FEATURE

R.E. Field *PhD, FRCS*
Consultant Orthopaedic Surgeon
& Director of Research
South West London Elective Orthopaedic Centre,
Epsom General Hospital, Epsom, UK

A. Shimmin *MB BS, FRACS*
Director of Melbourne Orthopaedic
Group Research Foundation
Melbourne Orthopaedic Group,
Melbourne, Australia

L. Cattani *BA*
Chief Executive
Eucomed
Eucomed,
Brussels, Belgium

Orthopaedics and industry:

an uneasy alliance?

The need to demonstrate probity and fair market competition has increased scrutiny of the relationships between orthopaedic surgeons and the industry that supplies them with their tools and devices. Investigations and judgements from the US Department of Justice and the introduction of the AdvaMed and Eucomed codes have defined new boundaries for interactions between these groups. This article summarises the current interplay between orthopaedic surgeons and industry, and provides recommendations for the future.

The ability, integrity and independence of orthopaedic surgeons to identify and undertake the best treatment for their patients is increasingly challenged by hospital managers, healthcare insurers, patients and the media. The need to demonstrate probity and fair market competition has also increased attention to, and scrutiny of, the relationships between orthopaedic surgeons and the industry that supplies them with their tools and devices.[1-5] Investigations and judgements from the US Department of Justice[6] and the introduction of the AdvaMed[7] and Eucomed[8] codes have defined new structures, processes and boundaries for interactions between these groups. While these changes are intended to protect all parties from wrongdoing, they also alter the nature and practice of collaborations that have underpinned the development of orthopaedic surgery over the past fifty years. This is a period that has seen the development and evolution of fracture fixation, joint

replacement, arthroscopic surgery and the naissance of orthobiologics. While it is widely recognised that this spectrum of technologies has delivered interventions that are among the most successful and provide the most dramatic quality of life improvements in the history of medicine, it is less clear how co-operation between orthopaedic surgeons and the medical devices industry has contributed to these developments. This paper reviews and reflects on the benefits and pitfalls of relationships between surgeons and the orthopaedic industry.

MARKET CONSIDERATIONS

Market analysts currently value the annual global orthopaedic market at around US$30 billion (£19 billion).[9] Historically, the US market has accounted for approximately half of the global orthopaedic spend.[10] The US, Europe and Japan remain the three most valuable orthopaedic markets but the development of Chinese and Indian economies is gradually altering this picture. The fastest-growing segments are orthobiologics, spinal and trauma. The markets for reconstruction, implants and arthroscopy equipment remain dominant segments and continue to grow at more modest rates. Growth of the orthopaedic market is driven by the ageing population, the growing demand for joint replacement at an earlier age, the increasing incidence of obesity, the development of new devices and the development of new surgical techniques. Long-term social and demographic trends indicate that the market will continue to grow until at least the 2030s.

Across all specialties, collaboration between surgeons and industry is required to develop new treatments and surgical techniques. Ideas conceived at the operating table must be articulated by surgeons, understood by engineers and, when commercially attractive, developed by industry. New devices, instruments and implants must be subjected to rigorous, preclinical, laboratory testing and careful clinical evaluation. The development of a new implant can take ten or 20 years with setbacks and false starts en route to a successful product. Whether a true innovation or simply an incremental improvement, the surgical community must be informed of new treatment options and be able to evaluate their potential benefit. They must also be trained to undertake new procedures safely and effectively. The latter necessitates education programmes. Historically, it has always been left to industry to resource and organise such training.

Fifty years ago, inventive and entrepreneurial pioneer surgeons were renowned for machining new equipment in their garden sheds.

INNOVATIONS AND COMMERCIAL RELATIONSHIPS BETWEEN INDUSTRY AND SURGEONS

To an outsider, the interplay between industry and surgeons may be interpreted as interactions between vendors of surgical hardware and purchasers of these goods. Indeed, from a patient, health insurance or hospital administrator's perspective, the surgeon is spending their money and it is reasonable to ask whether the surgeon is using his or her knowledge, experience and expertise to channel these resources in the most effective and cost efficient manner.

In practice, peer-reviewed publications, medical registries and the Internet enable patients and healthcare purchasers to scrutinise manufacturers' claims for their products, the qualifications and performance of surgeons and the outcome of different treatment options. Such data also facilitate the identification of surgeons and products with poor results. Recent experience with certain metal-on-metal hips has demonstrated that surgeons and implant manufacturers will be held to account through media exposure and the law courts when treatments fail. In this environment, it would be a foolish surgeon who failed to stay abreast of developments in their specialty or adopted unproven treatments for personal gain.

