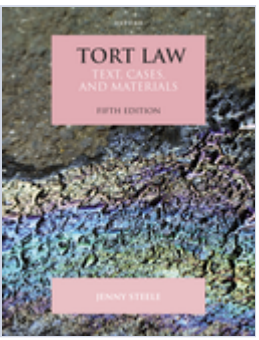

Tort Law: Text, Cases, and Materials (5th edn)
Jenny Steele

p. 891

16. Product Liability

Jenny Steele, Professor of Law, University of York

https://doi.org/10.1093/he/9780198853916.003.0016
Published in print: 29 September 2022
Published online: September 2022

Abstract

All books in this flagship series contain carefully selected substantial extracts from key cases, legislation, and academic debate, providing able students with a stand-alone resource. This chapter examines the statutory strict liability for damage arising from defective products as set out in the Consumer Protection Act 1987 and the EEC Directive on Product Liability. It begins by considering the apportionment of risks associated with products and the development risks defence before turning to similarities between statutory liability and common law liabilities based on negligence and on strict liability. It then looks at the reasons why it is misleading to consider 'product liability' in isolation and the concept of defectiveness.

Keywords: strict liability, damage, defective products, development risks defence, negligence, product liability, defectiveness

Central Issues

i) Part I of the Consumer Protection Act 1987 introduces a form of strict liability for harm done by defective products. The statute gave effect to an EEC Directive, and it bears the marks of political compromise. The central justification of the Directive is that it apportions risks associated with products between consumers and producers. It is one element in a broader European regime of product safety. The statutory liability is domestic law which survives

Brexit; existing European jurisprudence is important to the origin and objectives of the legislation, but future European law will not be authoritative in its interpretation and development.

ii) The key requirement of liability under the Consumer Protection Act 1987 and under the Directive is that harm must be caused by a 'defect' in the product; and a producer of goods may be exonerated if the state of knowledge at the time did not make it possible for the defect to be discovered. It was argued from the inception of the Directive that these key features would make the statutory liability little different from negligence; but the case law to date—relatively limited though it is—suggests that the statutory liability is in some respects easier to establish than liability in negligence; reasoning processes are clearly distinguishable.

1 Defective Products and the Standard of Liability

The unified tort of negligence emerged in a case of product liability. In *Donoghue v Stevenson*, the plaintiff claimed that she had consumed part of a bottle of ginger beer; that a decaying snail floated out of the bottle; and that she suffered personal injury in the form of gastro-enteritis, and 'shock'. The basis of her claim in tort was that the snail was present through the *negligence* of the manufacturer; and that this negligence led to consequential harm in the form of personal injury.

p. 892 ↵ The key significance of *Donoghue* was that it recognized a general legal relationship that is separate from contract. This legal relationship was marked by proximity or 'neighbourhood' between the defendant (whose alleged negligence created the risk of harm), and the plaintiff (who as ultimate consumer of the product was exposed to that risk). According to Lord Atkin, this relationship gave rise to a duty to take reasonable steps to protect the consumer from harm. The duty owed by the manufacturer to the consumer (provided that consumer is relevantly 'proximate' within the terms of the neighbour principle) is a duty *to take care*; and liability is restricted to *consequential harm*.

The Consumer Protection Act 1987 creates *additional* liability on the part of manufacturers where damage is caused by a defect in a product.[1] Like the action in negligence, liability under this Act only extends to *consequential damage* (in the form of damage to property or personal injury). There is no liability under the Act for damages assessed by reference to the purchase price or value of the product, or for damage done to the product itself. Unlike negligence, damage to what may be broadly called 'commercial' property is not covered under the Act (section 2(3)). It is 'consumer protection' legislation. On the other hand, personal injury is covered by the Act in all contexts.

Liability under the Consumer Protection Act 1987 is defined without reference to fault. The statute was intended to give effect to Directive 85/374/EEC, on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products (the 'Directive on Product Liability').[2] The Preamble to this Directive explicitly states that the relevant liability is 'without fault'. Accordingly, there is no need to show lack of care—or other wrongful conduct—on the part of the

manufacturer. The legislation largely remains in force following the UK's exit from the European Union. However, the former s.8, which enabled Orders to be made varying the legislation as appeared necessary to give effect to the Directive on Product Liability.

The statute does not create liability for all injuries caused by products. Liability under the Act requires that injury or damage is caused by **a defect in a product**. By section 3(1) of the Act, a 'defect' is defined in terms of the legitimate expectations of 'persons in general'. The key distinction between liability based on fault at common law, and 'strict' liability under the Consumer Protection Act 1987, lies in the difference between **showing negligence**—for example, in the design, manufacture, or marketing of the product (the position at common law); and **showing defectiveness in the product** (the position under the Consumer Protection Act 1987). It has been argued that this distinction may prove to be very fine or even insignificant; but the case law indicates that there is a distinction in effect nonetheless.[3]

Importantly, a controversial defence (**the development risks defence**) was included in both the Directive (where it was said to be at the discretion of Member States) and the Consumer Protection Act 1987. The effect
p. 893 of this defence is to further narrow the distinction between ↵ common law and statutory product liability. Broadly speaking, the impact of the defence is that the consumer takes the risk of defects which could not have been discovered at the time of manufacture, because scientific knowledge at the time did not permit the relevant risk to be known.[4] The exact breadth and meaning of this defence is very important to the nature of the liability introduced by the Consumer Protection Act 1987: 3.5.

The closeness to negligence of the Consumer Protection Act 1987 is highlighted by contrasting it with a new form of strict liability imposed by the Automated and Electric Vehicles Act 2018. Though there are also other routes to liability, for example, if a vehicle is uninsured, s.2(1) simply states that were damage is caused by an autonomous vehicle which is insured, the insurer will be liable for the damage.[5] This reflects a different balance between interests where there is a new type of product, bringing new issues and dangers.

1.1 From Negligence to Defectiveness: Allocation of Risks

The Directive on Product Liability is expressly concerned with the apportionment of risks associated with products. The Directive was the subject of extended political negotiation between Member States, and the apportionment of risks it incorporates is in effect a compromise. Broadly, producers take the risks of defectiveness, whether these risks are produced by lack of care or not; while consumers take the risks associated with non-defective products (subject of course to liability in contract and in tort).

The effect of the development risks defence (Section 3.5) is to introduce a major qualification to this basic apportionment. In the case of a defect which in the relevant sense could not have been discovered by the manufacturer (an undiscoverable defect), the risk will not lie on the manufacturer.

The development risks defence has the potential, depending on its interpretation, to undermine the strictness of the product liability regime.[6] The EC Commission has justified the defence as protecting socially desirable *innovation*:

Commission of the European Communities, *Third Report on the application of Council Directive 85/374/EEC*

(the 'Product Liability Directive') 14 September 2006

> The DRC[7] was defined in order to establish a satisfactory compromise between the need to stimulate innovation on the one hand and consumers' legitimate expectations for safer products on the other. The crucial argument of the current debate on the DRC is that removing the clause would stifle innovation.
>
> The findings presented in this report[8] seem to indicate that the often-used argument of the
> p. 894 Development Risk Clause being a significant factor in achieving the Directive's balance
> ↵ between the need to preserve incentives to innovation and consumer's interests is well-founded and is based on the following:
>
> - the DRC protects incentives to innovate in reducing the innovation-related risks, by not diverting resources from R & D to insurance policies and by pushing firms to align to state of the art knowledge;
> - the DRC is probably one key factor in determining the relative stability of product liability costs in European industry and keeping litigation at a reasonable level;
> - in a strict liability regime, companies in high-tech/high risk sectors would find it very difficult to obtain a reasonable insurance policy which covers their developmental risks.
>
> The combination of these factors lead Fondazione Rosselli to conclude that the costs of letting the producers innovate within a strict liability environment would be extremely high, and would affect consumers in the long term. In effect, both the Lovells and the Rosselli studies conclude that such a defence should be maintained.

It seems that companies in 'high tech/high risk sectors' effectively *do not* operate in a 'strict liability regime' under the Directive (see the third bullet point in the extract above). We give fuller consideration to this state of affairs when we consider Defences, in Section 3.

2 The Broader Context: The Limited Impact of the Consumer Protection Act 1987

Analysis of statutory strict liability for harm done by products is of course very instructive from the point of view of the general law of tort. There are interesting parallels between the statutory liability, and common law liabilities based on negligence and on strict liability. But in some respects, a focus on the terms of the Consumer Protection Act 1987 is misleading. There are two broad reasons for saying this.

2.1 Closeness to Negligence

First, there are relatively few successful product liability claims under the Act which would not also succeed at common law. Indeed, there still appear to be more books and articles written about the statute than there are successful claims under it.[9] Of course, this is partly because of the definition of 'defect' and the inclusion of a

number of significant defences, including the important 'development risks defence', which we have already noted and which will be explored in the following section. But there are other significant reasons too, which have received less emphasis.

p. 895

Causation

Whether an action in respect of harm caused by a product is brought at common law or under statute, and whatever the standard of liability, the claimant must show that the injury suffered was caused by the defect (under statute) or the negligence (at common law). Either way, proving causation will be far from straightforward in many cases where the mechanics of cause and effect are disputed and (particularly) where the major evidence is epidemiological. Among such cases are many pharmaceutical claims.

