

the Law Commission in 1977,² the Royal Commission on Civil Liability and Compensation for Personal Injury (the Pearson report) in 1978,³ the Council of Europe in 1977,⁴ and the EEC in 1976.⁵ All of these have recommended the introduction of product liability, though they do not agree on the all-important definitions and details. The concept of product liability requires the injured person to show that the product was produced by the drug company, that the drug was defective, and that he was injured as a result of taking the drug. The Pearson report defined a product as defective "when it does not provide the safety which a person is entitled to expect, having regard to all the circumstances including the presentation of the product." The producer would thus presumably not be liable for any adverse effects known to occur and warned against by the manufacturer. The crucial problem is the one of "development risk," when the drug has been designed as well as was possible; has been tested in accord with the law, licensed, and marketed; and is then discovered to cause damage, as happened with practolol.

The drug companies, the Royal College of Physicians, the BMA, the medical defence unions, and retail pharmacists, who were all represented at a recent symposium on product liability organised by the Medico-Pharmaceutical Forum, are unhappy with the proposed law. They think that not only will it fail to improve the system of compensation but it will also have many disadvantages for the practice of medicine in Britain. Many lawyers think that it will be just as difficult to prove defect as to prove neglect. It will also, as under the old law, be necessary to prove that the injury resulted directly from taking the drug. The drug companies argue that introduction of product liability will increase the costs of health care, and that it will be necessary for all pharmacists and doctors to keep elaborate, expensive, and time-consuming records of every drug supplied. The major fear is that the law would lead to defensive medicine, with the doctor being conservative in his prescribing, and the drug companies curtailing innovation in their research and development. Another worry is that it might be necessary to provide every patient with a detailed data sheet of any drug prescribed. The fact that it had publicised the hazards would be one of the few defences left to the drug company. This is where the doctor may become "the ham in the sandwich" if he has not notified the patient of the potential side effect, and he may then be liable.

Yet product liability already applies to pharmaceuticals in many parts of North America. There, too, the conference was told, the proposal was regarded with horror by the drug companies, but they do not seem to have been seriously damaged by the introduction of the law. In Sweden the drug industry has produced a voluntary drug insurance scheme. Any patient who believes he has suffered an unforeseeable drug adverse effect can make a claim. Fourteen claims have been allowed in the 11 months that the scheme has been working. With this system, compensation has been achieved without allocation of liability, negligence, or guilt.

If product liability is not to be accepted then another system must be devised, and the Association of the Pharmaceutical Industry has contemplated a scheme similar to the Swedish one. An injured person would have to prove before a tribunal that he was unforeseeably injured by a drug. The tribunal would have access to a fund and would be able to make immediate payments. The tribunal could later sue the drug company if it thought negligence could be proved. This system would have the advantages of being rapid and of avoiding the unequal conflict between a financially and scientifically weak

plaintiff and a strong drug company. But it would lead to yet another quasilegal body that did not have to accord exactly with the strict letter of British law.

The Consumers' Association has estimated that any legislation is at least five years away. Doctors in Britain know little of product liability and its implications, and yet, because of its potentially dramatic effect on health care and their own practice, they must be able to enter the debate. The profession will have only itself to blame if draft legislation is published before doctors have formulated clear proposals of their own.

¹ *British Medical Journal*, 1975, 4, 529.

² Law Commission, *Liability for Defective Products* (Cmd 6831). London, HMSO, 1977.

³ *Royal Commission on Civil Liability and Compensation for Personal Injury* (chairman Lord Pearson), Cmd 7054-1, 2 and 3. London, HMSO, 1978.

⁴ Council of Europe, *Convention on Product Liability*, Strasbourg, 1977.

⁵ EEC, *Proposal for a Council Directive Relating to the Approximation of the Laws, Regulations, and Administrative Provisions of the Member States Concerning Liability for Defective Products*, Brussels, 1976.

GMC election

On 27 September the reformed and enlarged General Medical Council will sit for the first time. The postal ballot for the elected members, who will be in a majority on the new council, is being dispatched to all doctors this week. There are 177 candidates standing, with several medical organisations sponsoring doctors. Election addresses by the 50 BMA-sponsored candidates, who were elected by the Representative Body,¹ appear at p 1723. It was 10 years ago in Aberdeen that the BMA's Representative Body fired the opening shots in a campaign that has led to a reformed GMC.² A medical Bill before Parliament during that summer made provision, among other things, for the GMC to charge an annual retention fee, and, though the Government had previously consulted the profession, doctors disliked this proposal. When later that summer the Government announced plans to enable the GMC to undertake the registration of specialists, demands by the profession for a complete reform of the GMC's constitution and functions grew louder. It has taken three inquiries, persistent professional lobbying, and some determined parliamentary work last year by Lord Hunt of Fawley³ to achieve the necessary reforms. The form and functions of the new GMC are described on p 1728. This achievement shows that democracy can work when a sufficient number of people are roused to action. Now it is up to all doctors to continue this exercise in democracy by voting in the ballot and thus ensuring a sound representative base for their statutory professional body.

¹ *British Medical Journal*, 1979, 1, 358.

² *British Medical Journal*, 1969, 2, 72.

³ Lord Hunt of Fawley, *British Medical Journal*, 1978, 2, 842.

Correction

ARM at Liverpool

The leading article in last week's issue (p 1589) stated, "GPs have also been angered by being told that, because their indirect expenses have been overpaid for the last three years, this year the increase awarded is only £200—a sum that will barely cover some doctors' higher petrol costs—thus reducing their net remuneration increase to around 18% on average." The final phrase of this sentence should have read, "Thus reducing their gross remuneration increase to around 18% on average." We apologise for confusing readers: an explanatory note from the BMA on the percentage increases for GPs is at p 1740.