widely and frequently prescribed ointments and drugs. No doubt general practitioners and dermatologists nationwide will be forced to rebuild confidence among their own patients. Doctors, indeed, come in for some biting observation and characterisation in *The Singing Detective*. All too many psoriasis sufferers who have been inpatients will recognise the awful consultant with his sycophantic juniors in the bedside scene of episode one.

Potter's serial has certainly bounced psoriasis into public prominence. This is good in the long term, despite immediate problems, for in common with all skin problems it has always been semihidden and "not quite nice to talk about." It also blurts out the anguish felt by the long term sufferer under the torture of not only the physical symptoms of the disease itself but also its potentially overwhelming impact on both the individual and key social relationships. Potter has also opened up the awkward problem posed to, and by, dermatology as a medical specialty. By definition dermatologists are experts on the skin as a bodily organ. As yet, however, most seem neither to have, nor to seek, expertise in dealing with persons, families, and communities who experience and react to skin disorder. Far more than the skin is affected, and yet it is only the skin which receives serious attention. In consequence, in teaching their specialty to generations of general practitioners and consultants in training, dermatologists neglect to prepare them for the obvious fact that major chronic skin disorder presents distinctive psychological and social problems that will inevitably be brought into their consulting rooms.

With honourable exceptions dermatologists can be appallingly ignorant of the psychosocial context of skin disorders and their "phenomenological" realities. Their approach to the "human" as opposed to the organic and physical problems they provoke can be amateur and even casual. Some just avoid them. When forced to recognise the singing detective's intense personal problems with the disorder, Marlow's dermatological consultant offers access to the padre and then the psychiatrist, in that order.

Faced with a near explosion of inquirers asking for help after the first episode, and the obvious urgent need to inform, educate, and counsel frightened people as well as the general public, the Psoriasis Association turned naturally to dermatologists. The response was disappointing in terms of recognition of the urgent need, and indeed opportunity, posed by Potter's serial. Apparently few could see a direct role or responsibility for themselves towards the wider community. As specialist professionals they apparently had nothing to say to the wider audience on a national stage. Or no one felt the obligation to take any initiative in relation to it. "Community" practice seemed to be an alien notion.

The enduring image of the massively and horrifyingly afflicted Marlow is now part of the public awareness of psoriasis. It would be naïve to believe that only sympathy will result. The existing stigmatising connotations will be elaborated and extended. Psoriasis will be known about, interpreted, and understood with scarcely any information or specialist professional explanation from the most obviously relevant professional group.

Most immediately this experience reinforces all of the arguments for independent, informed, active, well organised self help and mutual aid associations of patients. The Psoriasis Association must be, for example, the key agency for public information and education on psoriasis. There is still a need, too, surely, for efforts towards the firmer establishment of a collective, public, "community" role for specialist medical practitioners (of all kinds). Certainly there is a need to increase the sensitivity of dermatologists to psychosocial and "communal" dimensions of their work and the problems with which they deal. Many general practitioners know and understand this and would welcome time and space in programmes of advanced medical education for a more "whole person" "patient friendly" dermatological perspective so that they may play a more positive part not only with their own patients but also in the local community.

Perhaps general practitioners could educate their dermatological colleagues in this respect? Someone certainly should be listening to some of the messages in the detective's song.

RAY JOBLING, chairman, Psoriasis Association.

Medicolegal

Product liability comes closer

CLARE DYER

The Consumer Protection Bill, due to have its second reading on 8 December in the House of Lords, will tighten the United Kingdom's law on product liability by enabling consumers to sue the producers of defective products without having to prove negligence. The Bill is the UK's response to the European Community directive on product liability, which requires all the member states to bring in legislation by 30 July 1988 to make producers strictly liable for injuries, death, or damage to private property caused by their products.

Calls for a system of strict liability (liability without proof of negligence) for death or injury from defective products date back to the thalidomide tragedy, which highlighted the difficulties victims face in obtaining compensation under the fault based system. In 1977 the Law Commission and the Scottish Law Commission proposed the introduction of strict liability, a recommendation echoed a year later by the Royal Commission on Civil Liability and Compensation for Personal Injury (the Pearson commission).

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Ten years of the EC directive

The EC directive, first proposed 10 years ago, is intended to eliminate differences in product liability law throughout the community that might distort competition and affect the movement of goods. In the event, harmonisation will be less than total, for the directive leaves member states free to decide whether or not to let producers plead a "development risks" (or "state of the art") defence. This will allow a producer to escape liability if he can show that he could not be expected to have discovered the existence of a defect because of the state of scientific and technical knowledge at

the time the product was put into circulation. After vigorous lobbying, particularly by the pharmaceutical industry, which claimed that without the defence innovation would be stifled, the government has decided that the UK law, unlike the law expected to be adopted by France and Belgium, will include the development risks defence. The operation of the defence in those states that adopt it is to be reviewed in 10 years' time.

