Orthopaedic surgeons and the device industry: skeletons in the closet

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Abstract

The relationship between orthopaedic surgeons and the device industry is one that is mutually beneficial and productive. However there are skeletons in the closet. The financial implications of this relationship have come under intense scrutiny. The sponsorships and the financial benefits of this symbiotic relationship have been found to cross the boundaries considered acceptable to ethical practice of the profession. In India, the ethical transgressions resulting from unhealthy associations between the orthopaedic surgeon and the industry have yet to be given due importance. Adequate rules and regulations are yet to be enforced and self-regulation is practically non-existent. It is essential to deal with the problem and potential implications that can arise from this kind of misconduct at the organisational level and enforce them for compliance.

Some years ago, a major conference was held in a metropolitan city. I was part of the conference, as a delegate and an in-house organising member. I was to share a room with a colleague of mine who lived in interior Maharashtra and had a flourishing practice. I reached early, a day before the conference, as was my need owing to my responsibilities; my friend turned up early next afternoon, gushing with enthusiasm and energy, despite an overnight journey and an emergency surgery the night before. He opened his bag and exclaimed: "Ah, look at that!" There were three bottles of the choicest liquor and a book of tickets to all the tourist destinations in the nearby area. The cell phone jingled and he took the call. It was the local representative of "company ABC" asking if "sir" was comfortable and if he had any needs. "Sir" surely wanted a vehicle and a trip to the nearest five star discotheques. Could he arrange something special for him? And so it went on and on. In the lobby of the conference halls, as is so very common, the representatives stood all over, blocking the paths, fawning over their favourites and ignoring the rest. It doesn't take a genius to know who is sponsored and who is not. My friend was quite clear: "If I can use his stuff without questioning him at all, why shouldn't I reap the benefits?" I was surprised to know that the said company was one whose quality and manufacturing practices were dubious and there was a definite question mark on their marketing ethics. It was quite clear that many people did not share my concerns.

The pharmaceutical industry and its nexus with the medical profession have been in the focus for quite some time. The earliest example which hit the public realm was the Thalidomide controversy which occurred some decades ago. The drug had been promoted with scant attention to its potential side effects, with disastrous consequences.

The orthopaedic industry has a large turnover in terms of surgeon-specific and patient-specific services. It supplies implants, instruments, and other products required for patient care. The industry develops products and guides research which is applied by the surgeon who has then to use the developments to benefit the patient s/he treats. This is essentially the same pattern as in the pharmaceutical industry. The industry, the surgeon and the patient exist as individuals and in the process of dealing with the industry, conflicts of interest may arise for the surgeon and create cause for concern to the patient.

A recent case that has created a lot of interest is the case of hip resurfacing. Described as the best alternative restoring optimal function in the hip, the success of the Birmingham hip prompted many more big players to enter the market. Intense media hype and web advertising sent the business soaring. In India itself the numbers of hip resurfacing implants used have seen an exponential increase in the last few years; the data is unavailable but a casual look at conference scientific programmes is enough to understand which procedure is being performed most frequently. A technique-specific surgery, it has been heavily promoted by the industry with in-house training programmes and workshops sponsored at all major conferences.

A few months ago, concerns were voiced about two of these implants in the United States, and early unacceptable loosening was reported by a very senior orthopaedist. The Articular Surface Replacement (ASR) and the Zimmer Durom cup hip implant were under scrutiny. The implants were immediately withdrawn from the market (1).The Birmingham hip continues to be used under strict quality control and evaluation by a group of surgeons trained intensively in its use.

The issue has hardly been seen -- I suspect not seen at all -- in Indian media reports, whereas in the USA, groups of lawyers have already started suing the concerned companies and surgeons. These implants were used by a large number of surgeons in India, and their use was promoted intensively by the concerned manufacturers with well-attended training programmes and sponsorships. The ASR had been withdrawn from the Australian market in December 2009 and the adverse drug reaction reports in the USA started much before that.

