EDITORIAL

Current trends in the relationship between orthopaedic surgeons and industry

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It's a very common scenario: a patient needs a knee arthroplasty and his/her surgeon picks one from Company X. Before the operation he/she reads a report identifying the surgeon as one of the inventors of the implant and a key consultant for Company X. He/she goes to Company X’s website and finds that Company X paid the surgeon £20 000 last year. Now, does the patient: trust the surgeon and go ahead with the operation using the same implant; ask the surgeon to explain his choice of product?, or find another surgeon? Patients and surgeons increasingly face this dilemma.

The relationship between surgeons and industry for the purpose of research and product development provides great benefit, but, also raises questions. The surgeons are paid for this work to compensate for their time and expertise. Having been involved in the development of a device, a surgeon is likely to use it to treat his patients. Is this reassuring for the patient or a cause for concern? It should be reassuring, as all doctors have a primary duty of care to their patients. An additional step is full disclosure of the relationships to help patients and hospitals make informed choices.

Increasingly, and perhaps understandably, governments are challenging the potential conflicts of interest that arise from these relationships. Similarly, physicians and the medical industry wish to mitigate this potential conflict of interest in order to continue collaborating to advance surgical technology.

At the same time, the public is understandably concerned by, and suspicious of, any interaction that could create a conflict of interest between the independent medical judgement deserved by the patient and the monetary reward received by doctors through consulting payments, royalties and grants from medical device or pharmaceutical manufacturers. In order to prevent the erosion of public trust, both industry and physician associations are redoubling their efforts to adopt strong compliance programmes and transparency where these relationships are concerned.

Substantial industry settlements in 2007 after United States Government investigations have been an impetus for increasing scrutiny in this area. These settlements were with five major orthopaedic device manufacturers for a total of $311 million. The government found that most payments to physicians were for legitimate services, but alleged that in certain cases companies received little value or only minimal work in return. In this debate about the risks associated with collaboration between industry and physicians the essential role that physicians play in the research and development of technologies that improve and save patient’s lives is often overlooked. In most instances, doctors enable advances in medical technology by testing and often co-inventing new medical devices with experts from industry. They are also a fundamental part of the process for the training of their colleagues in the safe and effective use of new or improved medical devices. Although a rigid separation between industry and medicine might eliminate a conflict of interest, it would also result in a decline in innovation and the successful use of new devices, to the detriment of patients.

Some steps that might be taken to maintain the critical relationship between industry and doctors, while mitigating the perceived potential conflicts include the following: Controls. Compliance programmes within the industry, hospitals and professional bodies should provide effective safeguards to ensure proper controls are in place. Most companies that market orthopaedic implants have established standards for interaction with surgeons, and train all their relevant employees to those standards. They also regularly monitor and audit their activities to ensure compliance. Similar programmes are being implemented by hospitals and the professional bodies. The American Academy of Orthopaedic Surgeons, for example, at its last two annual meetings, held seminars on the relationship between industry and physicians as part of an educational initiative.
Transparency. Appropriate disclosure, both to patients and to the public of payments made to doctors can also raise public trust. A few implant manufacturers currently disclose on their websites payments made to health-care professionals who provide consulting services. Likewise, doctors are now usually required to disclose to patients and publishers any significant funds received from industry that might reflect a conflict of interest and introduce bias.

As a result, some doctors are seeing changes in the ways in which they have worked with industry in the past. Consulting arrangements undertaken by implant companies, including the selection of the surgeon, the required service levels and the amount of payments, should now be determined independently of the sales process. These arrangements are planned in advance on an annual basis, assessed for fair market value, and subjected to review by senior managers and compliance officers. Grants and fellowship which could benefit a doctor may be made either through an independent foundation or given after scrutiny by a grants committee, with safeguards to ensure independence and the best interests of the patient and the provider. Some hospitals, as may be seen from the quarterly disclosures by orthopaedic companies, have all payments made to surgeons paid directly to them. Interactions outside the clinic or operating room for business meetings are also standardised across the industry to ensure professional standards are met and maintained.

In conclusion, the relationship between doctors and medical device companies is benefited by compliance programmes and increased transparency and disclosure of payments. Innovation, product design and surgical techniques should proceed against a backdrop of good controls and transparency, and all relevant information should be available to allow a patient needing a knee arthroplasty to choose his or her surgeon with confidence and comfort.

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