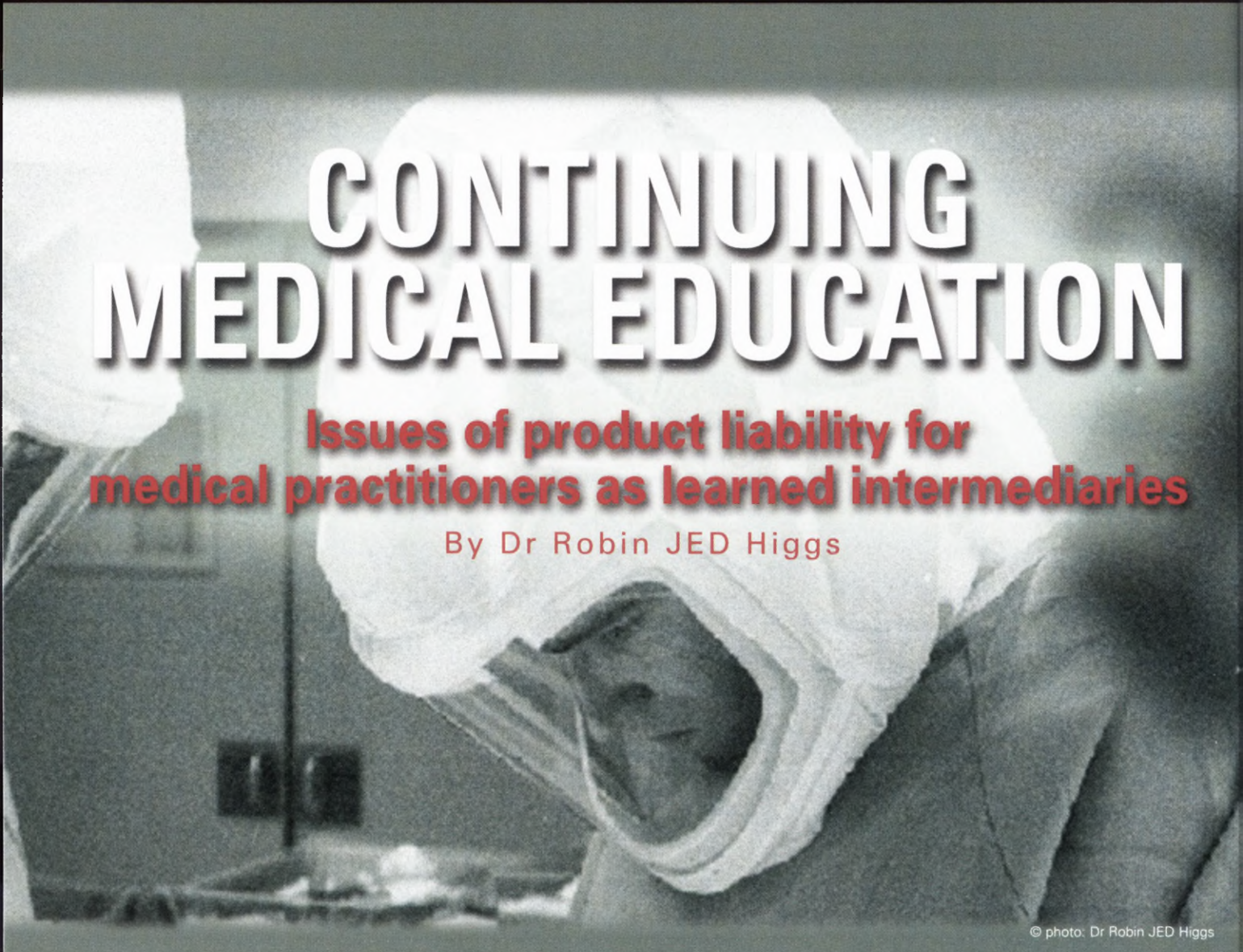

CONTINUING MEDICAL EDUCATION

Issues of product liability for medical practitioners as learned intermediaries

By Dr Robin JED Higgs

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The concept of the learned intermediary has achieved more recognition in the US than in Australia.

