the doctor to provide comfort and to alleviate distress are essential to the handicapped person, child or adult, and the family who accept his care.

The Secretary-General of Mencap writes: The suggestions given are based on the most commonly expressed anxieties and problems received by this Society over the past 25 years and are written from the point of view of parents. The Society

provides a selection of literature giving practical advice to parents and is grateful to the Royal College of General Practitioners for maintaining reference samples of these publications during the past 10 years.

On 24 June 1981 our Annual Mental Handicap Week Conference will deal with the theme "Right from the Start," an interdisciplinary forum which hopes to explore current practice and make recommendations for the future. BRIAN RIX CBE.

Compensation for Drug Injury

Two solutions to an insoluble problem

RICHARD SMITH

During the early 1970s in the United States manufacturers began to complain loudly about product liability problems. They claimed that the number of cases was increasing dramatically, that an increasing percentage were successful, that insurance to cover product liability was becoming much more expensive, and that some companies were being forced into bankruptcy. This was the "product liability crisis."

Consequently in April 1976 the President's Economic Policy Board set up a task force to look into the problem. The task force commissioned a legal study, an insurance study, and an industry study, and reported in December 1976.¹ I met Dr Edward Barrett, the task force's project director, in Washington. He explained that the task force members had started their job thinking that they were dealing with a problem of the law of tort. Two things became apparent, however: firstly, that the "product liability crisis" had been exaggerated; and, secondly, that the problem was more one of insurance than of tort law.

Findings of the task force

The task force had only limited data on which to base its conclusions. Product liability was not easy to study: most cases were settled out of court, and most insurance companies did not keep separate accounts of their product liability experience.

The task force did find that the number of product injury claims had increased "substantially." Lawyers who acted for injured people claimed that the average size of awards had not increased, and the task force could not find many data to oppose that claim. One survey in Cook County, Illinois, did show, however, a "substantial" increase in the size of the awards. There was also an increase in the number of "blockbuster awards" (\$1m or more). The study also suggested that the number of "wins" in appellate and jury cases was approaching 50%, though the number of injuries did not seem to have increased. This suggested that a higher percentage of injuries were leading to legal cases.

The task force was sure that insurance premiums had risen considerably in most industries; the drug industry was included among those most severely affected. Smaller firms suffered

particularly badly, but the task force found no evidence that any companies had been forced out of business because of product liability problems. Some companies had been unable to obtain product liability insurance, but this was more a problem of "affordability than availability." Nevertheless, for most companies, even those with severe increases, premiums were hardly more than 1% of sales. Disturbingly, some companies—even large ones—had chosen to trade without insurance.

Another finding was that in some industries—particularly the drug industry—manufacturers forwent and delayed the introduction of new products because of product liability problems. The task force was not sure whether this was a good thing or a bad thing. The drugs not introduced might have been potentially dangerous or they might not have provided much advantage over old drugs. Alternatively, they might have been drugs such as vaccines that offered little profit and yet provided considerable potential for injury—simply because of their wide use in healthy people. One encouraging finding of the task force was that manufacturers were devoting more time and money to avoiding producing defective products. Finally, although some injured people were receiving full compensation from the tort-litigation system, many were not.

The table shows data extracted from the report on the experience of some drug companies with product liability. Claims, damages sought, and damages paid did not increase at all between 1971 and 1976. In that time, however, total sales and product liability insurance premiums did increase. These limited

Impact of product liability on a sample of American drug companies (information extracted from the report of the Interagency Task Force on Product Liability)

	1971	1972	1973	1974	1975	1976
Average total sales (\$m) (31 to 38 companies)	164	188	207	234	292	329
Average general liability premium (\$m) (14 to 23 companies)	0.11	0.09	0.10	0.13	0.16	0.23
Average product liability premium (\$m) (11 to 21 companies)	0.08	0.08	0.09	0.10	0.13	0.21
Average pending claims (32 to 33 companies)	10	9	10	11	12	14
Average new claims (33 to 35 companies)	2	32	34	33	33	31
Average damages sought in new claims (\$m) (29 to 31 companies)	0.44	0.57	0.42	0.13	0.11	0.45
Average total amount paid out in settlements in and out of courts (\$m) (33 to 36 companies)	0.03	0.03	0.04	0.04	0.02	0.02

British Medical Journal, London WC1H 9JR

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data suggest that in those years the drug companies did not really have much to complain about.

Causes of product liability problems and recommendations

The task force thought that "past misjudgments and clumsy rate making processes on the part of product liability insurance premium writers" were some of the causes of the problems. Although "major areas of product liability law were most unstable" and "unpredictable," the insurance underwriters had too often over-reacted. "Panic pricing" was the term that Dr Barrett used.

The specific conclusions of the task force on the tort-litigation system were: "The law of product liability has become filled with uncertainties, creating a lottery for both insurance rate makers and injured parties. A basic cause of this is a doctrinal conflict as to whether tort law should be a compensation system for persons injured by products or a means of apportioning responsibility based on fault." The task force reported before the current diethylstilboestrol cases (see previous article), and it is possible that if it were to repeat its study it might find more severe commercial problems. Certainly the "doctrinal conflict" has become more heated.

