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THE REQUIREMENT OF A DEFECT: INTRODUCTORY ISSUES

A. Introduction

(1) Preliminary issues

10.01 The removal of a requirement of proving negligence, which is usually regarded as the distinguishing feature of the system of strict liability introduced by Pt I of the Consumer Protection Act 1987, will in all probability shift the focus of attention to the question of whether the claimant has established that the product is defective. As will be seen, the question gives rise to many difficult issues. Indeed, one writer has observed that 'the problem of defining defectiveness has exercised the minds of legal scholars perhaps more than any other aspect of product liability law'.[1]

10.02 There are a number of different respects in which it may be claimed that a product is defective and these will be examined in more detail in the following chapters. However, a few general and introductory observations may be helpful at this stage. In some cases the claimant may contend that a product is defective in the sense that there has been a miscarriage in the production process. Foreign objects or impurities in food or drink, the use of weak materials, and incorrect assembly are common examples. Here the essence of the

[1] Clark, *Product Liability*, 25.

Product Liability. Third Edition. Duncan Fairgrieve and Richard Goldberg, Oxford University Press (2020).
© Duncan Fairgrieve and Richard Goldberg 2020 DOI: 10.1093/oso/9780199679232.003.0012

complaint is that the product was not produced as intended and usually this will be because of an inadequate system of screening, inspection, and testing or through the failure of an individual employee properly to operate an adequate system. Where liability is strict, as under the 1987 Act, proof of negligence is not required, although there is some doubt as to whether the claimant must establish the respect in which the product is alleged to be defective.[2] Sometimes the consequences of a defect of this category may be catastrophic, but usually the problem will be a one-off or at least confined to a single production run.

10.03 In other cases the claimant may contend that a particular product is so designed as to be unsafe when used for its intended or foreseeable purpose.[3] Here the suggestion is not that there has been a miscarriage in the production process. On the contrary, the product will have been produced precisely as intended. The complaint relates rather to the very form in which it was conceived, or to the adequacy or suitability of the materials or ingredients used. Thus an agricultural machine may be so designed as to expose its operator to contact with moving parts;[4] a lawnmower may be dangerously defective in that its battery may be located too close to its petrol tank;[5] a child's sleeping bag may be designed with a dangerous attachment;[6] a feeding compound may contain ingredients fatal to the animals for whose use it is intended;[7] and a medicinal product or cosmetic may produce serious side effects whether on persons generally, or on those who are allergic to it.[8] In all such cases it is likely that the manufacturer will view an adverse decision with particular concern. At best, the inference is that the product should be withdrawn in its present form and appropriate warnings issued:[9] at worst, irreparable long-term damage may already have been inflicted on persons who have consumed or otherwise been in contact with the product.[10] Many such cases involve what a leading American author has described as 'polycentric' problems with attempts to establish product safety standards pushing courts to (and possibly beyond) the limits of their adjudication capabilities.[11]

10.04 At the other end of the line running from drawing board through to distribution, the allegation of defectiveness may refer, rather, to the manner in which the product has been marketed. The suggestion may be that the product is unsafe because it was marketed without sufficiently clear warning labels or directions for use.[12] Alternatively, the complaint may

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[2] See paras 10.06–10.15.

[3] Defects in design are discussed in ch 11 and paras 14.48–14.77.

[4] *Huset v JI Case Threshing Machine Co* 120 F 865 (8th Cir, 1903). See also *Griffiths v Arch Engineering Co Ltd* [1968] 3 All ER 217.

[5] *Nicholson v John Deere Ltd* (1986) 34 DLR (4th) 542 (Ont High Ct), affd (1989) 57 DLR (4th) 639 (Ont CA).

[6] *Abouzaid v Mothercare (UK) Ltd* [2000] All ER (D) 2436, CA, The Times, 20 February 2001.

[7] *Henry Kendall & Sons v William Lillico & Sons Ltd* [1969] 2 AC 31, [1968] 2 All ER 444, HL, and *Ashington Piggeries Ltd v Christopher Hill Ltd* [1972] AC 441, [1971] 1 All ER 847, HL, although in both cases the actions were in contract against the immediate vendor.

[8] For discussion of product liability for medicinal products, see paras 9.40–9.76. Allergies are discussed in paras 12.67–12.73 and 16.29–16.33. See also paras 4.102–4.103.

[9] The extent of any duty to warn of subsequently discovered dangers is discussed at paras 12.107–12.110, 14.116–14.123, and 16.75–16.78.

[10] As in *Wright v Dunlop Rubber Co Ltd* (1972) 13 KIR 255, CA, para 14.117.

[11] JA Henderson Jr and AD Twerski, *Products Liability: Problems and Process* (Aspen Law and Business, 2000) 566; JA Henderson Jr, 'Judicial Review of Manufacturers' Conscious Design Choices: The Limits of Adjudication' (1973) 73 Colum L Rev 1531, 1534–6, 1538–42, 1552, 1558, 1577–8.

[12] Inadequate warnings and directions for use are discussed in ch 12 and ch 14, paras 14.78–14.123.

specify the somewhat more positive claims made by the manufacturer in his promotion or labelling of the product.[13] Warnings or directions for use may serve a dual function. They may either enable the user to handle the product without danger to himself or others or they may appraise him of an unavoidable risk which he may thereafter choose to run.

10.05 Finally, there are cases in which safety and physical damage are not in issue and where the claimant's sole complaint is that he has incurred financial loss through his purchase or use of the product. The suggestion may be that the product was not of satisfactory quality, that is, unfit for the purpose or purposes for which such goods are commonly bought, or that it was unfit for the particular purpose for which the claimant was known to require it.[14] In either case the problem may stem from a miscarriage in the production process or from the product's basic conception or design. Consequential business losses may be involved or the loss may be confined to the difference between the price paid and the value (if any) of the defective product. English law has barely been troubled with such problems where claims by consumers against manufacturers are concerned and, as will be seen, they fall outside the scope of the 1987 Act and generally also of the tort of negligence.[15]

(2) Proof that the product was defective

10.06 Article 4 of the Product Liability Directive provides that: 'The injured person shall be required to prove the damage, the defect and the causal relationship between defect and damage.' However, while it is clear that the claimant must prove the 'defect', it is not clear precisely what this entails. The issue has arisen in at least two reported English decisions.

10.07 In *Foster v Biosil*,[16] which was heard in the Central London County Court, damages were claimed under the 1987 Act, it being alleged that two silicone breast implants manufactured by the defendant were defective in that the right one had leaked and the left one had ruptured. The defect alleged was claimed to originate in the manufacturing process, rather than in the implant's design. The Recorder, Cherie Booth QC, was satisfied, on the balance of probabilities, that the right implant had not leaked (and so was not defective), that the surgeon had not been negligent in carrying out the operation, and that the left implant had ruptured. The conclusions on these points were essentially ones of judgment and have no general application. The more interesting and controversial question was what precisely the claimant had to prove. In particular, was it sufficient, as the claimant maintained, to establish that the product had failed in a way which was unsafe and which was contrary to what persons generally were entitled to expect,[17] or was it necessary to establish, as the defendants maintained, not merely the fact but also the cause of the defect. On this it was held that the latter represented the correct approach because, although the Directive and the Act removed the need to prove negligence, they did not 'go any further than that and in addition reverse the burden of proof in respect of causation'. The conclusion was supported

[13] See paras 12.91 and 14.106–14.108. See also paras 1.41–1.44 and 3.39–3.44 for discussion of the express warranty theory of liability in American law.

[14] For discussion in the contractual context, see paras 4.39–4.84 (satisfactory quality), paras 4.85–4.106 (fitness for a particular purpose). See also paras 1.43–1.44 for a reference to the American implied warranty theory of *Henningsen v Bloomfield Motors* 161 A 2d 69 (NJ, 1960).

[15] See paras 16.55–16.81, 16.96–16.100.

[16] (2000) 59 BMLR 178; see P Popat, 'Defects and the Consumer Protection Act 1987' (2000) NLJ 1780. The author of this article appeared for the defendants in the case.

[17] For discussion of this test, see paras 10.18–10.20, 10.29–10.40 and 10.57–10.66.

by suggesting that, without identification of the nature of the defect, the defendant could not effectively rely on the defences provided by s 4(1)(d) and (e) of the Act.[18]

10.08 It is submitted that the reasoning in the above case is far from persuasive. Acceptance of the claimant's submissions does not impinge on the clear need to establish that the alleged defect (ruptured implant) caused the damage. Indeed, if the implant was defective the causal link to the damage associated with removing it was self-evident. The question is, rather, whether the claimant must establish the *respect* in which the product was defective and it is implicit in the decision that this is so.

10.09 In reaching her decision in *Foster v Biosil*, Cherie Booth QC relied in part on the decision of Ian Kennedy J in *Richardson v LRC Products Ltd*,[19] where the claim for damages was based on an unwanted pregnancy following the detachment of the teat end of a condom during sexual intercourse. The teat end was never found, but there was expert evidence on the probable cause of the fracture in the particular condom and on the failure of condoms in general. The defendants accepted that the condom had ozone-cracking and that they would be liable if this had been present from the time it left their factory. In relation to this, Ian Kennedy J held that the evidence indicated that the likelihood was that such cracking occurred after the fracture and did not cause it.[20] He also held that the fracture did not, of itself, prove a defect since condoms could fail for inexplicable reasons and the defendants had never claimed that their condoms would never fail.[21] This again appears to set a demanding level of proof, albeit that the decision would not be open to criticism in relation to the first point if the defendants had simply been relying on the statutory defence provided by s 4(1)(d) of the Act.[22]

10.10 In contrast to the above decisions of English courts, some other courts appear to have accepted that it is sufficient that a claimant prove that the product failed and that it resulted in injury. Thus in a decision of the Tribunal de Grande Instance of Aix-en-Provence in France,[23] a claimant was injured when a glass window in a fireplace exploded as a result of an unknown cause. The Tribunal concluded that the product's intervention at the time of the harm was sufficient and that the claimant did not have to prove the precise respect in which the product was defective.[24] Other similar approaches can be found in the French case law. The Toulouse Court of Appeal held that 'the finding of liability of a professional who has supplied a defective product is not subject to the establishment of the exact origin of the defectiveness of the product'.[25] The same reasoning was adopted by the Bastia Court

[18] These cover, respectively, the defence that the product was not defective at the time of supply (see paras 13.23–13.32) and the so-called development risk defence (see paras 13.33–13.125).

[19] [2000] Lloyd's Rep Med 280.

[20] ibid, 284. There have been similar decisions to the UK cases in Portugal: High Court of Coimbra, 8 April 1997, BMJ 466, 596; Col Jur 1997, 2, 38 as cited in J Meltzer, R Freeman, and S Thomson, *Product Liability in the European Union: A Report for the European Commission*, MARKT/2001/11/D (Lovells, 2003), 2.2(b), 49.

[21] ibid, 285. For further discussion of this point, see para 10.30.

[22] In other words, that the condom was not defective at the time of supply.

[23] 2 October 2001, Dalloz 2001, IR 3092, as cited in Meltzer, Freeman, and Thomson (n 20), 48; C Larroumet, Note, 'The Exploding Fireplace Case', Lovells' *European Product Liability Review*, December 2001, Issue 5, 30.

[24] ibid.

[25] Decision of 7 November 2000, No 1999/03960: available on the BIICL Product Liability Forum database: https://www.biicl.org/plf (French case concerning a car accident caused by an allegedly defective tyre in

of Appeal which, in a case of a defective life-vest, considered that regardless of the exact causes of the incident, the parties had demonstrated that the vest did not provide the safety one could legitimately expect.[26] The Limoges Court of Appeal held that the fact that the specific cause of the damage was unknown was irrelevant since it was demonstrated that the product in question was inherently defective.[27] A similar approach was adopted by a court in Italy in a case involving a motorbike accident which was presumed to have arisen from an (unexplained) problem with steering.[28] There is also some evidence that Spanish courts have in some circumstances presumed defectiveness.[29] Similarly, in the first case decided in Belgium under the Directive, the judge ruled that the explosion of an aerated beverage bottle was evidence of an abnormal feature of the product which was incompatible with the safety that consumers were entitled to expect. Under the Directive, the claimant was not required to prove 'the exact nature of the defect, in particular as regards all its technical aspects',[30] since the defect could be deduced from the abnormal behaviour of the product.[31]

10.11 The Austrian Supreme Court appears to have adopted a two-step approach to determining the level of proof required to establish the presence of a defect. First, the claimant need not prove exactly which part of a product was defective, providing he can establish that one such part was and that the defect caused the damage. Secondly, the more obvious a product's failure appears to be, the lower the burden of proof on the claimant to establish its exact cause.[32] In other decisions involving a bottle of sparkling water that, when opened, the top shot into the claimant's eye,[33] and a bottle of fruit juice that, when a seven-year-old

which the Court of Appeal of Toulouse was prepared to presume that a defect had occurred without being concerned to identify the precise cause).

[26] Bastia Court of Appeal, 9 June 2011, no 08/00778.

[27] Limoges Court of Appeal, 10 June 2010, no 08/00042

[28] Motorbike Steering Case (2004) Danno e Responsabilità 529, 3 November 2003 (Trib Roma).

[29] J-L Huerta and B Muñiz, 'An Overview of Product Liability in Spain' (2005) European Product Liability Rev 18, p 5: 'Spanish courts have found ways to provide remedies to claimants where the technical complexity of a product greatly increases the difficulty of proving its defectiveness. The most common means of achieving this is for there to be a presumption of defect, and there are a number of rulings in which courts have accepted the existence of a defect on this basis' (at pp 6–7). See also B Muñiz Calaf, 'A Consideration of the Burden of Proof in Product Liability Cases Involving Medical Products' (2007) European Product Liability Rev 29/15, p 15 who notes the impact of Article 217.6 of the Spanish Law of Civil Procedure which 'states that the court should bear in mind, in distributing the burden of proof, the availability of and ease of access to the evidence for each party' (p 17). The author therefore notes that '[i]t cannot be denied that, in relation to products of technological complexity, the manufacturer—who carries out quality controls of his products and owns laboratories specifically devoted to analysing them—is normally in a better position to prove that a product was manufactured properly than the damages party is to prove that it is defective' (p 17). Note also in a Supreme Court Decision of 21 February 2003 RJ 2003\2133 concerning an exploding lemonade bottle, the court held that the notion of defect 'must be connected, necessarily, with the safety that the product must offer, and if it does not offer this safety, the product must be considered defective, by reversing the burden of the proof, since it corresponds to the manufacturer to prove the suitability of the product or other grounds which could exonerate him from liability' (see Product Liability Forum database).

[30] *Riboux v SA Schweppes Belgium*, 21 November 1996, Civ Namour, 5e ch, JLMB, 1997, 104, as cited in Meltzer, Freeman, and Thomson (n 20), 49.

[31] Commission Green Paper, Liability for Defective Products, Brussels (COM(1999)396, final), 28 July 1999, 3.2, p 21.

[32] 10 Ob 98/02 p (22 October 2002) noted in S Lenze, 'Strict Liability for Manufacturing Defects—What Proof is Needed?', Lovells' European Product Liability Review, June 2003, Issue 11, 37, 37–9.

[33] 4 Ob 87/97 s (8 April 1997) noted in S Lenze, 'Proof of Defect', Lovells' *European Product Liability Review*, December 2002, Issue 9, 40, 41.

girl went to drink from it, exploded and a piece of glass cut her carotid artery,[34] it was held sufficient to establish that such bottles exploded when used in a normal way, without requiring the claimant to prove the precise cause. By contrast, in another case involving an aerosol spray can which carried a warning stating that the cans should not be exposed to direct sunlight and temperatures over 50°C, and which exploded, having been left in a car on a hot summer's day, the Austrian Supreme Court held that the claimant was required to show why the spray can exploded.[35] These cases might be thought to lie at the opposite ends of the spectrum and, as with any such case, it is not always clear whether the concern is primarily with *what* must be proved (substantive law) or with the sufficiency of evidence.[36]

10.12 Insofar as the concern is with what must be proved, it is submitted that there are very considerable drawbacks in adopting the approach favoured in *Foster v Biosil*[37] and perhaps also *Richardson v LRC Products Ltd*.[38] In effect, this appears to require the claimant to establish the respect in which the product was defective with a fairly high degree of specificity. It is not enough to indicate whether the alleged defect is one of manufacture, as opposed to design, or vice versa, but it is necessary, rather, to identify the nature or cause of the defect. As the *Biosil* case indicates, this leads one immediately into such matters as the incidence of other unsafe products within the same batch and the likelihood of there being only one such unsafe product within a given batch. Such considerations are central to a claim in negligence, but should have no place in a strict liability system. It should be sufficient, rather, to establish that the product was in a condition which did not satisfy the relevant definition of a defect to which we now turn.[39] Of course, this should not, on a proper analysis, have any effect on the additional requirement of proving that the defect caused the damage in respect of which the claimant seeks compensation.

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[34] 10 Ob 19/01 v (30 October 2001) noted ibid, 41.

[35] Decision of Supreme Court, 9 July 2002, 'Spray Can' 2 Ob 253/01 x, noted ibid, 40–2.

[36] See also *Restatement, Third, Torts: Products Liability* § 3, which is concerned with the use of circumstantial evidence to support an inference of a product defect and which provides: 'It may be inferred that the harm sustained by the plaintiff was caused by a product defect existing at the time of sale or distribution, without proof of a specific defect, when the incident that harmed the plaintiff: (a) was of a kind that ordinarily occurs as a result of product defect; and (b) was not, in the particular case, solely the result of causes other than product defect existing at the time of sale or distribution.' The language is that of *res ipsa loquitur*: see eg *Doyle v White Metal Rolling and Stamping Co* 618 NE 2d 909, 916 (Ill App, 1993) (step ladder); *Cassisi v Maytag Co* 396 So 2d 1140, 1146 (Fla App, 1981) (defective dryer); *Cincinnati Ins Co v Volkswagen of America Inc* 502 NE 2d 651, 653–4 (Ohio App, 1985). See also in relation to circumstantial evidence, paras 17.15–17.17.

[37] (2000) 59 BMLR 178, see para 10.07.

[38] [2000] Lloyd's Rep Med 280.