In North America, the concept was reaffirmed and developed in a series of cases during the 1970s and 1980s concerning the exposure to liability of manufacturers of prescription drugs.[1] Developed as a rule, the concept originally reflected – through an equitable distribution of tort duties – the tripartite informational relationship between drug (and therapeutic device) manufacturers,[2] medical practitioners and patients. The rationale for the rule is sound, as it represents the specific application of long-established common law principles of intervening cause and intermediate examination already developed and enshrined in *Donoghue v Stevenson*.[3]

When manufacturers place therapeutic products into the marketplace, a relationship is created with consumers,[4] who will generally have considerably less knowledge than manufacturers concerning the risks, benefits, and the balance between the two. This is particularly the case with the surgical implantation of any prosthetic device. For patients (as consumers) to be able to make informed decisions and provide informed consent, manufacturers have a duty to provide warnings of risks and benefits, and any other relevant information that will correct any imbalance of knowledge. The standard of care to be met by manufacturers to ensure that consumers are properly warned is necessarily high. This is particularly so for surgical devices that are implanted into the human body, where the risks can be substantial and at times life-threatening. The greater the risk of harm, the more detailed and comprehensive the warnings and information should be.[5]

Manufacturers of surgically implantable devices rarely have the opportunity to meet patients directly in order to give them information regarding the risks and benefits associated with the use of a particular implant. In this case the surgeon, who is regarded as the learned intermediary, is the 'informational interface' between the supplier of goods (manufacturer) and/or services, and the patient as a consumer. The learned intermediary is the conduit for transferring information from manufacturer to patient, and can fulfil the obligation implicit in a manufacturer's duty to warn. *H v Royal Alexandra Hospital for Children*[6] demonstrated a restricted application, in

Australia, of the concept of the learned intermediary and of the learned intermediary defence. Where the learned intermediary has been provided with all necessary information by the manufacturer but fails to inform a patient of all of the material risks and benefits of a surgical procedure, the manufacturer may benefit from the 'learned intermediary defence'[7] where the product is found to be defective[8] and unfit for the purpose[9] that was intended. The learned intermediary defence should be available in claims based in negligence and under strict product liability legislation, such as Part V Division 2A and Part VA[10] of the *Trade Practices Act* (1974) (Cth) (TPA). The defence is not available in claims based in contract.

The activities and responsibilities of the learned intermediary, though, are far broader and more wide-reaching than the defence and, in Australia, I believe that the role of intermediaries has been much understated.[11] Learned intermediaries have crucial obligations:

(a) the performance of the duty to warn patients (as consumers) giving them access to informed consent and the voluntary assumption of risk; and
(b) the roles and responsibilities of educators and learned institutions when satisfying their obligation of enabling continuing professional education.

The latter role, which has escaped consideration in Australian jurisdictions, is the subject of this paper.

THE LEARNED INTERMEDIARY'S EXPOSURE TO LIABILITY AS AN EDUCATOR

Continuing education is increasingly becoming an obligatory requirement for most professions. It is certainly the case that continuing medical education (CME) is a requirement that is not only obligatory but fundamental to maintaining any registration to continue practising medicine. In NSW the *Medical Practice Act [Principal Act]* 1992 (NSW) requires all registered medical practitioners to make an annual declaration about their participation in continuing professional development (CPD). The Medical Board in NSW expects that every registered medical practitioner will participate in CPD relevant to their practice of medicine and considers participation in CPD to be a good indicator of a practitioner's professionalism and commitment to maintaining an up-to-date body of knowledge and skill.

CME activities are undertaken in a variety of different ways. Individual medical practitioners are under a certain obligation to pursue a process of personal enlightenment by reading journals or undertaking research. And the professional bodies associated with each craft group have obligations to make available and to supervise a program of continuing education that can include lectures, seminars, workshops and conferences. These activities facilitate the presentation and dissemination of information that is current and appropriate to a particular specialist professional group, including aspects of professional undertakings relating to surgically implantable devices. The results of post-market surveillance (vigilance) programs enable product-users and potential users to evaluate the performance of devices that are already in the marketplace.

