The Law in Relation to Unforeseen Adverse Drug Reactions

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The English legal system does not possess any general theory of civil liability. This is due to the way in which our law has evolved historically. A lawyer therefore always starts any enquiry by investigating the relationship between the person who has suffered harm and the person said to have caused it.

In the case of drugs he is likely to be concerned, on the one side, with the person who takes the drug and with his immediate relatives who may all become affected in their person, their lives and their pockets. On the other side, he is likely to be concerned with three groups —

1. the manufacturer and all those concerned with him in the development and manufacture of the drug;
2. the prescriber and administrator of the drug; and
3. anyone who sells or otherwise delivers the drug.

In the way our society is organised it is unlikely that there will be any contract between the affected drug-taker group and the manufacturer. Yet, on any philosophical approach, if something goes wrong with a drug, it is likely that the prime moral responsibility must rest with the manufacturer. I therefore start by looking at their relationship in law.

Basically there are two theoretic ways in which that relationship can be organised. The choice between them is not one for lawyers but is one the whole body politic must make after taking into account the social and economic consequences.

The first way is a system of strict liability. Under such a system anyone who carries on an activity which in fact results in hazard to third parties, whether preventable or not, is liable to any such third party even though he has exercised the utmost possible care. The second way is to make liability depend on the conduct of the manufacturer. Has he fallen below the standard established by law for the protection of others against unreasonable risk of harm? If so, he is liable. If not, he is not.

The philosophical justification for the first alternative is, of course, that to the person injured it is of no consequence why he was injured. He ought to be able to go through life without injury. If something put into circulation by a human agency causes him injury, he ought to be compensated by the person who has put the thing into circulation.
Against this it is argued first, that such a system must inhibit progress. New developments are bound to be risky by reason of their very novelty. If anyone concerned to develop new drugs must accept the entire risk without regard to the care he has taken to reduce this, he will not be prepared and may not be able to afford to undertake that burden. Second, it is said that it is not right morally. New developments improve the quality of life. New drugs reduce illness and its consequences. There is therefore an overriding interest in their production. Provided the maker has taken all reasonable care he should be under no residual liability. If, nevertheless, something goes wrong, let the nation at large ameliorate the consequences by social insurance benefits and grants.

The advocates of strict liability point out that social insurance is never adequate compensation and that the manufacturer can and should insure. If he can find an insurer willing to take on the risk, the premium will be taken into his costs and will then be paid by the consumer at large. But, of course, if the potential market is small and the risk immeasurable (as it often must be) the actual result may still be to inhibit progress.

Our law characteristically has sought to compromise between these two ideas. As we became an industrialised society it was suggested that:

‘whenever one person is placed in such a position with regard to another that every one of ordinary sense who did think would at once recognise that if he did not use ordinary care and skill ... he would cause danger of injury to the person or property of the other, a duty arises to use ordinary care and skill to avoid such danger.’

This then revolutionary proposition was uttered by Sir Lionel Brett, later Lord Esher, the then Master of the Rolls, in Heaven v Pender (1883) 11 Q.B.D. 503 at p. 509, but was not accepted in its entirety by the other distinguished members of that Court (Lord Justices Cotton and Bowen). However, in 1932 the House of Lords, in the classic case of Donoghue v Stevenson (1932) A.C. 562, finally established our modern law of negligence. In the celebrated words of Lord Atkin (at p. 580) —

‘The rule that you are to love your neighbour becomes in law, you must not injure your neighbour; and the lawyer's question, Who is my neighbour? receives a restricted reply. You must take reasonable care to avoid acts or omissions which you can reasonably foresee would be likely to injure your neighbour. Who, then, in law is my neighbour? The answer seems to be — persons who are so closely and directly affected by my act that I ought reasonably to have them in contemplation as being so affected when I am directing my mind to the acts or omissions which are called in question.’

In the same case Lord Atkin applied this principle to manufacturers in these words (see p. 599) —
'A manufacturer of products, which he sells in such a form as to show that he intends them to reach the ultimate consumer in the form in which they left him with no reasonable possibility of intermediate examination, and with the knowledge that the absence of reasonable care in the preparation or putting up of the products will result in an injury to the consumer's life or property, owes a duty to the consumer to take that reasonable care.'

This is our modern law of negligence. It is a duty no manufacturer can escape. But it gives rise to endless debate and argument on the facts of each case. What is reasonable care? Has it been taken?

The law requires that 'the degree of care . . . must be proportioned to the degree of risk involved' (per Lord Wright in Northwestern Utilities Ltd. v London Guarantee and Accident Co. Ltd. (1936) A.C. 108 at p. 126. Risks may be so remote that a reasonable man may not need to guard against them. The reasonable man is objective, but he is not the average man. A manufacturer of drugs must take such care as a reasonably careful and skilful drug manufacturer would take. This will include taking advice and informing himself on up to date scientific knowledge available to him.