In an action for product liability at common law or under statute the claimant (or claimants) must show not only that the injury was caused by negligence or a defect; *but also* that the particular product causing the harm was manufactured by the defendant, and not by some other manufacturer. We saw the impact of some such problems—and the ways in which common law moves to some extent to accommodate them—in Chapter 6.

The issue of causation is sometimes linked to problems relating to 'defectiveness'. In *XYZ v Schering* [2002] EWHC 1420, a number of women brought actions against the manufacturers of 'third-generation' combined oral contraceptives. The claimants argued that these products were 'defective' within the terms of the Consumer Protection Act 1987, and that the defects in question had caused them to suffer cardio-vascular injuries such as deep vein thrombosis and pulmonary embolism. The claims failed. Mackay J held that the claimants had not established on the balance of probabilities that the contraceptives had increased their risk of sustaining these injuries, when compared with the risks associated with the previous generation of combined oral contraceptives. Only the *excess* risk associated with the new product would be unknown to the women, who were otherwise treated as making an informed choice to use this method of contraception (combined oral contraceptives). Thus, the products were not 'defective': the available evidence could not be said to establish that the risk of injury was enhanced by the defect. The same evidence would have been relevant to proof of causation, had the claims not failed at this initial hurdle.

In a far simpler case, it has proved possible to conclude that an injury was caused by a defect on the basis that the only serious alternative explanation could be discounted. In *Ide v ATB Sales* [2008] EWCA Civ 424; [2009] RTR 8, the Court of Appeal upheld a judge's decision to this effect. The claimant had been seriously injured while riding his Marin mountain bike off-road, and brought an action against the defendant importers (see later in this chapter for the range of defendants who may be liable under the Act). The left handlebar had snapped. The defendants argued that the rider had through his own actions caused the crash and that this had caused the handlebars to break. Having analysed the evidence and rejected this theory, the judge had been entitled to conclude that a defect had caused the crash. Since this was liability under the Consumer Protection Act, there was no need to discover or specify *what* defect had caused the handlebars to snap; it was enough that the only real alternative explanation had been discounted. A contrasting decision is *McGlinchey v General Motors UK Ltd* [2012] CSIH 91, an appeal to the Inner House of the Court of Session in Scotland. Here a car had rolled down a steep hill and injured its owner. The first instance court had rejected as implausible the only two causes of the accident proposed to it, namely a defect in the handbrake, and user error in failing to engage the handbrake. The Inner House decided that having rejected the possibility of failure to engage the handbrake—

on the basis that the car otherwise would have rolled down the steep hill much sooner—the court was nevertheless not obliged to accept that there had been a defect in the handbrake. Other possibilities—including wear and tear—existed. It was always the duty of the court to decide whether a cause was probable on the balance of probabilities, even if the other implausible explanations had been eliminated.

p. 896

Funding and Access to Justice

Liability rules will only have an impact if potential claimants have access to justice. On the other hand, in a regime of conditional fees, as we explained in Chapter 9, it is possible for speculative claims to be initiated. The importance of funding is illustrated by the case of *Paul Sayers and Others v SmithKline Beecham plc & Others* [2004] EWHC 1899 (QB) (the 'MMR/MR Vaccine Litigation'). Actions were brought on behalf of a number of claimants, who suffered from autism and whose families blamed that condition on vaccines manufactured by the defendants. It was clear that there would be significant difficulties in proving causation,[10] and the Legal Services Commission withdrew funding from the action. The claimants were therefore exposed to an order of costs against them, should they lose, and their actions were discontinued.

2.2 Regulation of Product Safety

The second general reason why it is misleading to consider 'product liability' in isolation is that the Directive is only one element in a European strategy for increasing product safety. Indeed in 2005, the UK responded to revisions in the EC Directive on General Product Safety with the General Product Safety Regulations 2005, incorporating new powers of recall on the part of regulators, and duties of notification on the part of producers.[11] To the extent that product liability is intended to achieve a measure of deterrence, it therefore overlaps with a developing regulatory regime.

Addressing this topic in the context of the law of tort takes product liability out of its broader context, of enhancing safety. Even so, we can appreciate an underlying theme of consumer safety law: how can we enhance safety and compensate the victims of product defects, without stifling innovation and thereby denying society the benefits of new products, and of economic development? Even simpler products may entail inherent dangers and some such products are wanted nevertheless.[12]

In the next extract, the last two points are brought together.

Chris Hodges, 'Approaches to Product Liability in the Member States', in D. Fairgrieve (ed.), *Product*

***Liability in Comparative Perspective*, at 201**

> The level of product liability claims in Europe has consistently remained far lower than that which has been produced in the USA by their procedural rules and constitutional climate, given in particular their different situation in relation to availability of healthcare and insurance. It is widely recognised that the overheated liability system in the USA produces economic results that encourage
> p. 897 lawyer-led litigation and in which lawyers can reap very substantial ↵ and disproportionate rewards. The impact of reforms to European rules on access to justice, class actions, funding mechanisms and damages should be carefully considered so as to avoid these American problems. Existing variations in national rules on litigation procedure and funding constitute significant barriers to consumers in bringing claims and confusion to all litigants and non-national lawyers in understanding some national systems.
>
> The function of a product liability mechanism is primarily to pay adequate compensation to those to whom claimable harm is caused. … A further function is to impose a deterrent on producers to take care that their products are designed, manufactured and labelled so as to minimise the safety risks of use. Deterrence is of limited value as a mechanism of behavioural control since it acts *post facto* whereas the considerable corpus of regulatory controls may be expected to be of greater impact in acting preventatively. …

3 Liability Under the Consumer Protection Act 1987

The Consumer Protection Act 1987 was enacted to give effect—as the UK was required to do—to the Product Liability Directive. Despite the breadth and depth of the academic literature surrounding the legislation, it appears that the first cases applying the Act were decided some 12 years after the statute came into effect: *Abouzaid v Mothercare* (strap of 'cosytoes' hitting child in the eye: defective); *Richardson v LRC* (2000) 59 BMLR 185 (failed condom: not defective); *A v National Blood Authority* [2001] 3 All ER 289 (blood products infected with hepatitis C virus: defective). By then, the UK legislation had already survived a challenge to the European Court of Justice in *CEC v UK* [1997] 3 CMLR 923.

3.1 The Liability Under the Act and Who Is Liable: Section 2

Section 2(1) of the Act states the basic liability introduced by the statute. Section 2(2) states the parties who will thereby be liable.

Consumer Protection Act 1987

> ## 2 Liability for defective products
>
> (1) Subject to the following provisions of this Part, where any damage is caused wholly or partly by a defect in a product, every person to whom subsection (2) below applies shall be liable for the damage.
>
> (2) This subsection applies to—
>
> (a) the producer of the product;
>
> (b) any person who, by putting his name on the product or using a trade mark or other distinguishing mark in relation to the product, has held himself out to be the producer of the product;
>
> (c) any person who has imported the product into a member State from a place outside the member States in order, in the course of any business of his, to supply it to another.
>
> p. 898 (3) Subject as aforesaid, where any damage is caused wholly or partly by a defect in a product, any person who supplied the product (whether to the person who suffered the damage, to the producer of any product in which the product in question is comprised or to any other person) shall be liable for the damage if—
>
> (a) the person who suffered the damage requests the supplier to identify one or more of the persons (whether still in existence or not) to whom subsection (2) above applies in relation to the product;
>
> (b) that request is made within a reasonable period after the damage occurs and at a time when it is not reasonably practicable for the person making the request to identify all those persons; and
>
> (c) the supplier fails, within a reasonable period after receiving the request, either to comply with the request or to identify the person who supplied the product to him.
>
> ...
>
> (5) Where two or more persons are liable by virtue of this Part for the same damage, their liability shall be joint and several.
>
> (6) This section shall be without prejudice to any liability arising otherwise than by virtue of this Part.

Primarily, liability is placed on *producers*. However, certain other parties may be liable under particular circumstances. These include 'own-branders' (who are effectively holding themselves out as producers), and parties who import the products from outside the Member States. As an alternative, the claim may be made against a supplier who does not identify who the producer is.

3.2 What Is a Product?

> 1 (2) (c) ...“product” means any goods or electricity and (subject to subsection (3) below) includes a product which is comprised in another product, whether by virtue of being a component part or raw material or otherwise; ... By section 2(3) (above), faulty component parts are treated as being separate products, and the party who is potentially liable if those components are defective is the producer (or importer, and so on) of those components, rather than of the product in which they are incorporated. *However*, the manufacturer of a component part will not be liable for damage done *to the larger product in which it is incorporated*: see section 5(2) extracted below, refining the definition of ‘damage’ recoverable under the Act.

3.3 Damage

5 Damage giving rise to liability

(1) Subject to the following provisions of this section, in this Part 'damage' means death or personal injury or any loss of or damage to any property (including land).