[39] In *Wilkes v DuPuy International Ltd* [2016] EWHC 3096 (QB), Hickinbottom J recognized the academic debate over the issue of the degree of specificity with which the defect had to be described and proved, and noted the suggestion from cases such as *Richardson* that considerable specificity might be required, though it was not an issue in the case in point. He did, however, posit the scenario whereby a pharmaceutical product that was highly beneficial to most patients but, in a minority, caused death or serious injury 'for a reason unascertained or unascertainable', could nonetheless be held to lack the appropriate level of safety and thus be defective: ibid, [73]. Moreover, it has been suggested that, in certain circumstances, the claimant may be required to establish the respect in which the product was defective with a greater degree of specificity about a feature or characteristic that is said to make the product unsafe. This could be the case if the injury or damage could have arisen even if the product met the objective standard of safety in s 3 of the Act, such as in consequence of the manifestation of a known risk that could arise in normal use. The claimant would need to establish that there was something abnormal that caused it to fail or something had elevated the risk to a level higher than the public was entitled to expect: *Gee v DePuy International Ltd* [2018] EWHC 1208 (QB), [100].

10.13 The English Court of Appeal has now taken a different approach to this issue, by stressing that a claimant is not required to prove the cause of the lack of safety that amounts to a defect, or why the product had failed.[40] The case of *Ide v ATB Sales*,[41] concerned two joined cases, one arising from a fire at a garage which was attributed to defective wiring in a car, and another arising from a mountain bike accident ascribed to a defective handlebar. The two appeals were heard together because they raised issues as to the approach a judge was entitled to take to the determination of proof of causation where alternative mechanisms of causation were put forward. On the causation issue, the Court of Appeal held that in the vast majority of cases where a judge had before him the issue of causation of a particular event, the parties would put before the judge two or more competing explanations as to how the event occurred, which though they might be uncommon, were not improbable, and in such cases it was a permissible and logical train of reasoning for a judge, having eliminated all of the causes of the loss but one, to ask himself whether, on the balance of probabilities, that one cause was the cause of the event. On the issue of proof, Thomas LJ indicated that it was 'unnecessary to ascertain the cause of the defect'.[42] Professor Mark Mildred has thus argued that this decision 'certainly trumps the view of Cherie Booth QC in *Foster v Biosil* to the effect that the claimant in a CPA case must prove the mechanism by which the defect in the product causes the damage'.[43] That it is unnecessary to show how a defect has been caused and the reason why it failed was reaffirmed by the Court of Appeal in *Baker v KTM Sportmotorcyle UK Ltd*.[44] The claimant had been riding his motorcycle when the front brake seized, causing him to be thrown from the motorcycle and to have sustained serious personal injuries. The trial judge found that the cause of the seizing of the brakes was galvanic corrosion, due to a defect in the motorcycle. The defendant appealed on the ground that there was no evidence or insufficient evidence that the galvanic corrosion was caused by a defect in the motorcycle.[45] Hamblen LJ, giving judgment for the Court of Appeal, noted that the *Ide* case showed that there may be a defect within the meaning of s 3 of the Consumer Protection Act, even though the precise mechanism by which that defect arose was not proven.[46] Mirroring the *Ide* case, where the handlebar was defective in that it failed from normal use in circumstances where a standard non-defective handlebar would not have failed, the motorcycle brakes in *Baker* were defective 'in that they allowed galvanic corrosion to develop following normal use in circumstances where standard non-defective brakes would not have done'.[47]

10.14 Uncertainty surrounding the question of what is required to prove the 'defect' has been discussed by the Commission Reports on the operation of the Directive.[48] Its Fourth

[40] *Ide v ATB Sales Ltd* [2008] EWCA Civ 424, [19]–[22] per Thomas LJ.
[41] ibid.
[42] ibid, [19].
[43] See also M Mildred, 'Case and Comment: Ide v ATB Sales Ltd' [2008] JPIL C117.
[44] [2017] EWCA Civ 378, [35] per Hamblen LJ (for the court).
[45] ibid, [3]–[4].
[46] ibid, [26].
[47] ibid, [39]. See also *AH v Greater Glasgow Health Board* [2018] CSOH 57, 2018 SLT 535, [116] (vaginal mesh products) as well as the Australian decisions of *Peterson v Merck Sharp & Dohme (Australia) Pty Ltd* v (2010) 184 FCR 1, [200]–[201] (Vioxx), and *Gill v Ethicon Sàrl & Ors (No 5)* [2019] FCA 1905, [3178] (vaginal mesh products).
[48] See European Commission, Third Report on the application of Council Directive on the approximation of laws, regulations and administrative provisions of the Member States concerning liability for defective products, September 2006 (COM(2006) 496 final), 10; European Commission, Fourth Report on the application of Council Directive 85/374/EEC (COM(2011) 547), 7; European Commission, Fifth Report on the application of Council Directive on the approximation of laws, regulations and administrative provisions of the Member States concerning liability for defective products (85/374/EEC) (COM/2018/246 final), 8.

Report on the operation of the Directive distinguished the early UK approach[49] illustrated by cases such as *Richardson v LRC*[50] and *Foster v Biosil*[51] with that found in countries such as Belgium, France, Italy, and Spain where it recounted that is enough for the plaintiff to show that the product did not fulfil the function for which it was intended. The Commission also referred to the aforementioned body of case law from the Austrian Supreme Court as reconciling those two positions. Concerns among consumers over the burden of proof of the defect were again noted in the Fifth Report[52] and its accompanying Evaluation Document.[53]

10.15 These differences can perhaps be explained by the different roles of the judiciary in the Member States. As Whittaker notes, in the French context, assessment of 'defect' is within the 'sovereign power of assessment' of the *juges du fond* ('judges of the lower courts').[54] Where the role of the judge is simply to apply the written law, more discretion is possible than in the common law system where judges have traditionally been required to give fuller explanations for their decisions.

B. The Definition of a Defect

(1) General observations

10.16 It is arguable that the definition of a 'defect' is the single most difficult part of the Product Liability Directive and Pt I of the 1987 Act.[55] As is apparent from the earlier discussion,[56] any preferred definition will be partly dependent on the types of damage or loss which it is sought to compensate. Thus a system which includes purely financial or economic losses will probably adopt a definition based on a standard of satisfactory quality or reasonable fitness for purpose. On the other hand, if compensation is to be limited to cases of death, personal injury, and property damage, it is likely that the definition would be based on a test of a reasonable or acceptable level of safety[57] or, as in the case of the *Restatement, Second, Torts* § 402A, an absence of unreasonable danger. More recently, in the United States the *Restatement, Third, Torts: Products Liability* has abandoned the doctrinal labels of strict liability and negligence and established separate functional definitions of liability for three types of defect, viz a manufacturing defect,[58] a design defect,[59] and a warning defect.[60]

[49] The Commission also notes that in Germany the plaintiff must prove the precise nature of the product's defect in more detail: p 7.

[50] *Richardson v London Rubber Company Products Ltd* [2000] Ll L Rep 280 (QBD) (Kennedy J).

[51] *Foster v Biosil* [2000] 59 BMLR 178 (London Central County Court) (Mrs Recorder Booth QC).

[52] European Commission, Fifth Report (n 48), 8–9.

[53] Evaluation of Council Directive on the approximation of laws, regulations and administrative provisions of the Member States concerning liability for defective products (SWD(2018)157), 25, 61.

[54] S Whittaker, *Liability for Products: English Law, French Law and European Harmonization* (OUP, 2005), 75.

[55] In *Wilkes v DuPuy International Ltd* [2016] EWHC 3096 (QB), [62], Hickinbottom J opined that '[f]ew would demur' from this submission.

[56] See paras 10.02–10.05.

[57] See *Liability for Defective Products* (Law Com No 82, Scot Law Com No 45, Cmnd 6831, 1977), para 46 (hereafter Law Coms Rep).

[58] *Restatement, Third, Torts: Products Liability* § 2(a).

[59] ibid, § 2(b).

[60] ibid, § 2(c).

10.17 There was some discussion during the passage of the Product Liability Directive about different functional definitions of defects. Taschner has noted that: 'When the Product Liability Directive was drafted, there was discussion as to whether or not to differentiate between manufacturing and design defects over liability. The overwhelming opinion in the Council was not to do so. So the strict liability rule of Article 1 of the Product Liability Directive covers design defects as well. The convincing argument for doing so was that in the case of design defects as well as in manufacturing defects 'liability turns on the existence of a defect alone ... no question of foresight of the danger arising for consideration.' The other argument was to ensure legal security: 'A clear-cut definition of both categories is not easy. Would it not be a paradise for defence lawyers to try to bring each case under the second category in order to win the case, if negligence would be allowed in design defect cases? There would be no longer manufacturing defects. Only the uniformity of applicable liability leads to the legal security needed mainly for the insurability of producer's risk.'[61] Ultimately, the Product Liability Directive has on its face retained a single common standard to determine if the product is defective. In *A v National Blood Authority*[62] Burton J expressly rejected the US distinction between manufacturing and design defects;[63] but his own distinction between standard and non-standard products[64] raises many of the same issues. Indeed, the distinction between manufacturing and design defects is found in the European literature and even in some case law, particularly in Germany[65] and Austria.[66] One commentator has thus written that 'German courts, through case law, have (re-) established the three known categories of defect: manufacturing defects, design defects and instruction (warning) defects. This has far-reaching consequences for the application of the concept of defect …The most important effect of this partition of defect is that strict liability in fact only remains for manufacturing defects.'[67] Even in those countries which have been resistant to such categorization, traces of design/manufacturing reasoning can be found. In his pioneering comparative law study on product liability,[68] Borghetti points to a number of cases where, in the absence of a manifest defect in the product, the French courts have made reference, in finding liability, to the fact that the producer had failed to

[61] H-C Taschner, 'Product Liability: Basic Problems in a Comparative Law Perspective' in D Fairgrieve (ed), *Product Liability in Comparative Perspective* (CUP, 2005), 161 (footnotes omitted).

[62] [2001] 3 All ER 289.

[63] ibid, [39].

[64] ibid, [36]. The distinction between a 'standard' and a 'non-standard product' was drawn as follows: '[A] standard product is one which is and performs as the producer intends. A nonstandard product is one which is different, obviously because it is deficient or inferior in terms of safety, from the standard product: and where it is the harmful characteristic or characteristics present in the non-standard product, but not in the standard product, which has or have caused the material injury or damage.' Cf *Wilkes v DePuy International Ltd* [2016] EWHC 3096 (QB), [2017] 3 All ER 589, [94] per Hickinbottom J, who viewed the rigid categorization of defects into standard/non-standard as 'unnecessary and undesirable' and 'positively unhelpful and dangerous'. It is not a classification present in the Directive or the 1987 Act. In his view, the issue as to whether a particular product is within the product's specification and is compliant with relevant standards may be relevant circumstances in determining the level of safety persons generally are entitled to expect. See further, paras 10.111–10.120.

[65] eg the German Mineral water bottle case: Bundesgerichtsgof, 9/5/1995 VI ZR 158/94.

[66] See B Koch, 'Austria' in P Machnikowski (ed), *European Product Liability: An Analysis of the State of the Art in the Era of New Technologies* (Intersentia, 2016), 126.

[67] S Lenze 'German Product Liability Law' in D Fairgrieve (ed), *Product Liability in Comparative Perspective* (CUP, 2005), 107–8.

[68] J-S Borghetti, *La Responsabilité du Fait des Produits: Etude de Droit Comparé* (LGDJ, 2004).

adopt a *reasonable alternative design*.[69] In another important comparative and economic analysis of product liability, Professor Erdem Buyuksagis has argued that despite the even-handed approach adopted in the Product Liability Directive, a distinction should be made as to different types of defect, and that as a consequence: 'liability for a simple defect is desirable and possible only in cases of manufacturing defects. For other defects, the liability of the manufacturer can only be incurred if he has not acted as he ought to have done.'[70]

10.18 Section 3 of the Consumer Protection Act 1987, which implements Article 6 of the Product Liability Directive, provides the following definition of defect:

> (1) … there is a defect in a product … 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 get-up, 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.

Article 6 of the Directive provides a somewhat shorter definition, which was modified in the light of the views of the European Parliament. It states that:

> 1. A product is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account, including:
> (a) the presentation of the product;
> (b) the use to which it could reasonably be expected that the product would be put;
> (c) the time when the product was put into circulation.
> 2. A product shall not be considered defective for the sole reason that a better product is subsequently put into circulation.[71]

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[69] Borghetti refers to a Court of Appeal case where, in the case of an alleged breach of a contractual obligation de sécurité when a lamp bulb had exploded: 'the defect of the product was not obvious enough considering the usual specifications of lighting fitting and the existence of such defect could not be found without discussing the facts of the case. However, the Court characterized such defect while stating that adding a simple safety mechanism on such type of device could have helped to eliminate the risk which occurred in this case. There actually is a reasonable alternative design, which can be easily implemented, and from which we can infer the existence of a defect' (CA Douai, 7 January 1999, RCA 2000 comm 73). See Borghetti, ibid, para 331.

[70] See E Buyuksagis, *La Notion de Défaut dans la Responsabilité du fait des Produits: Analyse Economique et Comparative* (Schulthess, 2005), 300.

[71] cf the Strasbourg Convention on Products Liability in Regard to Personal Injury and Death, Art 2(c), which provides that 'a product has a "defect" when it does not provide the safety which a person is entitled to expect, having regard to all the circumstances including the presentation of the product.' The Pearson Commission adopted the Strasbourg definition, noting that presentation would include warnings and instructions: Royal Commission on Civil Liability and Compensation for Personal Injury (Cmnd 7054-I, 1978), para 1237. The Law Commission and Scottish Law Commission had earlier concluded that there

Both definitions are comparatively brief and do not distinguish between manufacturing defects, design defects, and warning defects. This can be contrasted with the *Restatement, Third, Torts: Products Liability*, which, as noted earlier, establishes distinct functional definitions for the various types of defects.[72]

10.19 Since the cornerstone of the definition of a defect is the 'consumer expectation test', it might be thought that the definition was derived from contract law.[73] However, the Explanatory Memorandum which accompanied the first draft Directive explained that the definition is a non-contractual one, based on the product's safety, the safety being judged according to 'objective criteria on the basis of the circumstances in each individual case'.[74] The Explanatory Memorandum concluded that:[75]

> It is therefore irrelevant whether a product is defective in the sense that it cannot be used for its intended purpose. Such a concept of defectiveness belongs to the law of sale. A liability which applies in respect of all persons suffering damage from the defective article and the aim of which is to protect the rights of the consumer can be based only on lack of safety.

10.20 The idea that the definition of defect is based on the product's safety was further developed by the Law Commissions,[76] and the point was reinforced by the government in the DTI Consultative Note on the implementation of the Directive, which stated that: 'The defectiveness of the product will be determined not by its fitness for use, nor in the case of a medicine, by its efficacy, but by the level of *safety* that is reasonably expected of it. An inferior quality product is not considered "defective" for the purpose of this Directive unless

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were two fundamental propositions in providing a definition of defective, viz: (a) a product should be regarded as defective if it does not comply with the standard of reasonable safety that a person is entitled to expect of it; and (b) the standard of safety should be determined objectively having regard to all the circumstances in which the product was put into circulation, including, in particular, any instructions or warnings that accompanied the product when it was put into circulation, and the use or uses to which it would be reasonable for the product to be put in those circumstances: see Law Coms Rep, paras 48, 125(g). See generally ibid, paras 45–9, and Law Commission Working Paper No 64, *Liability for Defective Products*, paras 63, 88 and 94 ff.

[72] Section 2 provides:

> **2. Categories of Product Defect**
> A product is defective when, at the time of sale and distribution, it contains a manufacturing defect, is defective in design, or is defective because of inadequate instructions or warnings. A product: (a) contains a manufacturing defect when the product departs from its intended design even though all possible care was exercised in the preparation and marketing of the product; (b) is defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design … and the omission of the alternative design renders the product not reasonably safe; (c) is defective because of inadequate instructions or warnings when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings … and the omission of the instructions or warnings renders the product not reasonably safe.

[73] See Clark, *Product Liability*, 28–9.

[74] September 1976, EC Bull Supp 11/76, para 13.

[75] ibid.

[76] The Law Commissions stated that: 'In our consultative document we suggested that there were two possible approaches to the definition of defect. One was to make the definition turn on safety; the other was to make it turn on merchantability. Having regard to our general conclusion in this report that strict liability should be confined to personal injuries, the latter approach is less suitable. Moreover, as we pointed out in our consultative document, such an approach has conceptual and practical difficulties. The main problem is that the standard of merchantability required depends on the terms and circumstances of the contract under which the product is supplied, including the price': Law Coms Rep, para 46.

it actually introduces a risk of injury.'[77] Nonetheless, there is considerable overlap between the factors to be taken into consideration in determining defectiveness under s 3(2) of the 1987 Act and whether goods are of satisfactory quality under s 14(2B) of the Sale of Goods Act 1979 and s 9(3) of the Consumer Rights Act 2015.[78] However, whereas it is clear that products may be of unsatisfactory quality without being unsafe and 'defective' (eg a badly stained three-piece suite or a scratched Rolls-Royce when sold at full price), it is singularly unlikely that one could have a dangerously 'defective' product which was adjudged to be of satisfactory quality for the purposes of sales legislation. It is to be noted, however, that in Poland terminology was adopted so as to distinguish defects of quality from lack of safety. As Tulibacka explains: 'the Polish regulation replaced the notion of "defect" required by the Directive, with the notion of "lack of safety" (thus a "defective product" is referred to as an "unsafe product"—*product niebezpieczny*. The rationale behind this approach was the perceived need to distinguish defects of quality (governed by the contractual rules of legal guarantees …) from lack of safety.'[79] As Baginska has observed, 'This very detraction from the phraseology used by the Directive has been the subject of some controversy, but its purpose was to distinguish defects in a product liability context from defects in "mere" warranty situations.'[80] Whilst Tulibacka thus notes rightly that this 'is a truly unique approach within Europe', she goes on to explain that as the Polish Civil Code provides a definition of 'unsafe' which follows closely the definition of defect in the Directive, this may be a distinction without a difference: 'while the Code indeed uses a different notion, its further explanation follows the wording of the Directive'.[81]

10.21 It seems that in most American states proof that a product design is dangerous and thereby unmerchantable for the purposes of UCC § 2-314 or 'defective' or 'unreasonably dangerous' under § 402A of the *Restatement, Second, Torts*, or § 2(b) of the *Restatement, Third, Torts: Products Liability* usually amounts to the same thing. However, in *Denny v Ford Motor Co*[82] it was held that the causes of action for strict products liability and breach of implied warranty were not identical, and that in the circumstances it was possible for a manufacturer to be liable for breach of implied warranty even though he was not liable under strict products liability for a defective design. The court explained that while strict products liability and breach of implied warranty 'coexist and are often involved in tandem', the core element of a defect is subtly different in the two causes of action.[83] While the strict products liability concept of a defective product 'requires a weighing of the product's dangers against its over-all advantages', the concept of a defective product under an implied warranty theory 'requires an inquiry only into whether the production in question was fit for the ordinary purposes for which such goods are used', which focuses 'on the expectations for the performance of its product when used in the customary, usual and reasonably foreseeable manners'.[84] Nevertheless, *Denny* acknowledged that the two standards

[77] 'Implementation of the EC Directive on Product Liability: An Explanatory and Consultative Note' (DTI, 1985), para 55, 13–14.

