









# FOIL UPDATE 18<sup>th</sup> November 2021 **Product Liability Part I**

A review of current issues from the Product Liability Sector Focus Team

This review, published in three parts, provides an update on a diverse range of topics relevant to those who practise, or have an interest in, product liability law.

We look at topics ranging from the practical (e.g., Brexit, S41 CPA) to the inspirational (genomics, vaccine compensation). We give thanks to guest authors from 39 Essex Chambers, Hawkins, and 1 Chancery Lane. Parts II and III will appear over the next two months.

To watch bitesize videos on each of these topics, please visit <u>Forum of Insurance Lawyers -</u> YouTube





#### 1. The Effect of Brexit on Product Liability Law

**VICTORIA CURRAN** Browne Jacobson victoria.curran@brownejacobson.com

The UK's product liability and safety landscape is underpinned by EU law so the long-term impact of Brexit could be significant. Particularly given the current focus on the suitability of the existing product liability regime in the context of new technologies. In the short term, the changes are relatively minor.



By way of background, the law on product liability derives from 3 sources:

- 1) contract for the sale of a product;
- 2) tort, which holds a general duty to avoid causing harm to those that might reasonably be affected by negligence; and
- 3) legislation (Product Liability Directive 1985 and General Product Safety Directive 2001). These directives were implemented by the Consumer Protection Act 1987 and the General Product Safety Regulations 2005 and still remain in force, despite Brexit, with minor practical changes.

## The UKCA Mark

The UKCA mark replaces the CE mark for relevant products sold in England, Wales and Scotland. The CE mark is still lawful until 1 January 2022, except in limited circumstances, such as newly designed products. Products sold in the EU will require both the CE and UKCA mark, yet there has been no change with regard to product safety and compliance standards for products displaying these marks.

#### Change in status in manufacturer, importer and distributor

Brexit has had an impact on the status of the economic operators within a supply chain, which includes UKCA and CE marked products. This is important because the regulatory obligations differ between manufacturers, distributors and importers. They are more onerous on an importer, who pre-Brexit might have been classed as a distributor, and therefore it is important for those within the supply chain to understand their role and regulatory responsibilities.

# Impact of Brexit on the Consumer Protection Act 1987 ("the CPA")

Prior to Brexit, Section 2(2) of the CPA made 3 categories of persons liable in the event of a defective product:





- i) producer;
- ii) those holding themselves out as producers; and
- iii) those importing products to a member state.

Section 2(3) states that a supplier may also be liable but could avoid liability by identifying one of the parties listed in Section 2(2).

Since 3 January 2021, the third category has been amended to widen the interpretation of an importer to include any form of distribution into the UK, catching some former distributors and now making them strictly liable.

The direct link to this talk is: <a href="https://www.youtube.com/watch?v=KgdaXzoRbI8">https://www.youtube.com/watch?v=KgdaXzoRbI8</a>

#### 2. Genomics and Covid-19

# KARISHMA PAROHA Kennedys Law Karishma.Paroha@kennedyslaw.com



Genomics is an innovative process that identifies and analyses variations (Single Nucleotide Polymorphisms ("SNPs")) in our DNA. SNPs have the potential to modify the proteins created by a gene, which can make them more or less effective and has a direct impact on our health. The advantages of genomic testing include improving patient's health through knowledge, intervention, earlier diagnosis and effective use of therapies and medication, particularly in cancer patients.

Genomics has already enabled us to understand more about Covid-19 and discover further information regarding new variants and transmission. The establishment of Covid-19 Genomics UK (COG-UK) has resulted in the delivery of large-scale whole-genome virus sequencing to the NHS, resulting in an innovative partnership with NHS organisations and creating the largest dataset for real-time genomic viral epidemiology since the Ebola outbreak. Sequencing has had a global impact, but rather surprisingly, the USA is playing catch up in this area due to their lack of surveillance capabilities.

The implication genomics may have on product liability can be seen in pharmacogenomics. This is the study of how genes affect a person's response to drugs. Currently, we generally have a "one size fits all" approach but the future goal is to tailor drugs to an individual's needs to enable patients to get the best treatment.





Product liability claims being brought as a result of ineffective drugs due to an individual's genetic make-up are not yet considered as legitimate. It is unlikely this view will change until the FDA decide to assess drug approvals on the basis of genetic subgrouping.

Overall, the future of genomics and its role in product liability claims looks to be a game changer. Two specific examples are i) cases involving asbestos and the consideration that gene mutation is a verifiable alternative cause, and ii) the potential for genetic abnormality to be the cause of a plaintiff's condition and therefore a possible defence for the future.

The direct link to this talk is: <a href="https://www.youtube.com/watch?v=71tl5oQWEOM">https://www.youtube.com/watch?v=71tl5oQWEOM</a>

## 3. Product Safety – Regulatory and Compliance

**NEIL BLOCK** 39 Essex Chambers neil.block@39essex.com

Product liability focuses on consumer protection by ensuring products are safe to use. The General Product Safety Regulations 2005 ("GPSR"), CPA 1987 and Supply of Goods and Services Act 1979 ("SGSA") collectively set out the legal requirements for product safety,



which manufacturers and importers placing products on the UK market need to adhere to. In practice this involves minimising the risks associated with the product, maintaining records, issuing appropriate labelling and warnings for safe usage.

If claims arise due to a defective product, manufacturers should report this to their local trading standards service and consider appropriate corrective action. If a product poses a safety risk it must be recalled and its details must be communicated to purchasers in the form of a notice. There is no single enforcement authority that monitors recalled products. Under the Consumer Rights Act and SGSA, the consumer is entitled to a full refund or a replacement product. Central issues are whether a defect exists and establishing a causal link between defect and damage. If a consumer can prove defect, causation and damage then their claim will succeed.

Having a plan in place to deal with recalls is critical to identify and manage safety risks as early as possible and to protect the business' reputation. Failure to notify regulators in time may result in criminal sanctions.

Equally, if a recall is made and a manufacturer fails to render it safe then they may be liable for subsequent injury. Under CPA 1987 the simplest way for the consumer to bring a





compensation claim is to establish defect. Moving forward, the expectation is that we will see more claims of this simplistic nature.

The direct link to this talk is: <a href="https://www.youtube.com/watch?v=VII18I4b7Gc">https://www.youtube.com/watch?v=VII18I4b7Gc</a>

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