(2) A person shall not be liable under section 2 above in respect of any defect in a product for the loss of or any damage to the product itself or for the loss of or any damage to the whole or any part of any product which has been supplied with the product in question comprised in it.

p. 899

(3) A person shall not be liable under section 2 above for any loss of or damage to any property which, at the time it is lost or damaged, is not—

(a) of a description of property ordinarily intended for private use, occupation or consumption; and

(b) intended by the person suffering the loss or damage mainly for his own private use, occupation or consumption.

(4) No damages shall be awarded to any person by virtue of this Part in respect of any loss of or damage to any property if the amount which would fall to be so awarded to that person, apart from this subsection and any liability for interest, does not exceed £275.

(5) In determining for the purposes of this Part who has suffered any loss of or damage to property and when any such loss or damage occurred, the loss or damage shall be regarded as having occurred at the earliest time at which a person with an interest in the property had knowledge of the material facts about the loss or damage.

(6) For the purposes of subsection (5) above the material facts about any loss of or damage to any property are such facts about the loss or damage as would lead a reasonable person with an interest in the property to consider the loss or damage sufficiently serious to justify his instituting proceedings for damages against a defendant who did not dispute liability and was able to satisfy a judgment.

(7) For the purposes of subsection (5) above a person's knowledge includes knowledge which he might reasonably have been expected to acquire—

(a) from facts observable or ascertainable by him; or

(b) from facts ascertainable by him with the help of appropriate expert advice which it is reasonable for him to seek;

but a person shall not be taken by virtue of this subsection to have knowledge of a fact ascertainable by him only with the help of expert advice unless he has failed to take all reasonable steps to obtain (and, where appropriate, to act on) that advice.

(8) Subsections (5) to (7) above shall not extend to Scotland.

Clearly, some parts of this section (subsections (5)–(7)) are important in defining the date of damage for the purposes of determining when the limitation period will begin to run: see further Section 3.6 of this chapter.

The types of 'damage' recoverable under the Act are broadly similar to the types of damage recoverable through the tort of negligence. There must be damage either to the person or to *property other than the product itself*. Defectiveness in the product is not enough in itself; nor is harm to the property that is claimed to be defective.[13] By section 5(2), as already noted, a component part is not treated as having caused damage if it merely damages the product into which it is incorporated. Importantly, by section 5(3) only *consumer* property is protected. Damage to property not intended for private or family use (broadly, commercial property) is not recoverable under the Act.

p. 900

3.4 The Crucial Concept: Defectiveness

As we have already discussed, 'defect' is the central criterion for liability under the statute. 'Defectiveness' plays an equivalent role to 'negligence' at common law.

> ### 3 Meaning of 'defect'
>
> (1) Subject to the following provisions of this section, there is a defect in a product for the purposes of this Part if the safety of the product is not such as persons generally are entitled to expect; and for those purposes 'safety', in relation to a product, shall include safety with respect to products comprised in that product and safety in the context of risks of damage to property, as well as in the context of risks of death or personal injury.
>
> (2) In determining for the purposes of subsection (1) above what persons generally are entitled to expect in relation to a product all the circumstances shall be taken into account, including —
>
> (a) the manner in which, and purposes for which, the product has been marketed, its getup, the use of any mark in relation to the product and any instructions for, or warnings with respect to, doing or refraining from doing anything with or in relation to the product;
>
> (b) what might reasonably be expected to be done with or in relation to the product; and
>
> (c) the time when the product was supplied by its producer to another;
>
> and nothing in this section shall require a defect to be inferred from the fact alone that the safety of a product which is supplied after that time is greater than the safety of the product in question.

By section 3(1), the key question in respect of defectiveness is whether the safety of the product is not such as persons generally are entitled to expect.

It should be noted that in making a judgment as to defectiveness, 'all the circumstances' are to be taken into account (section 3(2)). The listed factors are merely illustrative.

Section 3(1) differs very slightly from the wording of the Directive itself:

Directive on Product Liability

> #### Article 6
>
> 1. A product is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account …

The language in the Directive is ambiguous, since it does not make clear whether the test is what 'a person' who is *consuming* the product is entitled to expect; or what 'a person' who is representative of the general public is entitled to expect. The UK legislation adopts the latter interpretation.

Defectiveness vs Negligence

Before the Act came into effect, there was some difference of view about the difference that the move to a defectiveness test would make. Christopher Newdick argued that 'defect' would be easier to establish than negligence. (He reserved his criticism for the development risks defence.)

p. 901 **C. Newdick, 'The Development Risk Defence of the Consumer Protection Act 1987' (1988) 47 CLJ 455–76**

> The European Directive on Product Liability introduces a new regime of strict product liability to the member states of the Community. Those injured by products may recover by showing that the product is 'defective', *i.e.*, that it 'does not provide the safety that a person is entitled to expect. …' The advantage of this approach for the individual is likely to be that liability turns on the existence of a defect alone. Unlike the law of Negligence, no question of foresight of the danger, or of the precautions taken to avoid it, arises for consideration. Strict product liability depends on the condition of the product, not the fault of its maker or supplier.

Jane Stapleton, on the other hand, argued that the concept of 'defectiveness' would itself not operate significantly differently from the 'negligence' standard. She further argued that a special strict liability regime for *products* was in any case anomalous and unjustified.

J. Stapleton, 'Products Liability Reform: Real or Illusory?' (1986) 6 OJLS 392–422, at 420–1

> The assumption that stricter liability for products will be provided by the new Directive is unwarranted. On examination, its central concepts such as cost-benefit assessments and the development risk defence are not only inconsistent with the theoretical arguments used to justify the reform but they are also so poorly thought out that it is debatable whether the liability foreshadowed in the Directive will have a significantly wider scope than the current negligence regime.
>
> Even if there are cases in which the new law will provide a remedy where there would have been none under negligence,[14] the reform can be criticised for generating … unattractive anomalies in the remedies available to classes of the disabled. Despite trenchant academic criticism the current vogue for *ad hoc* solutions such as products liability reform seems to survive. …

Although the volume of case law considering 'defectiveness' is still relatively modest, it has generally become clear that there is scope for a claimant to succeed under the Act, where a claim in negligence would fail. 'Defectiveness' is likely to be easier to prove than negligence in the simpler, more mechanical cases. These are also the cases least likely to attract the development risks defence. It remains true that (as Stapleton argued) the regime is not a full strict liability regime, even for damage done by products. It only applies in cases of 'defect'. But this should not be too surprising: it is normal for 'strict' liabilities to be strict in some ways, and not in others, and that is illustrated throughout this text.

The interpretation of defectiveness is therefore crucial, and if the definition of defect should prove to be capricious or anomalous, the regime that results will be defensible (if at all) ↵ only on the basis that it is a 'compromise'. That, however, is essentially the nature of the liabilities created by the Directive. They represent a balance between different interests; and this is also why the European jurisprudence requires that the liabilities are exhaustive—broader liabilities would unsettle the balance between interests achieved.

p. 902

Iman Abouzaid v Mothercare (UK) Ltd (21 December 2000, CA)

The claimant was helping his mother to attach a 'cosytoes', manufactured by the defendants, to his younger brother's pram. An elastic strap snapped out of his grasp and a metal buckle on the end of the strap struck him in the eye. His vision in that eye was very substantially impaired. The Court of Appeal held that the injury was caused by a defect in the product. No 'development risks' defence could arise because a simple test could have shown that the risk existed at the time the goods were manufactured. The risk was in no sense outside the reach of established knowledge at that time, even if it had not been explicitly recognized. By contrast, a claim in negligence at common law would fail, largely because the risk of injury was small, and a reasonable manufacturer may well have failed to recognize it.

Tesco Stores v Connor Frederick Pollock [2006] EWCA Civ 393

The claimant, aged 13 months, had swallowed dishwasher powder from a plastic bottle bought from Tesco (the first defendant), becoming seriously ill. The powder was Tesco's own brand (see section 2(2)(b)), but the bottle had been manufactured by the second defendant. The case against the defendants was that the bottle was too easily opened. It was supposed to have a 'child resistant' cap, but the claimant managed to open it. Evidence showed that the 'squeeze and turn' cap required considerably less resistance to open than would be required by a cap which met the British Standard for such lids (although in principle, it required more force than a child of 13 months would be *expected* to be able to apply). There was no legal requirement that all dishwasher powder should be sold in containers with caps which met the British Standard. The question was, rather, whether the cap could be opened sufficiently easily for it to be described as 'defective', within the terms of section 3(1) of the Act, extracted earlier. Did it provide the level of safety that persons generally would be entitled to expect? The Court of Appeal decided that it did. The product was not defective.

> **Laws LJ**
>
> 18 What, on the facts here, were 'persons generally entitled to expect' of the safety features of this cap and bottle? In my judgment they were entitled to expect that the bottle would be more difficult to open than if it had an ordinary screwtop. Anything more specific, as a test of public expectation, runs into the difficulties which I have just described. Here, the bottle was more difficult to open than an ordinary screwtop, though not as difficult to open as it would have been if the British Standard torque measure had been complied with. There was, in my judgment, no breach of the 1987 Act.