[78] See paras 4.48–4.74.

[79] M Tulibacka, *Product Liability Law in Transition: A Central European Perspective* (Ashgate, 2009), 270.

[80] E Baginska, 'Poland' in P Machnikowski (ed), *European Product Liability: An Analysis of the State of the Art in the Era of New Technologies* (Intersentia, 2016), 384.

[81] ibid, 271.

[82] 662 NE 2d 730 (NY, 1995).

[83] ibid, 735.

[84] ibid, 736.

will usually render the same result and that '[a]s a practical matter, the distinction between the defect concepts in tort law and in implied warranty theory may have little or no effect in most cases'.[85] Though eventually withdrawn, in the context of the Amended version of the Uniform Commercial Code, it was suggested in a preliminary official comment that where recovery is sought for injury to persons or property, the question whether goods are merchantable is to be determined by applicable state products liability law.[86]

(2) Alleged vagueness of defectiveness standard

10.22 Professor Stapleton has identified the core problem with the definition of a defect as being its inherent circularity, commenting that 'what a person is entitled to expect is the very question a definition of defect should be answering'.[87] In similar vein, Dr Clark has written that the major difficulty with the definition of defect in the 1987 Act 'is that it fails to provide a readily ascertainable objective standard against which a manufacturer, or indeed a court, can measure the safety of a product'.[88] However, the same objection could be made in numerous other areas of the law[89] and it is doubtful whether an expanded list of factors which are to be taken into account would remove the perceived deficiency. Any such list would necessarily be less than complete and would have to be non-exhaustive.

10.23 The notion of defect is a remarkably open-textured notion. Similar remarks have been made by commentators in domestic systems. In France, Viney and Jourdain conclude that the test of defect gives 'to the judge rather a large discretion',[90] whilst Professor Jamin has added that it allows first-instance judges to 'do what they want according to their perception, very largely subjective, of the sociology of the time'.[91] Another writer has observed that 'the inherent subjectivity of the evaluation of the legitimate expectations of the public will allow for continued divergence in the policy of judges in respect of consumers'.[92] In respect of English law, Professor Howells has noted that '[i]n truth the defectiveness standard was so open-textured and the rationale behind the Directive so opaque that almost any gloss could be given to them'.[93] Italian commentators have referred to the defectiveness standard as essentially a 'relative'[94] one.

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[85] ibid, 738.

[86] Comment 7. See also para 4.70.

[87] Stapleton, *Product Liability*, 234. See also J Stapleton, 'Products Liability in the United Kingdom: The Myths of Reform' 34 Tex Int LJ 45, 53 (1999); S Whittaker, 'The EEC Directive on Product Liability' (1985) 5 Ybk Eur Law 233, 242.

[88] Clark, *Product Liability*, 29.

[89] Examples include: (a) the standard of satisfactory quality of the Sale of Goods Act 1979, s 14(2) and the Consumer Rights Act 2015, s 9; (b) the guidelines for the application of the 'reasonableness' test in the Unfair Contract Terms Act 1977, Sch 2; (c) the factors relevant to determining whether an occupier has discharged the common duty of care to lawful visitors of the Occupiers' Liability Act 1957, s 2(2); and (d) whether a given activity constitutes an unreasonable interference with the use of land for the purposes of the law of nuisance.

[90] J Ghestin (ed), '*Traité de droit civil: G Viney and P Jourdain, Les conditions de la responsabilité* (2nd edn, LGDJ, 1998), 770.

[91] C Jamin, RTDCiv 1998.763, 765.

[92] S Taylor, *L'Harmonisation Communautaire de la Responsabilité du Fait des Produits Défectueux* (LGDJ, 1999), para 56.

[93] G Howells, 'Defect in English Law—Lessons for the Harmonisation of European Product Liability Law' in D Fairgrieve (ed), *Product Liability in Comparative Perspective* (CUP, 2005), 141.

[94] PG Monateri, 'La responsabilità civile' in R Sacco (ed), *Trattato di dir Civ* (Turin, 1998), 717. See also E Rajneri, 'La responsabilità per prodotti difettosi tra incentivi all'innovazione tecnologica e protezione del consumatore nei paesi dell'Ovest e dell'Est Europa' in *Temi e problemi della civilistica contemporanea* (Naples, 2005), 109–20.

(3) Overtones of a negligence standard

10.24 It is a widely held view that the core definition of a defect contains substantial overtones of a negligence standard. Certainly, this is true (and perhaps inevitably so) where the concern is with alleged defects of design or inadequate warnings which may be seen as requiring a balancing of the risks and benefits involved in supplying certain types of products.[95] We have already seen earlier that Professor Buyuksagis has argued that in case of non-manufacturing defects, 'liability of the manufacturer can only be incurred if he has not acted as he ought to have done'.[96]

10.25 In the Report on Product Liability in the European Union, the possibility was discussed of defining the defect concept in the Directive more precisely so as to clarify the issues that remain controversial. However, it was also noted that it might be better not to adopt this course, not least because this could restrict the ability of judges to address such matters on a case-by-case basis. The Report stated that it might be expected that a body of case law will emerge that will provide a guide to the interpretation of this concept, and that the concept may come to be clarified in due course by the ECJ.[97] However, the prevailing uncertainty was subsequently noted in the European Commission's Third Report on the Product Liability Directive that: '[t]he subjective nature of the "expectations" test means that this principle is incapable of precise definition …' As previously noted,[98] the Commission's Fifth Report[99] has now conceded that one of the concepts hampering the Directive's effectiveness is that of 'defect',[100] and that they intend to draft 'comprehensive guidance'[101] on the application of the Directive, so as inter alia to provide 'a better common understanding'[102] of the concept of defect, as well as 'clarifications' as to the issue of burden of proof.[103]

(4) Guidance from the Court of Justice

10.26 The first ever guidance as to the circumstances in which a product may be deemed defective emerged in two joined cases before the CJEU: *Boston Scientific Medizintechnik GmbH v AOK Sachsen-Anhalt-Die Gesundheitskasse and Others*.[104] The two related cases concerned two types of implanted medical devices—a pacemaker and an implantable cardioverter defibrillator (ICD)—which were both manufactured by Boston Scientific and imported into the EU. In each case, the manufacturer identified a risk of failure[105] and treating physicians

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[95] The Cologne Court of Appeal has reflected the tendency of the majority of Member States' courts to apply concepts and standards forming part of negligence in design defect cases under the Directive: Cologne Court of Appeal 'Broken Suspension Fork' case, decision of 27 August 2002 (3 U 116/00), NJW-RR 2003, 387 (mountain bike: defective suspension fork), noted in S Lenze, 'Take it from a Duck-Overlap between Negligence and Defective Products', Lovells' *European Product Liability Review*, December 2003, Issue 13, 40–1.

[96] See Buyuksagis (n 70), 300.

[97] J Meltzer, R Freeman, and S Thomson, *Product Liability in the European Union: A Report for the European Commission*, MARKT/2001/11/D (Lovells, 2003), 2.2(b), 49. To date, the first guidance provided by the CJEU.

[98] See paras 7.63–7.65.

[99] European Commission, Fifth Report (n 48).

[100] ibid, 8.

[101] ibid, 2.

[102] ibid, 6.

[103] ibid.

[104] Cases C-503/13 and C-504/13 *Boston Scientific Medizintechnik GmbH v AOK Sachsen-Anhalt-Die Gesundheitskasse and Others*, ECLI:EU:C:2015:148 (5 March 2015).

[105] The pacemakers implanted belonged to a product group which had a risk of failure 17 to 20 times greater than was normal for that kind of device: ibid, [24] (Opinion of AG Bot).

were written to in the form of a safety notification. Consequent upon these notifications, the devices were explanted and replaced. The patients' health insurers sought damages for the costs relating to the replacement of the devices.[106] In both cases, it had not been determined whether the devices themselves had malfunctioned, [107] and thus the question before the CJEU was whether the medical devices affected by the potential defect were defective within the meaning of Article 6 of the Directive. More specifically, the issue that was addressed by the Court was whether a product was defective if it belonged to or formed part of a product group which had a significant increased risk of failure, but where the defect had not been detected in the specific product in question. In construing Article 6 of the Directive, the CJEU held that in determining whether a product was defective in accordance with the consumer expectations test, regard must be had to the reasonable expectations of the public at large.[108] However, the Court then notably shifted its emphasis from the expectations of the public at large to taking into consideration, inter alia, 'the specific requirements of the group of users for whom the product was intended'; that is, patients.[109] In addition, account was to be taken of 'the intended purpose, the objective characteristics and properties of the product in question'.[110] The Court found that in the light of their function, and of the particularly vulnerable situation of patients using such medical devices, patients were entitled to expect particularly high safety requirements.[111] The Court held that where it is found that products belonging to the same group or same production series have a potential defect, it is possible to classify as defective all products in that group or series, without there being any requirement to show that the product is defective in each individual case.[112] This interpretation was seen as consistent with the Directive's objective in seeking to ensure a fair apportionment of the risks inherent in modern technological production between the injured person and the producer.[113] While emphasis was placed on the specific risks associated with the medical devices in issue, in reaching its conclusion the Court couched its reasoning in broader language which would appear to apply more generally, and at the very least to healthcare products, including medicinal products.[114] Adopting the analysis of Advocate General Bot,[115] the Court stated that the potential lack of safety which could give rise to liability under the Directive stemmed, 'for products such as those at issue in the main proceedings, from the abnormal potential for damage' which they might cause to the person concerned.[116] The broad definition of defect encompassing the

[106] ibid, [14], [17], [19].
[107] ibid, [25].
[108] ibid, [37].
[109] ibid, [14], [17], [19], [38].
[110] ibid, [14], [17], [19], [38].
[111] ibid, [39]. Cf the entitlement to have higher expectations about the level of safety attaching to permanent prosthetic implants as opposed to temporary prosthetics, prosthetics expected to wear out over time or medicines or drugs to be taken for a limited period and which have no serious side effects: *Gill v Ethicon Sàrl & Ors (No 5)* [2019] FCA 1905, [3180] (vaginal mesh products).
[112] ibid, [41], [43].
[113] ibid, [42].
[114] See further, para 10.44. For discussion of whether the costs of the operation to remove the product and implant another device constitute damage caused by personal injury for the purposes of Articles 1 and 9(a) of the Directive, see para 16.11.
[115] Cases C-503/13 and C-504/13 *Boston Scientific Medizintechnik GmbH v AOK Sachsen-Anhalt-Die Gesundheitskasse and Others*, ECLI:EU:C:2014:2306, [30] (Opinion of AG Bot).
[116] ibid, [40]. The concept of abnormal potential for damage appears to have been erroneously applied by the CJEU to the decision in Case C-621/15 *NW and others v Sanofi Pasteur MSD SNC*, ECLI:EU:C:2017:484.

scenario where a product is part of a product group which has an increased risk of failure seems to suggest a wider form of liability than was assumed by Article 4, which suggested the need to prove the specific product was actually defective as opposed to the presence of an increased risk of it becoming defective. This has led to considerable uncertainty as to the scope of *Boston Scientific*, including the argument that a defect could be characterized as a product's potential for damage. This issue was addressed in the important decision of the English High Court in *Gee v DePuy International*.[117] In that decision, the judge did not consider that *Boston Scientific* adopted a characterization of a defect as a product's 'potential for damage'.[118] In a detailed analysis of the scope of *Boston Scientific*, Mrs Justice Andrews distinguished it from cases concerning the natural risks inherent in the use of a product under normal conditions for the purposes intended.[119] She concluded that there was nothing to support the argument that the normal risks inherent in the use of a product or the normal propensity of a product to cause harm (here, the propensity of a 'metal–on-metal' hip prosthesis to result in metal wear particulate debris) could legitimately be characterized as a defect.[120] It is true that the characterization of a drug's inherent propensity to cause an adverse effect as a defect would be likely to create, as defendant's counsel put it, irrational results[121] that unduly circumscribe the scope of the development risk defence as well as making the need for proof of causation 'virtually redundant'.[122]

10.27 Further, the CJEU touched upon the issue of defect in the controversial decision of *NW and others v Sanofi Pasteur MSD SNC*.[123] Here the Court examined the issue of how to determine liability under the Directive, where there is an absence of scientific evidence establishing that a product (in this case, the hepatitis B vaccine) was capable of causing damage (multiple sclerosis).[124] Whilst the CJEU cautioned against national courts applying evidentiary rules in such a way that, where one or more types of evidence were presented together, an immediate and automatic presumption would operate of there being a defect in a product and/or a causal link between the defect and damage,[125] it has been argued that the Court proceeded to conflate the separate issues of causation and defectiveness.[126] This transpired through the Court concluding that, notwithstanding the absence of scientific consensus concerning a causal link between a vaccine and the occurrence of a disease, certain factual evidence constituting 'serious, specific and consistent presumptions' that could support a finding of causation could be relied on to prove that the vaccine was defective.[127] It has also been argued that the factors relied on by the Court to constitute 'serious, specific and consistent presumptions' (here, temporal proximity between the administration of a

[117] [2018] EWHC 1208 (QB).
[118] ibid, [110], [120].
[119] ibid, [127].
[120] ibid, [127], [131], [133].
[121] ibid, [113].
[122] ibid, [132].
[123] Case C-621/15 *NW and others v Sanofi Pasteur MSD SNC*, ECLI:EU:C:2017:484 (21 June 2017).
[124] See J Meltzer and C Derycke, 'Latest CJEU decision under the Product Liability Directive: national courts given a wide discretion in deciding what claimants have to do to prove defect and causation' (2017) 67 International Product Liability Rev 1.
[125] Case C-621/15, NW and others v Sanofi Pasteur MSD SNC (CJEU), [36],- [37].
[126] J Meltzer and C Derycke, 'Latest CJEU decision under the Product Liability Directive: national courts given a wide discretion in deciding what claimants have to do to prove defect and causation' (2017) 67 International Product Liability Review 1, 6.
[127] Case C-621/15 *NW and others v Sanofi Pasteur MSD SNC*, ECLI:EU:C:2017:484, [41], [43].

vaccine and the occurrence of a disease, the lack of personal and familial history of that disease, together with a significant number of reported cases of the disease following administration of such vaccines) do not include the majority of factors that a court must take into account in determining whether a product is defective under Article 6, including the risk–benefit ratio of the product and the regulatory regime applicable to it.[128]

C. Consumer Expectations Versus Risk–Utility

(1) Introduction

10.28 In discussing the standard to be achieved to avoid a product being adjudged defective, two approaches are frequently highlighted, namely one which is based on consumer expectations and a second which focuses, rather, on a risk–utility or risk–benefit analysis. However, the two may be seen as complementing each other and not as being mutually exclusive. In view of the importance of the two approaches and of their relationship to each other, the matter needs to be examined in some detail.

(2) Consumer expectations

(a) General observations

10.29 In basing liability on a failure to meet the level of safety which a person is entitled to expect, the wording of Article 6 of the Directive reflects the consumer expectations' terminology associated with § 402A of the *Restatement, Second, Torts* (1965). In particular, the test appears to be derived from comments g and i of § 402A's standard of a 'defective condition unreasonably dangerous to the user or consumer or to his property'. Since both comment g (defective condition)[129] and comment i (unreasonably dangerous)[130] are defined in terms of what is dangerous to an extent beyond a consumer's contemplations, many American courts interpreting § 402A assumed that 'defective condition unreasonable dangerous' established a single test of liability based on a single standard of product safety measured by consumer expectations.[131]

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[128] J Meltzer and C Derycke, 'Latest CJEU decision under the Product Liability Directive: national courts given a wide discretion in deciding what claimants have to do to prove defect and causation' (2017) 67 International Product Liability Rev 1, 6. Cf *Wilkes v DuPuy International Ltd* [2016] EWHC 3096 (QB), [65], where Hickinbottom J noted that in determining whether a defective hip prosthesis was defective, relevant circumstances in the assessment of the product's safety include the risk–benefit profile of the product ([82]), cost of the product ([83]), 'the ease and extent to which a risk can be eliminated or mitigated' (avoidability) ([89]), compliance with standards ([97]), regulatory approval ([101]), and the warnings and information provided with the product ([102]–[103]). Hickinbottom J also observed that a particular medicinal product such as a vaccine may require consideration of a wider range of risks and benefits, including the public interest: ibid, [66]. In *Gee v DePuy International* [2018] EWHC 1208 (QB), [80] whilst Mrs Justice Andrews noted the discussion in *NW and others v Sanofi Pasteur MSD SNC* (CJEU) warning against applying evidentiary rules in such a way that an immediate and automatic presumption would operate of there being a defect in a product and/or a causal link between the defect and damage, she eschews the issue of conflation of defect and damage.

[129] Comment g provides: 'The rule … applies only where the product is, at the time it leaves the seller's hands, in a condition not contemplated by the ultimate consumer, which will be unreasonably dangerous to him.'

[130] Comment i provides: 'The article sold must be dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as its characteristics.'

[131] Owen & Davis, *Products Liability*, §§ 5-3, 8-3.