Other causes of the product liability problem included: some manufacturers producing unsafe products; increasing awareness; increases in the number and complexity of products; product misuse; and inflation.

The task force thought that some kind of Federal action would be needed to reduce the problems. Apart from obvious measures such as improving premium-setting methods and injury prevention techniques, it thought that change in the tort-litigation system was needed. Possible changes in the laws governing insurance, more fundamental changes in tort law, and a no-fault system were all considered. As with the Pearson Commission in Britain, the task force discussed a no-fault system only to dismiss it: in Britain and the United States a no-fault system seems to be a political non-starter.

After this report the Department of Commerce prepared a paper on what kinds of action could be taken to deal with the problem. Public response to this paper was overwhelmingly that the best thing to do would be to draft a uniform product liability law, which could then be adopted by any State. The new law should balance the needs of consumers and manufacturers and try and make the whole business more predictable.

Changing the law on both sides of the Atlantic

The United States Department of Commerce published the first draft of the Model Uniform Product Liability Act in January 1979 and the final version in October 1979.² The Act is a guide for individual States that want to reform their law. Thus legal reform is being undertaken in the United States at the same time as legislatures in Europe are trying to change their laws. Both the Americans and the Europeans have opted to deal with the problems of compensating product injuries by reforming tort law rather than devising no-fault schemes.

The inspiration for reform, however, comes from completely different directions in the two continents. Changes in American law have been called for mainly by manufacturers. The United States has had strict liability for almost 20 years, and manufacturers think that common law has run away with itself and produced inconsistent and extraordinary decisions. As the introduction to the American Act says when talking about cases involving design defects:

Some courts have attempted to apply strict liability in these areas. They have sought to justify the results under a theory of "risk distribution," wherein the product seller distributes the costs of all product-related risks through liability insurance. The courts state that they are not imposing "absolute" insurer liability; nevertheless, they have not been able to articulate "why" they draw the line short

of that particular point. The reason for this is that the "risk distribution" rationale provides no stopping point short of absolute liability. Thus, a number of courts have plunged into a foggy area that is neither true strict liability nor negligence. The result has been the creation of a wide variety of legal "formulae," unpredictability for consumers, and instability in the insurance market.

Changes in European law, however, are called for mainly by consumer organisations. They think that compensation under existing law is hard to obtain, slow, and unfair. Indeed, the preamble to the EEC directive states:

An equal and adequate protection of the consumer can be achieved only through the introduction of liability irrespective of fault on the part of the producer of the article which was defective and caused the damage; any other type of liability imposes on the injured party almost insurmountable difficulties of proof or does not cover the important causes of damage. Liability on the part of the producer irrespective of fault ensures an appropriate solution to this problem in an age of increasing technicality, because he can include the expenditure which he incurs to cover this liability in his production costs when calculating the price and therefore divide it among all consumers of products which are of the same type but free from defects.³

The European law is an attempt to produce legal reform through the statute book, while, as Dr Edward Barrett (who helped draw up the American Act) told me in Washington, their act is more an attempt to "codify the existing law." Thus, intriguingly, if these two laws were to prevail on their individual continents compensation might be easier to obtain through tort law in Europe than in the United States. What is written down, however, is only part of the law and it is perhaps unlikely that Europeans will become more eager in tort law cases than Americans.

Two views of defect

Comparing and contrasting the two proposed laws is instructive. The first obvious difference is that the American law is longer and more detailed than the European. This is a reflection of their different aims: the American law is attempting to make precise definitions and remove uncertainty, while the European law is about reform.

The crucial part of both these documents and, indeed, of all product liability law is the definition of a defective product. On this issue the Americans exert their greatest efforts, while the Europeans are vague. In the American law a product can be defective in four ways: firstly, in construction; secondly, in design; thirdly, in a failure to accompany it with adequate warnings; and, fourthly, because a manufacturer makes an untrue statement about its safety. The Act applies strict liability for defects in construction and for expressly deceiving users about the safety of the product, but not for design or warning defects; with these defects a fault standard applies.

The Act then goes on to define how a court must decide if a manufacturer has been at fault in a design case. Basically, the courts are asked to balance risk against utility. Thus, considering drugs in a practical way, the court would require much more extensive tests of design for a mild analgesic than for a cytotoxic drug. The Act also lists other details that are to be considered in these cases and defines how a court must decide whether a product was defective because it was supplied with inadequate warnings.

The European directive, however, offers only a vague definition of defect:

A product is defective when, being used for the purpose for which it is apparently intended, it does not provide for persons or property the safety which a person is entitled to expect, taking into account all the circumstances, including its presentation and the time at which it was put into circulation.

With a definition like this individual courts are likely to make very different decisions whether products are defective or not.

