fellowship spots were still being subsidized by industry.[4]

As such, industry remains an integral part of most post-graduate medical education, either directly or indirectly. We asked several prominent orthopaedic surgeons and surgeon-educators to comment on their views on the relationship between the orthopaedic device industry and surgeons with a focus on resident education. Their answers to our questions are compiled below.

In general, almost all felt that they were now in less of a relationship with industry than they had been at an earlier point in their career, and that this distancing was purposeful. Moreover, most felt that the involvement of industry with resident education was generally beneficial for the residents, but needed to be recognized as in the companies' financial interest. Additionally, all emphasized the importance of the surgeon keeping the patient's best interest in mind when considering a relationship with industry for oneself and the hospital. Finally, it is clear that there is no consensus on the direction industry and orthopaedics are headed in the near future.

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UPOJ: How has your relationship with industry changed over the course of your career?

MRB: I had no relationship whatsoever with industry for the first 6 years of my career; I had no financial/consultant relationship through the first 13 years; at that point I began consulting, speaking, and my role in product design ramped up, and then down over the next 10 years. At one point it was a substantial relationship, with this income representing nearly one third of my clinical income. Very recently, since March of this year, I have NO financial relationships with industry again, and this has been by my choice.

JMF: Early in a surgeon's career, the role of industry is generally to provide service and support as you build your surgical practice and to provide some sponsorship so you can attend educational courses and stay at the top of your game. One thing residents and fellows rarely appreciate is how rapidly they must adopt new procedures and skills throughout their career; industry often provides one of the best ways to do this. As a surgeon enters midcareer and gains prominence, industry will begin to pursue the surgeon to teach at its surgical training courses. These courses can be outstanding opportunities to work alongside other leaders in the field and stay at the very forefront of your subspecialty. A small amount of

compensation for teaching these courses allows the young surgeon to offset some, but certainly not all, of the loss in income from closing his or her practice to teach. This loss in income is never subsidized by CME courses such as those put on by AAOS or our subspecialty organizations. If the surgeon becomes a national figure, and has some expertise in understanding the direction of the field and a sense of how to innovate and create new products, the final step in this relationship would be to design products to help patients and improve care. I moved into product design a few years ago, and moved away from teaching in courses, as the teaching is now perceived as a very large conflict of interest, while designing products and getting royalties (as long as you are not promoting those products you design) is considered "intellectual property", and is acceptable, for now.

JDH: I never received royalties or consulting fees from industry. Occasionally I naively gave advice on product development or collaborated with industry scientists in scientific projects.

LSL: I think it has been a pretty steady state through my career. I have never, for ethical reasons, engaged in any activity that would be counted as a conflict of interest with industry. I've had a relationship in terms of licensing patents, but have always done this through University policy of whatever University I have been engaged with at the time. My first obligation has always been to the universities I have been with rather than to the device industry.

RWS: My relationship has not really changed at all. The companies, however, have changed their relationship with surgeons, primarily because of the Deferred Prosecution Agreements developed as a result of the then N.J. Attorney General Chris Christie's probe of the Orthopaedic Device manufacturers. These agreements have severely limited the amount of education, teaching, as well as design work, that can be performed. The new compliance rules, which industry must follow (while Congress may for example, continue with legal insider trading), are at this point seen as draconian, as they have had the unintended consequence of stifling innovation in these large companies.

PJS: I've never had a relationship with industry.

PT: Early in my career I gave away intellectual property with no reimbursement as I enjoyed being involved with improving implants. Over time I have realized that surgeons should be compensated fairly for their contributions in product development.

ARV: I have less interaction now with industry in terms of helping educate surgeons and with scientific development projects.

UPOJ: How do you think the orthopaedic community views surgeon-industry relations? How do you think the rest of the medical community sees those relationships? The lay public?

MRB: I think the orthopaedic community understands the issues and the lines one should not cross; the other medical fields, I think, are somewhat envious of the opportunities and therefore judgmental. The public, I think, can be easily swayed by the viewpoint of the messenger they happen to hear.

JMF: The surgeon-industry relationship has been dramatically tarnished by a few bad actors whose exploits have been reported in the New York Times, the Wall Street Journal, and some of our national news shows. In the business world, it is standard practice to take your clients to sporting events and dinners, etc. as part of normal business. In medicine, we are expected by society to follow the highest human ethical standards (much stricter than businessmen, lawyers, politicians, teachers, clergy, and others). Surgeon industry relations are very, very different than they were when I started practice in the 1990s.