10.30 Prima facie, consumer expectations may appear a suitable test in that it focuses on the condition of a product, as opposed to a manufacturer's conduct, and recognizes the evolution of strict tort liability from the law of warranty.[132] Other commentators[133] have pointed to the weight to be attached to the word 'entitled' to expect[134] or have suggested that judges in the United Kingdom 'will test the reasonableness of consumer expectation' and that 'the claimant was only entitled to expect the product to be as safe as producers could reasonably make it'.[135] Perhaps there were elements of this in *Richardson v LRC Products Ltd*[136] where Ian Kennedy J explained that although the user's expectation was that the condom would not fail, the defendants had not claimed that a condom would never fail and no one supposed that any method of contraception would be 100 per cent effective.[137] However, having examined the expectations of consumers (albeit, not, in terms, the possibility of a higher level of legitimate expectation) he added, in a language analogous to a risk-utility analysis, that evidence showed that the condom had failed inexplicably under standards higher than the British one's applicable in the case. This might be read as suggesting that in assessing consumer expectations, risk–utility factors will also need to be taken into consideration,[138] supporting a dual or combined consumer expectations–risk benefit approach, or even an eclectic approach.[139] In using such approaches it should be borne in mind that the standard of defectiveness should be regarded as a minimum standard of what is an acceptable level of safety.[140] However, in the hepatitis C litigation, *A v National Blood Authority*,[141] Burton J rejected the application of such an approach to the facts of the case and concluded that the hepatitis C-infected blood products were defective since 'the public at large was entitled to expect that the blood transfused to them would be free from infection'.[142] By contrast, in the landmark decision of *Wilkes v DePuy International Ltd*,[143] it was established that risk–benefit may be relevant to the question of what is the entitled level of safety for a medicinal product under the Consumer Protection Act.[144] Whilst acknowledging the debate between consumer expectations and risk–benefit described in this section of this work, Hickinbottom J concluded that 'however consumer expectations are

[132] Clark, *Product Liability*, 34.

[133] J Stapleton, 'Restatement (Third) of Torts: Products Liability, an Anglo-Australian Perspective' 39 Washburn LJ 363, 377 (2000).

[134] See also Clark, who suggests that some of the criticisms of the test may result from a misunderstanding of its application. In his view, focusing on what the consumer is entitled to expect supports the protection of legitimate consumer expectations: 'Thus, a bystander may have no knowledge of the existence of a product but he has a general expectation of, or entitlement to, being safe in its presence. Complex or technological products give rise to the same general expectations or entitlement': Clark, *Product Liability*, 37. For support for the return of the consumer expectation test in US law on such grounds, see R Korzec, 'Dashing Consumer Hopes: Strict Products Liability and the Demise of the Consumer Expectations Test' 20 BC Int & Comp L Rev 227, 235–7, 249 (1997).

[135] G Howells in Howells (ed), *The Law of Product Liability*, para 4.151.

[136] [2000] Lloyd's Rep Med 280 (para 10.09).

[137] ibid, 285.

[138] For discussion of a risk–utility analysis more generally, see paras 10.41–10.56, 10.102.

[139] See RS Goldberg, 'Paying for Bad Blood: Strict Product Liability After the Hepatitis C Litigation' (2002) 10 Med L Rev 105, 129.

[140] Stapleton, *Product Liability*, 259.

[141] [2001] 3 All ER 289.

[142] ibid, para 80. For further discussion of this controversial decision, see paras 7.37, 9.76, and paras 10.59, 10.103–10.109, 10.111–10.120, 11.05–11.06, 11.25, 11.41, 11.48–11.49, 12.20, 12.22, 12.53–12.55, 12.96, 13.43, 13.45, 13.104–13.105, and 13.113–13.116.

[143] [2016] EWHC 3096 (QB). For further discussion of this important decision, see paras 7.03, 7.37, 9.52, 9.76, 10.12, 10.16–10.17, 10.27, 10.43, 10.45, 10.64, 10.70, 10.94, 10.98, 10.102, 10.109, 10.112, 10.119, 11.25, 11.31, 11.42, 12.55, 13.43, and 17.117.

[144] ibid, [67].

defined and gauged, there cannot be a sensible expectation that any medicine or medicinal product is entirely risk free'.[145] This risk–benefit balance, together with 'the ease and extent to which a risk can be eliminated or mitigated' (avoidability) were potential circumstances in the assessment of a product's safety.[146] In *Wilkes*, which concerned a metal component of an artificial hip—a steel femoral shaft called a 'C-Stem'—the claimant contended that the steel shaft was defective. In concluding that the steel shaft was not defective, Hickinbottom J radically departed from the approach of Burton J in *A*, holding that a test of what persons are generally were 'entitled to expect' required no gloss on the Act and did not benefit from being redescribed by Burton J as a 'legitimate expectation' test.[147] The test for safety required an objective approach, taking into account the information and circumstances before it, whether or not an actual or notional patient or indeed other members of the public would have considered each of the factors and all the relevant information.[148] This rejection of the so-called 'legitimate expectation' test was followed by Mrs Justice Andrews in *Gee v DePuy International*,[149] where she noted the dangers of such a reformulation omitting the essential word 'entitled' and adopting a phrase which is used as a term of art in a very different context.[150] The flexible holistic approach of Hickinbotttom J in *Wilkes* was reaffirmed by Mrs Justice Andrews in *Gee*. In her view, all the relevant circumstances noted by Hickinbottom J could be taken into consideration in determining defectiveness, including: avoidability, risk–benefit, and cost.[151]

10.31 The consumer expectation test has been criticized as being inadequate in cases of obvious dangers and foreseeable misuse and in cases where the claimant is someone other than the original purchaser of the product. There are also problems in applying it to complex design cases where a standard is neither agreed nor obvious.[152] Indeed, it may well be the case that where the alleged defect is of an esoteric or complex nature, it is likely that persons generally will have no expectations of the product whatsoever.[153]

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[145] ibid, [65].

[146] ibid, [82], [89].

[147] ibid, [71]. See *A v National Blood Authority* [2001] 3 All ER 289, [31](vi).

[148] ibid, [69], [72].

[149] [2018] EWHC 1208 (QB), [95].

[150] ibid.

[151] ibid, [144]–[167]. See also the approval of Hickinbottom J's holistic approach by the Outer House of the Court of Session in *AH v Greater Glasgow Health Board* [2018] CSOH 57, 2018 SLT 535, [114] per Lord Boyd of Duncansby. In *AH*, Lord Boyd concluded that in determining whether or not pelvic mesh products are defective, the risk benefit of the product will be an issue: ibid, [144].

[152] Stapleton, *Product Liability*, 235, also JA Henderson Jr and AD Twerski, 'What Europe, Japan and other Countries can learn from the new American Restatement of Products Liability' 34 Texas Int LJ 1, 4, 13 (1999) (criticism of the consumer expectations test as an 'abject failure as a test for defectiveness in classic design cases').

[153] Atiyah, *The Sale of Goods*, 544–5. This may have been one of the reasons why, in the opinion of one commentator, Burton J's decision in *A v National Blood Authority* was based on the evidence of consumers' actual expectations, even though he had previously held that a judge should decide defectiveness objectively, by ascertaining what the expectations of safety should have been. C Hodges, Note, 'Compensating Patients' (2001) 117 LQR 528, 529. Note, however, that the Austrian Supreme Court has held that in determining consumer expectations, the judge's role is not to impose his own view based on his own general experiences, but rather to assess them on the basis of evidence as to the actual expectations of users: Decision of the Austrian Supreme Court, 6 Ob 626/95 cited by G Howells in Howells (ed), *The Law of Product Liability*, para 4.155, n 1. But cf *Wilkes v DePuy International Ltd* [2016] EWHC 3096 (QB), [69], [72] (test for safety required an objective approach, taking into account the information and circumstances before it, whether or not an actual or notional patient or indeed other members of the public would have considered each of the factors, and all the relevant information).

10.32 In order to provide a further understanding of how the consumer expectation test might be applied, both in the United Kingdom and the European Union more generally, it is instructive to turn to the extensive experience of its use in the United States. The position in the United States is also discussed further in the following two chapters.[154]

(b) The experience of the United States

10.33 As has been noted,[155] modern American products liability law evolved out of the law of warranty, which had been absorbed into the law of sales and contracts. Since one of the fundamental goals of contract law has been the protection of the reasonable expectations of the contracting parties,[156] the consumer expectation test might seem a natural development, bearing in mind the evolution of the strict tort theory of liability[157] and that the law will protect consumer expectations generated from a manufacturer's representations.[158] However, there have been considerable difficulties in applying the test.[159]

10.34 One of the principal difficulties is that it might be argued that in as much as obvious dangers are known to and contemplated by consumers they are not entitled to expect that products will achieve a greater degree of safety in this respect. Accordingly, the consumer expectation test has been held to preclude liability in a number of earlier cases concerning obvious dangers. For example, in *Vincer v Esther Williams All-Aluminum Swimming Pool Co*,[160] a two-year-old child climbed a retractable ladder which had been left in the down position to an above-ground swimming pool and fell into the pool, suffering severe brain damage. The plaintiff alleged that the pool was defective since its fencing could have been extended with a self-latching gate at the top of the ladder opening. The Wisconsin Supreme Court held otherwise on the ground that the lack of a self-latching gate fell within the category of an obvious, rather than a latent, condition and 'the average consumer would be completely aware of the risk of harm to small children due to this condition, when the retractable ladder is left in a down position and the children are left unsupervised'.[161]

10.35 A similar approach was adopted in *Hartman v Miller Hydro Co*,[162] where the defendant had manufactured and sold a bottle-making machine to the plaintiff's employer. At the time of the plaintiff's injury, the machine had an unguarded drive shaft. While leaning over the shaft to set up some dirty bottles that had fallen over, his trousers became caught

[154] See ch 11, esp paras 11.15–11.18 (design defects) and ch 12, esp paras 12.26–12.30 (failure to warn).

[155] See para 10.30; also paras 1.41–1.44.

[156] JM Perillo, *Corbin on Contracts* (West, 1993), vol 1, § 1.1, at 2–4, reproduced in DG Owen, JE Montgomery, and WP Keeton, *Products Liability and Safety: Cases and Materials* (3rd edn, Foundation Press, 1996), 191–2.

[157] DA Fischer, 'Products Liability—The Meaning of Defect' 39 Mo L Rev 339, 348 (1974). See also JW Wade, 'On the Nature of Strict Tort Liability for Products' 44 Miss LJ 825, 833–4 (1973).

[158] MS Shapo, 'A Representational Theory of Consumer Protection: Doctrine, Function and Legal Liability for Product Disappointment' 60 Va L Rev 1109, 1370 (1974).

[159] See eg MJ Davis, 'Design Defect Liability: In Search of a Standard of Responsibility' 39 Wayne L Rev 1217, 1236–7 (1993); JN Kennedy, 'The Role of the Consumer Expectations Test Under Louisiana's Products Liability Tort Doctrine' 69 Tul L Rev 117, 143–52, 161 (1994) (concluding that there is a need for a restrictive application of the consumer expectations test, which has been applied indiscriminately).

[160] 230 NW 2d 794 (Wis, 1975).

[161] ibid, 799.

[162] 499 F 2d 191, 194 (10th Cir, 1974); see also *Crosswhie v Jumpking Inc* 411 F Supp 2d, 1228, 1231 (D Or, 2006) (teenager paralysed while attempting flip on trampoline: design that allows ordinary consumer to jump on it is exactly what is contemplated by ordinary consumer or user).

in the shaft and he was pulled onto the moving parts and injured. Applying the consumer expectation test of comment i, the court upheld a judgment for the defendant on a claim based on § 402A of the *Restatement, Second, Torts* and ruled that the plaintiff, as assistant production manager responsible for plant safety, 'was to be accredited with sufficient intelligence to realize that an exposed revolving shaft is dangerous'. Thus it could not be said that a danger existed which was beyond the contemplation of an ordinary user.[163]

10.36 While the consumer expectation test may operate effectively in cases where the claimant is the purchaser, it often fails to assist in cases which concern other victims of product accidents, whether as children, patients, employees, or bystanders. American courts have generally held that it is the expectations of the person who has responsibility for controlling the risk that are relevant. Thus, in respect of parent–child cases, in *Bellotte v Zayre Corp*[164] a five-year-old child was severely burned when his pyjama top ignited when he was playing with matches. In determining whether the pyjamas were unreasonably dangerous to the user or consumer on the basis that the fabric was not treated with an effective fire-retardant material, the court addressed the question whether the safety characteristics of the pyjamas should be judged in terms of the expectations of the five-year-old child who used them or of the child's parent who purchased them. It concluded that the standard for determining whether the product was unreasonably dangerous was to be framed in terms of the parent who purchased the pyjamas, reasoning that: 'Children of that age do not contemplate even the unavoidable dangers of cotton pyjamas and their flammable characteristics. There would therefore be no base from which to determine unreasonableness and the seller would become an insurer.'[165]

10.37 There is some uncertainty issue as to whose expectations should control an injury-producing prescription drug or medical device, namely those of the patient or those of the physician. In *Mueller & Co v Corley*[166] a personal injury action was brought against the manufacturer and distributor of an allegedly defective silicone breast prosthesis which had broken open inside the plaintiff after she had undergone a subcutaneous mastectomy with a prosthesis replacement. The defendants argued that the jury should have been instructed to measure the product's adequacy against the expectations of the physician who had selected the prosthesis, as opposed to the patient into whom it had been implanted. However, the appellate court disagreed and affirmed the verdict in favour of the plaintiff, holding that the defective condition in question rendered it unreasonably dangerous to the plaintiff, not to her physician. Thus the appropriate question for the jury was whether the defective condition

[163] ibid, 194. For comment i of § 402A, see para 10.29, n 130. See also *Horst v Deere & Co* 769 NW 2d 536, 553–4, n 24 (2009) (courts have 'resoundingly rejected' the argument that it is the expectations of an ordinary child that should govern, largely because children do not have expectations regarding the dangers of particular products. '[I]t is the ordinary consumer or user's expectations that goven'); *Calles v Scrito-Tokai Corp* 864 NE 2d 249, 257 (2007) (claim failed under consumer expectation test: utility lighter 'performed as an ordinary consumer would expect, when it produced a flame when used in a reasonably foreseeable manner by a child). For the contrasting approach in some more cases, see eg *Sperry–New Holland v Prestage* 617 So 2d 248 (Miss, 1993); *Hansen v New Holland North America Inc* 574 NW 2d 250, 254 (Wis App, 1997), see para 11.15.

[164] 352 A 2d 723 (NH, 1976).

[165] ibid, 725. See also *Calles v Scrito-Tokai Corp* 864 NE 2d 249, 257 (utility lighter used by three-year-old child started fire, resulting in child's death: ordinary consumer of a utility lighter was adult consumer (mother) (2007).

[166] 570 SW 2d 140 (Tex Civ App, 1978).

was one which was not contemplated by the user, viz the ultimate consumer. The trial court had correctly keyed its instructions to the mind of the person who would be injured by the dangerous condition of the product.[167]

10.38 Similar problems are presented by employer–employee situations. Although employees are reliant on their employers to maintain safe places of work and to select safe machinery and materials, manufacturers can often provide the best protection to employees by warning them directly of a risk.[168] Thus in *Jackson v Coast Paint & Lacquer Co*,[169] a painter was seriously injured while spray painting the inside of a railroad tank car when a fire occurred, the level of which increased with the accumulation of paint fumes in the tank. The plaintiff had sued the paint manufacturer for failing to warn adequately of this risk, and the defendants argued that the plaintiff's employer's knowledge of the risk obviated any duty to warn the plaintiff. Holding in favour of the plaintiff, the appellate court stated that warnings could have been placed on the paint container labels.[170] The community whose common knowledge and expectations were relevant were the painters who would be exposed to the danger by opening the containers and using the paints, and not the employers (the painting contractors) who bought the paint. Their possibly superior knowledge and understanding was irrelevant.[171] There are also difficulties in applying the test to cases where bystanders suffer injury, since they may have no knowledge of the existence of the product and thus, it may be argued, will have no expectations concerning its safety.[172]

10.39 Another criticism of the test concerns the vagueness of consumer expectations,[173] particularly in the context of complex products, since, it has been said, 'the consumer may have at most only a generalised expectancy—perhaps more accurately only an unconscious hope—that the product will not harm him if he treats it with a reasonable amount of care'.[174] Thus it is argued that 'an attempt to determine the consumer's reasonable expectation of safety concerning a technologically complex product may well be an exercise in futility'.[175] In particular, in the case of such products as cars or pharmaceuticals, persons generally may have no idea how safely a product ought to perform, perhaps because with such products 'consumer attitudes have not sufficiently crystallised to define an expected standard of performance'.[176] In the absence of factual data demonstrating what consumers do expect from

[167] ibid, 145.

[168] See Owen & Davis, *Products Liability*, § 5-6.

[169] 499 F 2d 809 (9th Cir, 1974).

[170] ibid, 813–14.

[171] ibid, 812–13.

[172] *Cornelius v Bay Motors Inc* 484 P 2d 299, 302–5 (Or, 1971) (court assumed that § 402A of the *Restatement, Second, Torts* applied to 'bystanders' or other third parties injured by defective motor vehicles); *Ewen v McLean Trucking Co* 706 P 2d 929 (Or, 1985) (pedestrian struck by truck, alleging that its defective design prevented driver from seeing her, could not recover as a 'consumer' under comment i of § 402A of the *Restatement, Second, Torts*); *Trespalacios v Valor Corp of Florida* 486 So 2d 649 (Fla Dist Ct App 3rd Dist, 1986) (defendant manufacturer's 'riot and combat' shotgun used by a 'mad' gunman to kill decedent and seize other individuals held not defective).

[173] Prosser and Keeton, *The Law of Torts*, 699.

[174] JE Montgomery and DG Owen, 'Reflections on the Theory, and Administration of Strict Tort Liability for Defective Products' 27 SC L Rev 803, 823 (1976).

[175] ibid.