Prior to this case, the case of the Sulzer hip implant, where early failure occurred due to manufacturing issues, was much debated in the media. The DePuy website (2) says:

> DePuy has just received new, unpublished 2010 data from the National Joint Registry (NJR) of England and Wales. The

> data shows that the five year revision rate for the ASR(tm) Hip Resurfacing System is approximately 12 percent and for the ASR(tm) XL Acetabular System is approximately 13 percent. These revision rates are across the entire size range. The risk for revision was highest with ASR head sizes below 50 mm in diameter and among female patients.

Today, the story for patients with this implant is disturbing. They received the implants in full faith, paying large amounts for their surgeries. Many of the surgeons were influenced by the companies after attending seminars, workshops and fellowships. Now that the implants have started failing, the futures of thousands of patients are in jeopardy. How many surgeons implanting these products in India actually went back to their patients to inform them of these problems? Probably none, as it would mean that the patient would lose faith in the doctor and blame him. It would be better to wait for the implant to fail and then say it was inevitable and then do the revision. Surgeons claim that they are on the development panel of many companies but when one scans their presentations at symposia, the conflict of interest statement is missing. The DePuy site has no names of surgeons outside the United States in their statements of doctors receiving honoraria.

A recent paper in the *Archives of Internal Medicine* (3) examined the 2007 disclosure statements of physicians from five major implant manufacturers and compared them to the disclosure statements in their publications. Of the 40 people who received in excess of one million dollars in honoraria in 2007, 32 published scholarly articles, and non- disclosure rates remained high (46%) amongst first-authored, single-authored and senior-authored articles; it was almost 50% in articles directly or indirectly related to payments.

Furthermore, it was found in the sample that, of the 27 authors who had more than one article, four authors consistently mentioned the company, 14 were inconsistent mentioning the company in some articles and nine did not mention the company payments at all (3).

This has put in question the reliability of authors in stating their conflicts of interest, a procedure which has been made mandatory for all academic events and publications.

In 2004, The United States National Institutes of Health (NIH) effectively banned all consulting and advising by NIH employees to biopharmaceutical firms and even supported research institutions and healthcare insurers and providers. This included both compensated and uncompensated work. A study of the responses to this move (4) examined the publishing rates and the frequency of external relationships amongst NIH scientists.

The study showed that almost 52% of faculty had some form of GIR (government industry relationship) prior to the introduction of these rules. About 43% of these faculty members felt that this relationship contributed to their most important work at the NIH. Interestingly, the industry relations also demonstrated negative relationships amongst the faculty. Many of the faculty felt that the presence of relationships with industry adversely affected the research of these scientists and that there was a tendency to conduct non-original research and a reluctance to share information and data. The restrictions placed by the new regulations did not alter the publication rate amongst the faculty. However, there were many who felt that the regulations did affect the morale and the efficacy of many scientists.

Conflict of interest: the American tale

The American Academy of Orthopaedic Surgeons (AAOS) on its website says (5):

> When an orthopaedic surgeon receives anything of significant value from industry, a potential conflict exists which should be disclosed to the patient. When an orthopaedic surgeon receives inventor royalties from industry, the orthopaedic surgeon should disclose this fact to the patient if such royalties relate to the patient's treatment. It is unethical for an orthopaedic surgeon to receive compensation of any kind from industry for using a particular device or medication. Reimbursement for reasonable administrative costs in conducting or participating in a scientifically sound research clinical trial is acceptable.

Now, what is acceptable and what constitutes a conflict of interest is entirely self-determined. The ability to determine what is right or wrong also rests with the user. The orthopaedic industry has its vested interests in influencing its surgeons to prescribe its products. The industry is a corporate enterprise and will run on the strength of its sales figures rather than having patient satisfaction as its goal. The first step in achieving its corporate targets is to influence the prescribing surgeon in order to increase sales. This is so commonly seen in the orthopaedic scenario. Whenever a new product or implant is launched, all the surgeons in this speciality are called and asked to try the product. A demonstration is organised by a senior or imported surgeon. Junior surgeons are also invited and the grapevine goes abuzz on the purported benefits of the said product, and on the basis of repeated symposia and word of mouth, the surgeon is coaxed to try the product. Benefits accrued are of course gently woven in as reminders, if not by the manufacturer then by the dealer. The evidence is presented as one or two articles and charts which business-minded surgeons hardly have time to peruse.