Here, of course, is the rub. He may not know of some relevant piece of research, perhaps carried out in the U.S.A., in Russia, or in Japan. Or the necessary research may not have been done and the need for it may not have been appreciated. Or he may not appreciate its relevance. In English law he will not be negligent if the occurrence was not reasonably foreseeable. Likewise he will not be negligent if he has acted in accordance with a practice accepted as proper by a responsible body of his peers skilled in the particular skill in which his field of activity lies. By definition that which is unforeseeable cannot be avoided by any degree of care or skill. The unforeseen is, of course, different. There the question becomes whether it could and should have been foreseen if the proper degree of care and skill had been exercised.

Even before the modern law of negligence developed, it was recognised that there are some things which are so dangerous in themselves that anyone who brings them into circulation must do so at his peril. Not untypically the rule was first stated in relation to property damaged when an owner built a reservoir on his land and water from it escaped and damaged an adjoining mine. 'The true rule of law is that the person who for his own purposes brings on his lands and collects and keeps there anything likely to do mischief if it escapes must keep it in at his peril', said Blackburn J. in Rylands v Fletcher (1866) L.R. 1 Ex 265, 279. But this doctrine was perceived to be capable of imposing undue restrictions on material progress. So the doctrine was confined, in the House of Lords, to non-natural uses of the land. How far this doctrine goes and indeed whether it really exists in our law has been hotly debated ever since. Is there any reason why it should not be applied to the manufacture of drugs? Attempts have been made to formulate a
comprehensive theory of strict liability (i.e. liability independent of negligence) for harm caused to persons by things dangerous in themselves. The obvious difficulty of defining what is a thing dangerous in itself is not the least difficulty. A drug is usually harmless enough unless consumed and it then probably needs consumption in the wrong dosage or at the wrong time or by the wrong person to render it dangerous. In 1947, the House of Lords in the case of Read v J. Lyons & Co. Ltd. (1947) A. C. 56 had before it a claim by a munitions inspector injured by an explosion in an explosives factory. She made no allegation of negligence. She simply said high-explosives are dangerous; they are not natural; the danger materialised; I was injured; I am entitled to be compensated. Her claim failed on the narrow ground that there was no escape from the land to a place outside the defendants’ control. But the House of Lords went on to reject the idea that there might be any general theory of strict liability for ultra-hazardous activities. So one can now postulate with some confidence that in this country manufacturers of drugs will be liable for negligence but not otherwise unless and until Parliament changes the law.

If, therefore, the result of consuming a drug is genuinely unforeseeable, its manufacturer will not be liable in law. Whether that will do him any good if the results are sufficiently charged with emotion is quite another matter. The thalidomide story is an example of questions of legal liability becoming utterly academic. Sadly it has to be said that journalists and politicians combined there to ensure that, because in their view the law was imperfect, the particular manufacturer should not be allowed to rely on it, come what may.

I am all for changing the law relating to future events if, after proper debate and consideration, it is thought desirable. I am entirely in favour of seeking to procure such a change by all possible publicity. But to bring about by the use of publicity and commercial threats a situation where one person is not allowed to rely on the law under threat of commercial annihilation is quite another matter. I believe that no thinking person can be proud of the thalidomide story in any of its aspects, however much we must all sympathise with the innocent victims of that disaster.

Difficult questions remain. What is and is not foreseeable? By whose vision do you test what is foreseeable? How far do tests have to go? The lawyers can only answer that the manufacturer must act reasonably in all the circumstances. No general rule can be laid down. If he uses chemical components known to be dangerous he will obviously be at risk. If the components have hitherto been harmless but have never been combined before, he will have to seek the best scientific advice he can. But if he has done all that and has performed all the tests contemporary science has devised and nevertheless something then goes wrong, he will escape liability in this country. If he has not done this, it will be no defence to him to show that he has complied strictly with the Medicines Act 1968 and the statutory procedures which this and Orders made under it prescribe. Non-
compliance with that code will bring in train criminal liability. No doubt it would also constitute strong evidence of negligence. On the other hand, compliance does not, conversely, mean that there can be no liability in negligence.

It should be noted that the law is different in the U.S.A. There, or at least in many of the States, manufacturers are nowadays under strict liability in respect of their products.

