Spine surgeons: spine industry

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Spine surgeons and the spine industry are intimately related. There has been a significant amount of bad press and some apparent Academic/Medical Society repercussions and/or negative aspersions when research is reported which has been supported from industry grants [7, 8, 10, 11, 14, 16]. My bias is that industry funds are not (or need not) be bad, or seen as tainted.

We are currently seeing decreased funding available from US (and possibly other) government research funding organizations. There is decreased money in Academic Medical Centers to support the basic academic requirements such as teaching, let alone money for pilot studies [1]. Clinical revenues are decreasing, monies which some physicians (private practice and/or University based) use in their group to support research.

Consulting from industry is reasonable if we are paid for our time and our input [3, 9]. These consultations should be value added and a win-win for the consultant and industry. It should not be monies that are for junkets or lures to use the equipment (unlike the practice by many US politicians). Many very strong academic US centers have a long, important, history of industry relationships [1]. These can be worth millions and for the most part have been productive and useful for training, education, and supporting research, much of it translational.

Industry funds can add “practice enhancers” to those able to accept them and use them appropriately. Consulting arrangements can be good for Academic Medical Centers to help keep faculty [3]. Often US Academic Medical Centers with geographic full-time faculty provide lower

salaries than community physicians receive and this can help improve department resources. Monies can be used to support assessment of clinical outcomes, laboratory projects, salaries for research residents and clinical/research fellows. In some cases it may go to the department to support educational efforts, improving the ability to train medical students, residents, and fellows. The support may allow the physicians/researchers to give papers at meetings and become more visible, enhancing their academic prestige [10].

The interdependence/interworkings between spine surgeons and spine industry are multi-factorial. These interdependencies include the development of new technology, advancements in spine research, medical education, and patient education efforts [3, 9]. There are, of course, potential negatives [1]. The amount of money paid to the consultant, or to the medical group, should not be related to the volume of products used. The volume of use of implants, devices, or products, should not lead to changes in the “consulting” agreement, particularly when there is no real consultation performed. Though the research presentations may be favorable towards a company product, it should be honest and not relate to the financial support. Good research could lead to more funding for more research and perhaps clinical support, if the research is cutting-edge and useful to all involved.

In addition to industry and surgeons, there are also shared interests with patients. This, too, can lead to real, or potential, conflicts. Industry’s primary goals are business success and customer support for increased sales. Physicians are primarily interested in patient care, practice success, advancing and enhancing skills through education, and (particularly for those in academics) advancing careers [2]. The working relationship between spine industry and spine professionals should greatly advance patient care,

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and my premise is it has and will. Industry is not purely greedy or purely altruistic, and physicians are not purely altruistic or purely greedy: the devil is in the detail. There are similar goals that both industry and physicians would see as success if accomplished. These include: maintaining high standards, improved patient care, being financially successful, and continuing to learn through research and education.

New technology has to, and will, continue to develop. This, however, requires interaction between industry and professionals. There are information exchanges and decisions that need to be made to move a device or product forward. In general, medical professionals have a sense of what is needed; so do knowledgeable, cutting edge, industry representatives. Industry, more than physicians, knows what technology is available or coming. Professionals, however, may have access to technology in other areas of research that may be valuable. Professionals are the only ones who have access to patients and can assess the outcomes. Clinical research protocols and clinical trials requires physician, greater than industry, input, but that reverses as the product moves out of protocol stage into wider development. Money for clinical, or basic science, research is primarily from industry and to a limited extent from professionals through medical societies or by groups taking money from their clinical income and placing it in a research pool. Only physicians present clinical papers; industry can support the work, but not readily have papers accepted. Education is a shared area, both by industry and professionals in terms of supporting meetings and workshops, presenting new technology and techniques. Marketing is the milieu and strength of industry, usually not professionals.