They select the implant on the basis of costs and benefits given to them by the dealer. They may often buy a cheap implant saying that the patient can't afford expensive implants; they buy them even cheaper, as the margins are higher with a particular implant, and sell them at a higher cost. They may stick to a manufacturer who takes them on "de-stressing" holidays and conferences in exotic locales. They forget that the substandard implant that offers them an above-average return will probably provide some of their patients with a below-average result. That's where the problem lies. We forget that in this business, the patient is the consumer and it is the patient

who has a lot at stake. For short-term gains, the long-term losses to the patient may be immense.

Fortunately, as was observed in a Department of Justice Investigation in the United States, most relationships between the orthopaedic fraternity and the industry are legitimate (6).

Dr Alan Rankin, a former president of the AAOS rightly said: "We believe that a cooperative relationship benefits patients. Orthopedists are best qualified to provide innovative ideas and give feedback, to conduct research, to serve on scientific advisory boards, to serve as faculty to teach new technology and we rely on industry to bring new ideas to fruition. (7)

In 2005, the Department of Justice in the United States issued subpoenas to five major orthopaedic device industries -- DePuy, Zimmer, Biomet, Stryker, and Smith & Nephew. The investigation, spearheaded by Justice Christopher Christie, aimed to investigate inappropriate relationships and dealings between orthopaedic surgeons and the manufacturing industry. These included consulting agreements for questionable work, gifts, meals for lectures, continuing medical education (CME) programmes in luxury resorts, and payments for using specific implants (6). The entire history and ramifications of this move were immense and were covered in detail by Healy and Peterson in the *Journal of Bone and Joint Surgery* in 2009 and this is probably the only comprehensive orthopaedic review of this extremely important event. Stryker was subjected to a non-prosecution agreement and the others were put under a deferred-prosecution agreement. The five companies preferred this to criminal prosecution and losing their license to supply joint implants to the multi-million markets for joint replacement. Companies were forced to rewrite their corporate policies and re-examine their arrangement with the orthopaedic fraternity. There was no admission of guilt and it was clearly stated that the conduct did not in any way construe any infringement of patient rights. There was a huge financial settlement and, under a Federal Monitor, the companies were expected to restructure and re-assess the physician needs on orthopaedic education and product development. Public posting of financial arrangements was made mandatory and it can now be found on these company websites. The investigation extended to individual orthopaedic surgeons and also institutions which received benefits for using joint implant products.

Over the next few years the impact could be felt on all interactions with the pharmaceutical and manufacturing industry, including freebies, meals and sponsored activities within educational institutions. This had a visible fallout on academic sponsorships and product development activities. Fellowship sponsorships were kept in abeyance pending decisions to sponsor academic activity through a third-party organisation like the OREF and the OMEGA (Orthopaedic Research and Education Foundation, Orthopaedic Medical Grants Association).

Healy and Peterson (6) summarised the impact of the Department of Justice investigation as manifold. Prior to the investigation, they had called the orthopaedic surgeon and industry a successful business model leading to educational opportunities, new product developments and opportunities for funding young orthopaedic surgeons involved in research. The investigation actually stalled this model and slowed down product developments and evaluations and also decreased opportunities in orthopaedic education. On the positive side, reorganisation of businesses, endorsement of so-called "fair-value" payments to surgeons and adopting standards for relations between the surgeon and the company are important favourable outcomes. A decrease in trust and change in favourable business and professional relationships has also been an unfavourable outcome of this investigation (6).This paper by Healy and Peterson is probably the most unbiased and detailed study of its kind to date.

Isn't medicine a business too?

Medicine is a sacred calling for most of us. We took up medicine primarily because of love for the profession and interest in patient welfare.

> Somewhere along the way to achieving a practice based on compassion and ethical evidence-based medical science, comes the realization that it is also the means to make a living. This becomes a rather difficult situation, wherein one has to be humane and, at the same time, deliver the highest standards of care and make money too. This equation is never as challenging as in the field of medicine - hence the difficulty in viewing doctors as one would view another professional. Isn't the doctor just another guy trying to do his job? Isn't this his "business" too? (8)

The business of orthopaedics or the business of money has major connotations. Patient welfare is paramount in our minds whereas the business of making money surely cannot take a backseat. Whereas physicians' payments in private consulting rooms are pretty much a matter of the physicians' choice, certain limitations do accrue with the combination of corporate hospitals, which have different revenue-sharing models, and medical insurance payoffs, which are paltry.

