THE WORKING OF THE STRICT LIABILITY SYSTEM IN THE UK

Mark Mildred[1]

The definition of a defective product as one whose safety is not such as a person may be entitled to expect[2] is circular and opaque. Until recently there have been no decided cases in England to assist in the interpretation of the concept. The Act has been generally regarded as modestly effective in prompting early settlement in straightforward cases (particularly in the area of food poisoning) and as having produced no rush to litigation by consumers.

Since December 1999 there have been three judgments at first instance on the proper approach to the question of defectiveness. All have been in the field of healthcare products.

In Worsley v Tambrands Ltd.[3] the claimant suffered toxic shock syndrome ("TSS") which she alleged was caused by a tampon manufactured by the defendant. The defendant denied causation and argued that there was at most a statistical association between tampon use and TSS. Since the claim was disposed of on the defendant's submission that there was no case to answer the question of medical causation was unresolved.

The evidence took an unusual turn: the claimant's husband had thrown away the leaflet contained in the box which incorporated warnings of the symptoms of TSS and the steps to be taken in the event of their manifestation. Thus the claimant was forced to argue that the full warnings should have been displayed on the box and/or that the warnings over the years (which she had read) should have been designed to make a greater impact on her memory.

The judge decided that (i) the defendant had placed on the outside of the box a clearly legible warning directing the user to the leaflet contained inside; (ii) the leaflet was legible, literate, unambiguous and adequate to inform the user of the warning signs of TSS and the steps to be take, if those signs manifested themselves. These findings were sufficient to dispose of the allegation of an information defect in the product. The judge went on to find that (iii) the defendant was unable to "cater for lost leaflets or those who choose not to replace them as the claimant could have done".

A number of points arise:

1. the case was pleaded in negligence as well as under the Act. The judge did not appear to deal with these separately since, for example, the first two findings were relevant to both causes of action whereas the third was relevant to negligence only.
2. The judge appears to have dealt with causation without making a distinction between the two causes of action to which different tests, it is submitted, should be applied. On page 5 the judge stated that the claimant must prove the tampon was defective and that the damage was caused in whole or part by the defect. This follows closely the statutory wording. At page 16, however, the issues are

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[1] Solicitor, Professor of Litigation, Nottingham Law School.

[2] The test in Consumer Protection Act 1987, s. 3(1) implementing Article 6 of the Directive.

[3] [2000] PIQR P95.

characterised as whether the British leaflet fell below the common law or statutory standard and, if so, whether a different design would have caused the claimant to act differently. It is arguable that the second question is only relevant to the causation test in negligence but was applied to both causes of action. The statutory test is whether the defect caused the damage. In relation to manufacturing and design defects there appears to be no place for a requirement for the claimant to prove a different outcome in the absence of the defect complained of. In the case of a design defect, however, the position is less clear because the effect of the defect is to influence the conduct of the claimant. In those circumstances it is arguably necessary to look at the hypothetical conduct of the claimant in the absence of the influencing factor in order to complete the link between defect and damage.

3. The application of the expectation to the menstruating woman appears the best approach to the question whose entitled expectation is to be taken into account, notwithstanding the use of the phrase "persons generally" in the Act.
4. The failure to condemn the design of the UK warning information leaflet on the ground that it was inferior to that approved for use in the USA appears to be correct although the abandonment of the comparator emphasises the need for a value judgment as to the safety of the product which is all but identical to the assessment of the reasonableness of the acts and omissions of the producer for the purpose of judging negligence. This is underlined by the judge's description of the statutory test as "objective"[4].
5. Given that there are apparently a large number of claimants claiming damages for TSS, it seems extraordinary that this was chosen as the lead case in circumstances where the attack on the product literature was so clearly affected by the disposal of the leaflet inside the box in question.

In Richardson v LRC Products Ltd[5]. proceedings were brought only for breach of the statutory duties imposed by the Act. The claimant became pregnant when a condom used by her husband fractured during intercourse, the teat parting from the body of the condom at shoulder level. The claimant alleged that the condom was defective because it failed. No criticism was made of the product information.

A large part of the judgment deals with the competing expert evidence. The claimant alleged that the fracture was caused by weakness of the latex caused by ozone damage which must have occurred before the product left the factory. The judge concluded that it was probable that the damage observed to the body of the condom occurred after the fracture and not during the production process in the factory.

That left the claimant with her alternative case that the fact of the fracture itself proved the existence of a defect in the product.

Here the claimant faced evidential problems. Fractured used condoms are not generally called in for analysis of the cause of fracture. There were no "material" examples of discovery by the manufacturers of strength defects in unused condoms from the same pack as that the fractured condom. Epidemiological evidence called by the defendant suggested that failures occurred by chance, even though particular couples experienced an unusual number of failures.

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[4] Page 5.

[5] Unreported, 2 February 2000, Ian Kennedy J.

In the application of the law to the facts the judge stated that the expectation of the user was that a condom would not fail but recorded that the defendant had not claimed that one would never fail and that no method of contraception will be 100% effective. He then asked himself the question whether the existence of a fracture of itself proved a defect in the product and answered it in the negative on the ground that the evidence had showed (a) that there were inexplicable failures and (b) the condoms in question were manufactured to a more demanding standard than the relevant British Standard.