"State of the art"

"State of the art" is one of the most controversial issues in the product liability debate. A state of the art defence would mean that a manufacturer would not be liable for a defect in his product if he could not have known about the defect because science and technology were insufficiently advanced when the product was designed. Consumers' organisations are very keen that the state of the art defence should not be permissible: they argue that sufferers like the thalidomide victims would not be compensated if it was. Manufacturers' organisations in Britain, however, are anxious that this defence should be permissible, and the Minister for Consumer Affairs, Mrs Sally Oppenheim, agrees with them.⁴ The EEC directive as it stands says:

The producer of an article shall be liable for damage caused by a defect in the article, whether or not he knew or could have known of the defect. The producer shall be liable even if the article could not have been regarded as defective in the light of the scientific and technological development at the time when he put the article into circulation.

The American Act avoids the term "state of the art" because it "has come to mean different things to different parties." It adopts instead a phrase "practical technological feasibility." The Act states:

If the product seller proves, by a preponderance of the evidence, that it was not within practical technological feasibility for it to make the product safer with respect to design and warnings or instructions at the time of manufacture so as to have prevented claimant's harm, the product seller shall not be subject to liability for harm caused by the product. . . .

Should drugs be a special case?

Both the medical profession and the pharmaceutical industry in Britain have argued that drugs are a special category of product and should have different laws governing compensation for injury caused by them.⁵ This appeal falls on deaf ears in Europe, but the Americans do have a part of their Act which deals with "unavoidably dangerous aspects of products." This part of the Act, which is based on Comment K of Section 402A of the Restatement (Second) of Torts states:

(A) An unavoidably dangerous aspect of a product is that aspect incapable, in light of the state of scientific and technological knowledge at the time of manufacture, of being made safe without seriously impairing the product's usefulness.

(B) A product seller shall not be subject to liability for harm caused by an unavoidably dangerous aspect of a product unless:

- (1) The product seller knew or had reason to know of the aspect and with that knowledge acted unreasonably in selling the product at all;
- (2) The aspect was a defect in construction under Subsection 104(A);
- (3) The product seller knew or had reason to know of the aspect and failed to meet a duty to instruct or warn under Subsection 104(C), or to transmit warnings or instructions under Subsection 105(A); or
- (4) The product seller expressly warranted that the product was free of the unavoidably dangerous aspect under Subsection 104(D) or 105(B).

The lawyers had drugs in mind when they drafted this part of the law—as the accompanying analysis makes clear.

One issue that has caused much controversy is compliance with government standards of manufacture and marketing. The drug companies think, for instance, that they are caught in a double bind: they must labour to obtain a licence to market a drug, yet if the drug is subsequently found to have a defect compliance with government standards will not be a defence. The European law does not mention this thorny problem, but the American law does. If the product has conformed to government requirements (and a drug would have to in order to be on the market) then it will be deemed not defective unless the

plaintiff can show that "a reasonably prudent product seller would and could have taken additional precautions." The EEC lawyers are perhaps unwise to avoid this issue.

Limitations, contributory negligence, and distributors

Both proposed laws limit the time that a manufacturer can be liable for an injury caused by his product. The European law says 10 years from when the "producer put into circulation the individual product which caused the damage." The American law says that a producer will not be liable after his product's "useful safe life" has expired. The "useful safe life begins at the time of delivery to a purchaser who is not engaged in the business of selling the product and extends through to the time in which it would normally be likely to perform or be stored in a safe manner." The "useful safe life" is presumed to be not more than 10 years unless the plaintiff can provide evidence to the contrary. In the American law the plaintiff must make his complaint within two years of discovering this injury, and in the European law after three.

One interesting difference between the American and the European law is that the European puts a financial limit on both the total liability of a manufacturer and his liability in an individual case. The American law applies no financial limitations. This difference may be crucial as it does mean that, although the European law does not allow a "state of the art" defence, the limitation on total liability makes the problem more predictable for insurance purposes.

Both laws allow defences of contributory negligence if somebody interferes with the product and if the plaintiff misuses the product. Both also state that if the manufacturer cannot be identified then the distributor or retailer will be liable as the producer.

Conclusion: tort law has failed

Thus both the United States and Europe are both trying to improve their systems of compensating people injured by products by tinkering with tort law, and I think that they are doomed to failure. The aims are to make life more tolerable for injured people and to do this without inadvertently killing commercial competition and innovation. This should not be difficult, but tort law—either through fault or strict liability—cannot do it, because it is inefficient, slow, arbitrary, expensive, almost incomprehensible, and in many ways unjust. Adopting strict liability in tort for product injury in Europe and abandoning some aspects of it in the United States will not help; it just does not seem possible to stretch tort law into an efficient and humane compensation system. Perhaps, then, some sort of no-fault system is needed after all.

Numerous people both in Britain and the United States have helped me in preparing these articles, and I thank all of them. Particularly I thank B J Anderson, Nancy Cahill, and Patricia Hutar of the American Medical Association; Dr W I H Shedden, Dr R H Furman, J R Root, and W Dutton of Eli Lilly; Dr Edward T Barrett of the United States Department of Commerce; and Ian Kennedy of King's College, London. I emphasise that of all the people with whom I spoke none are likely to agree with everything I have written.

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