[176] R Dickerson, 'Products Liability: How Good Does a Product Have to Be?' 42 Ind LJ 301, 307 (1967); *Heaton v Ford Motor Co* 435 P 2d 806, 809 (Ore, 1967) (highlighting the difficulty of proving consumer expectations for product strength in determining a design defect).

the product in question, a trier of fact would merely be substituting its own speculative opinion for that of the generality of consumers.[177]

10.40 Although several courts have continued to use the test, either alone or in combination with a risk–utility analysis,[178] an increasing number of courts have rejected it.[179] In general, it seems that the trend has been towards applying a risk–utility analysis.[180] Nevertheless, there has been continued support for retention of the test (eg by focusing on what the consumer is entitled to expect in the manner of the Product Liability Directive) on the ground that such an approach supports the protection of legitimate consumer expectations.[181] In this connection, a decision of the Wisconsin Supreme Court has departed from the national trend of using a risk–utility analysis in cases involving allegedly defective designs by upholding a consumer contemplation test to determine such defects.[182]

(3) Risk–utility

(a) General observations

10.41 As was noted earlier, the majority of American jurisdictions have supplanted the consumer expectation test with an approach based on balancing a product's costs and benefits or, in other words, the balance between its risks and utility. Professor David Owen succinctly encapsulates the test: 'a product is considered "defective" under a risk–utility test if the costs of eliminating a particular hazard are less than the resulting safety benefits'.[183] Owen argues that, in design cases, risk–utility is based upon solid theoretical foundations: '[b]y judging the sufficiency of a product's safety according to the balance of the costs and benefits of improving its safety in a particular manner, the test provides a powerful standard of responsibility: failure to adopt a safety feature is wrongful if the feature should have been expected

[177] *Heaton v Ford Motor Co* (n 176) (holding consumer expectation test inappropriate in assessing design defectiveness when rock hit wheel of a pickup truck while moving on a highway, causing it to tip over some 35 miles later).

[178] *Allison v Merck and Co Inc* 878 P 2d 948, 952, 961 (Nev, 1994) (MMR vaccine that had allegedly caused infant's blindness, deafness, and mental retardation, failed to perform in the manner reasonably to be expected of a vaccine); *Lester v Magic Chef Inc* 641 P 2d 353, 361 (1982) (applying consumer expectations test and explicitly rejecting *Barker v Lull Engineering Co Inc* 573 P 2d 443 (1978) two-pronged approach) (see paras 11.36–11.38). Cf dissenting Justice Prager J, joined by Miller and Herd JJ, criticizing the consumer expectation test as not being objective: 641 P 2d 353, 363 (1982).

[179] DA Fischer, 'Products Liability—The Meaning of Defect' 39 Mo L Rev 339, 348–52 (1974).

[180] *Nichols v Union Underwear Co Inc* 602 SW 2d 429, 432–4 (Ky, 1980); Banks *v ICI Americas, Inc* 450 SE 2d 671, 673–4 (1994) (Sup Ct of Georgia) (risk–utility analysis adopted to evaluate design defectiveness); *Sperry–New Holland, a Div of Sperry Corp v Prestage* 617 So 2d 248, 255–6 (Miss, 1993): *Branham v Ford Motor Co* 701 SE 2d 5, 14–17 (2010) (abandonment of consumer expectation test and move to risk–utility test on grounds consumer ill-suited to determine whether a product's design is unreasonably dangerous; noting that thirty-five of the forty-six states that recognize strict products liability utilize a form of risk–utility analysis: ibid, 14, n 11). Some courts have clandestinely converted their consumer expectations analysis to a risk–utility analysis: *Seattle–First Nat Bank v Tabert* 542 P 2d 774, 779 (1975).

[181] R Korzec, 'Dashing Consumer Hopes: Strict Products Liability and the Demise of the Consumer Expectations Test' 20 BC Int & Comp L Rev 227, 235–7, 249 (1997). Cf JW Little, 'The Place of Consumer Expectations in Product Strict Liability Actions for Defectively Designed Products' 61 Tenn L Rev 1189, 1201–2 (1994) (support for consumer expectation concept merged into the perspective of the ordinary person of reasonable prudence as opposed to the reasonable consumer).

[182] *Green v Smith & Nephew AHP Inc* 629 NW 2d 727 (2001) (latex gloves: allergic reaction of hospital worker). See para 11.18.

[183] DG Owen, *Products Liability Law* (3rd edn), 300, § 5:7; and Owen & Davies, *Products Liability*, § 5-19.

to produce more good than harm, and such a failure is justified if such action might have been expected to exceed its benefits'.[184]

10.42 The relevance of such considerations in a European context is the subject of some debate. From one perspective, the opportunities for the deployment of risk–utility considerations are very limited. Under the Directive, entitled expectations intuitively seem closer to the rival US standard of consumer expectations, suggesting that the risk–utility notion was consciously avoided. Indeed, the Directive's drafter, Taschner, was very critical of the risk–utility approach as a test for design defectiveness. He has thus argued that: 'The majority of the suggested characteristics of the "risk/utility"-test are undoubtedly in favour of the producer. It is hard to accept that producers' financial ability to bear the costs of an alternative design should be a determining factor of whether his product was defective or not. If a producer is unable to manufacture a safer product in design, then he must abstain from production.'[185] It is true that the recitals of the Directive give a centrality to the notion of a 'fair apportionment of risks',[186] rather than the cold calculation of costs and benefits enshrined in the US risk–utility calculus. The American experience shows that once risk–utility is adopted, the ultimate test inevitably becomes close to that of a negligence-style analysis. That would be problematic in a European context, given that the standard of defect in the Directive should not require proof of fault.[187] However, that seemingly uncontroversial premise has attracted much discussion (and clarity has not been helped by the fact that the European Commission observed in the Third Review of the Directive that the Directive may well 'involve the need to show fault' (p 4)). By contrast, Professor Stapleton considers that the experience of the United States in its shift from consumer expectations to risk–utility confirms the view that, notwithstanding the Directive's adoption of the language of expectations, 'the only coherent approach to a *tortious* standard of "defect" in the area of product liability is one based on a general view as to what a reasonable level of *minimum* safety should be *quite apart* from the contractual history of the product in question'.[188] She concludes that the core of the 'defect' inquiry reflects a negligence standard—in that it is 'a trade-off between risk–taking and social costs as reflected in the magnitude and gravity of risk balanced against the costs of production and social utility'.[189] By way of criticism of the consumer expectations approach in s 3(1) of the 1987 Act, she considers that the criteria of liability should simply have been expressed in terms of costs and benefits and that the expectation concept should have been dropped. As she explains: 'what reformers really mean when they say that a product meets "expectations of safety" is that on balance its benefits outweigh its costs'.[190] This appears consistent with the view of Lord Griffiths et al that although English judges would not overtly adopt a

[184] ibid, 303, § 5:7; and Owen & Davies, *Products Liability*, § 5-21.

[185] H-C Taschner, 'Product Liability: Basic Problems in a Comparative Law Perspective' in D Fairgrieve (ed), *Product Liability in Comparative Perspective* (CUP, 2005), 160.

[186] Recital 2: '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.' Cf Recital 7: '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 as to the existence of certain exonerating circumstances.' See para 7.21.

[187] H-C Taschner, 'Product Liability: Basic Problems in a Comparative Law Perspective' in D Fairgrieve (ed), *Product Liability in Comparative Perspective* (CUP, 2005), 159–161.

[188] Stapleton, *Product Liability*, 236 (emphasis in original).

[189] ibid.

[190] J Stapleton, 'Products Liability Reform—Real or Illusory?' (1986) 6 OJLS 392, 405.

risk–benefit approach, they would, 'as an educated response to the facts of a particular case undertake a balancing exercise of an analogous kind'.[191]

10.43 As will be seen later,[192] it is entirely possible for such a risk–utility or risk–benefit approach to be accommodated within the framework of the Directive and the 1987 Act. Indeed, in the case of alleged defects of design, it has often been argued that it seems almost inevitable that the standard of safety which persons are entitled to expect will depend in part on a weighing of the risks and benefits associated with the product.[193] Whilst the English case law in point was once problematic,[194] it is now clear that that risk–benefit may be taken into account in determining the appropriate level of safety of a medicinal product for the purposes of the 1987 Act.[195] Emphasis has now been placed on adopting a 'holistic' and 'flexible' approach in determining defectiveness, involving the balancing of all relevant considerations.[196] While this does not mean that the detailed specific aspects of risk–utility as formulated in the United States will be applicable or that English courts will adopt the same approach,[197] it would now seem settled that in cases involving medicinal products, the risk–benefit ratio of a medicinal product will be relevant to the determination of the level of safety of a product that persons are entitled to expect. It is submitted that this is a welcome clarification of English law. It seems that the potential now exists for the development of future case law and an indication of the importance of categories of product, such as whether the product is a prescription-only medicine.[198]

10.44 By contrast, it seems that the relevance or otherwise of the conduct of the producer and of a risk–benefit analysis remains largely unresolved by the courts of other Member States,[199] and that the Court of Justice has thus far only touched upon this issue. The Third Commission Report on the Application of the Directive noted that the appropriateness of a court undertaking a risk–benefit analysis when assessing what a person is entitled to expect, and the extent to which the actual conduct of a producer is relevant 'have yet to be finally resolved by the courts in any Member State'.[200] In the first ever guidance as to the circumstances in which a product may be deemed defective,

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[191] Rt Hon Lord Griffiths, P de Val, and RJ Domer, 'Developments in English Product Liability Law: A comparison with the American system' 62 Tul L Rev 353, 382 (1988).

[192] See para 11.42.

[193] ibid.

[194] See, in particular, *A v National Blood Authority* [2001] 3 All ER 289; also *B v McDonald's Restaurants Ltd* [2002] EWHC 490 (QB).

[195] *Wilkes v DePuy International Ltd* [2016] EWHC 3096 (QB), [67]. Approving this approach, Mrs Justice Andrews found in *Gee v DePuy International* that all the relevant circumstances noted by Hickinbottom J could be taken into consideration in determining defectiveness, including: avoidability, risk–benefit, and cost: [2018] EWHC 1208 (QB), [144]–[167].

[196] ibid, [78]; approved in *Gee v DePuy International Ltd* [2018] EWHC 1208 (QB), [143]. See also the approval of Hickinbottom J's holistic approach by the Outer House of the Court of Session in *AH v Greater Glasgow Health Board* [2018] CSOH 57, 2018 SLT 535, [114] per Lord Boyd of Duncansby. In *AH*, Lord Boyd concluded that in determining whether or not pelvic mesh products are defective, the risk benefit of the product will be an issue: ibid, [144]. Cf J Eisler, 'One step forward and two steps back in product liability: the search for clarity in the identification of defects' (2017) 76 CLJ 230, 235 (criticising the approach of Hickinbottom J as formalising 'a test that is so "flexible"…that courts have little meaningful guidance').

[197] ibid, [67].

[198] ibid, [79]. It should be noted, however, that Hickinbottom J considered that any attempt at formal rigid categorization of such products was contrary to the 'inherent flexibility' of the Directive and was likely to be both difficult and unwise: ibid.

[199] J Meltzer, R Freeman, and S Thomson, *Product Liability in the European Union: A Report for the European Commission*, MARKT/2001/11/D (Lovells, 2003), 2.2(b), 48.

[200] European Commission, Third Report (n 38), 10.

Boston Scientific Medizintechnik GmbH v AOK Sachsen-Anhalt-Die Gesundheitskasse and Others,[201] the CJEU adopted the analysis of Advocate General Bot[202] in stating that the potential lack of safety which could give rise to liability under the Directive stemmed, 'for products such as those at issue in the main proceedings, from the abnormal potential for damage' which they might cause to the person concerned.[203] It is arguable that the final sentence of Advocate General Bot's analysis is instructive as it would appear to support the argument that it is the *risk* of damage which affects legitimate expectations. He explains abnormal potential for damage as being 'a risk of damage of such a degree *of* seriousness that it affects the public's legitimate expectations in so far as concerns safety'.[204] There was therefore no express mention of the risk–benefit calculus, and the reference to risk to the defect standard was within the context of the relevance of *risk of damage*, rather than the balancing of risk against potential benefits.

10.45 While the risk–utility approach to defectiveness has been mooted by some French courts in the context of medicinal products,[205] the French Cour de cassation[206] overruled the use of a general risk–utility analysis in the context of the hepatitis B vaccination litigation. The Court of Appeal of Versailles[207] had ruled that the temporal proximity between the hepatitis B vaccination and the appearance of the demyelinating disease, in the absence of any other known cause for the disease, allowed a presumption that the vaccine had caused the claimant's injury. Nonetheless, the appellate court rejected the claim against the vaccine producer, by determining, utilizing a risk–benefit analysis, that the vaccine was not defective.[208] The decision on defectiveness was subsequently overturned by the Cour de cassation, which held that the Court of Appeal should have checked if the elements, on the basis of which causation had been presumed, did not also allow a presumption that the vaccine was defective. The Cour de cassation suggests that defectiveness could be assessed on a case-by-case basis, independently from a 'general' risk–benefit analysis, taking into account the specific considerations of the product. In rejecting the risk–benefit analysis as a general test, the Cour de cassation did not give any details about what exactly the alternative test could be. The court only mentioned some elements that could be used to establish defectiveness, on a case-by-case basis.[209] On a reference to the CJEU, *NW and*

[201] Cases C-503/13 and C-504/13 *Boston Scientific Medizintechnik GmbH v AOK Sachsen-Anhalt-Die Gesundheitskasse and Others*, ECLI:EU:C:2015:148 (5 March 2015).

[202] ibid, [30] (Opinion of AG Bot).

[203] ibid, [40].

[204] ibid.

[205] This risk–benefit approach had been adopted in two previous decisions involving medicinal products, viz Isomeride (Versailles, 17 March 2006, no 04/08435; Paris, 19 June 2009, no 06/13741) and in three cases involving the vaccine against hepatitis B (Versailles, 16 March 2007, no 05/09525; 29 March 2007, no 06/00496; 5 November 2007, no 06/106435). For commentary in favour of this approach, see eg G Viney, observations on Cass civ 1re, 23 September 2003, JCP G 2004, I, 101, no 23; L Clerc-Renaud, 'Quelle responsabilité en cas de dommages causés par des produits de santé?', Revue Lamy droit civil 2007, 34, no 14; J-S Borghetti, 'Quelles responsabilités pour les laboratoires fabricants de médicaments dangereux?', Revue générale de droit médical, special issue 'Les responsabilités du fait des médicaments dangereux. Perspectives nationales et transfrontalières', 2012, 19, 25.

[206] Cass civ 1re, 26 September 2012, no 11-17.738. See also Cass civ 1re, 9 July 2009, no 08-11073, Bull civ I, no 176, D 2010, 49, obs P Brun, JCP G 2009, 308, note P Sargos, RTD civ 2009, 735, obs P Jourdain, RDC 2010, 79, obs J-S Borghetti.

[207] Cour d'appel de Versailles, 10 February 2011.

[208] This risk–benefit approach had been adopted in two previous decisions involving medicinal products and in three cases involving the vaccine against hepatitis B (see n 205).

[209] J-S Borghetti, 'Qu'est-ce qu'un vaccin défectueux?', Recueil Dalloz 2012, 2853. This approach of examining all elements at hand, when considering the product's defectiveness and the existence of a causal

others v Sanofi Pasteur MSD SNC,[210] the Court examined the issue of how to determine liability under the Directive, where there is an absence of scientific evidence establishing that a product (in this case, the hepatitis B vaccine) was capable of causing damage (multiple sclerosis).[211] As previously noted,[212] some commentators have argued that the CJEU conflated the separate issues of causation and defectiveness by concluding that, notwithstanding the absence of scientific consensus concerning a causal link between a vaccine and the occurrence of a disease, certain factual evidence constituting 'serious, specific and consistent presumptions' that could support a finding of causation could be relied on to prove that the vaccine was defective. [213] The factors relied on by the court to constitute 'serious, specific and consistent presumptions' did not include the majority of factors that a court must take into account in determining whether a product is defective under Article 6, including the risk–benefit ratio of the product. It is clear, however, that while the Court was silent on the matter of risk–benefit, Advocate General Bobek did expressly raise the matter in his Opinion, and stated that he disagreed with the proposition that the notion of defect involved '[a] broader assessment of the cost/benefits of the product … going beyond the concrete case'.[214] Advocate General Bobek went on to state that the test of defectiveness 'essentially refers to baseline expectations of the product under normal conditions of use. It does not mean that where the product is used normally and causes serious harm in an individual case, that a conclusion of defectiveness necessarily requires a balancing of the costs and benefits of the product.'[215] In his view, such an approach would result in the court 'creating (or at least boldly deducing) new conditions of liability'.[216] There has been some debate as to the impact of this statement, but it is clear that it does not illustrate any great enthusiasm for the balancing of the costs and benefits of the product as part of the defectiveness equation. Nor does it, however, entirely rule that out.

10.46 In the light of the determination in English law that risk–benefit may be relevant to the question of determining the appropriate level of safety of a medicinal product for the purposes of the 1987 Act,[217] it is helpful initially to trace the developments of the risk–utility analysis of defectiveness in the United States and to understand the reason why such an analysis has largely supplanted a test based on consumer expectations.

link, has been upheld by the Cour de cassation: Cass civ 1re, 29 May 2013, no 12-20.9033; and, further, R Goldberg, *Medicinal Product Liability and Regulation* (Hart Publishing, 2013), 30–2.

[210] Case C-621/15 *NW and others v Sanofi Pasteur MSD SNC*, ECLI:EU:C:2017:484 (21 June 2017).

[211] See J Meltzer and C Derycke, 'Latest CJEU decision under the Product Liability Directive: national courts given a wide discretion in deciding what claimants have to do to prove defect and causation' (2017) 67 International Product Liability Rev 1.

[212] See para 10.27.

[213] Meltzer and Derycke (n 211), 6. In his opinion in Case C-621/15 *NW and others v Sanofi Pasteur MSD SNC*, ECLI:EU:C:2017:484, AG Bobek opined at [87] that Art 6 of the Directive 'essentially refers to baseline expectations of the product under normal circumstances of use. It does not mean that where the product is used normally and causes serious ham in an individual case, that a conclusion of defectiveness necessarily requires a balancing of the costs and benefits of the product'. Cf *Wilkes v DuPuy International Ltd* [2016] EWHC 3096 (QB), [65], where Hickinbottom J noted that in determining whether a defective hip prosthesis was defective, relevant circumstances in the assessment of the product's safety include the risk–benefit profile of the product ([82]), cost of the product ([83]), 'the ease and extent to which a risk can be eliminated or mitigated' (avoidability) ([89]), compliance with standards ([97]), regulatory approval ([101]), and the warnings and information provided with the product ([102]–[103]). Hickinbottom J also observed that a particular medicinal product such as a vaccine may require consideration of a wider range of risks and benefits, including the public interest: ibid, [66].