There are problems with this very brief analysis of the statutory requirements:

1. the test is not what the consumer expects but is entitled to expect. This question was not addressed as such.
2. The claimant did not allege an information defect. On a literal reading of the judgment it appears she might have been bound to fail on such an allegation, if the defendant had simply included in the information the words "This product may fail". This can scarcely have been the intention of the Directive.
3. The fact that the defendant had not claimed that a condom would never fail is in any event of only marginal relevance. If the correct view is that a fracture does not of itself prove a defect, the question should have been: (a) what proportion of condoms may be expected to fail without explanation and (b) did the product information adequately draw this risk to the attention of the consumer? If so, did a higher than expected proportion of the condoms in question fail? A burden on the claimant to prove at least the last of these matters to an appropriately rigorous scientific standard would surely be insupportable.
4. There is no statutory basis for treating the mere fact that a product is manufactured to or in excess of a British Standard as evidence that it is not defective for the purpose of the Act. Such compliance does not provide a defence under section 4(1)(a) of the Act and is relevant only as a fact to be taken into account when questions of safety are addressed.
5. If the fact of fracture does not prove a defect and the requirements under paragraph 3 above have not been satisfied, the claimant must prove either a manufacturing defect or a design defect. It is hard to see how the claimant could prove the former in relation to a single product against a background of evidence that there are inexplicable failures occurring by coincidence unless there is a fundamental fault in the product. In this case the severance of the teat from the body of the condom was held not to be such a fault because (it appears) the claimant could not prove the means by or reason for which it occurred. It is highly unlikely that a claimant would ever be in a position to prove that the actual design of the product or the process leading to its manufacture was defective.
6. In the event of the claimant seeking to establish either a manufacturing or design defect the process and legal hurdles would be indistinguishable from an action in negligence. Thus the "no-fault" or "strict" element of the liability regime the Directive was explicitly introduced to provide would be at best redundant.

In Foster v Biosil[6] the claimant had breast implants after a bilateral mastectomy. She brought proceedings under the Act only alleging that they were defective, the left implant having ruptured and the right implant having leaked. It was found as a fact that the right implant had not in fact leaked and thus the substantive dispute was over

[6] Unreported, 18 April 2000, Cherie Booth QC. I am grateful to Counsel for the Defendants for supplying a transcript and to Counsel for the Claimant for comments on the judgment.

the left implant. The defendant alleged that the rupture had been caused by the surgeon "nicking" it on implantation but this was rejected by the judge. Thus the only question remained was whether the left implant was defective.

The defendant argued that the claimant was obliged to prove the fact of the defect and also the cause of the defect whilst the claimant responded that it was necessary only to prove unsafe failure and that it caused the damage.

The deputy judge upheld the defendant's approach on the basis that, although the Directive did "overturn the law of negligence by imposing strict liability" it did not also reverse the burden of proof in relation to causation. The provisions of Article 6 were designed to elucidate the meaning of "defect" and not reverse the burden of proof. The claimant must establish on the balance of probabilities that there was a defect in the product and not merely that the product failed in circumstances which were unsafe and contrary to what persons generally might expect. The concept of "defect" is directed to the fact that something is wrong rather than the consequences of something being wrong.

In the light of this analysis the fact that other parts of the same batch were satisfactory and the rarity of failures shown by the defendant's records led the judge to conclude that the implant was not defective. That the fact of rupture of an implant after five months' use without surgical damage on implantation and necessitating removal did not imply a defect would surely appear extraordinary to the common-sensical observer.

Again, a number of points arise from the judgment:

1. it was never the claimant's case that she was absolved from proving that the defect had caused the damage. The textbook references in the judgment[7] merely repeat that the claimant bears the burden of showing that the defect in the product has caused the damage to the claimant. These extracts appear to have been misconstrued as dealing with the cause of the defect (that is, the reason why a product is defective) rather than the fact that the defect has caused the damage.
2. The statutory definition of defect involves a falling short of the standard of safety which persons generally are entitled to expect. If persons generally are entitled to expect that a surgically implanted device will not fail in five months, why should they be obliged to prove the reason for that failure before the product can properly be characterised as defective? To revert to the judge's analysis, the fact that something is wrong is the fact of rupture and not the medical consequences of rupture. By reason of the rupture the implant was unsafe and, the claimant's case runs, persons generally were entitled to expect more safety from the product.
3. Whilst the definition of "defect" may be circular, this does not require or permit the imposition of a further demand on the claimant to explain the mechanism of failure.
4. On this analysis it would be open to the defendant to call evidence to the effect that any such product would have an unavoidable failure rate and, if that were accepted, the question would become whether this had been fairly and accurately put before the user in the product information. It would also be open to the

[7] Product Liability: Law & Insurance, Mildred M. (ed.), LLP Ltd, London, looseleaf.

claimant as set out above to prove a higher than unavoidable failure rate in the product although this would in most cases be an impracticable task.

The last two of these cases might well have been paradigms of the advantages of a "strict liability" system. Rare product failures with reasonable expectations disappointed would lead to compensation financed by product users generally through insurance with the transaction costs of fighting the claims saved.

The imposition of an impossibly heavy demand on the claimant to prove why product failure has occurred (and that it should not have) make the statutory cause of action indistinguishable from the fault-based system of negligence and frustrate the explicit purposes of the Directive.