When innovations are announced, the information provided is frequently of a nature that is at times indistinguishable from a recommendation or an endorsement. In many cases these educational activities are financially underwritten by surgical implant manufacturing organisations and/or by their sponsors and distributors. Many events such as seminars and conferences therefore act as a shopfront for trade exhibitions that are, at times, not unlike a boat or motor show. Most of these activities are generally organised ethically and with transparency, but some sponsored surgical-society meetings and other legitimate CME activities have been described as not very different from 'tupperware parties'[12] that are designed to sell surgical implants, and to enrich clinician-presenters, manufacturers and sponsors (distributors).[13]

It is logical, and not unreasonable, to assume that those involved in presenting, administering and endorsing scientific information at CME events have an informational advantage over those medical practitioners who are attending for educational purposes. Furthermore, it is not unreasonable to consider those responsible for disseminating education to be learned intermediaries. In all of this there is a question that has so far remained untested in Australia:

> *In the event of exposure to a product liability matter, could a treating surgeon, who has participated in CME activities, find a need for, and an opportunity in, the learned intermediary defence in the event that the CME activity endorsed and promoted the use of the product that is now at the heart of a product liability issue?*

A second question arises that might, for some, be even more absorbing:

> *Will professional bodies, such as universities, craft groups and colleges, etc, have exposure to liability and be joined in a surgical product liability matter in the event that it can be shown that a particular implantable surgical device has not only been recommended and promoted for use, but has also been endorsed during the course of a CME activity?*

If these two questions can be argued successfully, the legal consequences might see the elimination of associations, craft groups, and colleges as we currently know them in Australia. This is not simply pure speculation, as events in the US have already demonstrated.

THE TURN OF THE PEDICLE SCREW

Many patients have undergone the procedure of spinal fusion for the treatment of disabling and painful spinal conditions. A successful fusion, or arthrodesis,[14] immobilises the affected spinal segments and provides relief from pain. Surgical implant devices are often used to augment the fusion because they can stabilise the site. The commonly used, and very popular, form of implantable instrumentation involves pedicle[15] screw fixation. However, the significant incidence of screw failure has in the US triggered numerous class actions in various jurisdictions. In August 1994, more than 2,000 civil actions, originally filed in approximately 60 of the 94 federal districts in the US, were consolidated in the Eastern District of Pennsylvania.[16] All of the approximately 5,000 individual claimants alleged that they had suffered physical injuries >>

caused by defective surgically implanted pedicle screw devices. In most cases, claimants alleged that the devices broke after being implanted. In some instances, claimants required further surgery to have the devices removed. In some cases the broken devices could not be removed.[17]

The use of pedicle screw devices had been widely promoted in the US by manufacturers, both independently and in association with orthopaedic and neurosurgical conferences, seminars and workshops. These educational events can effectively be sales events masquerading as CME seminars. Consequently, many surgical associations were named as respondents in the pedicle screw litigation. It was alleged that these associations may have aided and abetted, in conspiracy with manufacturers, the unlawful promotion of the pedicle screw devices.[18] The pedicle screw litigation soon became viewed as the *turn of the pedicle screw*.[19] A number of surgical societies have had to fight to prove their innocence in the first mass tort case to hold associations liable for what they teach in seminars. Embroiled in this litigation were the North American Spine Society, the Scoliosis Research Society, the American Academy of Orthopaedic Surgeons (AAOS), and the American Association of Neurosurgeons. All were accused of conspiring and acting in concert with manufacturers to promote the use of pedicle screw devices. Not unnaturally, the medical associations denied that they were involved in any conspiracy and contended that they had merely held educational meetings at which scientific information was discussed.

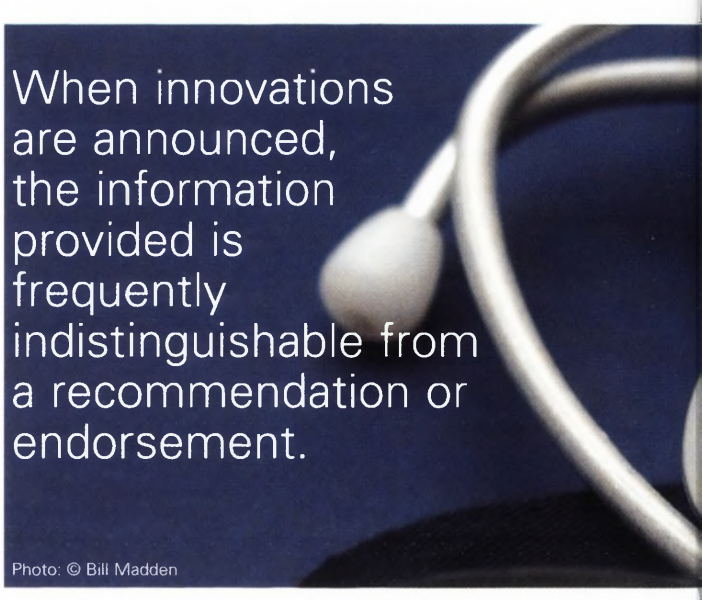
SURGICAL ASSOCIATIONS AND SOCIETIES UNDER THREAT

William Tipton, Executive Vice-President of the AAOS,[20] is recorded as having said:

> "We must hear about advances and future treatments in order to make the best decisions for our patients. I believe this threat, at its worst, could bankrupt our organisations and eliminate what has been the best platform for the exchange and accumulation of this information."

In the pedicle screw debate, the AAOS moved for summary judgment, arguing that there was no causal nexus between any of the claimants' injuries and anything that the Academy had done. Furthermore, the AAOS argued that speakers at Academy meetings did not fraudulently induce surgeons to implant pedicle screw devices by failing to disclose their financial arrangements with manufacturers, the (Food and Drug Administration) clearance status of the pedicle screw, or the risks and complications of using pedicle screw fixation devices.[21]

Understandably, the surgical associations and societies in the US would have preferred not to have been involved in this case. In the event, neither conspiracy or concert with manufacturers was proven. However, the respondents were arguably guilty of the non-disclosure allegations and the entire case may still have the potential for serious long-term ramifications in terms of changing both undergraduate and post-graduate teaching programs as we know them. And a particularly disturbing consequence of this case is the potential for 'scientific speech' or 'educational speech' at seminars, workshops and conferences to be regarded as



'commercial speech'[22] and, as such, be at risk of being false, deceptive or misleading.[23] For 'scientific' or 'educational' speech to be regarded as 'commercial speech' in the US, three questions must generally be answered in the affirmative:

1. Is the speech an advertisement?
2. Does the speech refer to a specific product or service?
3. Does the speaker have an economic motivation for the speech?

An affirmative answer in each case is strongly persuasive that the speech is commercial speech.[24]

In Australia, surgeons (and other clinicians and researchers) frequently deliver presentations of their experiences, and give demonstrations of implantable surgical devices, as advocates for those devices. It remains arguable that statements made at such events are 'in trade or commerce'; and should therefore be subject to the TPA,[25] particularly in circumstances where the presenter or the event has benefited from the financial support and sponsorship of the manufacturer (or sponsor) of the product in question.

CONCLUSION

The role of the learned intermediary has three main dimensions.

Many drugs, medical devices, and a legion of surgical procedures are known by the medical profession to have unwanted and undesirable side-effects and risks. Patients as consumers, and the pharmaceutical and medical device industry, properly rely upon medical practitioners to communicate appropriate information of the risks, side-effects and potential benefits of drugs and devices. Traditionally, the concept of the learned intermediary has focused on the role and obligation of those qualified professionals who intercede between manufacturers and consumers. The learned intermediary performs a vital role in conveying information when the former has no opportunity to communicate with the latter. The learned intermediary must be appropriately qualified in order to carry out this role, and is much privileged by the nature of the information at their disposal.

The learned intermediary has the qualifications and the opportunities to assist the manufacturer with many of the obligations normally associated with the supply of goods and services to consumers. But it is in this environment that manufacturer can also regard the role of the learned intermediary as a defence in a product liability matter where the issue concerns the (manufacturer's) duty to warn.

Notwithstanding its importance, however, the learned intermediary defence is only one of the three major tasks that can be attributed to medical practitioners in their learned intermediary roles. Medical practitioners also have a duty to warn patients of all material risks associated with any therapeutic intervention. So facilitating informed consent from patients is a second major role for the medical practitioner as a learned intermediary.

This article has identified a third major responsibility for the learned intermediary. In the event of exposure to liability in a product liability-related matter, it is a role that is only marginally more medical than legal. The conduct of learned professional bodies, when providing continuing education, embraces important obligations that might potentially involve an exposure to liability that, to date, remains untested in Australia. The pedicle screw lawsuit in the US represents the first time that any medical society or association has been sued in a product-liability case for illegally promoting a therapeutic device. Implicit in this case is a salient warning to those professional bodies, associations and craft groups charged with the undertaking of CME activities in Australia.