JDH: There is more suspicion of selected surgeon involvement with industry and there has been great surprise at the amounts of compensation received by a relatively few surgeons. The field of orthopaedics is looked down upon by others in medicine because of the large sums of money received in the last 15 years. I think the lay public has mixed reactions, most lay people still have a relatively high regard for orthopaedic surgeons.

LSL: This has been an ongoing problem subject to public scrutiny for a long time. Recently, the New York Times and Wall Street Journal, the Philadelphia Inquirer, have all been full of articles—with people we know well—a very telling sign that this relationship has not been above the board for a long time. And now the DOJ is trying to regulate this, very appropriately. I think the issue is to try to balance the opportunity for physicians to be entrepreneurs and benefit their practice and also continue to innovate for the benefit of their patients, and mankind.

RWS: The truth is that engineers can design, but without surgeon input the devices are not useful. The surgeon knows what is needed, but cannot build it alone, nor does the surgeon have the funds, or regulatory and manufacturing expertise to bring a product to market. Therefore the collaboration is of critical importance. I believe that the orthopaedic community understands this. They know that industry innovation is important. They understand that no matter how well an implant performs, there are limitations with all current devices, and that innovation will truly improve outcomes. Our lay public looks to the companies, and design surgeons, to develop the new technologies. While they have no real understanding of how this works, they correctly expect that whatever innovation is offered them, is safe, tested, and performs as advertised.

PJS: Since the Chris Christie DPA with industry, the "in-bed" relationship changes. Relationships now are

much more based on industry representatives advising in the OR. Orthopaedic consultants are fewer in number, probably receiving less compensation, and are working to earn their money. I do not think industry-orthopaedic surgeon relationships were ever an issue with the rest of the medical community and lay public.

PT: Orthopaedic surgeons, who work hard with industry to improve or design implants, understand the tremendous amount of work that goes into these projects at the expense of things like family time and vacations. They see the relationships as real partnerships that improve patient care. Other surgeons, and others in medicine who do not participate in these activities, tend to look down on them as if the surgeons are getting something for nothing, which could not be further from the truth. Non-surgeons have the additional challenge or discriminating between the development process for implants and the standard consultancies in the drug industry. Surgeon designers are necessary to create the most effective implants, whereas consultants for drugs have far less to offer in terms of development.

ARV: The orthopaedic community views the relationship as a necessity, other medical societies in suspect, and the lay population with indifference.

UPOJ: Are you familiar with the AAOS Standards of Professionalism (SOP) and do you think they are sufficient enough to keep a surgeon's relationship with industry ethically sound? What would you change in the SOP, if anything?

MRB: I am reasonably familiar with the SOP, but not enough to suggest changes.

JMF: The AAOS SOP is on target and ethically sound.

JDH: They are sound but they have done little to change behavior. I do not know what I would change.

LSL: I am aware of them, and of course have read and signed them. These came into existence out of necessity, to help address the crisis of confidence between the public and ourselves. The SOP have been extensively vetted by the leadership in our field, the Academy and the AOA, and I believe in the principles they espouse.

RWS: The AAOS SOP is a good start. I would hope that everyone in medicine would inherently understand these, as physicians are ethical by nature, it is the basis of their profession, after all. One of the real dilemmas is that what is perfectly acceptable in most industries in the U.S., is not acceptable in medicine, because physicians, hospitals, implant manufacturers, and insurance companies receive Medicare payments from the U.S. government. Because of these funds, a constant set of regulations and administrative rules are developed that change with each election cycle. It becomes very hard to understand how something that once was acceptable, suddenly is not, when nothing has changed but the seats in Congress.

PJS: I am familiar with the SOP: the AAOS penalties are well intended but perhaps not stiff enough. The only way to eliminate illegal relationships would be at the level of the State Medical Board—with loss of licensure—and that is not going to happen. The ABOS has no regulatory power, it only certifies.

PT: It is a reasonable standard. I would leave it as is.

ARV: I think the AAOS professional guidance rules are working and helpful.

UPOJ: Does industry support the educational or research mission of your residency or fellowship program? What benefits and consequences do you see in this relationship? What impact does industry have on your residents and fellows?

MRB: Yes industry does support education for our residents, and I believe the net effect is definitely quite positive. The one major drawback I see is actually the sense of entitlement the residents acquire: most would not even dream of spending their own money to learn something to benefit their career.