In this case, there was some scepticism that the young claimant could genuinely have opened the screw top (and therefore some suspicion that the bottle had been left open by an adult), although on balance this matter was settled in favour of the claimant to the satisfaction of the first instance judge. It could be argued that the
p. 903 resistance required to open this cap, ↵ being significantly more than a small child would be expected to be able to apply, was sufficient to avoid being held to be 'defective'. But is it really sufficient to say—as Laws LJ did at [18]—that the *only* reasonable expectation of people generally is that a 'child resistant cap' will be 'more difficult to open' than an ordinary screwtop? This is surely expecting too little, since it means (literally) that *any* extra resistance is enough. This is not, it is suggested, what people could legitimately expect of a 'child resistant cap'. On the other hand, the actual resistance of the cap in this particular case could have been held to be within the legitimate expectations of the public. It remained something of a mystery how this particular child had managed to open it.

An earlier case which indicates that consumer **responsibility** is relevant to the fair apportionment of risk is *Sam Bogle and Others v McDonald's Restaurants* [2002] EWHC 490 (QB). Each of the claimants (most of them children) were injured by spillage of hot tea and coffee served at McDonald's restaurants. The claims call to mind a widely known American case in which a claimant secured substantial damages for scalding injuries sustained when hot coffee sold at a McDonald's 'drive-thru' restaurant spilt on to her lap. In *Bogle v McDonald's* by contrast, the defendants were held not to be liable either in negligence, or under the Consumer Protection Act 1987.

The claim under the Act turned on the heat of the drinks and the design of their container, the lid of which was to be removed for drinking. Later, a differently designed cup was introduced, allowing the coffee to be drunk through a spout. (In this regard note the terms of section 3(2) extracted earlier: the introduction of a safer product at a later date does not by itself mean that the product which caused the harm was defective. But note also that people may prefer *not* to drink tea and coffee through a spout.)

Despite the passage of time since the legislation, there remains relatively little case law, and the most significant judicial analyses of 'defectiveness' are to be found in decisions at first instance. The decision in *A v National Blood Authority*, controversial though it was thought to be in some respects, was the most sophisticated analysis available until more recent decisions concerning hip replacements have supplemented, and to some much more limited extent superceded, its analysis.

A and Others v National Blood Authority and Another [2001] 3 All ER 289 (Burton J)

The claimants had all contracted Hepatitis C from blood transfusions. They brought actions against the defendants as suppliers of the relevant blood products. At the time that the transfusions were carried out, the defendants and the medical profession were well aware that there was a risk of infection by Hepatitis C through blood products. This knowledge was not shared with the general public. There was an actual expectation of 'clean blood'. An actual expectation is not, however, sufficient; section 3(1) refers to the level of safety that people are *entitled* to expect—not the level that they *do* expect. Further, there was no available test that could be used to check individual units of blood for the virus, and therefore the risk of infection was unavoidable. Therefore, it was assumed that an action could only be brought under the Consumer Protection Act 1987, and that no action could be brought at common law.[15]

p. 904 ↵ The chief question for the court was whether the blood products, some of which were unavoidably infected by the Hepatitis C virus, were 'defective'. If they were, a subsidiary question was whether the 'development risks defence' could be applied. There was no way of finding the defect. It was held that the infected blood products were defective, and that the development risks defence was not made out. The claimants were successful.

A curious feature of this case was that the judge, Burton J, dispensed with any reference to the Consumer Protection Act 1987 in respect of the primary issues, surrounding defectiveness and the development risks defence. Instead, he referred directly to the corresponding Articles of the Directive (Articles 6 and 7(1)(e) respectively). His reason for this was that the European Court, in *CEC v UK* [1997] 3 CMLR 923, had recently confirmed that the courts of the UK should interpret the Consumer Protection Act 1987 in accordance with the wording of the Directive.

> **Burton J, *A v National Blood Authority***
>
> 21 Although the United Kingdom Government has not amended s4(1)(e) of the CPA so as to bring it in line with the wording of the directive, there is thus binding authority of the Court of Justice that it must be so construed. Hence … the major discussions in this case, and all the areas of most live dispute, have concentrated entirely upon the wording of arts 6 and 7(e) of the directive, and not upon the equivalent sections of the CPA, to which I shall make little or no further reference.

It is important to point out that this approach—bypassing the wording of the CPA itself—has not been adopted in other cases that have analysed the meaning of 'defect', or the development risks defence, and was expressly rejected by the decision in *Wilkes v DePuy International Ltd* [2016] EWHC 3096 (QB).

It is hard to capture the dense reasoning in *A*, but we can point out some crucial elements in the finding that the blood was 'defective'.

1. Although the medical profession was aware of the unavoidable risk that blood would be infected, the public generally was not aware of this risk. This in itself was not decisive, because Article 6 (like section 3) refers to what people were *entitled* to expect. The public's expectation of 'clean blood' was not unreasonable, even though the medical profession knew it to be unattainable. Members of the public were 'entitled', given the information made publicly available, to expect clean blood. Therefore, although the products made by the defendants were no worse—in terms of the risks of infection—than any blood supplied at the time could have been, they were still 'defective' on the 'expectation' test.
2. Unavoidability of the risk was not relevant to the test for 'defectiveness' (at [63]). Although it has been queried how any issue could be excluded from the expression '*all* the circumstances' (which is used in both the Act and the Directive), Burton J pointed out that avoidability was not relevant to the purpose of the Directive—which was to apportion liability for defects to producers, subject to the defences available. Avoidability, then, was not part of the definition of a 'defect'. In support of the judge's interpretation, it can be said that avoidability is in no way similar to the kinds of considerations listed
p. 905 in Article 6 and section 3(2), all of which are likely to affect the safety, in practice, of the product (who is going to use it and when? What instructions are provided?). Avoidability does not go to safety.
3. Burton J held that the infected bags of blood were **non-standard products** (also referred to in the judgment as 'lemons' (at [65])). The importance of this in respect of 'defectiveness' was as follows:

The defendants argued that all bags of blood carried the same *risk* of infection. Since there was no test for determining which were the infected bags, they were all to be regarded as equally dangerous. The bags were a standard product. Where a standard product carries an inherent risk, but is still regarded as worthwhile and desirable, the standard product cannot be regarded as defective. This would be true of alcohol, for example, or tobacco, whose risks are inherent and cannot realistically be described in terms of 'defects'. Similarly, many drugs have known potential side-effects. All packs of aspirin, for example, carry the same risk of causing internal bleeding, and a pack of aspirin which does turn out to have this effect on a consumer cannot be described as defective. Any pack of aspirin has the potential to do this.

The judge dismissed this argument on two grounds:

1. The infected bags were not the same as the other bags. The injury was not caused simply by a difference in the reaction of the patient: some of the bags were infected ('non-standard'), the others were not. The infected bags were a non-standard product.
2. Even in the case of a standard product (such as a normal pack of aspirin), adverse side-effects are only acceptable if they are made known. (We may now add to this that they need not be made known if they are obvious—following subsequent cases such as *Bogle v McDonald's* (discussed earlier in this section.)

Burton J, *A v National Blood Authority*
[2001] 3 All ER 289

> [66] … I am quite clear that the infected blood products in this case were non-standard products (whether on the basis of being manufacturing or design defects does not appear to me to matter). Where, as here, there is a harmful characteristic in a non-standard product, a decision that it is defective is likely to be straightforward, and I can make my decision accordingly. However, the consequence of my conclusion is that 'avoidability' is also not in the basket of circumstances, even in respect of a harmful characteristic in a standard product. So I shall set out what I consider to be the structure for consideration under art 6. It must be emphasised that safety and intended, or foreseeable, use are the lynchpins: and, leading on from these, what legitimate expectations there are of safety in relation to foreseeable use. …
>
> [67] The first step must be to identify the harmful characteristic which caused the injury (art 4). In order to establish that there is a defect in art 6, the next step will be to conclude whether the product is standard or non-standard. This will be done (in the absence of admission by the producer) most easily by comparing the offending product with other products of the same type or series produced by that producer. If the respect in which it differs from the series includes the harmful characteristic, then it is, for the purpose of art 6, non-standard. If it does not differ, or if the respect in which it differs does not include the harmful
> p. 906 characteristic, but all the other products, albeit different, share the harmful characteristic, then it is to be treated as a standard product.
>
> ## Non-standard products
>
> [68] The circumstances specified in art 6 may obviously be relevant—the product may be a second—as well as the circumstances of the supply. But it seems to me that the primary issue in relation to a non-standard product may be whether the public at large accepted the nonstandard nature of the product—ie they accept that a proportion of the products is defective (as I have concluded they do not in this case). That, as discussed, is not of course the end of it, because the question is of legitimate expectation, and the court may conclude that the expectation of the public is too high or too low. But manifestly questions such as warnings and presentations will be in the forefront. However, I conclude that the following are not relevant: (i) avoidability of the harmful characteristic—ie impossibility or unavoidability in relation to precautionary measures; (ii) the impracticality, cost or difficulty of taking such measures; and (iii) the benefit to society or utility of the product (except in the context of whether—with full information and proper knowledge—the public does and ought to accept the risk).