The unequal distribution of payment among the surgeon, the hospital and the pharmacy (which deals with the implants and consumables) leaves the surgeon at the losing end. Additional income from payoffs from implant manufacturers and dealers comes as a necessary temptation in times of need, especially to young orthopaedic surgeons. It then becomes a matter of right and is demanded as an essential to practice, like kickbacks for referrals. The vicious cycle continues with more demands from the surgeon and more gifts from the companies and dealers. With the mushrooming of small dealers and smaller implant manufacturers, the struggle for survival has become more acute in our country (India). There are cheap copies of almost any implant in the market, and benefits accruing to the surgeon who uses these implants range from local conferences and small trinkets to paid holidays. The pharmaceuticals are no better; but these are better known than the device industry and its dealers.

The public is not blind to the surgeon's rapid accumulation of wealth. It knows fairly well that there is more to the neighbourhood surgeon's affluence than meets the eye. This is yet to hit the media's attention as much as in the West. The hounds that wander near the nursing home and the clinic rooms, and wait with a very humble attitude, are proof enough that touts exist in the professional arena.

Of late, it has become a business indeed; groups of surgeons are booked by implant manufacturers for conferences and meetings in the guise of workshops. Recent scrutiny has humbled, but not tamed, a number of these multi-nationals. The same event continues, but a carefully worded disclaimer is shown to the surgeon and signed over cocktails, to absolve the company of guilt. The game still goes on as before. When will we learn that education is best imparted to us by our fellow orthopaedic surgeons at our own meetings? We do not need to be herded as groups to be trained in what we already know. The sham of sponsored CMEs proves beyond doubt the influence of corporate sponsorship on orthopaedic education. The case of CMEs on the same topic by the same surgeons in different cities attended by almost similar groups of surgeons (who later become "educators") is again eminently exemplified by the field of arthroplasty.

We may say that we are not influenced by the glib talk and the freebies, but at the national conferences, look at the line in front of the stall offering the most "free gifts". There is enough evidence to prove that any inducement, however small, can influence prescription practices (9).

We must not forget that these conferences do catch the public eye, doctors being shepherded around in sponsored buses with company banners and lavish five-star dinners with no holds barred, and entertainment thrown in as a surplus. Enough must be seen and registered in the public mind. The fact that not much has come out in the media shows the immense respect the profession still receives in society.

Making money is good, but it can be made in legitimate ways. There are relationships with the industry that have been legalised and acceptable, provided one declares the conflict of interest appropriately. Corporatisation is likely to induce and provide temptations to its consumers to promote sales. Humans, by nature, succumb to greed. In the absence of adequate legislation, the doctor has become the scapegoat. What should have been the exception has become the rule, when all the doctor has done is act as per human nature. What is being touted as education and recreation by the corporate entity is nothing more than a commercial exploitation of the medical professional. The need of the hour is for the doctor to put the brakes on this juggernaut. And what better way than to enact appropriate rules and legislation? These are lacking in our system as of now. We need to regulate and reform ourselves first.

The first steps need to be taken by professional organisations in formulating codes of conduct.