KJB: Industry does support our residency, and this relationship has evolved in the last several years: we went from having a loose policy to a strict policy with industry. We had historically allowed the device companies to provide broad sponsorship in the form of textbooks, conferences, travel, etc., until about three years ago, when we changed to be in accordance with the new AAMC/ACGME guidelines. Then we entirely stopped that practice. But now we are back to doing it on a case-by-case, review-mediated process. A resident submits a request, and then the faculty vote on whether they approve or not. We have entirely freed our grand rounds, journal clubs, et cetera from all industry sponsorship, but we will allow industry to pay for courses in the appropriate setting.

JMF: To a dramatic extent, industry has pulled out of resident and fellows support. They now play little or no role, compared to a very significant role when I was a resident and the young attending.

JDH: No, they do not support our residency. Thus, their impact is virtually none.

LSL: They do support both our residents and fellows; I wish we did not have to rely on them but it is a necessary evil. We cannot make it on pro-fees alone to send our residents to all the great courses that are available. The industry groups who support education with unrestricted educational funding really should be commended for what they do to enhance resident education.

RWS: Whether the industry is "complying", or whether they have used the compliance rules to save a significant amount of money is difficult to say, looking at it from the outside. It is true that the new implant tax will affect corporate discretionary spending. The recession, as well

as high insurance co-pays, and confusion as to the future direction of health care in the U.S. have resulted in lowered revenues as well. If revenues go down, to keep profits the same or growing, overhead must be slashed. The bottom line is that the companies no longer see the same "value" in supporting the educational or research mission of academic programs. While these programs are truly beneficial, in most situations, industry has been told that these sorts of program support initiatives are probably in violation of the new compliance rules anyway, so this funding has, for the large part, dried up.

PJS: Yes, and this leads to better educational opportunities for our residents and research support for orthopaedic clinician scientists. I believe the relationship between residents/fellows and industry is positive and healthy. Our residents and fellows benefit from courses and labs from industry—however, there is no question there is a component of industry marketing during any educational event.

PT: We used to receive scholarships from multiple companies and send residents to courses that were industry supported but independent. We can no longer do this and it has a hugely negative effect on resident education. There is NO funding for these activities now for most centers, so it must come from clinical revenue at a time that this revenue is drastically decreasing, necessitating difficult discussions with faculty as they are essentially paying out of pocket to send residents to courses.

ARV: Industry does not directly sponsor fellowship or residency training but does provide a research grant for CME for learning.

UPOJ: What is your impression of the four-way relationship between surgeons, vendors, patients, and hospitals? How are the relationships of any two of these parties influenced by the others?

MRB: The "four-way relationship" is a disaster. In the current system, surgeons have no reason to reign in cost, and hospitals have no reason to invest in anything that would offer long-term benefit for patients. The patients and the vendors are not the culprits.

JMF: The four-way relationship varies greatly depending on the specific hospital. In my environment, surgeons are given wide latitude to select the best products for their patients, while being as cost-conscious as possible.

LSL: To optimize this relationship, we are trying to maximize contribution to health care systems, which means lowering costs of implants. There will be certain times when a surgeon may have a clear preference for an implant, and in that case, that implant is the one that should be used and purchased by the hospital; but if not, then the lowest bidder should win—if the technology is equal. In that case, the health system and physician benefits from reduced cost, and also the consumer and the public, who avoid worsening in terms of rising cost of healthcare.

RWS: With respect to hospitals, they need to get a handle on costs so they want to desperately make all the products commodities (which they are not—some products are simply better than others). The only way that companies can survive the recession and the downward price pressures demanded of them by hospitals is to downsize their work force. Furthermore, as more and more surgeons are forced into hospital employment (one of the stated goals of Congress is to end fee-for-service medicine), doctors will have very little say regarding product selection. Most of the decisions will be made between hospital buyers and the large companies, who will heavily discount their implants, and downsized their sales force to stay in business. In the future, I predict that for-profit hospital chains, such as HCA, will dominant the national landscape, and they will have only two implant manufacturers to deal with.

PT: Each affects the others. The individual hospital situation dictates how these relationships go. As an aside, it is my experience that patients, when informed that the surgeon has designed the implant they will have, gain more confidence in the surgeon as they understand that not all surgeons are able to design. It gives them a tremendous sense of security and they express the general emotion, "Wow, I'm in the right place."