Burton J also added some comments relating to *standard* products:

> [73] I can accept that resolution of the problem of the defective standard product will be more complex than in the case of a non-standard product. This trial has been in respect of what I am satisfied to be a non-standard product, and I see, after a three-month hearing, no difficulty in eliminating evidence of avoidability from art 6. It may be that, if I am right in my analysis, and if it is followed in other cases, problems may arise in the consideration of a standard product on such basis, but I do not consider any such problems will be insurmountable if safety, use and the identified circumstances are kept in the forefront of consideration. Negligence, fault and the conduct of the producer or designer can be left to the (limited) ambit of art 7(e) … This approach leaves all questions of conduct to the 'development risks defence'. The statutory product liability was clearly interpreted as a strict liability regime, albeit one that is relatively confined in scope. On the other hand, because the court laid such emphasis on the fact that knowledge of the risks concerned was not shared with the public, the burden placed on producers of medical products may not be very difficult to avoid. *Advice* as to risks may be sufficient to avoid the judgment of defectiveness, by altering legitimate expectations of safety.

Wilkes v DePuy International Ltd [2016] EWHC 3096; [2018] Q.B. 627.

The claimant had surgery to insert an artificial hip joint manufactured by the defendant. Three years later, there was a fracture in the artificial joint. The claimant argued that there was a defect in one of the components of the joint, but the defendants argued that the design of the component was a beneficial feature, and not a defect. The product was not a 'lemon' or 'non-standard' product, in the terminology of *A v National Blood Authority*. If there was to be liability, it would be premised on a designed feature of the product. Perhaps
p. 907 confusingly, Hickinbottom J rejected the usefulness of the distinction between 'standard and ↵ non-standard products' for at least some purposes, but essentially utilized the same distinction in terms of 'design' defect or 'manufacturing' defect. At any rate, the questions about defectiveness are inherently rather different from the ones that arose in *A v National Blood Authority*.

The judge emphasized that the interpretation of whether a characteristic of a product is a 'defect' is a broad and deliberately flexible process. Although it may be difficult to assess, it is and should remain 'conceptually simple'. The key test is whether the product is as safe as people are reasonably entitled to expect.

> 79. Accordingly, whilst over time cases may indicate which characteristics may be relevant in particular sets of circumstances (eg where the product is a prescription-only medicine), in my view, any attempt at formal rigid categorisation of products for these purposes is in conflict with the inherent flexibility of the Directive, and is likely to be both difficult and unwise. The issue raised by the Act in terms of defect is necessarily one of open-textured judgment, untrammelled by any rigid rules outside the few that appear in the Act itself. It is noteworthy that the Act implements the Directive, which applies to ensure, amongst other things, that competition in respect of the supply of goods is fair across Europe; and so it would be wrong for domestic law to distort the balance of risk-bearing between producers and consumers of products set by the Directive. The Act, reflecting the Directive, simply requires consideration of whether, at the time the producer first put the product into circulation, that product did or did not have the level of safety that persons generally are entitled to expect (in the sense that I have described), taking into account all relevant circumstances including those set out in section 3(2) of the 1987 Act. Like other such questions raised in the law, on the particular facts of a specific case, the assessment may be difficult in practice; but it is conceptually simple. In my view, the courts should guard against either over-complicating, or over-analysing, the exercise.

It is this general openness and flexibility which is the key feature of the approach in *Wilkes*. However, certain particular factors were raised by the parties :

> 80. Before me, the following circumstances came under particular scrutiny: (i) risk-benefit; (ii) the 'avoidability' (or 'non-avoidability') of the defect; (iii) whether the product is 'standard' or 'non-standard', in accordance with the distinction drawn by Burton J in *A v NBA [2001] 3 All ER 289* (see para 56(ii) above); (iv) the compliance (or non-compliance) with appropriate standards; (v) the compliance (or non-compliance) with any relevant regime under which the product is regulated; and (vi) warnings and other IFU, and the role of any intermediary. I will deal with those in turn.

Hickinbottom J concluded that the hip joint was not defective. Risks and benefits of a product must be weighed against the possible harm that may be done as a consequence of a feature of the design. Here, other manufacturers had made a similar choice, for similar reasons. Compliance and non-compliance with appropriate standards and regulatory regimes were not determinative but would be significant aspects of the enquiry into defectives. In a case such as this where advice is received from a surgeon, the presence of an intermediary who can explain the risks and the benefits of a product would have a significant impact on the assessment of defectiveness.

p. 908

Gee v Depuy International Ltd [2018] EWHC 1208 (QB)

The decision deals with a group action concerning a different alleged defect in replacement hip joints. The claimants had been implanted with a particular type of artificial joint which involved 'metal on metal' articulation, and claimed to have suffered an adverse reaction to 'metal wear particulate debris' (ARMD),

requiring revision surgery. They argued that this resulted from a defect.

The claims were rejected. Safety, as Andrews J emphasized, is a relative concept (at least, within the context of the Consumer Protection Act). No product could be absolutely safe. Since ARMD was one of the normal risks associated with hip replacement joints, the public was not entitled to expect that the artificial joint would not produce debris. As a matter of principle, even if there was a demonstrably higher risk of failure for the defendant's products, relative to competitors' products (which was not established on the facts), this would only be one factor. If there were other advantages to the product, these would be relevant to the question of whether the design contained a 'defect'.

Andrews J, *Gee v DePuy Ltd* [2018] EWHC 1208 (QB)

> 110. As Hickinbottom J pointed out in *Wilkes*, safety is inherently and necessarily a relative concept, because no product, and particularly a medicinal product, if effective, can be absolutely safe. Even such commonly prescribed medicines as penicillin or aspirin can cause a hypersensitive response in certain patients which, in an extreme case, can prove fatal. The public is not entitled to expect that a product which is known to have an inherently harmful or potentially harmful characteristic will not cause that harm, especially if (as in the present case) the product cannot be used for its intended purpose without incurring the risk of that harm materialising.
>
> 111. The European Commission has accepted that there will be some products that would, by their very nature, carry some known risk of harm or damage (or, in other words, have a 'harmful characteristic') but which cannot be regarded as defective for that reason alone. Viscount Davignon, answering a question from a MEP, stated:
>
> 'The Commission agreed with the Honourable Member that nobody can expect from a product a degree of safety from risks which are, because of its particular nature, inherent in that product and generally known, e.g. the risk of damage to health caused by alcoholic beverages. Such a product is not defective within the meaning of.. the.. Directive'.
>
> That exchange was referred to in *A v NBA* at [31]. Burton J commented: '*this does not of course amount to an exemption for such a product from the article but simply an explanation of how the article operates*.'
>
> 112. However, if the incidence of that harm, either in nature or degree, is abnormal, then the product *may* be regarded as falling below the standard of safety that persons generally are entitled to expect. If that is the case, the defect is not the inherently harmful characteristic which is part of the normal behaviour of the product, for so to characterise it would be to make all products of that type 'defective,' as they all bear that characteristic. That is the fundamental flaw in the claimants' original formulation. The defect is the abnormal potential for harm, i.e. whatever it is about the condition or character of the product that elevates the underlying risk beyond the level of safety that the public is entitled to expect. That approach is not a blurring of the distinction between relevant circumstances and defect as Mr Oppenheim contended; it is identifying what it is about the condition or state of the product that makes it unsafe by the objective yardstick set out in s.3 of the Act.

p. 909

3.5 Defences

The following defences are available *in addition to* the possibility that the product was not defective (Section 3). The most important defence as we have said is the 'development risks' defence, in section 4(1)(e).

4 Defences

(1) In any civil proceedings by virtue of this Part against any person ('the person proceeded against') in respect of a defect in a product it shall be a defence for him to show—

(a) that the defect is attributable to compliance with any requirement imposed by or under any enactment or with any Community obligation; or

(b) that the person proceeded against did not at any time supply the product to another; or

(c) that the following conditions are satisfied, that is to say—

(i) that the only supply of the product to another by the person proceeded against was otherwise than in the course of a business of that person's; and

(ii) that section 2(2) above does not apply to that person or applies to him by virtue only of things done otherwise than with a view to profit; or

(d) that the defect did not exist in the product at the relevant time; or

(e) that the state of scientific and technical knowledge at the relevant time was not such that a producer of products of the same description as the product in question might be expected to have discovered the defect if it had existed in his products while they were under his control; or

(f) that the defect—

(i) constituted a defect in a product ('the subsequent product') in which the product in question had been comprised; and

(ii) was wholly attributable to the design of the subsequent product or to compliance by the producer of the product in question with instructions given by the producer of the subsequent product.

(2) In this section the relevant time in relation to electricity, means the time at which it was generated, being a time before it was transmitted or distributed, and in relation to any other product, means—

(a) if the person proceeded against is a person to whom subsection (2) of section 2 above applies in relation to the product, the time when he supplied the product to another;

(b) if that subsection does not apply to that person in relation to the product, the time when the product was last supplied by a person to whom that subsection does apply in relation to the product.