Some commentators argue that strict product liability is a misnomer when the law allows a state of the art defence; they say that retaining the defence means that the law will still be fault based and will merely shift the burden of proof. It will no longer be for the plaintiff to prove negligence but rather for the defendant to prove that he was not negligent. As Professor Aubrey Diamond, then director of the Institute of Advanced Legal Studies, University of London, and Professor D R Laurence, professor of pharmacology and therapeutics at University College London, put it in a joint article in the *BMJ* last year: "In truth, such a defence is one of the distinctions between strict liability and negligence liability. To speak of strict liability with a state of the art defence is a contradiction in terms; one is speaking of negligence liability."[1]

To invoke the defence, according to the Department of Trade and Industry's layman's guide to the Bill, "in the light of knowledge at the time, the producer must have been in the position where it was not reasonable to expect him to seek out the defect or the means to discover the defect must not have been available." The department insists that this will be a heavy burden for the producer to discharge, but it is arguable that the victims of recent drug disasters such as the thalidomide tragedy would still have faced formidable obstacles had this Bill been law at the time. On the other hand, it is also arguable that the defence would not help manufacturers of products—some of the non-steroidal anti-inflammatory drugs, for instance—that have been withdrawn from the market not so much because the nature of the adverse reactions to them was unforeseen as because of the numbers suffering side effects.

When is a product defective?

The plaintiff will still have to prove that he suffered damage, that the product was defective, and the causal relation between the defect and the damage suffered. A product is defective, in the words of the Bill, "if the safety of the product is not such as persons generally are entitled to expect." Particular difficulties arise with drugs, as all medicines are potentially unsafe; they act by interfering with the normal processes of the body, they have to work on already faulty organs, and some patients will have idiosyncratic reactions. Risks must be balanced against benefits, and a drug whose risk:benefit ratio is unacceptably high will be defective.

Warnings and instructions are to be taken into account in deciding whether a product is defective. The commonest allegation in drug product liability cases is that the manufacturer failed to warn adequately, or at all, of a particular adverse reaction. To what extent manufacturers will fulfil their duty to warn by giving adequate warnings to the doctor, given that many doctors will edit heavily in passing on these warnings to their patients, will be a matter for the courts to decide.

Speakers representing the medical and pharmaceutical professions at a recent meeting of the UK Interprofessional Group predicted that the change in the law would speed up the introduction of original pack dispensing with warnings enclosed. But even this, as Alan Davidson, deputy head of the law department of the Pharmaceutical Society, pointed out, is fraught with problems. "The doctrine of informed consent will almost certainly apply. Not only must the warnings be included but does the patient really understand them sufficiently to be said to have assumed the risk? If this view is accepted, then the House of Lords decision in Sidaway (Sidaway *v* Bethlem Royal Hospital (1985)) is seen in a new light. In that case it was held that although a doctor must normally tell his patients of reasonable risks, the final decision lies with the doctor. How does this view compare with the attitude of the manufacturers that all foreseeable risks should be the subject of warnings, even though the risk to a particular patient might be remote? Clearly, the most absurd results could be obtained where, for clinical reasons, the nature of the illness of a cancer sufferer is kept from him whilst his treatment carries a warning 'caution—this medicine may shorten your life.'"

Effects on doctors

Dr Alan Rowe of the BMA's committee on the EC told the meeting that a majority of doctors would be affected by the legislation. Liability rests not only with the producer but with any person who by putting his name on the product has held himself out to be the producer. Pharmacists and dispensing doctors are required by law to affix their name and address to a dispensed medicine. The Department of Health and Social Security and the Department of Trade and Industry have made it clear that they do not consider that in doing so a doctor would be presenting himself as a producer. A doctor could, however, become a producer if he mixed a preparation of his own or diluted a medicine or cream, unless this was in accordance with the manufacturer's instructions. Another uncertainty is the position of a doctor who modifies apparatus used to treat patients.

But doctors should particularly note that the supplier of a product will be liable unless he can supply the injured person with the identity of the producer or importer. All general practitioners from time to time supply their patients with drugs—for instance, at night. The consequence, warned Dr Rowe, is that doctors will need to keep detailed records of the sources of supply of every drug given to a patient for at least 10 years (there is a 10 year long stop period in the Bill after which no action can be taken). The burden of this record keeping will be substantial and will affect clinical record keeping as well as dispensing record keeping. A move to original pack dispensing would be one answer to this problem.

One concern for the medical profession is the status of drugs used in premarketing clinical trials. The view of the Department of Trade and Industry and the DHSS is that, under the definition of "supply" in the Bill, these drugs will not have been supplied and the producer or researcher will be able to invoke the defence "that the person proceeded against did not at any time supply the product to another."

Small benefit to victims

For the victims of drug injuries the Bill is a step forward. But how far forward? "Although the litigation process may have been made marginally easier, I share the view that this is not a significant measure," Professor Gerald Dworkin, professor of law at Queen Mary College, University of London, told last month's meeting of the Medico-Legal Society. "The majority of the defects in the present system will still be with us: costs will still be disproportionately high, problems of causation will still be with us, and it will still be necessary to show something approaching fault."

Reference

1 Diamond AL, Laurence DR. Product liability in respect of drugs. *Br Med J* 1985;**290**:365-8.

Is a long distance aeroplane flight likely to cause an exacerbation of haemorrhoids? If so what treatment is advised?

There is no reason why a long aeroplane flight should exacerbate piles. I suppose the long and tedious queues for the lavatory may inhibit defecation and a patient with haemorrhoids should avoid becoming constipated. It may be just as well therefore to ensure a good bowel action before take off by a suitable bolus of fruit, or by a mild aperient—HAROLD ELLIS, consultant surgeon, London.