The US pedicle screw case might have serious implications for the nature and activities of professional associations. Furthermore, it might potentially stifle medical education as we currently know it, involving greater disclosure by associations, colleges and universities in an environment when it is almost inevitable that their educational activities will influence the decision-making processes of clinicians, with considerable ramifications for the doctor-patient relationship. ■

Notes: **1** *Schenebeck v Sterling Drug, Inc*, 423 F2d 919 (8th Cir 1970); *Hoffman v Sterling Drug, Inc* 485 F2d 132 (3rd Cir 1973); *Dunkin v Syntex Laboratories Inc*, 443 F Supp 121 (WD Tenn 1977); *Lindsay v Ortho Pharmaceutical Corp*, 637 F2d 87 (2d Cir 1980); *Timm v Upjohn Co*, 624 F2d 536 (5th Cir 1980); *Cert Denied* 449 US 1112 (1981); *Stanback v Parke Davis & Co*, 657 F2d 642 (4th Cir 1981); *Walker v Merc & Co*, 648 F Supp 931 (MD Ga 1986; *Affirmed* 831 F2d 1069 (11th Cir 1987); *Plummer v Lederle Laboratories*, 891 F2d 349 (2d Cir 1987). **2** The learned intermediary rule was first elaborated in *Sterling Drug, Inc v Cornish*, 370 F2d 82 (8th Cir 1966). The rationale for the rule was further outlined by Wisdom J in *Reyes v Wyeth Laboratories* 498 F 2d 1264 (5th Cir CA), cert denied 419 US 1096 (1974). **3** [1932] All ER Rep.1; [1932] AC 562; 101 LJPC 119; 147 LT 281; 36 Digest (Repl) 85,458. **4** *Courtney v Medtel Pty Ltd* [2003] FCA 36: BC 200300120. **5** *Lambert v Lastoplex Chemicals Co* (1971) 25 DLR (3d) 121: [1972] SCR 569, see Laskin J at 124-5. **6** [1990] Aust Torts Reports 67, 503. **7** *Holmes v Ashford* [1950] 2 All ER 76 CA. See also *Griffiths v Arch Engineering Co (Newport) Ltd & Anor* [1968] 3 All ER 217. **8** TPA s75AC. **9** TPA s71(2) and *Sale of Goods Act* 1923 (NSW) – s19(1). **10** E Beerworth, *Product Liability Australia* (2001) Vol 2, 36,019 [29.30]. See also *Carey-Hazell v Getz Bros & Co (Aust) Pty Ltd*, [2004] FCA 853; (2004) ATPR 42-014. **11** Product Liability, 'Role of Intermediaries', *Australian Trade Practices Reporter*, 17864 [Paras 24-240]. **12** Orthopaedic Bone Screw Pedicle Liability Litigation 193 F 3d 781 (3rd Cir. 1999). **13** Craig de Borzo, 'Product Liability Law Suits Raised Questions about CME vs Promotion', *AM News* (USA), 12 May 1997. **14** Fusion is synonymous with the term 'arthrodesis'. Fusion or arthrodesis occurs when two skeletal segments that were previously mobile are rendered immobile. **15** Each vertebral body has two pedicles that are situated posteriorly and join the body of each vertebra to its neural arch. Within this neural arch is the spinal cord. **16** Under 28 USC §1407. **17** See vide supra n.12 **18** Allegation attributed to Arnold Levin, Co-Chairman of the Claimants' Legal Committee – see A Levin, Editorial, 'Pedicle Screw: First Cases Naming Academy Sent to Local Courts' (1998) 26 (2) *American Academy of Orthopaedic Surgeons Bulletin*. **19** See *vide supra* n.18. **20** William Tipton MD, 8th Annual Conference on CME Provider Industry Collaboration, Fort Lauderdale, Florida, 5-8 October 1997. **21** See *vide supra* n.18. **22** Commercial speech is broadly defined as speech that is related to the economic interests of the speaker and its audience. Commercial speech generally takes the form of a commercial advertisement for the sale of goods and/or services. **23** See *vide supra* n.18. **24** *US Health-Care Inc v Blue Cross of Greater Phila.*, 898 F. 2d 914, 933 (3rd Cir. 1990). **25** Personal communication, Professor G Pearson, Professor of Business Law, University of Sydney, 2005.

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