Notice that under section 4(1)(d), the producer will be exonerated if it can establish that the defect was not present at the relevant time (which is, broadly, the time of first supply). This defence was successfully relied
p. 910 upon in *Terence Piper v JRI (Manufacturing) Ltd* [2006] ↵ EWCA Civ 1344, where it was held that an artificial hip was probably damaged at the time of surgery, and was not defective when supplied. On the other hand, undue fragility in a product may itself amount to a 'defect'. By section 6(4), the partial defence of contributory negligence (as set out in the Law Reform (Contributory Negligence) Act 1945) is applicable to actions under the Consumer Protection Act.

Section 4(1)(e): The Development Risks Defence

As we have seen, the incorporation of the development risks defence has been controversial. Its effect is that a producer of goods only takes the risk of defects that could have been discovered at the relevant time. The risk that defects will be discovered later falls on the consumer. Why is this? The key idea is 'apportionment of risk', and the preamble to the Directive makes this plain:

> **Directive 85/374/EEC of 25 July 1985, Preamble**
>
> Whereas liability without fault on the part of the producer is the sole means of adequately solving the problem, peculiar to our age of increasing technicality, of a fair apportionment of the risks inherent in modern technological production;
>
> …
>
> Whereas a fair apportionment of risk between the injured person and the producer implies that the producer should be able to free himself from liability if he furnishes proof that as to the existence of certain exonerating circumstances. …

This does not get us very far, however, because it simply states that the burden of risk should be apportioned 'fairly'. It is hard to know how to ascertain fairness as between two faultless parties. Such questions, one would have thought, could only be resolved by looking more broadly at the opportunities to manage or minimize unknown risks,[16] and (equally importantly) to the distribution of the *benefits* with which the risks are accompanied. This is the sort of idea which is expressed by Jane Stapleton in terms of 'enterprise liability': the enterprise which benefits from the risks, and has the greatest potential control over those risks, ought to be liable if the risks materialize.[17] The development risks defence, in *any* form, undercuts this goal, as it also undercuts the goal of deterrence.

As we saw in the introductory section to this chapter, the newest justification for the defence turns on encouragement to innovation and the wish not to stifle productive risks. In other words, deterrence *of beneficial risk-creation* is not desired.

Apart from the general controversy surrounding the very existence of the defence, there is also a more particular controversy surrounding the way in which the UK has transposed the Directive in this respect. The UK wording departs from the wording of the Directive, and it appears to most commentators that the defence

p. 911 as expressed in the UK legislation is ↵ capable (depending on its application) of exonerating more producers than is envisaged by the Directive. The relevant forms of wording are as follows.

Consumer Protection Act 1987

> #### Section 4(1)(e)
>
> … the state of scientific and technical knowledge at the relevant time was not such that a producer of products of the same description as the product in question might be expected to have discovered the defect if it had existed in his products while they were under his control …

Directive on Product Liability 1985

> #### Article 7
>
> The producer shall not be liable as a result of this Directive if he proves:
>
> …
>
> (e) that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered; …

Broadly, there are two criticisms of the UK's particular version of the development risks defence, compared with the version in the Directive.

1. There is claimed to be a substantial difference between what a producer might be *expected* to discover, as in the Act; and what it would be *possible* to discover, given the existing state of knowledge, as in the Directive. It is argued by some that the former sets a standard of reasonable expectation, and is therefore quite similar to negligence.
2. The UK wording seems to suggest that the relevant knowledge (when judging whether it would have been possible to recognize the defect) is knowledge of *producers in the industry*. The wording in the Directive seems to encompass scientific knowledge *wherever* it was being developed.

There has been some support for the UK's interpretation of the development risks defence. For example, Christopher Newdick suggested at the time of enactment that the version adopted by the UK simply expressed more clearly what would be the inevitable content of the test.

C. Newdick, 'The Development Risk Defence of the Consumer Protection Act 1987' (1988) 47 CLJ 455–76, at

459–60

> There are two reasons for thinking that the government may be right. First, when a court assesses the relevant state of scientific and technical knowledge, it will not require the defendant to prove, conclusively and absolutely, a worldwide absence of knowledge of the ↵ defect. It would be impracticable to insist on proof that all the libraries of the world had been scoured and all the unpublished theses in universities, in every language, had been read. More probably, the court will make a judgment on the basis of expert evidence. …
>
> Secondly, it is conceivable that the plaintiff could present information which revealed the existence of the defect, but which could not reasonably be expected to have been known to the producer … There is no doubt that the development risk defence in this form sits uneasily in a measure designed to introduce strict product liability. In effect it relieves the producer of liability when he had not been negligent in failing to discover the defect. This apparent contradiction of purpose is the unavoidable result of the inclusion of the defence in the Product Liability Directive.

p. 912

CEC v UK [1997] 3 CMLR 923

Given the difference in wording between Article 7(e) of the Directive, and section 4(1)(e) of the Consumer Protection Act (extracted above), the European Commission took the view that the UK had not properly transposed the Directive. It therefore began infringement proceedings against the UK.

Before the European Court of Justice, the Commission failed to prove its case. On the narrowest point, the Commission agreed that some aspects of the wording were inconsistent with the Directive; but pointed out that the Commission had failed to refer to any UK case law which showed that section 4(1)(e) would actually be *interpreted* so as to depart from the Directive.[18]

More importantly for the general interpretation of the Directive throughout the Member States, the Court of Justice also commented on the defence itself. The Court specified that the relevant state of knowledge for the purposes of Article 7(e) was the objective state of knowledge, not the knowledge to be expected of a producer in the particular industry. However, most controversially, the Court accepted the analysis of Advocate General Tesauro which preceded the judgment, to the effect that the relevant knowledge must be 'accessible'. This seemed to go some way towards accepting that the UK approach represented the *proper* interpretation of the Directive.

Opinion of Mr Advocate General Tesauro

A number of key points can be extracted from the Advocate General's quite lengthy opinion, as follows.

1. The defence does not help a defendant who is able to show simply that the risk was unknown *among producers of the product in question*. The defence only applies where the risk genuinely cannot be discovered in the light of existing knowledge. Existing knowledge for these purposes includes

knowledge among those at the forefront of research. Indeed, even one 'isolated opinion' will do (subject to 'accessibility', see later in this chapter). This is partly because it is an objective of the strict liability regime to encourage investment in research and development relating to risks.[19]

p. 913

2. The 'development risks defence' *only* assists a defendant in respect of *risks* which cannot be discovered. It does not apply where the risk is known, but no methodology has been developed for identifying the defect in a particular product, or for removing it. It does not assist a defendant in respect of risks which cannot be *avoided*, either because no method for doing so has been discovered, or because that method is too expensive to be applied. This is because the defence is a narrow exception to the general allocation of risk to producers rather than consumers. It is up to producers to manage, internalize, or (so far as possible) avoid risks that were—in the objective sense—'known' or 'knowable' at the time of manufacture. The decision as to defect in *A v National Blood Authority* (see Section 3.4) is compatible with this.

3. Most controversially from the point of view of those who support strict liability, the Advocate General accepted the UK's position that knowledge must be in some sense **accessible** if it is to defeat the defence. This does not mean that the producer *ought to have discovered it* in the full negligence sense. But the Advocate General does suggest that research published only in Manchuria, for example, may not be regarded as sufficiently accessible to defeat the defence against a European producer. The producer is expected to *find* developing knowledge; but there is a limit to this

The interpretation of the defence in the decision has been criticized from very different perspectives.

Chris Hodges, 'Development Risks: Unanswered Questions'
(1998) 61 MLR 560, at 569

> At first sight, the test in the defence seems to be whether the defect could have been discovered by any human, using, it is implied, all available powers of logic, data and techniques. Relevant techniques might include the most sophisticated information technology, computing, testing and monitoring in use. Clearly, if this analysis is correct, the standard set by the defence is very high. It would only succeed in very rare circumstances, if ever. It requires all producers to adopt the very highest standard of methodology. Given that many innovations are discovered by small and medium enterprises, is it reasonable to expect all enterprises to adopt the same highest possible standard, irrespective of resources and cost?
>
> These considerations undermine the credibility of this defence. The charge against the wording of the defence in the Directive is, therefore, that it is not capable of being interpreted in practice. It is unworkable on a literal reading and requires interpretation if it is to reflect the policy of protecting innovation ...

M. Mildred and G. Howells, 'Comment on "Development Risks: Unanswered Questions"'
(1998) 61 MLR 570, at 572

> The existence of powerful computerised databases will allow the producer to satisfy itself of the nature of published knowledge in the various fields of knowledge before putting a product into circulation. Since they will be available without regard to the industrial sector within ↵ which the producer works there is no reason to confine discoverability by accessibility to a particular sector. There is no doubt that this will be a burden to producers but the very title of the Consumer Protection Act 1987 shows that the interests of the producer (which Hodges sets out to defend) are by no means paramount. The producer is, of course, undertaking innovation for competitive and economic advantage just as much as, if not more than, for philanthropic purposes.

p. 914

Does the motive of the producer make a difference? 'Risky' products may of course be produced by non-profit-making organizations (as in *A v National Blood Authority*) but for the most part it is true that innovation is carried out in pursuit of profit—as indeed products such as hot tea and coffee are made available through the market. Beneficial products are still beneficial no matter what the incentive for producers to make them available, or to develop them. Should profit motive make a difference? If so, does this leave a major gap in justification for strict liability?