Fifty years ago, inventive and entrepreneurial pioneer surgeons were renowned for machining new equipment in their garden sheds. In the current era, surgeons seeking a role in the development of new products and treatments can involve themselves in several different ways:

1. A new idea may be both innovative and have commercial potential. Through scientific work

Surgeons and industry must demonstrate that their interactions improve clinical outcomes and benefit patients.

and persistence, an inventor-innovator attracts the interest of industry and a device is produced which becomes a milestone in the development of orthopaedics. Müller, Ling, Hungerford and Spotorno have all conceived, developed and disseminated new implants and surgical techniques that have achieved global adoption and changed the history of orthopaedic surgery, in this way.

2. A minority of inventor-innovators is sufficiently committed to start their own company. Successful examples include Zweimüller and McMinn. Such ventures are typically based on a product that is considered high risk by the established manufacturing companies. If the new product proves successful or attracts a significant share of the market, an established orthopaedic company will purchase the innovator's company and absorb the new product into their own portfolio. In many regards, this process parallels the global trend of established, high-tech companies reducing their internal spend on research and development in favour of purchasing third-party innovations that are deemed to have commercial value.

3. The most active areas for involvement of orthopaedic surgeons in new product and treatment development are those of incremental innovation implementation, vetting and clinical validation. Such work is generally undertaken by advisory, developmental, educational and clinical evaluation consultancies.

Implant manufacturers typically appoint surgeon advisory boards of established opinion leaders to keep abreast of changing attitudes among the orthopaedic community and to gauge how new product ideas and strategic developments may be received. Companies are now obliged to make public the names of their advisory consultants and the amount that the consultants are remunerated for their services. This information can be found on the company websites.[11-13]

The same rules apply to surgeons who are employed by companies to help develop new products. According to the Eucomed code[14]:

The compensation paid to Healthcare Professionals engaged as consultants must be the fair market value for the services provided and must not be tied in any way to the value of medical devices which the consultants may use for their own practice.

In the event that a healthcare professional can demonstrate an inventive involvement with assignment of intellectual property (IP) rights related to the product in question, the healthcare professional may be able to negotiate a royalty. Typical industry ground rules for royalty payments require that royalties are only paid when IP is assigned.

THE EVIDENCE BASE FOR CLINICAL DECISIONS AND EDUCATION

As hospitals and healthcare purchasers become more attuned to the relative cost and clinical performance of implants, manufacturers need to ensure that they can provide sound clinical evidence to support the purchase of their products. In the UK, the Orthopaedic Data Evaluation Panel (ODEP)[15] assesses the suitability of hip implants for use within the National Health Service (NHS) and is the first real step towards the aspiration of the National Institute for Health and Clinical Excellence (NICE) that tax payers' money is only spent on products of proven safety and efficacy.

From industry's perspective, the involvement and support of recognised opinion leaders is critical to the adoption of their products. University departments may be contracted to undertake pre-clinical studies and high volume or high profile clinical centres may be supported to undertake clinical trials. The results of such studies will be reported through scientific congresses and peer-reviewed journals

As evidence accumulates to support the use of a particular implant or surgical technique, the company supplying these products will wish to maximise dissemination of this information. While there is a growing trend for direct marketing to patients, this strategy is still viewed with some disdain and "surgeon education" remains more acceptable. Many companies employ a speaker bureau and use opinion leaders to moderate, chair or present at company-sponsored meetings. Other educational roles that may be commercially supported include teaching on a surgical skills course or mentoring a fellow surgeon who is learning a new technique or procedure.

While a small number of acclaimed educational meetings have been organised by surgeons with sponsorship from industry, the majority of industry-sponsored meetings are events at which a company will present selected products in the most favourable light. The perceived blurring of the boundaries between the educational and marketing meetings will always be open to criticism and the place of industry-sponsored meetings will undoubtedly evolve over time.

Theatre staff training and operating room support is a contribution provided by industry that is often overlooked and inadequately recognised. This role provides theatre staff with invaluable assistance in dealing with an ever-increasing complexity of instrumentation and technology. This type of technical support is quite unique to orthopaedic surgery and if this service were not provided by industry there would be no obvious alternative. In this respect industry involvement clearly benefits both the hospitals and patients.

