EDITORIAL

Ethics in orthopaedic surgery

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Medicine, law and religion are the three traditional learned professions. With professionalism should come both privilege and responsibility. As surgeons we study to achieve specialised knowledge and supplement this with training and experience. Our patients and our Governments grant us certain privileges, but expect us to be guided by ethical principles. We set the standards for entry, assessment, training and certification into our specialty and seek to ensure these standards are maintained throughout a professional lifetime. Our patients allow us the right, after careful explanation, to perform operations upon them which cannot be free of potential complications.

Our responsibilities commit us to develop and maintain our skills, to further medical knowledge and to train the next generation of surgeons. We are expected to show altruism and to remember that care for our patients should take preference over personal gain, whether this be financial, social or professional.

It is inevitable that conflicts of interest arise when the aspiration of the individual is in conflict with obligation. Such conflicts may stem from methods of payment, our links with the pharmaceutical and manufacturing industries, our ambitions in both medical and political spheres and our impulse to perform unnecessarily an operation which we do well.

Relman1 in 1984 noted in The New England Journal of Medicine that authors must disclose their financial connections with industry. In 1990 he updated that Journal’s policy2 which prohibited editors and authors of review articles from having any financial connection with a company that could benefit from a drug or device discussed in the article. Most scientific publishers have followed this example.

The Executive of the Pharmaceutical Research and Manufacturers of America (PhRMA) adopted a new code3 in 2002 to govern the relationship of the pharmaceutical industry with physicians. This stated “that all interactions should be focussed on informing healthcare professionals about products, providing scientific and educational information, and supporting research and education”. The code advises: “Nothing should be offered or provided in a manner or on conditions that would interfere with the independence of a healthcare professional’s prescribing practices”. It adds that nominal consulting or advisory arrangements do not justify compensating healthcare professionals for their time or their travel, lodging or other out-of-pocket expenses”. The code allows that “modest” meals, but not entertainment or recreational activities, may accompany informational presentations by companies. Financial support of scientific and educational conferences should go to the conference organisation and not to an attendee directly. Recompense for expenses should be payable only to the Faculty. It is entirely reasonable for companies to sponsor scholarships and fellowships, but the selection process should be in the hands of the academic or training institution. Fundamental to the code is the understanding that no reward should be offered to an individual in return for a commitment to the prescribing of a particular product. Many countries with major pharmaceutical sectors have similar national codes.

Medicines Australia4 has clarified company relationships with the medical profession. The Association of the British Pharmaceutical Industry5 has a clinical trial agreement for sponsored research in National Health Service Trusts. For countries without national codes, two international guidelines may apply: the World Health Organisation’s Criteria for medicinal drug promotion6 and the Code of pharmaceutical marketing practice from the International Federation of Pharmaceutical Manufacturers Associations.7

The Advanced Medical Technology Association (AdvaMed) updated its own voluntary ethical guidelines8 in 2004. Its members recognise that adherence to ethical standards and compliance with applicable laws is critical to the medical device industry’s ability to collab-
orate with surgeons. Product development is based on this close collaboration. Once developed, its evaluation and subsequent safe and effective use depends upon further collaboration. Most of AdvaMed’s recommendations mirror those of the pharmaceutical industry. It encourages support of education and product-related training and allows remuneration of expenses for attending health-care professionals, but not for their guests. It encourages support of bona fide national, regional and specialty conferences. Members may give grants to reduce conference costs and facilitate the attendance of trainees. Grants may also be given to faculty for reasonable honoraria, travel, lodging and meals. The relationship between a company and the surgeon who provides ‘consulting services’ is defined: the services include research, participation on advisory boards, presentations at company-sponsored training and product collaboration. Any such arrangement should be clearly understood, written and signed by both parties. Any gifts must be valued at less than $100 and demonstrably for the patient’s benefit. Members may make donations for a charitable purpose, to advance research or to foster education by surgeon or patient. “It is not appropriate for members to make donations ... to health-care professionals to purchase, lease, recommend or use ... members’ products”.8 In Europe, Eucomed has made similar recommendations.9 Most larger manufacturing companies are voluntary co-signatories but smaller companies may not be.

Blumenthal10 noted the extent of inducements, ranging from gifts to residents to lavish entertainment and hospitality. He commented that on display “are the grandeur and weaknesses of the medical profession”. Studdert, Mello and Brennan11 recorded that the pharmaceutical industry spent $12 billion annually on gifts and payments to physicians. While the apparent conflicts of interest seemed initially to apply largely to the pharmaceutical industry, there has been increasing concern about the relationship between surgeons and the manufacture of implants. Zuckerman et al12 tested their hypothesis that industrial support of orthopaedic research had increased by analysing the self-reported conflict of interest statements at the annual American Academy of Orthopaedic Surgeons meetings at three-yearly intervals from 1985 to 2002. They found a steady rise from 3% to 39% for scientific papers.12 In 1999, only 27% of these conflicts suggested individual as opposed to institutional support; in 2002, this had increased to 43%.

The types of interaction between manufacturer and surgeon differ from country to country. In poorer countries, company sponsorship is almost essential to allow trainees to attend meetings. In some countries, surgeons would not think of paying their own costs to attend educational meetings. The institutional charge for implants varies widely around the world. In some institutions, implant charges are increased to create department funds which may be used to support research and education. For some, further education is supported by the health authorities, while in others the individual is responsible for all costs. Against this background it is difficult to give ethical advice.

Manufacturing companies need orthopaedic surgeons to develop new techniques and conduct well-designed trials of their efficacy. Our local, national and international institutions need financial support from industry to run their educational meetings and research programmes. Transparency in all these dealings is essential. Properly-constituted research and education committees should supervise all meetings and research agendas. Any potential conflict of financial interest should be identified and resolved early, if needs be by an independent expert committee. It must be made clear to all that the participation of industry is to further research or educational goals.

How then should we proceed? In an increasingly critical world none of the three great learned professions has survived public scrutiny without censure. We cannot simply look back to a perfect world where all surgeons were supposedly above reproach and revered. As Associations, however, we should set standards which reassure our patients and confound the politicians into recognising that we uphold those ethical principles that have always guided us. These standards should protect us from public odium and limit the ability of politicians and administrators to interfere in the essential trusting relationship between patient and doctor. As surgeons, our dealings with those industries which provide our medicines and devices must be clear cut, open and defined. Benefits should be a simple recompense for out-of-pocket expense, for the design and delivery of new products, to support the education of our trainees and less-advantaged surgical fraternity and to encourage research, wherever possible through a non-personal institutional structure. Any benefits should be documented and recorded, not just in our own notes, but in our institutions. Our patients should be told if we benefit from the implants we use, whether by royalty, consultancy fee or contract. We should be absolutely transparent in declaring any conflict of interest in articles, research projects and lectures.

Foster13 attempted definitions of ‘conflicts of’ and ‘competing’ interests. He defined ‘professionalism’ as an expectation to have a dominant commitment to serving others rather than to personal gain.13 Conscience is a tender plant and must be nurtured in each of us. We all know when our actions are not solely in the best interests of our patients. Above all our dealings must be seen to be ‘reasonable’. If we uphold our ethical principles, we will pass on to the next generation of surgeons the ideals which are as important as the surgical skills which they develop.

References