A v National Blood Authority: Development Risks Issues

Here we return to the leading UK case, *A v National Blood Authority*, and turn our attention to its treatment of the development risks defence.

For the reasons we explained earlier, Burton J referred directly to the Directive, rather than to the Act, when interpreting both 'defectiveness', and 'development risks'. His interpretation drew upon the Advocate General's opinion in *CEC v UK*, extracted above. In particular, he explained that the development risks defence does not assist a defendant where the *method for identifying and removing* the defect is unknown, provided the risk of that defect *is* known. Given that the risk of infection with Hepatitis C was clearly recognized, this finding was itself sufficient to dispose of the defence in this case. However, Burton J added a gloss regarding non-standard products (such as the bags of infected blood in this case). That is, non-standard products will very rarely attract the development risks defence. If they do so at all, they will do so only once, until the first non-standard product or 'lemon' is discovered.

Burton J, *A v National Blood Authority*

> [75] The purpose of the directive, from which art 7(e) should obviously not derogate more than is necessary (see Recital 16) is to prevent injury, and facilitate compensation for injury. The defendants submit that this means that art 7(e) must be construed so as to give the opportunity to the producer to do all he can in order to avoid injury: thus concentrating on what can be done in relation to the particular product. The claimants submit that this will rather be achieved by imposing obligation in respect of a known risk irrespective of the chances of finding the defect in the particular product, and I agree.
>
> [76] The purpose of art 7(e) was plainly not to discourage innovation, and to exclude development risks from the directive, and it succeeds in its objective, subject to the very considerable restrictions that are clarified by European Commission v UK: namely that the risk ceases to be a development risk and becomes a known risk not if and when the
p. 915 producer in question (or, as the CPA inappropriately sought to enact in s 4(1)(e) a producer of products of the same description as the product in question) had the requisite knowledge, but if and when such knowledge were accessible anywhere in the world outside Manchuria. Hence it protects the producer in respect of the unknown (inconnu). But the consequence of acceptance of the defendants' submissions would be that protection would also be given in respect of the known.
>
> [77] The effect is, it seems to me, not, as the BGH[20] has been interpreted as concluding (or perhaps as it did conclude, but if it did then I would respectfully differ) that nonstandard products are incapable of coming within art 7(e). Non-standard products may qualify once —ie if the problem which leads to an occasional defective product is (unlike the present case) not known: this may perhaps be more unusual than in relation to a problem with a standard product, but does not seem to me to be an impossible scenario. However, once the problem is known by virtue of accessible information, then the non-standard product can no longer qualify for protection under art 7(e).

The decision in *A v National Blood Authority* has been subjected to some academic criticism (from different perspectives) by C. Hodges, 'Compensating Patients' (2001) 117 LQR 528; and G. Howells and M. Mildred, 'Infected Blood: Defect and Discoverability. A First Exposition of the EC Product Liability Directive' (2002) 65 MLR, 95. Counsel for the claimants and defendants offer some reflections on the case in M. Brooke and I. Forrester, 'The Use of Comparative Law in *A & Ors v National Blood Authority*', in D. Fairgrieve (ed.), *Product Liability in Comparative Perspective* (Cambridge University Press, 2005). The chapter includes a postscript by the judge, Sir Michael Burton. The decision is more strongly criticized by J. Stapleton, 'Bugs in Anglo-American Product Liability', in the same collection (at pp. 325–90). In Stapleton's view, the judge tried too hard to give the Directive 'work to do', and to avoid the conclusion that the Directive (and the Consumer Protection Act 1987) were 'not only … toothless but pointless'. An alternative reading is that the judgment was thereby true to the objectives of the legislation. On the other hand, the treatment of 'non-standard products' in *A v National Blood Authority* has been met with some considerable doubt.

3.6 Limitation Period

Limitation Act 1980

11A Actions in respect of defective products

(1) This section shall apply to an action for damages by virtue of any provision of Part I of the Consumer Protection Act 1987.

(2) None of the time limits given in the preceding provisions of this Act shall apply to an action to which this section applies.

p. 916

(3) An action to which this section applies shall not be brought after the expiration of the period of ten years from the relevant time, within the meaning of section 4 of the said act of 1987; and this subsection shall operate to extinguish a right of action and shall do so whether or not that right of action had accrued, or time under the following provisions of this Act had begun to run, at the end of the said period of ten years.

(4) Subject to subsection (4) below, an action to which this section applies in which the damages claimed by the plaintiff consist of or include damages in respect of personal injuries to the plaintiff or any other person or loss of or damage to any property, shall not be brought after the expiration of the period of three years from whichever is the later of—

(a) the date on which the cause of action accrued; and

(b) the date of knowledge of the injured person or, in the case of loss of or damage to property, the date of knowledge of the plaintiff or (if earlier) of any person in whom his cause of action was previously vested.

(5) If in a case where the damages claimed by the plaintiff consist of or include damages in respect of personal injuries to the plaintiff or any other person the injured person died before the expiration of the period mentioned in subsection (4) above, that subsection shall have effect as respects the cause of action surviving for the benefit of his estate by virtue of section 1 of the Law Reform (Miscellaneous Provisions) Act 1934 as if for the reference to that period there were substituted a reference to the period of three years from whichever is the later of—

(a) the date of death; and

(b) the date of the personal representative's knowledge.

Claims under the Consumer Protection Act 1987 are not within the operation of section 33 of the Limitation Act 1980, which confers a discretion on the court in certain cases of personal injury to allow extension to the limitation period.[21]

Horne-Roberts v SmithKline Beecham [2001] EWCA Civ 2006; [2002] 1 WLR 1662

In this case, the claimant had brought an action for damages under the Consumer Protection Act 1987 in respect of injuries that he argued were caused by a vaccine. The batch number of the vaccine was identified, but was wrongly attributed to another producer. It was in fact produced by SmithKline Beecham. The error came to light in August 2000, the action having been commenced (against the wrong party) in August 1999. The vaccine was administered in June 1990, so that by this time the action was outside the ten-year limitation period set out in section 11A of the Limitation Act 1980 (above).

The Court of Appeal held that the claimant could substitute a different defendant pursuant to section 35 of the Limitation Act 1980, and the Civil Procedure Rules, rule 19.5, even when the ten-year period had expired. For the purposes of this rule (and of section 35), claims under the Consumer Protection Act 1987 are to be treated
p. 917 in the same way as claims ↵ in contract and tort. But the limitation periods applied to common law actions in contract and tort are *procedural*: generally (and with the exception of the action in conversion) the expiry of the limitation period bars the *remedy*, but does not extinguish the *right*. There was a powerful argument that the variation of defendant in this case should not be permitted, because the Directive on Product Liability itself states that after the ten-year period has expired, the *right to an action* is extinguished. The long-stop provision is not a merely procedural bar.

> **Article 11**
>
> Member states shall provide in their legislation that the rights conferred upon the injured person pursuant to this Directive shall be extinguished upon the expiry of a period of ten years from the date on which the producer put into circulation the actual product which caused the damage, *unless the injured person has in the meantime instituted proceedings against the producer.*
>
> [Emphasis added]

Section 11A(3) of the Consumer Protection Act 1987 also expressly states that the section operates to *extinguish* the right of action.[22]

The Court of Appeal seems to have thought that in a case where by mistake proceedings had been instituted against the wrong producer, the final proviso of Article 11 (italicized above) would be satisfied: this *is* a case where the injured party had 'instituted proceedings against the producer' (albeit the wrong producer).[23] That being so, the time limit for claims under the statute set out in section 11A was to be treated for these purposes as a normal time limit, and the claim was not extinguished.

In *O'Byrne v Aventis Pasteur MSD Ltd* (Case C-127/04, 9 February 2006), the European Court of Justice (ECJ) appeared to have conceded that the issue of substitution of defendants was an issue of *procedural law*, and was therefore a matter for the national court, preserving the authority of *Horne-Roberts v SKB*.[24] Unfortunately, however, the ECJ added a rider to the effect that Articles 1 and 3 of the Directive must be taken to state exhaustively the category of defendants against whom actions can be brought. It seems highly unlikely that this was meant to contradict the general finding that the question was one for national courts. But the comments could not be said to be completely clear. That being so, the House of Lords in *O'Byrne v Aventis*

Pasteur SA [2008] UKHL 34; [2008] 4 All ER 881 determined that the issue must be referred to the ECJ for a second time, in order to obtain a clear statement of the ↵ position where a claimant by mistake names the wrong producer on their initial claim, but does so within the limitation period.

p. 918

The possible and likely meanings of the ECJ's remarks in its first ruling in *O'Byrne* have been analysed by Geraint Howells: '*O'Byrne v Aventis Pasteur SA*—how many trips to Luxembourg are necessary?' (2009) JBL 97–101. Howells draws attention to the delays and difficulties which have, in this argument over a preliminary legal issue, been placed in the way of a brain-damaged claimant, and underlines that this sort of effect was not the intention of the harmonized limitation period. Howells particularly draws attention to the nature of the compromise effected by the Directive, including as it does a development risks defence for producers of products such as these.