There is a curious twist when one comes to consider the law in relation to the person who sells the drug to the consumer. By statute (section 14 Sale of Goods Act 1893 as now amended by the Supply of Goods (Implied Terms) Act 1973 and the Consumer Credit Act 1974) a seller who sells goods in the course of business has two conditions implied in his contract of sale. These are first, that the goods are of merchantable quality, and second, where the buyer expressly or by implication makes known to the seller any particular purpose for which the goods are being bought, that the goods supplied are reasonably fit for that purpose. Consequently it is obvious that, if a member of the public goes to a chemist and buys a particular drug, say as a sedative or as a means of controlling headaches, and it subsequently affects his chest or his unborn children, he may very well have a claim against that retailer. The fact that the retailer has no means of finding out that this effect may come about is neither here nor there.

Whether a legal system which thus imposes a greater burden on the retailer (who often may be quite unable to meet that burden) than on the manufacturer is sensible in the second half of the twentieth century is something the Pearson Commission and the Law Commission are now debating. I should add that since there are some doctors who in the course of their practice dispense drugs by way of business, their liability for unforeseen consequences flowing from the taking of such drugs may well be the same as that of retail chemists.

Lastly, there is the position of the person who prescribes or administers the drug. There may well be a contract between such a person and the consumer. But, since normally no sale of goods is involved, this will make no difference in law. The liability of such persons in law once more depends on whether they have exercised reasonable care and skill. Normally, it is unlikely that either a nurse or a doctor would become liable. In circumstances in which a substantial body of doctors or nurses would regard the prescribing or administration of the particular drug as reasonable he or she will not be liable. Somewhat different considerations must apply to a new drug. Here, again, the test is easier to formulate than to apply. Liability depends on whether in all the circumstances the doctor or nurse exercised reasonable care and skill, that is such care and skill as a careful doctor or nurse would exercise in the circumstances. In the case of new drugs this must involve forming a balanced judgement and not relying blindly on the manufacturers' advertising material. Experimenting with an unknown drug may well be justified in some cases, but it would plainly not be justified in others.

I have not, so far, discussed whether a warning of possible danger may
discharge the duty of care. Would it, for example, be enough if a manufacturer were to warn that a particular drug is new and therefore in some respects untested. It is obvious that no such warning could be of the slightest effect unless it had been communicated to the consumer and the consumer is in a position to evaluate the warning. If the drug is given to an unconscious patient or to a young child, no amount of warning can be effective. Further, warning notices tend to be obliterated or to become detached from containers. From a manufacturer's practical point of view, therefore, a warning will not be enough. But if the warning is sufficiently specific and is in fact seen, it could lead to a successful defence that the consumer has of his own free will elected to run the risk. For this purpose two things must be shown. First, that the consumer knew of the risk concerned, and second, that of his own free will he assumed it. It is inconceivable that a court would hold a general warning to be sufficient. If the warning is sufficiently specific the risk will not be unforeseen. Clearly, drugs known to carry a risk should always carry a warning in clear and specific terms, but it is unlikely that any warning would avail as a defence against an unforeseen risk since no warning could be sufficiently specific for this purpose.

DISCUSSION
Dr A. B. Wilson (Medical Director, Association of the British Pharmaceutical Industry) cited the problem of a doctor who used a drug for a condition not recommended on the drug data sheet or where there was an 'inverted triangle' warning in MIMS. Mr Wilmers said that the doctor had to be very careful indeed if there was such a warning and had to satisfy himself that, before prescribing, he had done all that he ought reasonably to have done in acquiring knowledge of the patient and the drug and that in prescribing he was acting reasonably. Mrs E. J. M. Leigh (Vice-President, The Pharmaceutical Society) wanted to know the responsibilities of the pharmacist who dispensed a drug on the orders of a doctor. Mr Wilmers replied that there was no problem if the pharmacist fulfilled the order of the doctor. Dr Goulding asked what was the position of the pharmacist if he recognised that the doctor had ordered a ridiculous dose. Mr Wilmers thought that if the pharmacist knew that the patient only had a headache and recognised the prescription as a lethal dose of some drug, he might be held negligent if he did not warn the patient. In ordinary circumstances the chemist did not have to concern himself with the size of the prescription. Mrs Leigh intervened to say that a chemist would not dispense a prescription he recognised as dangerous; he would contact the doctor. He would be up before a disciplinary committee if he did otherwise.