How does a new product develop? An idea leads to a design on paper (this can be through physician or industry leaders). Then a decision has to be made: Is this worth while? Often this is a shared decision, with both sides working on it. If it is worth while investors are enticed to provide funding and a physician panel has to be created to assess the device and develop clinical research protocols for the implant or drug. This is then vetted through a scientific advisory board. Once it is ready for clinical trial, protocols are established through the SAB with some industry support, more physicians are recruited for the trials, and then the results have to be collated, assessed, presented, and published. Then it is time to bring this to the FDA, and once through it, Medicare and insurance companies. Once these are approved, sales can begin and formal, open, education of physicians can occur without restrictions for the labeled (approved) use of the device/product/drug. This process has some interest conflicts.

The investors want financial returns. The scientific advisory board members want rewards, including

consulting time fees, possibly stock-options if they spent a significant amount of time/effort in helping develop the device, and involvement in the study through presentations and publications, which leads to prestige by the academic and physician communities. It should be remembered, however, that for the most part members of the scientific advisory board also, and perhaps primarily, are interested in improving patient care and solving a clinical problem [12].

As the product develops, and if the clinical results are encouraging, there are issues related to presentations and publications. Most academic medical/surgical societies require disclosure of conflicts (such as stock-options, consulting fees, research grants, outcome specialist funding, institutional or personal/personnel support, etc.) [1, 3, 9]. Is a mere disclosure enough? Does saying “I received money from Company X” mean you have now made a full disclosure and that the results you are describing are more honest, or tainted, depending on the listener? Do those giving the disclosure state what they may be getting from another arm of the company to avoid having to disclose what is related to this particular product? The wording of the “disclosure” can camouflage the truth, but hopefully not. It is because of this possible camouflage and/or the fact that industry money appears in some people’s minds to be “tainted” that once the disclosure is made the validity of results may always be questioned by some.

The clinical researcher is in a somewhat difficult position. If the results are positive they want rewards, particularly in the early phase. Developers of the product, and/or members of the SAB, want academic recognition, but increasingly medical societies and CME accreditors feel that clinical studies should be done and reported by those who are not rewarded financially; but who will do that work? The developers and SAB members do not want to give to others what they have done. Many of those doing the clinical work, particularly establishing and doing clinical trials, want to be rewarded financially, since often there is no billing allowable for a research study/new product, as well as academically.

How can these issues be separated? Industry is aware of these conflicts and through AdvaMed and other groups is trying to minimize the negative interactions. Increasingly, industry is trying to keep studies and research “clean”, but they still have to promote, sell, and get the studies done and published, aware that disclosure of financial associations may taint the study. Why is this? How many people will do the early work, if not rewarded financially, since there may be time spent with no real gain; and who cares more than those involved early (both from industry and physician sides). On the other hand some physicians not invited into the trials early may become mad, insulted, angry, and try to denigrate the studies, perhaps for selfish (jealous), rather

than purely scientific, reasons. Some medical societies ask in their disclosure statements to identify the role of the implant designer. How much time, effort, and thought from the physician presenter went into the design and how much went into other activities that were rewarded as a “member of the design team”. How can new products and techniques advance, without the inventor who knows it best and is most enthusiastic about it, and how can it advance without a committed scientific advisory board? The industry behind the product is vested in it and also is committed and enthusiastic. The clinician/researcher developer becomes an entrepreneur, promoter, possibly head of the scientific advisory board, and perhaps as this develops could become head of the company and the designer of the protocols. With all this self-energy, how can clinician researchers stand aside? That is a difficult question with no answer other than: they can not.

Industry’s responsibility in the process is to make the best product possible, and make it the safest. They have to get it through the FDA by following rules, developing approved/rigid protocols, help develop the studies, and supply an often (un)limited amount of money. They are also involved in the education of physicians and patients related to new products, and they must sell the product staying ahead of the competition.