EVOLVING LEGISLATURE AND FUTURE RELATIONS

As working relationships between surgeons and industry have evolved, so have the complexity and extent of the economic relationships between them. In the early years of this century the ethical probity of these interactions was challenged when a minority, on both sides, was perceived to have exceeded acceptable boundaries. These relationships became the subject of an extensive enquiry by the United States Department of Justice. Five of the leading orthopaedic companies were indicted for violations of the Foreign Corrupt Practices Act (FCPA) and four of the five were given heavy fines (approximately $300 million). The companies were also required to sign a 'Deferred Prosecution Agreement', imposing a probation period of almost two years. For an 18-month period, all marketing, sales, and scientific initiatives were vet-

ted and could not be implemented until approved by a Department of Justice appointed monitor.

Regulations are now evolving to ensure that relationships between surgeons and industry are robust and compliant with ethical standards that demonstrate absence of inducement. The Advamed[7] and Eucomed[8] codes have permanently changed the relationship between surgeons and industry and some now argue that the pendulum has swung so far that productive collaborations between surgeons and industry will be stifled.

In our view, the orthopaedic industry and orthopaedic surgeons should be encouraged to share engineering and clinical expertise. Advancement of clinical practice requires the development of new ideas and techniques. Many of these will be conceived and generated in the clinical setting. Surgeons must be able to bring their ideas to industry and industry must be able to share its technologies with clinicians. Surgeons and industry must demonstrate that their interactions improve clinical outcomes and benefit patients. When new devices and treatments are developed, transparent collaboration between industry and clinicians should be encouraged to provide meaningful evaluations with unbiased reporting of the results. When new products and techniques are proven effective, surgeon involvement in peer group training should be encouraged, both to share clinical experience and mitigate learning curves. Finally, just as companies must generate profits for their shareholders, and clinicians who treat patients receive financial reward, those clinicians who advance clinical practice through the development of new devices and techniques should be rewarded. In the rare case that a new device or treatment is adopted into global practice, the reward for all parties will be great.

REFERENCES

1. **Crowninshield RD, Callaghan JJ**. The orthopaedic profession and the industry partnership. *Clin Orthop Relat Res* 2007;457:73-77.
2. **Brand RA, Buckwalter JA, Talman CL, Happe DG**. Industrial support of orthopaedic research in the academic setting. *Clin Orthop Relat Res* 2003;412:45-53.
3. **DelSignore JL**. Current guidelines regarding industry-sponsored continuing medical education. *Clin Orthop Relat Res* 2003;412:21-27.
4. **Wurth GR, Sherr JH, Coffman TM**. Orthopaedic research and education foundation and industry. *Clin Orthop Relat Res* 2003;412:54-56.
5. **Okike K, Kocher MS**. The legal and ethical issues surrounding financial conflict of interest in orthopaedic research. *J Bone Joint Surg [Am]* 2007;89-A:910-913.
6. **Healy WL, Peterson RN**. Department of Justice investigation of orthopaedic industry. *J Bone Joint Surg [Am]* 2009;91-A:1791-1805.
7. **No authors listed**. AdvaMed. http://www.advamed.org/memberportal/ (date last accessed 20 February 2012).
8. **No authors listed**. Eucomed Ethics and Compliance. http://www.eucomed.org/key-themes/ethics (date last accessed 20 February 2012).
9. **No authors listed**. Espicom. http://www.espicom.com/Prodcat2.nsf/Product_ID_ookup/00001955?OpenDocument (date last accessed 20 February 2012).
10. **Wright S**. Global orthopaedic markets: bridging the divide. http://www.globalbusinessinsights.com/content/rbhc0029m.pdf (date last accessed 20 February 2012).
11. **No authors listed**. DePuy Surgical consultants. http://www.depuy.com/about-depuy/depuy-divisions/depuy-orthopaedics/find-surgeon (date last accessed 20 February 2012).
12. **No authors listed**. Stryker surgeon consultants. http://www.stryker.com/meetourconsultants/consultants/consultants.php (date last accessed 20 February 2012).
13. **No authors listed**. Zimmer company consultants. http://www.zimmer.com/z/ctl/op/global/action/1/id/10373/template/CP/navid/10548 (date last accessed 20 February 2012).
14. **No authors listed**. Care of ethical business practice: Eucomed guidelines on interactions with healthcare professionals. http://www.eucomed.org/uploads/Modules/Publications/110504_eucomedcebp_broch_210x297mm_v20_pbp.pdf (date last accessed 20 February 2012).
15. **No authors listed**. NHS supply chain: orthopaedics. https://www.supplychain.nhs.uk/product-areas/orthopaedics/odep/ (date last accessed 20 February 2012).