ARV: Surgeons should not be involved in hospital decisions on purchasing if a conflict of interest (COI) exists. Hospitals, through surgeon consensus, should strive for value in implant selection. Every decision should be focused on the highest standards with regard to patients' wellbeing.

UPOJ: Are physicians in academic practice relatively more shielded from industry pressures?

MRB: I don't know what pressure industry exerts, so does that mean "yes," as I am in academics?

JMF: In academic practice, we are not more shielded from industry pressure, but we are under much more extreme scrutiny by our institutions, colleagues, and professional organizations.

JDH: The administrative restrictions now in place in most universities limit unrestrained behavior more so that occurs in private practice.

LSL: No, I think we have more industry pressures, because we are always working in partnership with the health systems to get the best bid. If you are in private practice, it is easier to get implants you want irrespective of costs, because you call your own shots.

RWS: I am in private practice so I do not really know how to answer that. However, only very few people would work to design and develop revolutionary products where their University received 100% of the royalty stream from that product. It is somewhat un-American I would think…

PJS: No—if I had to GUESS, I think industry proportionally has *more* relationships with academic health care centers and academic orthopaedic surgeons than community orthopaedic surgeons.

PT: Less shielded, as academic surgeons' income is substantially less.

ARV: Physicians in academic practice are not more shielded from industry pressure.

UPOJ: How do you see the role of industry in the future of orthopaedics?

MRB: I think the role of industry will have to shift to be more formally at "arm's length" from practicing surgeons.

KJB: It is in our best interest as a profession to have a true firewall between surgeons and the device industry; we need to work collaboratively to optimize the safety and efficacy of new medical devices, but at the same time we need to ensure that we are delivering value to our patients and not using our relationships to influence the way the device companies negotiate with hospitals.

In their defense, they are publicly traded companies with responsibility to their shareholders. There is no return on investment if they make a donation to a group like the OREF. If a company funds a course to expose residents or surgeons to their products, however, that is money well spent from the perspective of the shareholder. They should be able to direct their money, but we need to do our job and make sure that the value gets delivered to our patients appropriately. Going forward, we as surgeons will need to work collaboratively with hospitals and device companies to drive "positive sum competition" in the form of higher value care for our patients.

JMF: With declining reimbursement for medical products and greater competition, industry will likely pullback from contributing to surgeon education to the extent it does now and has in the past. There will be increasing efforts to wash industry donations through organizations, which will function to collect then award the same money, but at arm's length.

JDH: We must find a way to preserve the role of the "surgeon-inventor" in orthopaedics or improvements in patient care will slow dramatically.

LSL: We need a better way to advantage physician inventors; with accountable care organizations (ACOs) coming on line, there have to be closer relationships, but how we do that is difficult to answer in this forum.

RWS: It depends on how you define "industry." The metal companies will merge or be acquired so that only two or at most three will remain. To stay competitive they will strip down their sales force and sell the product as commodities. This will create tremendous price pressure on them. As their profit margins decrease, it will have a significant impact on their fixed costs – most notably R & D—which they will cut or eliminate altogether. The only innovation the traditional companies may spend real money on going forward will be in orthobiologics. This whole industry is just evolving now. But I suspect that these products will be so heavily regulated, and so costly to produce, that only the pharmaceutical companies will develop them.

Is there a "silver lining" in an otherwise dark and cloudy sky? Orthopaedics cannot stagnate, it lives on innovative solutions to real problems. I believe that this will now come from the "start-ups"—exclusive design houses that can provide "proof of concept" solutions. This is where the real innovation will come from—small groups of forward thinking, entrepreneurial surgeons, who can fly under the radar and develop a product for relatively little cash outlay. This may in the end be a good thing, we shall see!

PJS: I think orthopaedic surgery and industry MUST have a relationship. The devil is in the details—how does the government or our profession regulate this relationship to get the best from both worlds? Industry flourishes on profit; orthopaedic surgery needs funding for education and research; society needs better and safer products.

PT: My hope is that they will be willing and supportive partners with surgeons to advance the care of our patients.

ARV: Hopefully industry will provide a vital educational role in surgeon training.

Thus, the role of industry in orthopaedic residency remains a shifting one, with individual surgeons and residency programs determining their own relationships with the device manufacturers. A clear understanding of the forces involved and awareness of the various motivations all parties bring to the table will only help residents as they enter into this world, and begin making important decisions about the treatment of their patients. Federal support or increased resources from Health Systems may impact the "need" to have orthopaedic industry involvement within graduate medical education.

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