Research funding may come from a number of sources [17]. Government funding (in the US, examples would be NIH or VA) has a number of advantages. These include: it creates stability; it allows the PI to be innovative; it offers the PI a breadth of research experimentation; and the peer review process is rigorous. There are, however, a number of disadvantages. These include: submitted proposals are lengthy; the review is rigorous, often making it difficult for M.D.’s to compete against Ph.D.’s; funding is limited and decreasing; many quality proposals are given good scores but not funded; the money goes where the budget describes, which may be politically directed; and the pilots must be done somehow. The latter are usually not funded by NIH grants; they must come from either industry or using leftover money, perhaps from other grants (perhaps using money for projects that were not on the original budget). Another source of research funding is industry. The advantages, compared to Government agencies, include: shorter applications; they are easier to obtain, though the amount of money is often less; it allows flexibility in categories of lab expenditures; and they are most helpful for pilot studies. The disadvantages include: they are “less innovative” in that the PI often has to answer specific questions; there is a strong commitment to the contract, so again less innovation is allowed; the PI must sign a release of the patent which may conflict with their university or hospital expectations/contract; disclosure forms must be checked before all presentations; and many

companies expect an option be given to the company to review data prior to the presentation or publication [1]. All of the disadvantages, of course, lead to “challenges” and “issues” during presentations and publications that are industry supported.

Science depends on openness. Early presentation is often encouraged. Industry, however, may want to delay the presentation to get/enroll more patients and more patents set. Physicians may want to delay the presentations to get grants approved before others learn about it [1]. With presentations funded by the NIH, papers are easily accepted with no boxes to check, and often are looked on as “pure”, but are they? How does one get refunding through the NIH? Not with primarily negative results, but with positive ones. If the results are negative is the money returned to the NIH? Or do the researchers tend to put a positive, or at least neutral, spin on the results? [8] Shah and colleagues [13] wrote that industry funded studies report positive results more often than non-industry. They found that non-industry funded studies had 50% neutral results while industry funded had only 20% neutral results. Their conclusion was that the results can be biased by study design, experimental technique, and or result interpretation; and this is more likely in industry than government funded projects. However, that may not be the case. It may be that early, industry funded limited clinical trials have too few patients with too short follow for publication, but the results are encouraging and positive. This leads industry and the PI to pursue larger enrollments, knowing beforehand that they can anticipate positive results, as they are known from the early trials (which were not published because they were too small with too short follow up). So one would assume, therefore, that the larger study would be positive because if it was negative the project would have been dropped by the industry and the PI at the first stage. Also, related to this, if the results of the clinical trial are poor and the project (implant/drug) dropped, why publish it and who would care if you tried to publish it? Maybe these are some reasons that industry funded studies are mostly positive. In contradistinction, any publication by an academician is worthwhile (for their personal CV) so a neutral study is at least useful, even if it does not help with NIH renewal.

Continuing Medical Education also leads to significant interaction between physicians and industry [4, 6, 12, 15]. Physicians need: basics, updates, new advances, understanding of new techniques/drug, and what is coming in the future. Industry desires to assure “clinical benefits” of a product by having physicians use it right, and that techniques/doses are understood and used/performed correctly. In this regard industry likes to start educating early [16]. One example in recent times is Kyphon which helped develop educational symposia at many national and

international medical/surgical society meetings related to osteoporosis. This occurred years before anti-resorptives were fully available, or Kyphoplasty was cleared by the FDA. Waiting until everything was approved could have delayed that industry and the treatment of osteoporosis (anti-resorptives and percutaneous vertebral augmentation) many years. Therefore, Kyphon started early, in anticipation of good clinical outcomes based on early clinical trials helping/encouraging the development of educational symposium on osteoporosis (patho-anatomy, biology) through the entire medical-surgical treatment spectrum; and who has the podium?, Physicians.