Dr Compston referred to the nightmare of modern prescribing, with so much to remember about drugs and their interaction. The doctor must have ready access to all available information; maybe the facilities of an on-line computer would be needed. He took up the distinction between unforeseen and unforeseeable effects.
For the latter it was not a question of who was to blame but of what should be done, a matter of moral responsibility. Mr Wilmers said that, by definition, the unforeseeable was something that by any absolute standard could not be foreseen. There was the problem that, in practice, the allegedly unforeseeable could be the unforeseen if all the knowledge in the world was available. Problems of moral liability had been set out in a recent working paper from the Law Commission. He took a simple example. If a woman broke her leg falling down the stairs of a bus, she was likely to be compensated; if a woman broke her leg falling down the stairs at home, she would not get compensation. The injury was the same in both cases. If every injury was to be compensated the State could not afford to make adequate compensation. There was limited compensation through National Insurance.

Dr Dollery pursued this point, thinking there might be a greater moral liability in the case of a drug like practolol, which, after thorough study, had produced a serious toxic effect, than in the case of a drug with known adverse effects which was prescribed after full assessment of the risks and benefits. In the case of practolol the manufacturers had decided that there was something for which they were prepared to pay compensation. Mr Wilmers replied that this was a question of morals, not of law. One view of morality was that drugs should be introduced because of the good they did. Morally, should there be punishment if something went wrong? These problems were also social and economic and could be approached from those angles.

Dr J. Maddox (The Nuffield Foundation) enquired whether the existence of the Medicines Commission and the Committee on Safety of Medicines had any bearing on the legal responsibilities of doctors and pharmacists. Mr Wilmers said that the existence of those bodies had no such effect.

Dr Laurence was worried by the two classes of broken leg. Drugs that raised the incidence of natural disease could not be classified in this way. If a diabetic had a coronary thrombosis, was that thrombosis a spontaneous natural disorder or was it due to the drugs he was taking? It would be impossible to make a distinction for the purposes of compensation. He was also concerned by the recent EEC directive on liability for defective products, which went into the matter of drugs. Mr Wilmers said that the European debate was still in progress but it did look as if a doctrine of strict liability was favoured. He did not consider such a doctrine to be a sensible answer.

Dr Wade felt that the world was unfair. If his ears dropped off after taking a drug and he could prove negligence, he would get a big reward, otherwise he would have to depend on National Insurance. If an abnormal child was born, the help given was relatively small unless the abnormality was due to thalidomide, when the help was disproportionately large. Mr Wilmers agreed that life was unfair; there would be less inequality if the amount of National Insurance was increased, but many felt that their contributions to this were large enough. If the
law of negligence was abolished and everybody qualified for compensation, all would get less. Dr T. D. Whittet (D.H.S.S.) said that the EEC directive on strict liability would have to be adopted in British law. He believed that strict liability would extend to cover everyone including the doctor and the pharmacist. This would have to be worked out carefully and the demands on public funds examined.

Dr Dollery wanted to know if a doctor could avoid strict liability by getting the patient to sign a form stating that he knew the drug prescribed was likely to benefit him and that it might cause certain adverse effects but that, nevertheless, he was willing to take it. Mr Wilmers considered that the law, when formulated, would not allow anyone to opt out. However, Parliament, in its wisdom, might or might not allow exceptions and Parliament was strictly unforeseeable.

Mrs Jean Robinson wanted it to be known that patients who complained to the Patients Association about the adverse effects of drugs were not concerned with compensation. They wanted everything to be done to prevent similar disasters.

**THE INVENTIVE DR RICHARDSON**

In 1867, Dr Lauder Brunton, while a house physician in Edinburgh, discovered the effect of amyl nitrite on angina pectoris, and the use of it was accepted at once. But he had been preceded by Dr Benjamin Ward Richardson, who in 1863 demonstrated the physiological effects of the same drug, and in 1864 its effect on angina, at two successive meetings of the British Association. His work was not noticed, although it had the most dramatic presentation. He told the Association that he was going to put a few drops of amyl nitrite on a filter-paper and wave it in the air, and everyone in the hall would perceive that their hearts beat faster. Professor George Rolleston, in the chair, smiled incredulously and held out his hand for the paper. He was given it, but warned to be careful; nevertheless he took a good sniff at it, went scarlet in the face, and was frightened as well as astonished. When he recovered, he apologised, and warned the audience about disbelieving an experimental observer.

Richardson made an amazing number of other discoveries. Apart from finding fourteen volatile anaesthetics, he was the first to apply the numbing effect of cold, by spraying the skin with ether before operating. He applied the knowledge that in the Midlands the smoke from lycopodium powder (the spores of the puff-ball) stupified bees, to the painless destruction of animals in what he called 'a lethal chamber'. He introduced the method to the Dogs' Home in Battersea with complete success. It was really carbon monoxide that did it. He also found that hydrogen peroxide was a good treatment for infected wounds, and from noticing that when he stirred it with feathers, they went a beautiful golden colour, he impressed on the Medical Society that it did the same on hair, and started at once the fashion for 'peroxide blondes'.