The Consumer Protection Act revisited - new light on defective products

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For 15 years, the most thorough examination of when a product is defective, pursuant to the Consumer Protection Act 1987 ("the CPA"), was the judgment of Mr Justice Burton in A v National Blood Authority, the Hepatitis C litigation, where DACB acted for the defendant. The decision has been subject to much academic criticism but until now has not received significant judicial scrutiny. In Wilkes v DePuy [2016] EWHC 3096, Mr Justice Hickinbottom has radically reappraised the CPA's interpretation.

In a judgment that will be welcomed by all manufacturers, he concluded that an artificial hip component that fractured was not defective and that the defendant manufacturer was not liable under the provisions of the CPA.

The Background - a fractured hip stem and the Medical Devices Directive

In January 2007, the Claimant underwent a surgical procedure to insert an artificial left hip comprising metal components manufactured by DePuy International Limited, the Defendant. One of these components was a steel femoral shaft called a “C-Stem”. In January 2010, that stem fractured, necessitating further surgery.

The C-Stem fell within the scope of the Medical Devices Directive (93/42/EEC). The Directive's General Requirements provide that manufacturers must apply certain principles in a set order:

- eliminate or reduce risks as far as possible;
- where appropriate take adequate protection measures in relation to risks that cannot be eliminated; and
- inform users of the residual risks.

The Judge explained this requirement involved an assessment of whether the "risks” of the medical device are “acceptable”. Whether a product has an acceptable level of safety therefore necessarily involved some balancing of risks against benefits. The need for such a risk-benefit analysis has long been a matter for contention when applying the CPA.

A New Approach - balancing risks and benefits

In what the court described as the "monumental judgment" of Burton J in A v National Blood Authority [2001] 3 All ER 289 (“A v NBA”), the fundamental purpose of the Product Liability Directive (85/374/EEC), and therefore the CPA, was seen to be the protection of consumers' interests. This was achieved by eliminating the need for the injured party to have to prove negligence or fault on the part of the producer and by replacing it with the concept of whether or not a product was defective.

For the purposes of the Act, there is a defect in a product if the safety of the product is “not such as persons generally are entitled to expect”, taking into account “all the circumstances”. Burton J ruled that the first step was to identify the harmful characteristics that caused the injury.

Hickinbottom J's starting point was different. He noted that the Directive was not driven solely by the protection of consumers' interests but referred to other recitals to the Directive, including the need to "solve the problem, peculiar to our age of increasing technicality, of a fair apportionment of the risks inherent in modern technological production". The "required hallmark" of a defect was a lack of safety, which was inherently a relative concept. In determining the appropriate level of safety of a product, he said that the potential benefits of such a product had to be balanced against its risks.

In considering whether a product suffered from a defect, the court must assess the appropriate level of safety, exercising its judgment, and taking into account the information and the circumstances before it, whether or not an actual or notional patient or member of the public, would in fact have considered that information.

The Court's task – weighing all relevant circumstances

While the Judge acknowledged such an assessment might be difficult in practice, he considered it conceptually simple and

urged a holistic approach. Courts should guard against over-complicating or over-analysing the exercise.

So, any assessment required a balancing of the risks against the benefits, as well as the costs involved in reducing those risks. Whether a particular risk was “avoidable”, in that it could be eliminated or mitigated, might be a circumstance that bears upon the level of safety that the public was entitled to expect.

The categorisation of defects into “standard” or “non-standard” which, Burton J devised in A v NBA, was considered unnecessary and undesirable. It was not a classification deriving from the CPA. The Judge explained that whether a product was within the producer’s specification and compliant with relevant standards may be relevant in relation to the level of safety but any rigid distinction was "positively unhelpful and potentially dangerous".

Non-compliance with any mandatory standards would provide evidence of defect. While compliance with such standards would not provide a complete defence, it would provide considerable weight as evidence that the level of safety required by the Act had been satisfied and the product was not defective.

Crucially, warnings given would qualify the expectation that the public generally were entitled to expect and therefore go to the issue of whether a product was defective. Where a product, such as a C-Stem, was available to a patient only via a professional healthcare intermediary, the position was more complex. Whereas, in A v NBA, the role of a 'learned intermediary' was not considered a circumstance relevant to the purpose of the CPA, Hickinbottom J disagreed and reinstated consideration of this factor.

Was the C-Stem defective?

The failure of the C-Stem was unfortunate but not as a result of a defect.

The court found no evidence of any manufacturing defect or other defect in the sense of the particular device being outside the design specification. The Judge also took into account that the failure rate as a result of fatigue failure for this product was very small indeed and none of the reports suggested a design problem.

He was unpersuaded the issue could have been simply and easily avoided as design was necessarily holistic. The assessment of safety was objective but it was, in the Judge's view, important that the relevant regulators, acting in the public interest and on the basis of full information, had assessed the C-Stem to be acceptably safe. The fact that a safer design could be envisaged did not mean that the current product was defective. The biomechanical variables in the use of artificial hip implants made reliable prediction of when failure might occur impossible. What could be done, as the Instructions for Use ("IFU") information in this case did, was to identify factors which were associated with such failure.

The fracture of the C-Stem was "rare, unpredicted and unpredictable; and it was a risk that was expressly warned in the IFU". The Defendant would only be liable for the failure of the C-Stem if it had a defect, as defined in the Act, at the time it was put onto the market. The claimant had not satisfied the court that the C-Stem had such a defect.

Comment

This case revisits the notoriously difficult concept of how to determine when a product is defective. The CPA defines defect in terms of consumer expectation as to safety. The judgment approaches this in a materially different manner and also questions many of the strands that formed the opinion in A v NBA.

The judgment rejects the identification of the harmful characteristic which caused the injury as the starting point for any investigation. It considers the balancing of potential benefits of products against their risks as essential to any determination, although it is interesting to note that the Judge considers this necessary because of the provisions of the Medical Devices Directive, which has a very different aim and purpose to the Product Liability Directive. It rejects the concept of standard against non-standard products that was introduced in A v NBA, and it accepts that professional intermediaries have an important and valid role to perform.

After A v NBA, it was expected that either the Court of Appeal or further caselaw would help in the determination of the level of safety persons generally were entitled to expect in relation to a whole range of products, not just in the medicinal products sector. No additional commentary was ever forthcoming.

While Wilkes v DePuy is, like A v NBA, a first instance decision, it does at least open up the debate again. It is anticipated that it will be widely welcomed by manufacturers and producers.

If you would like to discuss any aspect of this judgment, please contact:

Alison McAdams amcadams@dacbeachcroft.com **or Simon Pearl** spearl@dacbeachcroft.com**.**

Authors

Alison McAdams

Simon Pearl

London - Walbrook
amcadams@dacbeachcroft.com

London - Walbrook
spearl@dacbeachcroft.com

DAC BEACHCROFT