A code of conduct: the American way

The American Academy of Orthopaedic Surgeons (AAOS) has formulated a model code of conduct regarding the relationship of its members with industry (5). In the fallout of the Department of Justice investigations, the American Orthopaedic Association, the Association of American Medical Colleges and individual states came out with their own policies on relationships with the industry (6). There are guidelines to industry funding of academic activities, publishing of industry-sponsored research and academic activities and stringent conflict of interest policies. The AAOS in its guidelines says that (5) the patients' interest is paramount and that any gift that is accepted by an orthopaedic surgeon should entail a benefit to the patient, and should not in any way influence the choice of therapy for the patient. Gifts with any kind of strings attached are strictly to be avoided. Social functions without an educational element are best avoided. The AAOS condemns in general any industry-sponsored social event. Cash gifts are to be neither proffered nor accepted. As for CME events, underwriting of expenses for CME events where CME credits are provided can contribute to patient care and are acceptable. Subsidies are acceptable if disclosed and content of CME is not under industry control. The industry shall not provide direct or indirect support to any surgeon to attend any educational event. However, faculty expenses and honoraria for educational events where CME credits are provided are appropriate. Learning new techniques may need industry-sponsored on-site learning but this should not entitle honoraria for time off or any condition that the surgeon adopts the particular instrumentation or technique. Scholarships may be provided for surgeons-in-training provided selection is determined by a course director. Consultants' expenses and honoraria are acceptable when genuine services as faculty in educational symposia are provided. Token attendance and casual mention of a product device does not justify receiving travel and lodging and other subsidies. Careful scrutiny is essential, and payments, which must be declared and legitimate, may be appropriate. The AAOS specifies that a symbiotic relationship between the orthopaedic surgeon and industry is desirable and is necessary to provide trials, research, product developments and improvements. Inappropriate relations include receiving a consultant fee for simply attending a meeting, receiving remuneration for using a particular implant; and receiving consultant fees or other financial inducement for switching from one manufacturer's product to another (5).

The Academy has therefore put in perspective what is appropriate and what is not. In the code of ethics summarised above, it is essential to appreciate that the most important criterion laid down is that orthopaedic surgeons must strive to improve patient care continually, through every endeavour, and that they must collaborate with industry in a positive manner to achieve that end. Conflict of interest can occur at both institutional and individual levels and must be disclosed whenever appropriate.

Needs of the hour

The positive role of the industry in orthopaedic surgery, practice and education cannot be ignored. One cannot put aside the fact that a symbiotic relationship between the industry and the surgeon spurs new product developments and new techniques within the easy reach of the practising surgeon. Academic surgeons can conduct their activities also with industry support. One, however, should not perceive the subtle underlying persuasion to use specific products as an act of good will in exchange for favours received. When it comes to patient welfare, we are obliged by the noble profession we practise, to be judgmental only for the patients well-being, not our own. We must establish a self regulatory set of guidelines and enforce them, as an example, to ensure maximum benefit to our consumers -- the patients. We need to avoid being swayed by needless small and big temptations to prescribe and use substandard equipment, to ensure long-lasting and sustainable results. To achieve this, we need to be enabled and empowered by our peers, our professional organisations. The Indian Orthopaedic Association, along with its state counterparts must lay down a model code of ethics and ensure its compliance, before an event like the Department of Justice investigation hits our members. The government has a major role to play in cutting the unethical practices of the manufacturing industry. It has to enact checks and balances on industry sponsorships and make the industry accountable for its behaviour. Educational institutions must also play an active role in curbing industry influence. Training of future residents must be free of industry influence so that they learn to act by informed and trained decision and not financial benefits. This ethical mindset needs to be inculcated in the training period itself.

The path has already been laid down. The Indian Association of Pediatrics conducted a no-sponsors conference in Mumbai some years ago. The Mahatma Gandhi Institute of Medical Sciences (MGIMS) at Wardha, in Maharashtra, discussed ways and means of keeping the drug and manufacturing industry out of academic activities (9). It was decided that equipment manufacturers and drug companies would not sponsor any workshop, conference or CME at MGIMS. The institute would underwrite part of the expenses; the rest would come from delegate fees, grants from the Medical Council of India (MCI) and government funding agencies. This model had hosted two state conferences in obstetrics already at the time that Kalantri published his paper in 2004 (9).Whilst it is unknown whether the model survived, it is worthwhile understanding that it is possible to exist without industry influences and be empowered to make our choices freely.

A scan of the websites of the professional societies of doctors in the country shows that such guidelines have not yet been posted.The MCI however made sweeping changes in its policies and laid down stringent guidelines for professional conduct in relationships with the industry (10). It leaves no ground for any ambiguity and, unlike the AAOS guidelines, does not specify any grounds for "reasonable" practices. It lays down what the doctor should not accept and lays down penalties graded by the amount of graft money accepted by the practitioners. Accepting more than a lakh of rupees as gift money entails being struck off the council rolls for more than a year. This is a landmark amendment to the Council rules, but its efficacy is limited by the fact that the MCI as a quasi-judicial body has limited legal powers. The threat of bans and deregistration should, however, be a strong deterrent to unfair practices. It is worth noting that within the pharmaceutical industry in India, the Organisation of Pharmaceutical Producers of India came out first with its own new code of ethical marketing practices in 2007 for self- regulation in this important area. (11)