On 2 December 2009, in *Aventis Pasteur v O'Byrne* (Case-358/08); [2010] 1 WLR 1375, the ECJ made its second ruling on the limitation question in respect of these proceedings. The Court ruled that although the ten-year limitation period is to be regarded as strict, there are certain relevant exceptional circumstances where substitution of defendant could take place outside that period. One such exception is where the party proceeded against is in effect the same party as the producer. Another is where the claimant cannot reasonably be expected to know who the producer is. In these circumstances, in accordance with Article 3(3) of the Directive, the supplier may be treated as the producer, unless the supplier informs the claimant of the identity of the producer once proceedings are commenced.

The case returned to the UK's highest court, by now the UK Supreme Court, in *O'Byrne v Aventis-Pasteur* [2010] UKSC 23; [2010] 1 WLR 1412. The Supreme Court interpreted the ECJ's decision as requiring the national court to consider not only whether the manufacturer wholly owned the distributor, as it did here, but whether it had *controlled* the distributor: the core of the ECJ's ruling was that a producer could not be sued after expiry of the limitation period. Unanimously, the Supreme Court allowed the appeal, ruling that the claim was out of time.

4 Conclusions

i. The Consumer Protection Act 1987 appears to enact a clear form of strict liability, in which defectiveness of products is the key determinant of liability for harm those products cause, rather than reasonableness of conduct on the part of a manufacturer. The reality, however, is more complex. In many respects, liability under the statute resembles the tort of negligence more closely than might be expected, and issues of causation and proof remain important. The key dilution of the strictness of the regime comes, however, in the form of the 'development risks defence'. The consumer takes some of the risks of defective products, to the extent that they could not have been discovered at the time of manufacture given the state of scientific knowledge at that time. The exact parameters of the defence are of course important; but its very existence illustrates that liability under the Act performs an allocation of risk. Not all risks of defectiveness have been placed with manufacturers; and in this respect, something akin to the fault standard in negligence continues to operate. In fact, there has been relatively little take-up of the Act considering the length of time since enactment, and negligence frequently continues to be argued alongside it.

p. 919

Further Reading

Clark, A., *Product Liability* (London: Sweet & Maxwell, 1989).

Fairgrieve, D. (ed.), *Product Liability in Comparative Perspective* (Cambridge: Cambridge University Press, 2005).

Fairgrieve, D., and Goldberg, R., *Product Liability* (Oxford University Press, 2020).

Fairgrieve, D., and Howells, G., 'Rethinking Product Liability: A Missing Element in the European Commission's Third Review of the Product Liability Directive' (2007) 70 MLR 962.

Goldberg, R., *Causation and Risk in the Law of Torts: Scientific Evidence and Medicinal Product Liability* (Oxford: Hart Publishing, 1999).

Hodges, C., 'Development Risks: Unanswered Questions' (1998) 61 MLR 560.

Hodges, C., 'Approaches to Product Liability in the EU and Member States', in D. Fairgrieve (ed.), *Product Liability in Comparative Perspective* (Cambridge: Cambridge University Press, 2005).

Hodges, C., 'Product Liability: Suppliers, Limitation and Mistake' (2006) 122 LQR 393.

Howells, G., *Comparative Product Liability* (Aldershot: Dartmouth, 1993).

Mildred, M., and Howells, G., 'Comment on "Development Risks: Unanswered Questions"' (1998) 61 MLR 570.

Newdick, C., 'The Future of Negligence in Product Liability' (1987) 103 LQR 288–310.

Newdick, C., 'The Development Risk Defence of the Consumer Protection Act 1987' (1988) 47 CLJ 455–76.

Nolan, D., 'Strict Product Liability for Design Defects' (2018) 134 LQR 176–181.

Stapleton, J., 'Product Liability Reform—Real or Illusory?' (1986) 6 OJLS 392–422.

Stapleton, J., *Product Liability* (London: Butterworths, 1994).

Stapleton, J., 'Bugs in Anglo-American Product Liability', in D. Fairgrieve (ed.), *Product Liability in Comparative Perspective* (Cambridge: Cambridge University Press, 2005) 295–333.

Whittaker, S., *Liability for Products: English Law, French Law, and European Harmonization* (Oxford: Oxford University Press, 2005).

Notes

[1] It is additional because other potential actions against the producer, including the action in negligence, are expressly preserved by s 2(6).

[2] There had already been discussion in the UK concerning strict liability for products, prompted largely by the failure of tort law to compensate the victims of Thalidomide. This was a drug prescribed during the 1960s to pregnant women in order to combat morning sickness, but which led to significant birth defects. In the UK, the issue of strict liability for defective products was for a time treated as part of a wider debate over compensation for disability and disease. That being so, the Directive (and the Consumer Protection Act 1987) have been criticized as introducing a mere sectoral solution to the problem of compensation. It is restricted to products, and even then only to defective ones: see J. Stapleton, *Product Liability* (Butterworths, 1994) and J. Stapleton, 'Product Liability Reform—Real or Illusory?' (1986) 6 OJLS 392–422.

[3] See in particular our discussion of *A v National Blood Authority* [2001] 3 All ER 289, later in this chapter.

[4] Defects which could not be discovered for reasons unconnected with lack of knowledge (for example, because there is no known *method for detection*) are not within the defence.

[5] By s.5, the insurer may seek reimbursement from the person responsible for the damage. But the person suffering harm need only proceed against the insurer.

[6] See the articles extracted and referred to in our analysis of the statutory provisions, later.

[7] The 'Development Risk Clause' (the clause of the Directive that sets out the development risk defence: Directive on Product Liability, Art 7(e)).

[8] The Fondazione Roselli Report (published in 2004), carried out for the European Commission.

[9] The Directive is harmonizing legislation and there is also European case law to draw upon. However, D. Fairgrieve and G. Howells (Further Reading) report low take-up of the Directive in all countries with the exception of Austria, where previous protection was less strong.

[10] Numerous studies have been conducted and none have shown a connection between the MMR/MR vaccines and autism.

[11] D. Fairgrieve and G. Howells, 'General Product Safety—a Revolution Through Reform?' (2006) 69 MLR 59–69; P. Cartwright, 'Enforcement, Risk and Discretion: The Case of Dangerous Consumer Products' (2006) 26 LS 524–43.

[12] See, for example, *Sam Bogle v McDonald's Restaurants* (Section 3.4): hot tea and coffee in container with a removable lid not 'defective'.

[13] For the position in negligence see *Murphy v Brentwood* [1991] 1 AC 398; *Muirhead v Industrial Tank Speciality Ltd* [1986] QB 507.

[14] Stapleton noted here that the Directive does have some unequivocal advantages for certain claimants—notably in the extended definition of 'producers' in Article 3.

[15] Could an action have been brought on the basis of a *failure to advise*? The problem with such a claim would lie in causation, if the defendants could argue that the transfusions were emergency treatment and that they would have been accepted even if the risk was known. The test of causation under the Consumer Protection Act 1987 is simpler: did the defect cause the harm?

[16] This depends on the idea that although the specific danger is unknown, the general risk that the product will contain dangers is known. But of course as we get further from known dangers, the risks become harder to quantify.

[17] Jane Stapleton, 'Product Liability Reform—Real or Illusory?' (1986) 6 OJLS 392–422.

[18] Necessarily, since there would appear to have been *no* UK case law applying the Act at the relevant time.

[19] On the other hand it has been argued that this incentive to research can be overdone, so that it begins to stifle innovation: see Chris Hodges, 'Development Risks: Unanswered Questions', extracted later.

[20] This is a reference to the 'German bottle case' of 9 May 1995, NJW 1995, 2162 (German Federal Supreme Court, 'BGH'). A mineral water bottle with a hairline crack was defective, and the development risks defence was not made out, even though the producer applied the latest technology in its production process.

[21] Section 33 applies only to claims which are within s 11; and s 11A states that the preceding sections (including therefore s 11) do not apply to claims under the Consumer Protection Act 1987.

[22] The *exclusivity* of the strict liability regime under the Directive was also important to the decision in *Wilson v Beko plc* [2019] EWHC 3362 (QB). Here, a consumer had been killed by a house fire caused by a defective freezer bought from the defendant 11 years previously. The claim was outside the longstop 10-year period permitted by the Directive, and the claim could not proceed on the different basis that there had been an actionable breach of statutory duty under s.41(1) CPA 1987. This will remain the case, since s.6 European Union Withdrawal Act 2018 only releases courts (other than the Supreme Court) from following *subsequent* developments in EU law.

[23] If this seems to be a stretch to benefit the claimant, it may indicate that courts in personal injuries actions are very used to operating a discretion to permit claims outside the limitation period.

[24] See, however, the note by C. Hodges, 'Product Liability: Suppliers, Limitation and Mistake' (2006) 122 LQR 393, arguing that *Horne-Roberts* is wrong or the UK has not properly transposed the Directive.