[214] *NW and others v Sanofi Pasteur*, [85]–[86].

[215] ibid, [87].

[216] ibid, [88].

[217] *Wilkes v DePuy International Ltd* [2016] EWHC 3096 (QB), [67].

(b) The experience of the United States

10.47 **(i) Factors to be weighed in the balance** The majority of American cases and commentators support a risk–utility or cost–benefit analysis to the determination of defectiveness under strict liability principles. The factors to be weighed in the balance in a cost–benefit analysis have their origins in the seminal negligence case of *United States v Carroll Towing Co*.[218] Judge Hand concluded that a determination of the caution appropriate to an occasion reflected a calculus of several factors, namely: the burden of taking adequate precautions to avoid a risk of harm balanced against the product of the probability that an actor's conduct would result in harm and the probable magnitude of the harm.[219] The so-called Learned Hand formula has been viewed as 'simply another way of expressing a cost–benefit approach to decision-making in negligence cases, where the benefits are those consequent upon accident assistance and the costs are the costs of avoiding the accident'.[220] As Green has observed: 'The basic notion of cost–benefit assessment is not new. Any individual decision is usually the consequence of the actor's assessment of the advantages (benefits) and disadvantages (costs) of the action.'[221]

10.48 American risk–utility analysis draws heavily upon the writings of Professor John Wade, who refined and applied a risk–benefit analysis to product liability, based on balancing the following factors:[222]

> (1) The usefulness and desirability of the product—its utility to the user and to the public as a whole. (2) The safety aspects of the products—the likelihood that it will cause injury and the probable seriousness of the injury. (3) The availability of a substitute product which would meet the same need and not be as unsafe. (4) The manufacturer's ability to eliminate the unsafe character of the product without impairing its usefulness or making it too expensive to maintain its utility. (5) The user's ability to avoid danger by the exercise of care in the use of the product. (6) The user's anticipated awareness of the dangers inherent in the product and their avoidability, because of general public knowledge of the obvious condition of the product, or of the existence of suitable warnings or instructions. (7) The feasibility, on the part of the manufacturer, of spreading the loss by setting the price of the product or carrying liability insurance.[223]

Professor Wade's factors build on the risk–utility analysis of negligence law and have been used as a tool by courts for deciding cases.[224]

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[218] 159 F 2d 169, 173 (2d Cir, 1947), per Learned Hand J.

[219] ibid; Judge Hand stated that: 'if the probability [of harm] be called P; the injury L and the burden [of adequate precautions] B; liability depends upon whether B is less than L multiplied by P: i.e. whether B < P L'; see, further, Owen & Davis, *Products Liability*, § 5-20.

[220] Clark, *Product Liability*, 31. See also Oliver Wendell Holmes Jr, 'The Path of the Law' 10 Harv L Rev 457, 474 (1897) (observing that 'every lawyer ought to seek an understanding of economics' and that 'for everything we have to give up something else, and we are taught to set the advantage we gain against the other advantage we lose …').

[221] HP Green, 'Cost-Risk–Benefit Assessment and the Law: Introduction and Perspective' 45 Geo Wash L Rev 901, 903–4 (1977).

[222] JW Wade, 'On the Nature of Strict Tort Liability for Products' 44 Miss LJ 825, 837–8 (1973).

[223] See also Prof Wade's earlier article 'Strict Tort Liability of Manufacturers' 19 Sw LJ 5, 17 (1965); also JE Montgomery and DG Owen, 'Reflections on the Theory and Administration of Strict Tort Liability for Defective Products' 27 SC L Rev 803, 814 (1976).

[224] See eg *Roach v Kononen* 525 P 2d 125, 128 (Or, 1974) (see para 10.50); *Dorsey v Yoder Co* 331 F Supp 753, 760 (E D Pa, 1971), affd 474 F 2d 1339 (3rd Cir, 1973) (para 10.51).

10.49 **(ii) Conversion from negligence to strict liability** In the United States, the risk–utility test was converted from its application to negligence to strict liability in tort at an early stage. In *Helicoid Gage Div of American Chain & Cable Co v Howell*,[225] a pressure gauge manufactured by Helicoid burst while in use, throwing a piece of the lens of the gauge into the plaintiff's eye, resulting in the eye's eventual loss. Affirming a verdict for the plaintiff, the court applied a risk–utility test, stating:[226]

> To determine whether a product is unreasonably dangerous … it is necessary to weigh the risk of harm against the utility of the product, considering whether safety devices would unreasonably raise the cost or diminish the utility of the product. The evidence at trial showed that shatterproof glass would have increased the cost of each gage by approximately one dollar and would not have reduced the gage's utility. Further, there was testimony that this injury would not have occurred had shatterproof glass been used.

The court added that the utility of the gauge would not have been diminished by the addition of an inexpensive safety shield, the cost of which would have been in the range of $2.00 to $2.50.[227]

10.50 The risk–utility test factors adumbrated by Professor Wade were applied in *Roach v Kononen*.[228] The plaintiffs brought an action against Ford Motor Co for injuries sustained in a car accident occurring when the hood of a Ford motor car suddenly flew up blocking the driver's vision and resulting in a collision with the plaintiff's vehicle. The Supreme Court of Oregon held that before a court submitted a design defect case to a jury, the factors suggested by Professor Wade and set out above[229] should be considered in balancing the utility of the product against the magnitude of the risk.[230] On the facts, the evidence was conflicting. The plaintiff's expert, a research engineer, suggested an alternative hood design which would permit visibility to the driver if the hood flew open. A product quality engineer for Ford testified that Ford was aware of only about six or seven inadvertent hood openings over a seven- or eight-year period. Ford's design engineer testified that the proposed design alteration would require reinforcements to the hood, which would cost between $5 and $10 per car. In the light of such conflicting evidence, judgment was affirmed in favour of the defendant, the court holding that the evidence was insufficient to entitle the motorist, as a matter of law, to judgment on either a strict liability or negligence theory.[231]

10.51 In another early decision, *Dorsey v Yoder Co*,[232] a metal shutter machine operator brought an action against the machine's manufacturer when his right hand and arm were almost severed by its blades. Denying the defendant's motion for judgment, the court again applied a risk–utility approach. While on the one hand acknowledging that the plaintiff's knowledge of the danger of unguarded cutters weighed against a finding of defectiveness, it stated that a guard would not eliminate the machine's usefulness, nor would the cost

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225 511 SW 2d 573, 577 (Tex Civ App, 1974).
226 ibid, 577.
227 ibid, 577.
228 525 P 2d 125 (Or, 1974).
229 See para 10.48.
230 525 P 2d 125, 128–9.
231 ibid, 130.
232 331 F Supp 753 (ED Pa, 1971), affd 474 F 2d 1339 (3rd Cir, 1973).

of $200 to $500 on an $8,000 machine be unreasonable and that the seriousness of the potential harm was great. It was thus open to the jury to find that the balance had tipped in favour of the plaintiff and that the machine was defective.[233] While risk–utility is used mainly in design cases,[234] it is also applicable in cases concerning the adequacy of warnings and instructions.[235]

10.52 The importance of assessing product hazards in terms of risks and benefits was stressed by a group of law and engineering professors who worked on an interdisciplinary research project in the early 1970s. They stated:[236]

> It is time to abandon the perspective of the reasonable consumer and the reasonable seller and formulate the strict liability question for what it is. The issue in every products case is whether the product *qua* product meets society's standards of acceptability. The unreasonable danger question, then, is posed in terms of whether, given the risks and benefits of and possible alternatives to the product, we as a society will live with it in its existing state or will require an altered, less dangerous form. Stated succinctly, the question is whether the product is a reasonable one given the reality of its use in contemporary society.

(c) Problems with the risk–utility approach

10.53 As Dr Clark has pointed out,[237] the major difficulty associated with a risk–utility or cost–benefit approach is the complexity of assessing risks and utility since the balancing factors should be quantified in the same or equivalent units of measurement. In most areas of decision-making, such quantities should be assessed in monetary terms, but courts are ill-equipped to do so. The alternative, albeit more haphazard, approach and one which is probably carried out, is to trade-off costs and benefits in accordance with the decision-maker's conception in the light of the evidence and arguments advanced of the relative values of the various factors.

10.54 The question whether risks and utility are assessed with the benefit of hindsight remains problematic.[238] In the United States, a variant of the risk–utility test, known as 'the imputation of knowledge doctrine', converts negligence into strict liability by abandoning the requirement of foreseeable risk in the context of strict liability[239] and imputing knowledge of the danger to the seller where the product marketed subjected the consumer to an unreasonable risk of harm.[240] Wade and Keeton proposed a definition of defectiveness under strict products liability which imposed on the manufacturer constructive knowledge of dangers in its products and relieved the plaintiff of the burden of proving foreseeability of such risks, as would be necessary under negligence.[241] Thus it is said that on this approach

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[233] ibid, 760.

[234] For discussion of design cases, see paras 11.10–11.63, esp paras 11.19–11.22 (strict liability) and paras 14.48–14.77 (liability in negligence).

[235] For discussion of warnings and instructions, see ch 12 (strict liability) and paras 14.78–14.123 (liability in negligence).

[236] WA Donaher, HR Piehler, AD Twerski, and AS Weinstein, 'The Technological Expert in Products Liability Litigation' 52 Tex L Rev 1303, 1307 (1974).

[237] Clark, *Product Liability*, 33.

[238] G Howells in Howells (ed), *The Law of Product Liability*, para 4.126.

[239] DG Owen, JE Montgomery, and WP Keeton, *Products Liability and Safety: Cases and Materials* (The Foundation Press Inc, 1996), 213.

[240] WP Keeton, 'Products Liability—Inadequacy of Information' 48 Tex L Rev 398, 404 (1970); JW Wade, 'Strict Tort Liability of Manufacturers' 19 SW LJ 5, 15 (1965).

[241] WP Keeton, 'Products Liability—Current Developments' 40 Tex L Rev 193, 210 (1961); JW Wade, 'On the Nature of Strict Tort Liability for Products' 44 Miss LJ 825, 834–5, 839–40 (1973).

the principal distinction between strict liability and negligence-based decisional models involving risk–benefit analysis is that with negligence the balancing process only includes risks or costs which are foreseeable, whereas with strict liability the manufacturer 'is held to have absolute prevision of all harm the product actually causes in his evaluation of the relative costs and benefits of his proposed course of action'.[242] The position appears to be broadly equivalent to the strict liability associated with breach of the implied terms as to quality of sales legislation.[243]

10.55 Several cases have adopted this risk–utility variant, including *Phillips v Kimwood Mach Co*.[244] In *Phillips* a worker was injured when a commercial sanding machine regurgitated a fibreboard sheet, hitting him in the abdomen. He sued the manufacturer for failing to warn of the danger or install a safety device, in this case an inexpensive line of metal teeth that would have prevented the ejection while maintaining the machine's efficiency. The Supreme Court of Oregon reversed a summary judgment for the seller and formulated the following test:[245]

> A dangerously defective article would be one which a reasonable person would not put into the stream of commerce if he had knowledge of the harmful character. The test, therefore, is whether the seller would be negligent if he sold the article knowing of the risk involved. Strict liability imposed what amounts to constructive knowledge of the condition of the product.

The court observed that while the tests in negligence and strict liability were similar, the difference between the two doctrines for design defects was that in strict liability focus was on 'the condition (dangerousness) of an article which is designed in a particular way', whereas with negligence the focus was on 'the reasonableness of the manufacturer's actions in designing and selling the article as he did'.[246]

10.56 However, although it has several attractive features, the imputation of knowledge doctrine was ultimately repudiated by its proponents.[247] The *Third Restatement*, which adopts a negligence-based risk–utility approach to determining design defectiveness based on risks foreseeable at the time of marketing, explicitly rejects the Wade–Keeton test.[248] Indeed, the Reporters' Notes to the *Third Restatement* observe that the idea that knowledge of risk will be imputed in a strict liability case and not a negligence case 'has not worn well with time'.[249] Most courts and commentators in the United States now consider that foreseeability must be established by the plaintiff in a strict tort action, as well as in negligence. Thus a risk–utility analysis should normally be identical in both contexts.[250]

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[242] JE Montgomery and DG Owen, 'Reflections on the Theory and Administration of Strict Tort Liability for Defective Products' 27 SC L Rev 803, 829 (1976).

[243] See paras 4.107–4.111.

[244] 525 P 2d 1033, 1036–7 (Or, 1974).

[245] ibid, 1036.

[246] ibid, 1037.

[247] JW Wade, 'On the Effect in Product Liability of Knowledge Unavailable Prior to Marketing', Postscript 58 NYU L Rev 734, 761–4 (1983). See also WP Keeton, 'Product Liability—Inadequacy of Information' 48 Texas L Rev 398, 401 (1970); Prosser and Keeton, *The Law of Torts*, 697–8, n 21.

[248] *Restatement, Third, Torts: Products Liability* § 2(b).

[249] ibid, § 2, Reporters' Notes, comment m, 1, 103.

[250] Owen & Davis, *Products Liability*, § 8-1, n 11. For discussion of the test to be applied under the Product Liability Directive and the 1987 Act, see paras 10.57–10.67.

D. Defectiveness under the Consumer Protection Act 1987

(1) Introduction

10.57 As was noted earlier in this chapter,[251] the test of a 'defect' or of 'defectiveness' under the 1987 Act is framed in terms of what persons generally are entitled to expect. In applying this necessarily broad standard, s 3(2) states that certain factors 'shall be taken into account' to the extent that they are relevant. However, the list is non-exhaustive and on appropriate facts other considerations may be similarly relevant.

(2) Expectations of 'persons generally'

10.58 The reference in s 3(1) of the 1987 Act to what persons generally are entitled to expect is not without difficulty. According to Mr Michael Howard QC, who was the minister responsible for piloting the Consumer Protection Bill through the House of Commons, '[t]he intention here is that this reference should be regarded as a reference to general expectations; not general persons but general expectations'.[252] This rather infelicitous wording can be compared with the more helpful sixth recital to the Preamble to the Product Liability Directive which refers to the 'safety which the public at large is entitled to expect'.[253] Hence the expectations of the individual consumer are not significant except to the extent that they are a reflection of more general public expectations,[254] the standard being an objective minimum one.[255] Under the Competition and Consumer Act 2010 (Cth), Sch 2, s 9, Australian law similarly defines goods (its equivalent to a product) as being defective 'if their safety is not such as persons generally are entitled to expect'. Reference has been made in the literature to the different possibilities of interpretation of the phrase 'persons generally',[256] such as 'the public at large',[257] the foreseeable users of a product,[258] and persons holding the 'accumulated knowledge of the community at large', including '[t]he knowledge of expertly-qualified sections of the community'.[259] The public at large interpretation was endorsed by the Full Federal Court of Australia in *Glendale Products Pty Ltd v Australian Competition and Consumer Commission*,[260] affirming the trial judge's decision.[261] Referring

[251] See paras 10.19–10.20 and 10.29–10.32.

[252] HC, Official Report, Standing Committee D, col 26 (5 May 1987).

[253] Dir 85/374/EEC.

[254] See also the Explanatory Memorandum to the Trade Practices Amendment Bill 1992, para 13 (which inserted Pt VA into the Trade Practices Act 1974 (Cth)) (introducing similar law to the Directive in Australia). For the definition of defective, see (now s 9 of Sch 2 to the Competition and Consumer Act 2010 (Cth)) (previously s 75AC Trade Practices Act 1974 (Cth)).

[255] *Worsley v Tambrands Ltd* [2000] PIQR P95, P103; *Wilkes v DePuy International Ltd* [2018] 2 WLR 531, [61]; *Gee v Depuy International Ltd* [2018] EWHC 1208 (QB), [86].

[256] M Hammond, 'The Defect Test in Part VA of the Trade Practices Act 1974 (Cth): Defectively Designed?' (1998) 6 Torts LJ 29, 53; J Kellam and R Giblett, 'Australian appeal court considers issues under EC Product Liability Directive 1985' (2000) 8 Consum LJ 7, 18–19.

[257] Explanatory Memorandum to the Trade Practices Amendment Bill 1992, para 13.

[258] M Hammond, 'The Defect Test in Part VA of the Trade Practices Act 1974 (Cth): Defectively Designed' (1998) 6 Torts LJ 29, 53.

[259] RC Travers, 'Australia's New Product Liability Law' (1993) 67 ALJ 516, 518. This possibility of interpretation was problematic in that the standard of safety was indistinguishable from the state of the art and thus would leave no role for the state of the art defence: ibid, 519.

[260] (1999) FCR 40, 47.

[261] *Australian Competition and Consumer Commission v Glendale Chemical Products Pty Ltd* (1998) 40 IPR 619, 629.

to the Explanatory Memorandum to the Trade Practices Amendment Bill 1992,[262] Emmett J stated that the standard to be adopted in defining a defect was an objective test, based upon what the public at large, rather than any particular individual, is entitled to expect and thus it was the objective knowledge and expectations of the community which were to be assessed and not the subjective knowledge and expectations of an injured party.[263]

10.59 The matter was considered further by Burton J in his important decision in *A v National Blood Authority*,[264] where the claim was in respect of hepatitis C contracted from infected blood transfusions. The case is discussed in more detail later.[265] Here it is sufficient to state that there was considerable common ground between the parties as to the nature of the test to be applied. As Burton J explained:[266]

> The question to be resolved is the safety or the degree or level of safety or safeness which persons generally are entitled to expect. The test is not that of an absolute level of safety, nor an absolute liability for any injury caused by the harmful characteristic … In the assessment of that question the expectation is that of persons generally, or the public at large … The safety is not what is actually expected by the public at large, but what they are *entitled* to expect … The common ground is that the question is what the legitimate expectation is of persons generally, ie what is legitimately to be expected, arrived at objectively. 'Legitimate expectation', rather than 'entitled expectation', appeared to all of us to be a more happy formulation (and is analogous to the formulation in other languages in which the directive is published) … The court decides what the public is entitled to expect: Dr Harald Bartl in *Produkthaftung nach neuem EG-Recht* (1989) described the judge (as translated from the German) as 'an informed representative of the public at large' … Such objectively assessed legitimate expectation may accord with actual expectation; but it may be *more* than the public actually expects, thus imposing a higher standard of safety, or it may be *less* than the public actually expects. Alternatively the public may have no *actual* expectation—e.g. in relation to a new product—the word coined in argument for such an imaginary product was a 'scrid'.

