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# GNL38: Product liability – what is a "defect"?

The question of whether a product is defective is central to a claim against manufacturers under the strict liability regime for compensation in respect of injury said to have been caused by use of a product.

What do manufacturers need to know and how can they best protect themselves against such claims?

### The legal framework

The Consumer Protection Act 1987 (CPA) enables individuals (not only the consumer but anyone who uses the product) to bring claims against manufacturers directly without the need to prove fault if they have suffered personal injury as a result of a defective product. Provided a defect is established and proven to have caused the injury, there is no need to investigate what caused the defect or how it could have been avoided.

The question as to what extent the manufacturer has been negligent in its design of the product is also not relevant. It is instead an objective question as to whether the product has met the safety standards that the reasonable person is entitled to, having regard to the product's intended use and any relevant safety warnings.

There have been surprisingly few cases in the UK determining the question of "defect" and what needs to be established to prove a product was defective. Over the last couple of years, however, the courts have considered the question in more detail. We now have a better understanding of the general approach and what manufacturers need to know to best protect themselves against product liability claims under the CPA.

Both the English and Scottish courts have recently addressed the question of "defect" in the context of claims against manufacturers of medical devices. The approach, while not being a one size fits all, will likely apply to most products in all sectors. The challenge, however, is how it is applied in the context of IoTs (internet of things) and other advancing technologies.

### National Blood Authority

The leading authority on the question of "defect" was a 2001 case between 114 patients and the National Blood Authority (NBA) following the infection of Hepatitis C through blood transfusions which had used blood from infected donors. In that case, the court emphasised the importance of needing to identify the "harmful characteristic" of the product which was said to have caused the injury.

Further, whether the product had performed as intended or there was some other "non-standard" issue (such as the product not falling within the manufacturer's specification) which could have a bearing on whether it was defective.

Under the CPA, there is a defect in a product if the safety of the product is not such as persons are generally entitled to expect. In the context of medical devices, the safety expectation is particularly high considering their function (for example, pacemakers and implantable cardioverter defibrillators) and the vulnerable situation of patients using such devices. The potential lack of safety which stems from the abnormal potential for damage which those products might cause to the person concerned is also significant.

### The current approach

The courts have more recently moved away from the approach laid down in the NBA case and adopted a more holistic approach to the question of defect – a key issue being whether the benefit of the product outweighs its risks acknowledging that no medical device, in particular, can ever be completely free from risk.

Safety has to be a relative concept based on a risk-benefit analysis taking into account a person's reasonable expectation having regard to the product's intended purpose and its objective characteristics. As such, where a product complies with regulatory requirements, while not a complete defence, this will go some way to proving the product is not defective. It will be challenging for a claimant to prove that the level of safety that persons generally are entitled to expect is at a higher level than that required by the regulators.

The recent Scottish court in Hastings v Finsbury Orthopaedics and Stryker UK Ltd has broadly followed the recent English decisions on the question of "defect". Mr. Hastings claimed that the metal-on-metal hip replacements he had been implanted with were defective and unsafe under the CPA.

In this case, the Judge held that while Mr. Hastings had established the presence of metal debris from the product and soft tissue damage near to the site of the prosthesis, he had failed to show that this had been caused by the implants or that the product did not meet the required safety standard as being one that a person generally was entitled to expect with use of the product having regard to its inherent risk (being the propensity to shed metal debris through wear in use and admitted risk that some patients may suffer an adverse reaction which may necessitate early revision).

The Scottish court considered the two leading English court decisions in Wilkes v DePuy International and Gee and others v DePuy International (which also concerned claims for metal-on-metal hip prostheses) and determined that the entitled safety expectation had been met and as such the product was not defective.

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This has reinforced the approach taken by the UK courts under the CPA on the question of "defect". The test is an objective one. How a product complies with regulatory requirements and compares to alternative products will be key. The Scottish court may, however, have set the bar lower in this regard dismissing the test set out in *Gee* that the product should not be materially worse than those it was intended to replace holding that this imposes an unnecessary burden on the claimant and that "subject to de minimis considerations, its level of safety would not be worse, when measured by appropriate criteria, than existing non [metal-on-metal] products that would otherwise have been used".

### Application to IoTs and technology products

This approach works in the context of those products which fall within sector-specific safety regulations and are required to meet mandatory standards under conformity assessments such as medical devices, as well as other products which fall within the Europe-wide CE marking regime (and now the new UKCA marking post Brexit) such as machinery and electrical goods. Compliance with the regulatory requirements will be powerful evidence that the level of safety of the product was that which persons generally were entitled to expect to defeat a claim under the CPA.

But what about consumer products under the General Product Safety Regulations 2005 (GPSR) where safety is assessed by reference only to voluntary standards and is therefore arguably more subjective? Even more challenging is the position in respect of IoTs and other advanced products. "Safety" in the context of the CPA is a legal concept and not a medical term of art.

It is for the court, not the experts to decide what, as a matter of law, is the entitled expectation in relation to the safety of a product. How then will this be applied to relatively new products which embed advanced technologies combining hardware with software? The regulatory regime for such products has not kept pace with product development. How would a court approach the question of a defective IoT in circumstances where knowledge of inherent risks may be unknown or at least limited and comparisons with alternative products difficult?

With the courts so far only addressing the question in the context of medical devices which have been in circulation for many years, it remains to be seen how they will approach it when applied to new advancing technologies where the question of identified inherent and admitted risks is likely to be more challenging.

In *Hastings*, the Scottish court dismissed the IFU (instructions for use) as being of little weight as it was heavily qualified. This will be surprising to manufacturers which rightly understand the importance of providing adequate safety warnings and unwelcome if this cannot assist with considerations of safety and defects in the context of a claim under the CPA. We would hope the *Hastings* decision at least on this point can be confined to its facts, given that the CPA itself expressly provides for the consideration of warnings and IFUs when determining whether a product is defective.

### What should manufacturers do?

Manufacturers should continue to monitor how the courts approach the issue of establishing whether a product is defective in respect of a claim under the CPA and further decisions on how safety expectation test is applied. With IoTs increasingly becoming a part of consumers' everyday life, it seems highly likely that product liability claims will follow. Given such products are so new and the law has not kept pace, there is a high degree of uncertainty for potential manufacturer and software developer defendants.

Some practical steps manufacturers can take to protect themselves against such product liability claims include:

- Maintain detailed, accurate and up to date records on product safety testing.
- Regularly review product risk assessments and update with any changes to product information and/or newly identified risks.
- Comply with regulatory requirements and procedures, industry technical safety standards, and conformity assessments.
- Ensure all marketing of the product, IFUs, warnings and safety guidelines are accurate and kept under constant review and regularly updated.
- Amend warnings and IFUs where required to address newly identified risks but avoid overly qualified and generalised wording.
- Maintain good records of customer complaints to track and assess alleged product risks.

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For further guidance please contact Katie Chandler (Tel: 020 7300 4163).

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