

## US meeting focuses on product liability of medical devices

The first-ever symposium in the US covering product liability of medical devices and orthopaedic implants was held at the University of California, San Diego, in the fall of 1990. Attorneys, biomedical engineers, designers of biomedical devices, and manufacturers participated.

The guest lecture 'Product liability of medical devices, an attorney's viewpoint' by Anita Hotchkiss from Morristown, New Jersey, highlighted the legal liabilities that confront the manufacturer of biomedical devices. For example, when defects in devices come to light after they are implanted, legal decisions given have found the manufacturer liable for *patients' fear* that their device might fail. Recent advances in biotechnology have thrown up difficult-to-resolve problems such as: are body parts like cells and fluids owned by the donor or the manufacturer who subsequently processes them; at what stage does a donated organ become a medical device subject to FDA (Food and Drug Administration) regulations; can a biotechnology product like a transgenic mouse or bacterium be patented? Legal liabilities must be considered by every manufacturer. 'Idiot-proof' instructions must accompany all devices to minimize errors in use.

Giving an overview of the principles of law applicable to product liability, Daniel P. Hann of Biomet Inc., Warsaw, Indiana, indicated that, though there is a keen awareness among medical-device manufacturers regarding product liability, both physicians and manufacturers must acquire a basic understanding of the laws applicable to product liability. This would minimize violations of FDA regulations and various state laws. His paper 'Manufacturer's role in minimizing product liability litigation in the United

States of America' discussed the role played by 'informed consent' in limiting liabilities, the duty of manufacturers to label the products indicating associated risks including instructions to both patients and physicians on proper use, and the ways in which designers and manufacturers can analyse liability claims and avoid future liability.

The pitfalls awaiting unwary physicians were discussed by an orthopaedic surgeon, Gary Russotti, from Rochester, New York, in his paper 'Strict product liability of medical devices: implications for physicians'. Any doctor issuing appliances, dispensing general practitioners, and the health authority will all be liable under strict product-liability law unless they can clearly identify the manufacturer with detailed documentation. While there is some doubt whether devices undergoing clinical trials would be covered under this policy it seems clear that everyone involved in the chain of delivery of the appliance to the final recipient will have to bear the burden of maintaining detailed records for as long as legal action is possible.

In their paper 'Product approval and manufacturing practices related to medical devices', R. J. Arnsberger and D. A. Cutshall of Becton and Dickinson, Franklin Lakes, New Jersey, reviewed the classification of medical devices by the US FDA. Manufacturers must comply with applicable FDA Good Manufacturing Practices covering manufacturing and distribution. Investigational Device Exemption, Premarket Notification, and Premarket Approval were other issues discussed.

Guidelines for the design, and *in vitro* and analytical evaluation of orthopaedic implants were proposed in the paper 'Criteria for the design of reconstructive orthopaedic implants with a view to minimizing product liability' by C. S.

Bachtler of Paramus, New Jersey. Minimizing liability is one of the aims of the guidelines. Bachtler stressed the need for proper understanding of the skeletal anatomy of human somatotypes and the requirements of normal physical activity.

The burgeoning costs of product-liability insurance and lawsuits were discussed by H. S. Ranu of New York. The magnitude of the problem was highlighted by a recent award of \$500,000 in the case of a liability associated with an orthopaedic implant. Such cases were seen to have an adverse impact on both manufacturers and clinicians.

In another presentation, on regulatory controls related to manufacture and marketing of medical devices and implants, Ranu described the FDA classification of medical devices into Class I devices needing only general control, Class II devices regulated by FDA standards, and Class III devices which are regulated by premarket approval application and an FDA premarket review.

The third presentation by Ranu, on standardization and product liability, covered the advantages of standardization for minimizing product liability. The role of the Technical Committee of the International Organization for Standardization and its various working groups was discussed.

The symposium on product liability proved of interest to everyone in the biomedical field. A second international conference on product liability has been proposed for 1992.

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