For reasons which are considered later in this chapter, Burton J concluded that the blood products were defective since 'the public at large was entitled to expect that the blood transfused to them would be free from infection'.[267] This was not least because of the lack of warnings or material publicity of the risks involved.

10.60 The absence of a public awareness of a risk was also relevant to the determination of the issue of defectiveness in *Scholten v Foundation Sanquin of Blood Supply*,[268] a decision of the County Court of Amsterdam. In that case Scholten underwent heart surgery in an

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[262] Paras 13–14 (see n 254).

[263] See n 261. In approving this approach, the Federal Court of Australia in *Morris v Alcon Laboratories (Australia) Pty Ltd* [2003] FCA 151 (6 March 2003) provided support for an inferential evidentiary foundation in establishing defectiveness. The court held that the 'public at large' interpretation of *Glendale* made apparent the consumer protection character of the Trade Practices Act 1974 (Cth), s 75AC, and that there was no reason in law or under the Act why an evidential inference could not be drawn that the goods (here, a lens) in causing the injury (visual disturbances) were defective: ibid, paras 22–3. See also the decisions of *Carey-Hazell v Getz Bros & Co (Aust) Pty Ltd* [2004] FCA 853; *Merck Sharp & Dohme (Australia) Pty Ltd v Peterson* (2011) 196 FCR 145 at [191]; and *Gill v Ethicon Sàrl & Ors (No 5)* [2019] FCA 1905, [3170].

[264] [2001] 3 All ER 289.

[265] See paras 10.103–10.109 and 10.111–10.120; also paras 13.112–13.116, 13.124–13.125.

[266] [2001] 3 All ER 289, para 31.

[267] ibid, para 80.

[268] H 98.0896 (3 February 1999). For further discussion, see CC Van Dam, 'Dutch Case Law on the EU Product Liability Directive' in D Fairgrieve (ed), *Product Liability in Comparative Perspective* (CUP, 2005), 128–30.

Amsterdam hospital, during which he received an HIV-infected blood transfusion from a donor. The donor had only just contracted the virus, so that his infection could not be detected during this 'window period' between the donor acquiring the infection and the formation of HIV antibodies. Scholten claimed that the blood was defective within the definition of Article 6, and that, when determining whether the blood product was as safe as persons were entitled to expect, it was the expectation of the general public that was relevant. The court held that the blood product was defective because the general public expected that blood products in the Netherlands had been 100 per cent HIV-free for some time. In a conclusion that seemed to weaken the defendants' arguments in *A*, the court stated:[269]

> The fact that there is a small chance that HIV could be transmitted via a blood transfusion, which the foundation estimates at 1 in a million, is in the opinion of the court, not general knowledge. It cannot therefore be said that the public does not or cannot be expected to have this expectation. The fact that the foundation acted in accordance with the relevant guidance and that the use of an HIV-1 RNA test at the time could not have detected the HIV virus does not have any bearing on this.

10.61 Burton J's test of the legitimate expectations of persons generally was applied by Field J in *B (A Child) v McDonald's Restaurants Ltd*,[270] where a group of claimants sued for personal injuries caused by spillage of hot drinks served by the defendant. Field J held that the hot drinks which McDonald's sold to customers were not defective since persons generally expected that such drinks purchased to be consumed on the premises would indeed be hot and the risks of spilling a hot drink on someone and their being scalded as a result were well known.[271]

10.62 One of the difficulties with this test is in its application to products which pose a danger to certain sections of the public only, such as children or those who are likely to suffer an allergic reaction.[272] In appropriate cases, this should be taken into account in the product design or in accompanying warnings.[273] Thus in *Buckley v Henkel Ltd*,[274] the claimant's personal injury arose as a result of a severe allergic reaction to a hair dye product manufactured by the defendant. In holding that the presence of an allergen in the hair dye did not make the product defective, the court stressed that the instructions clearly indicated that a severe

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[269] The translation is taken from the judgment in *A v National Blood Authority* [2001] 3 All ER 289, para 44.

[270] [2002] EWHC (QB) 490.

[271] ibid, para 77. However, see the case of *Tesco Stores Ltd v Pollard* [2006] EWCA Civ 393 in which the English Court of Appeal overturned the trial judge's decision finding the manufacturer and own-brander of a dishwater powder bottle liable for personal injury to a child aged 13 months, who had been able to remove the bottle's safety cap. There was a British Standard applying to the safety cap design, and it was accepted that the torque needed to open the safety cap was less than that stipulated in the relevant British Standard. The claimant had argued that this shortfall rendered the safety cap defective within the meaning of the Consumer Protection Act 1987. The court rejected this argument. The court ruled that the public were entitled to expect only that the safety cap would be more difficult to open that an ordinary screw top which, in the instant case, it was. This decision has been subject to some critique due to emphasis in the decision on the actual perception of the individual claimant in the case, at the expense of an objective test of entitled expectation (Mark Mildred [2006] JPIL C130–3).

[272] Miller, *Product Liability and Safety Encyclopaedia*, Div III, para 255. For further discussion of allergies, see paras 12.67–12.73 and 16.29–16.33; also paras 4.102–4.103.

[273] ibid.

[274] (Unreported, 25 November 2013, St Helens County Court) 2013 WL 6537240, [82].

allergic reaction could be experienced in use of the product, and a number of warnings and precautions were highlighted.

10.63 The term 'legitimate expectation' was not used in *Piper v JRI (Manufacturing) Ltd*.[275] After a hip replacement operation, that involved the implantation of a prosthesis, the prosthesis sheared in two. Rejecting the claimant's action under the Consumer Protection Act 1987, the Court of Appeal held that the prosthesis was not defective at the time it was supplied to the hospital. The statutory defence under s 4(1)(d) that 'the defect did not exist at the relevant time' was therefore established.[276] Thomas LJ made no reference to the term 'legitimate expectation', preferring to place his emphasis on what persons generally were entitled to expect. In the context of prosthesis, a person:[277]

> was plainly entitled to expect a prosthesis to be so designed and manufactured as to withstand the procedures and forces ordinarily used on implantation. If it was not so designed and manufactured, then it would be defective at the time it was supplied to the hospital.

10.64 In the English courts, use of the 'legitimate expectation' test has now been judicially disapproved of in two High Court decisions. The shift towards enhanced consumer protection through the legitimate expectations test in *A v National Authority* was emphatically rejected by Hickinbottom J in the landmark decision of *Wilkes v DePuy International Ltd*.[278] In *Wilkes*, which concerned a metal component of an artificial hip—a steel femoral shaft called a 'C-Stem'—the claimant contended that the steel shaft was defective. In rejecting the claim, Hickinbottom J radically departed from the approach of Burton J in *A*, holding that a test of what persons are generally were 'entitled to expect' required no gloss on the Act and did not benefit from being redescribed as a 'legitimate expectation' test.[279] The test for safety required an objective approach, taking into account the information and circumstances before it, whether or not an actual or notional patient or indeed other members of the public would have considered each of the factors and all the relevant information.[280]

10.65 This rejection of the so-called 'legitimate expectation' test was followed by Mrs Justice Andrews in *Gee v DePuy International*,[281] where she noted the dangers of such a reformulation omitting the essential word 'entitled' and adopting a phrase which is used as a term of art in a very different context.[282] The judicial approach in England and Wales will thus be an objective determination of what persons generally are entitled to expect.

10.66 There has been some discussion about various aspects of the test in other Member States. For instance, there has been some interesting case law in Germany about the reference point for consumer expectations. In a case concerning liability arising from an exploding water boiler, it was held that the expectation is to be determined by reference to the consumer with the least expertise. As one commentator has noted: 'Given that the boiler was aimed at different user groups and sold at a hardware store catering to both specialists and

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[275] *Piper v JRI (Manufacturing) Ltd* [2006] EWCA Civ 1344.
[276] ibid, [30].
[277] ibid, [34].
[278] [2016] EWHC 3096 (QB).
[279] ibid, [71].
[280] ibid, [72].
[281] [2018] EWHC 1208 (QB), [95].
[282] ibid.

homeowners, the justified expectation should be determined according to the person with the least expertise; the homeowner.'[283]

(3) Risks affecting safety

10.67 For the purposes of assessing safety, s 3(1) provides that 'safety' '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'. The former element in this part of the definition makes it clear that a producer of a finished product must have regard to and be accountable for the safety of any component parts or raw materials that are comprised in it. The latter element similarly establishes that risks of damage to property, as well as of death or personal injury, are relevant to an assessment of safety. The wording of s 3(1) of the Act partially ties in with the definition of damage in s 5(1), which includes 'any loss of or damage to any property (including land)'.[284] However, the 1987 Act does not provide a basis for compensation in respect of damage to commercial, as opposed to consumer, property.[285] Thus it seems that the risk of damage to all property is relevant to an assessment of safety, whereas damages may be recovered only for damage to a restricted range of property. Also, the definition of defect in s 3(1) is not entirely apt to cover cases in which the obvious risk is that of *loss* of property, rather than of damage to it. Such risks could be associated with, for example, defective locks or burglar alarms.[286]

E. Circumstances Taken into Account in Assessing Defectiveness

(1) Introduction

10.68 As was noted earlier,[287] s 3(2) of the 1987 Act provides a non-exhaustive list of circumstances which are to be taken into account in determining what persons generally are entitled to expect in relation to a product.[288] The specified circumstances are examined initially with additional circumstances, which may or may not be considered relevant, being examined thereafter.

(2) Express factors in determining defectiveness

10.69 While Article 6 of the Directive and s 3(2) of the 1987 Act state that all circumstances shall be taken into account, the following are expressly defined as factors to be taken into consideration. These have been classified into three categories, which correspond with

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[283] M Burckhardt and V Parr, 'Justified product safety expectations' (2013) 51 International Product Liability Rev 17.

[284] For discussion of s 5(1), see esp paras 16.07 and 16.35.

[285] See s 5(3).

[286] See paras 16.40–16.43.

[287] See para 10.18.

[288] A similar list of factors is adopted for the purposes of the 'general safety requirement' imposed by s 10(1) of the 1987 Act. The list of factors is adumbrated in s 10(2)(b). See also Art 2 of Dir 2001/95/EC on general product safety. The Federal Court of Australia has stressed the inclusive and non-exhaustive nature of the circumstances listed in s 75AC(2)(a)–(f) of the Trade Practices Act 1974 (now s 9(2) of Sch 2 to the Competition and Consumer Act 2010 (Cth)) (the equivalent to the circumstances listed in s 3(2)(a)–(c) of the 1987 Act), and that the absence of evidence supporting any of the circumstances listed would not be fatal to making out a cause of action for defective goods under s 75AC(1): *Morris v Alcon Laboratories (Australia) Pty Ltd* [2003] FCA 151, paras 16–17.

the sub-paragraphs of s 3(2) of the Act and Article 6(1) of the Directive, concerning: (a) marketing, presentation, instructions, and warnings; (b) reasonably expected use; and (c) the time of supply of the product by the product to another.

(a) Marketing, presentation, instructions, and warnings

10.70 Although the Directive merely refers to the presentation of the product,[289] the Act provides a more detailed elaboration of this factor, which includes:

> … the manner in which, and purposes for which, the product has been marketed, its get-up, the use of any mark in relation to the product and any instruction for, or warnings with respect to, doing or refraining from doing anything with or in relation to the product.

This category essentially concerns products which are alleged to be defective because (and often solely because) they are not accompanied by adequate warnings, or instructions for safe use or installation. Typical examples of such products include those which are explosive, inflammable, toxic, dangerous when inhaled or ingested, or which behave in an unpredictable manner.[290] Medicinal products will often fall into this category.[291] It is clear that warnings given in relation to a product will qualify the expectation that persons generally are entitled to expect, and thus go to the issue of a product's defectiveness.[292]

10.71 (i) **The manner in which, and purposes for which, the product has been marketed** This expression indicates that the relevant circumstances include statements and claims made in relation to the product in general advertising and promotional material. Accordingly, industry will need to consider such sales and marketing material (in addition to instruction brochures, etc) when assessing whether a product is defective. Of critical importance will be the need for a manufacturer's sales force to refrain from overselling a product's safety, since advertising or statements by sales personnel may reduce the effect of written warnings in product information.[293] Indeed, the over-promotion of medicinal products by so-called 'detail men' in the United States, and also in the United Kingdom and Europe more generally, has continued to be a source of concern. The relevance of marketing is consistent with a consumer expectations standard of defectiveness. Thus safety expectations are heightened if a product is marketed as being safe for children or the elderly.[294]

10.72 The purposes for which the product is marketed will also play a part in determining whether a product is defective. It is a matter of considerable notoriety that, in the light of the uncontroverted evidence showing that the drug caused malformations in unborn foetuses, thalidomide would be considered defective if marketed as a pregnancy drug.[295] However, thalidomide received an FDA authorization in 1998 for non-pregnancy uses in the treatment of leprosy and in 2008 the EMEA granted approval for it to be used for the treatment of multiple myeloma;[296] it has also been used in the treatment of

[289] Dir 85/374/EEC, Art 6(1)(a).

[290] See, generally, ch 12 (strict liability) and paras 14.78–14.123 (liability in negligence).

[291] See further, R Goldberg, *Medicinal Product Liability and Regulation* (Hart Publishing, 2013), 24–5.

[292] *Wilkes v DePuy International Ltd* [2016] EWHC 3096 (QB), [103], approving the view expressed in the text at para 12.20.

[293] Hodges, *Product Liability: European Laws and Practice*, para 2-014.

[294] G Howells in Howells (ed), *The Law of Product Liability*, para 4.136.

[295] H Sjöström and R Nilsson, *Thalidomide and the Power of Drug Companies* (Penguin, 1972), 156–9.

[296] See 'Lenalidomide and thalidomide for multiple myeloma', MHRA, Drug Safety Update, Vol 2, Issue 1, August 2008, available at: https://www.gov.uk/drug-safety-update; N Hawkes, 'Fifty years on, thalidomide is back. Now they say it's a good thing' The Times, 22 April 2008.

AIDS,[297] and is used in the United Kingdom on a named patient basis.[298] Thus thalidomide would not appear to be defective if it was marketed solely for these safe purposes.

10.73 **(ii) Get up** The manner in which a product is presented may be relevant to the issue of defectiveness. Thus s 3(2)(a) refers to account being taken of the product's 'get up' in making such an assessment. This expression seems apt to cover such matters as the product's style, general design, and the way in which it is packaged.[299]

10.74 **(iii) Use of any mark in relation to the product** Reference to a mark used in relation to a product may render an otherwise acceptably safe product defective if it failed to satisfy expectations of safety associated with the mark; this is particularly true where the marks are explicitly related to safety, such as the British Kitemark, the German GS Mark, and the European Keymark.[300] In *Pollard v Tesco Stores*[301] the Court of Appeal overturned the trial judge's decision finding the manufacturer and own-brander of a dishwater powder bottle liable for personal injury to a child aged 13 months, who had been able to remove the bottle's safety cap. There was a British Standard applying to the safety cap, and it was accepted that the torque needed to open the safety cap was less than that stipulated in the relevant British Standard. Laws LJ rejected arguments that the child-resistant closure 'CRC' cap on a dishwasher bottle should comply with the British Standard torque measure, since that standard was not referred to on the product and members of the public could not be supposed to have appreciated that any public authority would have pronounced on the matter.[302] Clearly, if the child-resistant closure had referred to the British Standard on the bottle, it would have been defective.

This decision has been subject to some critique due to the perceived failure of the court to give an explanation of its approach to the notion of defect.[303]

10.75 **(iv) Instructions and warnings** Instructions and warnings frequently play a key role in determining whether a product has achieved the level of safety which persons generally are entitled to expect. It seems entirely proper to qualify the safety expectations which would otherwise be associated with a product by instructions, contra-indications, warnings, and indicative precautions.[304] Industry is required to steer a careful balance between spelling out the dangers with sufficient clarity and doing so in ways which would detract

[297] Stapleton, *Product Liability*, 234; M Schulz, Review, 'Dark Remedies: The Impact of Thalidomide and its Revival as a Vital Medicine' (2001) 322 BMJ 1608.

[298] RJ Powell, Editorial, 'New Rules for Thalidomide' (1996) 313 BMJ 377–8.

[299] The term 'get up' is most commonly associated with the tort of passing off. It refers to the way in which products are packaged, in the context of a claimant acquiring goodwill through use of such packaging or 'get up' for their products: WR Cornish, D Llewellyn and T Aplin, *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights* (9th edn, Sweet & Maxwell, 2019), para 17-08; L Bently and B Sherman, D Gangjee, and P Johnson, *Intellectual Property* (5th edn, OUP, 2019), 867–8.

[300] The point is made by G Howells in Howells (ed), *The Law of Product Liability* (2nd edn, 2007), para 4.164. As Prof Howells adds, the product would usually be adjudged to be defective in any event since such marks typically reflect a consensus so far as safety is concerned. See *Gill v Ethicon Sàrl & Ors* (No 5) [2019] FCA 1905, [3272], [3377], and [3458] (stress urinary incontinence medical device carrying CE mark; failure to comply with requirements for CE marking).

[301] *Pollard v Tesco Stores* [2006] EWCA Civ 1393, [2006] All ER (D) 86.

[302] ibid, [16]. For criticism of this as a 'relatively weak interpretation of consumer expectations', focusing on actual expectations of consumers rather than the legal test that requires consideration of what persons generally are entitled to expect, see G Howells (n 300), para 4.151 and, further, M Mildred [2006] J of Personal Injury Law C130–3.

[303] Mildred, ibid.

[304] Hodges, *Product Liability: European Laws and Practice*, para 2-014.

significantly from sales. However, it is of crucial importance for manufacturers never to understate known dangers.[305]

10.76 The circumstances in which instructions or warnings are typically necessary in relation to products and the factors affecting their adequacy or sufficiency are discussed in more detail in later chapters.[306] At this point it is appropriate to note that the reference in s 3(2)(a) to 'doing or refraining from doing anything with or in relation to the product' appears apt to cover both inappropriate modifications to the product and the incorporation of accessories where such an incorporation would render a product dangerous. In such circumstances, the product could be regarded as defective, providing such a use was reasonably foreseeable and that supervising the accessories market was reasonable in the circumstances—a test akin to negligence.[307] This has been reflected in German law, where a motorcycle manufacturer was held to be negligent for failing to supervise an accessories market when parts made by another producer but targeted at its products rendered them unsafe.[308] In respect of 'instructions', these will often be appropriately addressed to the end user, as when they refer to the assembly of a product from a kit, but in certain circumstances it may be necessary to address them to installers and servicers of products.