The Accreditation Council for Continuing Medical Education developed guidelines in 1992 that stated “Commercial exhibits should not influence planning, or interfere, with a CME event” and that “Funds should be in the form of an educational grant”. However, commercial support of CME is commonplace. Industry provides more than one half of reported funds to support CME courses in the United States [16]. This is due to financial constraints on physicians and medical societies [6]. The 2006 guidelines have toughened and in some cases prohibit anyone with industry funding from presenting a paper, or being a PI of a paper presented, if CME credit is given. Physicians need CME, industry wants to support CME, both want to interact and learn what is new and needed [15]. One alternative for direct support of CME meetings could be that industry supplies money to medical societies for guest lectures, support meetings, and support events; but who is invited? It is unlikely that it would be someone anti-industry or anti-surgery (if a surgical society). It is more likely it will be someone positive, supportive, knowledgeable, and friendly to the topic and friendly to the industry providing financial support, or they may stop that support to the society in the future. In that sense who selects what occurs and who is invited? It should be the Society with no restrictions from industry, but that may not always be the case.

Patient education is an increasing challenge. More educational tools and handouts are expected. More are available through the internet. Who provides this? Is it the physicians’ office, the internet company, hospital, medical society (aka “industry”), or true industry? It is often industry, distributed through the physicians’ office and internet sites.

Is the relationship tainted? Is it overblown? Are only those not involved with industry pure and their research clear and clean? Richard Lieber, Ph.D., Professor of Muscle Physiology in the Department of Orthopaedic Surgery at UCSD stated “I think it is absolutely critical that we form strong, long, and functional ties with industrial partners. It is hogwash to say we need them for our money and they need our research facilities. We are very good

experimentalists and they are outstanding manufacturers and marketers. Together, these are extremely powerful forces for progress. If both sides respect the talents of the others, you can’t beat the combination.” (R. Lieber, Ph.D., personal communication 2005). I agree with those statements. Biomedical research funding in the United States went from 37 billion in 1994 to 94.3 billion in 2003. However, 50% of research funding comes from industry (and is increasing) [5]. The 1999 NIH monies for basic research were \$17.8 billion, and industry support for clinical research was \$22.7 billion (listing only the top few reporting companies). There was more if all company funding was included [5]. In 2004 NIAMS, a branch of NIH, gave approximately \$499,417,000 for research. Orthopaedics only received \$126,680,000 of it. The rest went to the other specialties in NIAMS. At that time the priority score was 154. In the year 2005 NIAMS provided \$507,755,000 of which orthopaedics received only \$114,000,000. At this time the priority score was 150, making it more difficult to expect to get money as there was less of it and the scoring was more rigorous (particularly for M.D. clinicians). Industry, on the other hand, has increased funding, but the price is increasing scrutiny (which by itself is not necessarily bad).

The FDA clinical requirements now expect new products to “beat the gold standard”; “no worse than” does not routinely work. There has to be proven medical and economic benefit, but one has to do expensive, potentially risky, studies to decide. These are long, costly, and challenging. The future brings even more financial implications when biologic products and manipulations become dominant with these clinical products passing implants. These lead to perhaps even longer-term studies. In that sense, how long does one follow patients to determine any biologic consequences, and who funds that? Other expenses include the cost of randomized controlled trials and necessity for two-year (or longer) follow-up for publication and often FDA approval. Who supports those studies? Who supports the follow-up? Who collects the data? Who does the reporting, and who provides the coordination for multi-center studies? The obvious answer is industry, though in some recent trials the NIH is becoming, fortunately, involved.

Separate from the funding, who does the work? Private M.D.s, academic medical centers, the developer/venture capitalist, medical societies, industry, or government.

In the United States expectations from patients is that they will get well quick, there are no, or few, significant risks, as there is government oversight. It is assumed the M.D.s get paid, and if things go wrong one can always sue. In other countries, however, the expectations are to help patients (instrumentation is provided when otherwise the patient may have to pay for it) and the physicians gain

(patients, prestige, and international relationships). There is often less government oversight than in the US. Lawsuits seem to be rare and the reporting standards are not always as rigorous as in the US.