Whereas regulating doctors and the industry is definitely desirable, it is essential to see that the mutually beneficial educational and developmental research activities between doctors and the manufacturing industry are allowed to go on, for the obvious benefit these updates provide to the end consumer, the patient. It is necessary, however, to qualify what programmes would come under the purview of acceptable activities. This definition would need hard thinking and would lead to some disagreements; but can be ironed out eventually. The American Academy of Orthopaedic Surgeons has recommended in its code that those CMEs which have credit points may be included in this category. Similar changes can be instituted at our level also.

After the MCI, it is the turn of professional bodies like the Indian Orthopaedic Association and the Association of Medical Consultants to lay down specific ethical guidelines as also a policy of self-regulation to control professionals, as well as the industry at large. This, in time, will reverse the current state of affairs.

Maybe we will pay for a few more meals, a few more pens and a few more family holidays, but in the end it will mean a peaceful night's sleep and money well earned and well spent. Patient decisions and implant choices will have no external influences and informed decisions will rule. That is what matters in the long run and it will yield well sustained long term gains.

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Ethical aspects of the Revised National Tuberculosis Control Programme

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Abstract

This paper identifies some ethical concerns regarding the Revised National Tuberculosis Control Programme (RNTCP).

Only 10% of those with chest symptoms visiting public health facilities get specific treatment as they are diagnosed with TB. The remaining 90% who suffer from non-TB diseases are not given scientific treatment. This compartmental approach denies treatment to millions of people with chest symptoms. It has also eroded the popularity of public health facilities.

Second, though 87% of those diagnosed on the basis of x-ray alone are unlikely to have TB, such unethical wrong diagnoses continue to be carried out under the TB programme. Still worse, the RNTCP's expectation that only half of TB cases should be smear positive effectively permits up to 50% of diagnoses to be wrong. The actual extent of wrong diagnosis is even higher as the majority of people with chest symptoms first visit private health facilities which base their diagnosis almost exclusively on radiological examination.

Third, though 25% to 33% of TB cases get cured spontaneously, and at least two-thirds were cured even with incomplete treatment, the RNTCP insists on full treatment for all TB cases. This over-treatment is unethical, wasteful and also tantamount to scientific dishonesty. Studies to identify different categories of cases (those needing full treatment, short treatment or no treatment) have not been attempted. The introduction (under the RNTCP) of the "success rate" in preference to the well recognised "cure rate" was unethical and unwarranted. "Crying wolf" over Multiple Drug Resistant (MDR) TB to justify DOTS when there is no apparent alarming increase in the incidence of initial MDR tuberculosis cases is also questionable.

Other ethical concerns about the RNTCP include the irrational choice of districts leading to exclusion of those that need the services most; exclusion of diagnosed patients from the DOTS scheme, and exclusion from treatment on non-medical grounds. Such exclusions can be up to 58% of TB cases.

Introduction

The Revised National Tuberculosis Control Programme (RNTCP) (1) was initiated in the early 1990s. This paper identifies some ethical aspects of the programme for discussion.

A compartmental approach

Case finding under the RNTCP is based on the diagnostic examination of outpatients with complaints of chest problems visiting health facilities, mainly in the public sector. Even if case finding (as designed under the RNTCP) is totally successful, not more than 10% of these chest symptomatics (CS) seeking relief, who alone are likely to be suffering from pulmonary tuberculosis (TB), can be diagnosed and treated. The programme has nothing specific to offer to the remaining 90% of sufferers who are knocking at the doors of health facilities with chest problems. Is it ethical to continue, year after year, to deny proper treatment to millions of such persons seeking help, on the ground that the RNTCP is expected to give relief only to those suffering from TB? This compartmental thinking and approach have led to large-scale denial of specific treatment to millions of people who suffer from chest symptoms but who do not have TB. What makes it even more unethical is that no serious attempts have been, or are being, made to overcome this gap in services. This has eroded the popularity