There is, also, the company/physician partnership that has to be looked at from a legal perspective. The relationship between industry and physicians is critically important. Companies can not develop and introduce new and useful technologies and backing without clinicians. Physician inability to interact fully with companies will delay, potentially indefinitely, the introduction or improvement of technologies. The relationship between industry and physicians is being increasingly scrutinized: (a) subpoenas for orthopaedic and cardiac companies, investigating potential violations of US anti kick-back laws based on company-physician relationships, (b) adoption of restrictive codes and policies by governing organizations, (c) prosecutions of drug companies, (d) eroding public trust in the medical industry due to recent recalls such as malfunctioning products (pacemaker recalls), malfunctioning drugs, and corporate scandals. There are relationship restrictions seen in the laws (e.g., anti kickbacks, false claims), professional societies codes of conduct (AdvaMed, AMA, etc.), internal company codes and policies, hospital codes and policy, OIG and JCAHO guidelines, contractual provisions between corporations and M.D.s, and our own internal ethics.

There are a number of considerations that must be kept in mind. Physicians and companies must be aware of the restrictions on the relationship, or risk investigation and enforcement. Both must learn from the misstep of others. The potential for short term gain with questionable payment/conduct may be outweighed by the risk of longer-term consequences. Both parties have responsibilities that can not be ignored. Of note, the stronger the relationship between the company and the M.D., whether it is through the prominence of the position (senior advisor, technical support, advisory board), the volume of business from the M.D., or the total consulting fees paid, the relationship is more likely to be subjected to scrutiny. While one questionable transaction with a single doctor may seem innocuous, the sum of small violations can cause immeasurable damage to a company's reputation and future. If business is conducted it must be documented. Companies can not afford to risk their futures based on questionable demands of a few physician consultants; and physicians cannot afford to work with companies that overlook the existing restrictions. There is an ethical responsibility to set an example by all actions and interactions.

Related to the above, recent events are of concern. The US government has subpoenaed records from many (if not all) orthopaedic companies to determine if any broke the

law in collaborating with surgeons by providing “money”, meaning direct dollars, trips, entertainment, etc., without direct consulting obligations or other development/benefits to the company. The concern is that surgeons who are highly compensated by industry and high-volume users (selecting only one or two companies in their clinical armamentarium) will be next. To complicate this, many hospitals want physicians to limit implants to one or two companies; but the government may choose to investigate physicians who have limited their use to just one or two companies. So then are we investigated because we helped “choose” the companies for our hospitals and institutions? Go figure!

From this long, sauntering editorial, and the homework that went into it, I can provide a few conclusions and observations.

The money for basic science and clinical research will increasingly come from industry, less so from government. Industry may have to fund at a much higher level, fewer, but better studies that prove the new intervention/therapies efficacy over the gold standard, with an excellent safety profile and economic benefit. Industry will spend a lot to gain solid data from a well-organized, efficient, research/clinical and basic science facility. Studies performed in poorly regulated markets will come under fire. Researchers in highly regulated markets may eventually have the best access to research money. Medical societies could/should play larger roles by coordinating studies, enrolling participants, providing peer review, and funding (how do they get the money?). In the process there will be short-term losers, but the process must start.

Unfortunately, there is a downside to medical societies as they are often seen as “lobbyists” for industry (medicine is an industry of physicians). So does this help, or hurt, to have funding through medical societies? In the future industry studies will be more coordinated and perhaps there will be fewer, but larger, studies. NIH, hopefully, will fund large clinical studies, but few.

In my view research money from industry remains important, significant, and growing to some degree.

AdvaMed, a group composed of many implant companies, developed voluntary, self-imposed guidelines for proper collaboration between surgeons and industry. AdvaMed attempts to prevent collaboration to be dominated by “money”, where “money” in this case equals resort based meetings, expensive dinners, surgeon entertainment, gifts, etc. The government feels money (like power) corrupts. I feel research funded by industry, done with M.D.s, can produce outstanding ways to treat patients. We need to work together in all phases. We need to work out the arrangements, the ethics, the pass-through, and the reporting. None of this is, or will be, easy, but it cannot be ignored, and need not be negative.

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