(b) Reasonably expected use

10.77 As s 3(2)(b) makes clear, the relevant circumstances include 'what might reasonably be expected to be done with or in relation to the product'. The issue will be whether the use to which the product was in fact put when it caused the damage was a reasonably expected one, based on an objective test of reasonableness.[309] The provision works both ways. It acknowledges that while most (if not all) products are capable of causing harm if used in an unreasonable way, if they do so, this does not mean that they have failed to achieve the required level of safety. Frequently cited examples include the claim of the apocryphal American lady who is said to have placed her poodle in a microwave oven where it was predictably incinerated, and the man said to have used a hedge trimmer to cut his hair. It goes without saying that neither the microwave nor the hedge trimmer would lead to the imposition of liability for the sole reason that they caused damage in such circumstances. In both cases, the claimant's injury results from gross misuse of the product; so liability could be denied on the ground that the product was not defective or on the basis that the claimant's actions were the sole effective cause of the damage. There are also less extreme examples in European jurisdictions. For example, in one case from the Netherlands a District Court rejected a claim that an OB 'comfort mini' tampon was defective because it was possible to insert it into the urethra, as a young girl had done. The court held that the way in which the tampon had been used could not reasonably have been expected by the producer, not least because Johnson & Johnson had sold a considerable number of such tampons, but had never received a report or a complaint of a similar kind.[310]

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[305] Miller, *Product Liability and Safety Encyclopaedia*, Div III, para 255. See paras 12.90–12.91 and 14.102.

[306] See ch 12 (strict liability) and paras 14.78–14.123 (liability in negligence).

[307] The point is made by Howells (n 300), para 4.139.

[308] [1986] NJW 1009, as cited in Howells (n 300), para 4.139.

[309] Hodges, *Product Liability: European Laws and Practice*, para 2-014.

[310] District Court Zwolle d.d. 24 April 2002 (noted in L Mattheussens, 'District Court of Zwolle Considers Questions of Defect and Adequacy of Warnings', Lovells' *European Product Liability Review*, December 2002, Issue 9, 43, 44). For more general information on the position in the Netherlands, see

10.78 However, on the other side of the coin, it is frequently predictable that accidents will occur when a product is used in a manner which was not intended but which is nevertheless to be expected.[311] If such a misuse is reasonably foreseeable, the manufacturer may well be liable. For example, a small child may stand on an open oven door, or an elderly person may grab hold of an oven or other appliance in an attempt to regain their balance and prevent a fall. It could be argued that the oven or other appliance is 'defective' if its centre of gravity is not such as to prevent it toppling over; such a danger may well have been avoided by a simple change of design.[312] In an appropriate case the outcome will be a reduction in damages to reflect the claimant's contributory negligence.[313]

(c) Time of supply of product by producer to another

10.79 Both s 3(2)(c) of the Consumer Protection Act 1987 and Article 6(1)(c) and (2) of the Directive recognize that the level of safety which has to be assessed in determining what persons generally are entitled to expect is the one which was considered appropriate at the time when the product was supplied[314] by its producer to another. It is not the standard which might have been achieved at the time the damage was suffered. The point is reinforced in the closing words of s 3(2), reflecting those of Article 6(2), whereby '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'. It is to be noted that in the recent decision of *Gee,* Andrews J held that in determining whether a product is defective as at the time it was put into circulation, the court may take into account all information available as at the date of legal proceedings: 'in determining whether the product *met* that level of safety, the Court is entitled to have regard to everything now known about it that is relevant to that enquiry, irrespective of whether that information was available at the time it was put on the market or has come to light subsequently'.[315]

10.80 The significance of this provision can be seen in cases where there has been clear improvement in safety standards over the years. Relevant examples include interior design features providing greater safety to car passengers (including seat belts and, more recently, airbags), improvements which are not mirrored in external design features (bull-bars, etc) affecting pedestrians. Another significant improvement was the introduction of refrigerators which can be opened from the inside, thus providing a means of escape for children who find

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K Bisschop, L Mattheussens, and J Krens, 'An Overview of Product Liability in the Netherlands', Lovells' *European Product Liability Review*, September 2002, Issue 8, 4. Note also the discussion of the 'Koolhaas/Rockwool' case (involving a product used in potting compost): ibid, 9. In relation to Italy, see the decision of the Italian Supreme Court (no 10274 of 29 September 1995) (noted by R Marengo and D Bunaca, 'An Overview of Product Liability Law in Italy', Lovells' *European Product Liability Review*, December 2001, Issue 5, 9), where it was held that 'damage must be considered as caused by a defect of the product if the product was used according to the intended use that the manufacturer (or the custodian) could reasonably predict'. On the facts there was no liability to a 12-year-old child who had climbed onto the arm of a swing, holding onto a knot in the chain and causing an injury to his hand.

311 As, perhaps, in *Hill v James Crowe (Cases) Ltd* [1978] 1 All ER 812 (lorry driver standing on badly nailed packing case to load lorry).

312 Miller, *Product Liability and Safety Encyclopaedia*, Div III, paras 120 and 255. For further discussion of misuse, see paras 11.54, 11.59–11.62.

313 See s 6(4) of the 1987 Act, discussed at paras 17.124, 17.130–17.134 and, further, *Wilkes v DePuy International Ltd* [2016] EWHC 3096, [79], followed in *Gill v Ethicon Sàrl & Ors* (No 5) [2019] FCA 1905, [3169].

314 For the definition of supply, see s 46(1) of the 1987 Act (paras 8.61–8.64).

315 *Gee*, [84].

themselves locked inside. Since the relevant moment is the time of 'supply', manufacturers will be unable to avail themselves of the provision to the extent that they have designed and produced goods at an earlier date (say, the first year), stored them in a warehouse, and distributed them later (say, in the third year). The relevant standard of safety would be that adjudged appropriate in the third year. The other side of the coin is that if injury is suffered in the third year and the relevant product was supplied in the first, the manufacturer will not be prejudiced by the advance in the state of the art and will be entitled to be judged by the standard prevailing at the earlier date.

10.81 It is true that the adoption of this approach goes some way towards assimilating the principles to be applied in strict liability and in negligence. It is not without its critics. For example, Professor Stapleton has observed that the approach involves the need to reconstruct the state of the art at a point often considerably in the past and act on information which is usually complex and costly to gather, and often more within the knowledge of the defendant than the plaintiff.[316] The area is one where expert evidence is likely to be crucial. However, a different approach would hardly provide an incentive to improve safety standards over the years,[317] at least during the period in which the ten-year period for potential liability under the Act was still running.[318]

10.82 There will be cases in which legitimate expectations of standards of safety will not change over the years. This was the case in *Abouzaid v Mothercare (UK) Ltd*[319] which involved the defendant's product 'Cosytoes'. This had been purchased from one of the defendant's stores, and in 1990 whilst the claimant was helping his mother attach the product to his brother's pushchair by joining its two elasticated straps around the back of the pushchair, one of the elastic straps slipped from his grasp and the buckle hit him in the left eye. As a consequence, the claimant virtually lost the sight of that eye. The trial judge held that there was a failure to provide instructions and that there was a design or safety defect since the product could not be secured safely. He held that if there was a safety defect in 1999 there was similarly one in 1990. On appeal, the defendant argued that while the hazard in question was regarded as a safety defect in 1999, it was not so regarded in 1990. The Court of Appeal held that although the case was close to the borderline, the product was defective within the meaning of s 3 of the Act. The product was 'to be judged by the expectations of the public at large as determined by the Court'.[320] Public expectations had not changed between 1990 and 1999. Elasticated products had been in use for many years and there was no suggestion of any technical advance that might reasonably affect the level of safety which persons generally were entitled to expect in relation to a product of this nature.[321]

10.83 Another important point is the need to distinguish s 3(2)(c) from the development risk defence of s 4(1)(e). The term 'development risk' refers to defects undiscoverable in the

[316] J Stapleton, 'Products Liability Reform—Real or Illusory?' (1986) 6 OJLS 392, 412–13; also Stapleton, *Product Liability*, 244–7. Suppose also that with the advance of time additional beneficial effects of a product supplied in 2006 are discovered only in 2014 when the damage is suffered and the claim made. It would be strange indeed if the manufacturer were unable to lead evidence of these beneficial effects in any risk–utility analysis.

[317] See also para 14.24, where the same point is made in relation to a potential liability in negligence.

[318] See the Limitation Act 1980, s 11A(3), which was added by Sch 1 to the 1987 Act (paras 17.157–17.163).

[319] [2000] All ER (D) 2436, The Times, 20 February 2001.

[320] ibid, per Pill LJ, para 25.

[321] ibid.

light of the state of scientific and technical knowledge at the time of supply, whereas s 3(2)(c) focuses on the state of the art, which is the relative standard of safety required to ascertain whether a product was defective at the time of supply.[322] This view was reaffirmed by the trial judge in the Vioxx class action, *Peterson v Merck Sharp & Dohme (Australia) Pty Ltd*,[323] who opined that s 75AK(1)(c) of the Trade Practices Act 1974 (the equivalent of s 4(1)(e)/Article 7(e)) contemplated the existence of a defect capable of being discovered by reference to the current state of scientific or technical knowledge.[324] It was 'not concerned with the kind of contextual circumstances referred to in s 75AC (2) [the Australian equivalent of s 3(2)/Article 6(1)]'.[325] Some eliding of issues relevant to the state of the art and to development risks was present in the defendant's arguments in *Abouzaid*. In particular, it appears to have been suggested that there was a role for the state of scientific and technical knowledge at the time of supply in ascertaining whether a product was defective when in fact it was relevant only to the availability of the development risk defence. Chadwick LJ emphasized that in determining whether the product was defective under strict liability, the test was what level of safety persons generally were entitled to expect and not, as an expert witness appeared to assume, the level of safety which consumers could reasonably expect. So, it was irrelevant whether the hazard causing the damage had come, or ought reasonably to have come, to the producer's attention before the accident occurred. To hold otherwise would reintroduce negligence concepts into the strict liability regime which gave effect to the Product Liability Directive.[326]

10.84 Finally, the use of the words 'require' and 'from the fact alone' in the closing words of s 3(2) of the 1987 Act are consistent with the view that improved safety standards may have evidential value if they were feasible at the time of the product's supply. For example, they may suggest that alternative and better safety standards were practicable at an earlier time.[327]

(3) Relevant but non-specified circumstances

10.85 There are several other circumstances which are not specifically referred to in s 3(2)(a), (b), and (c) but which are relevant in determining whether a product provides the standard of safety which persons generally are entitled to expect. They include: (a) whether the danger is obvious or hidden; (b) whether the product complies with regulations and equivalent standards of safety applicable to it; and to an extent which is open to discussion; and (c) the

[322] See eg Clark, *Product Liability*, 151; C Newdick, 'The Development Risk Defence of the Consumer Protection Act 1987' (1988) 47 Camb LJ 455. Indeed, AG Tesauro seemed aware of this distinction when he said that since Art 7(e) referred 'solely to the scientific and technical knowledge at the time when the product was marketed, it [was] not concerned with the practices and safety standards in use in the industrial sector in which the producer [was] operating': Case C-300/95 *Commission v United Kingdom* [1997] ECR I-2649, [20] per Tesauro AG. This position was affirmed by the ECJ's judgment; ibid, [26]. For further discussion of this case, see paras 13.53–13.67.

[323] *Peterson v Merck Sharp & Dohme (Australia) Pty Ltd* (2010) 184 FCR 1.

[324] ibid, [929].

[325] ibid. See, further, the decision in *Gill v Ethicon Sàrl & Ors* (No 5) [2019] FCA 1905, [3354]–[3359].

[326] [2000] All ER (D) 2436, per Chadwick LJ, paras 43–4.

[327] *Lambert v Lewis* [1978] 1 Lloyd's Rep 610, 616–17 per Stocker J (evidence of subsequent remedial measures to towing coupling after accident, taken in consultation with manufacturer's suggested alternative and better safety standards were practicable at an earlier point in time. Accordingly, the coupling was held defective in design for use on the public highway). For further discussion in the context of negligence, see paras 14.142–14.144.

balance between the risks and benefits associated with the product and the cost and practicability of a safer design.

(a) Obvious or hidden dangers

10.86 **(i) General observations** The fact that a danger is widely known or obvious will often suggest that a product has achieved the level of safety persons generally are entitled to expect. This is particularly so where a certain element of danger is inherent in a product's use, such as with razor blades, knives, and hammers, etc.[328] In general, it is certainly the case that it is the latent or hidden danger which is most likely to cause harm.[329] However, a blanket rule denying liability for patent dangers should be regarded as too simplistic and in need of refinement.[330] Thus, for example, while some products may be dangerous to children but not to adults who understand the danger, they may be capable of being made safer, whether through childproof containers or warnings to parents or otherwise. This suggests that obviousness should be regarded as a mere factor in a cost–benefit analysis of risk.[331] In this context it is instructive to examine the reasons for the rise and fall of the patent danger rule in the United States.

10.87 **(ii) The experience of the United States: rise and fall of the patent danger rule** The extent to which obviousness plays a role in strict liability is largely dependent on the theory of defectiveness adopted. Thus if design defectiveness is determined by consumer expectations then persons injured by obvious dangers will in all probability lose.[332] As has previously been noted,[333] one of the principal reasons for abandoning consumer expectations as a standard for design defectiveness is its failure to provide a resolution in cases involving obvious dangers. Nowadays, the majority of American jurisdictions assessing design defectiveness by risk–utility balancing consider obviousness as merely one factor in the balance, albeit an important one. The change in the judicial approach to patent dangers developed broadly along the following lines.[334]

10.88 Prior to the 1970s, most victims of obvious design dangers were barred from recovery under the so-called patent danger doctrine. In 1950, in the leading decision of *Campo v Scofield*,[335] the New York Court of Appeals established the primacy of the patent danger rule. The plaintiff's hands had been caught in the revolving steel rollers of an onion-topping machine. In an action in negligence against the defendant manufactures of the machine, the court held that a manufacturer was 'under no duty to guard against injury from a patent peril or from a source manifestly dangerous' and was under no duty to render a machine more safe providing the danger to be avoided was 'obvious and patent to all'.[336]

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[328] This was common ground in *A v National Blood Authority* [2001] 3 All ER 289, para 31.

[329] The reason for the obvious nature of a danger being relevant to the issue of design defectiveness is that it provides a warning to persons so that they may act to protect themselves: Owen & Davis, *Products Liability*, § 8-8.

[330] Miller, *Product Liability and Safety Encyclopaedia*, Div III, para 255.

[331] Owen & Davis, *Products Liability*, § 10-2.

[332] *Vincer v Esther Williams All–Aluminum Swimming Pool Co* 230 NW 2d 794 (Wis, 1975) (para 10.34); *Sacks v Phillip Morris Inc* 139 F 3d 892 (4th Cir, 1998 (Md law)) (obvious and commonly known danger that cigarette could start a fire precluded liability under both consumer expectations and risk–utility tests).

[333] See paras 10.31 and 10.34–10.35.

[334] See also Stapleton, *Product Liability*, 258–9.

[335] 301 NY 468 (1950).

[336] ibid, 472.

10.89 By 1970, courts had started to reject the patent danger rule. In an important case, *Pike v Frank G Hough Co*,[337] the Californian Supreme Court expressly rejected the rule in an action against the manufacturer of a paydozer, which had backed up and struck an employee. In the absence of a rear view mirror, the paydozer's structural design created a blind spot such that its operator could not see someone standing behind the machine. The plaintiffs sought to establish liability for defective design relying both on negligence and strict liability. The manufacturer denied liability and contended that the peril of being struck by the paydozer was obvious. The Supreme Court of California rejected this argument and concluded that 'the obviousness of peril is relevant to the manufacturer's defenses, not to the issue of duty'.[338] Even if the obviousness of the peril were conceded, the manufacturer's liability was not precluded solely because a danger was obvious.[339]

10.90 In the landmark decision of *Micallef v Miehle Co*,[340] the New York Court of Appeals departed from its earlier decision in *Campo v Scofield*.[341] It noted the main thrust of the criticism of the rule which 'stem[med] from the belief that, in our highly complex and technological society, we fall victim to the manufacturer who holds himself out as an expert in his field',[342] adding that *Campo* amounted to an assumption of risk defence 'with the added disadvantage that the defendant was relieved of the burden of proving that plaintiff had subjectively appreciated a known risk'.[343] Also, it suffered from rigidity in precluding recovery whenever it was shown that the defect was patent. There was thus a need for '[a] casting of increased responsibility upon the manufacturer, who stands in a superior position to recognize and cure defects'.[344] The New York Court of Appeals held that the manufacturer would be required to exercise that degree of care in its plan or design so as to avoid any unreasonable risk of harm to anyone likely to be exposed to a foreseeable danger.[345] The openness and obviousness of the danger was but a factor in determining whether the plaintiff had exercised that degree of reasonable care required[346] and obviousness was a mere factor in the design cost–benefit calculus of risk. [347]

10.91 While a few offshoots of the patent danger rule for obvious design dangers existed into the 1990s,[348] it has been said that it is now clear that '[t]he overwhelming majority of

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[337] 467 P 2d 229 (Cal, 1970).

[338] ibid, 234.

[339] ibid, 235.

[340] 348 NE 2d 571 (1976).

[341] 301 NY 468 (1950) (para 10.88).

[342] 348 NE 2d 571, 576 (1976).

[343] ibid, citing P Rheingold, 'Expanding liability of the Product Supplier: A Primer' 2 Hofstra L Rev 521, 541 (1974).

[344] 348 NE 2d 571, 577 (1976).

[345] ibid.

[346] ibid, 578.

[347] See also the valuable discussion explaining that the patent danger rule does not bar recovery for all apparent dangers, but limits strict product liability 'only when doing so furthers the value of informed consumer choice' in MA Geistfeld, 'The Value of Consumer Choice in Products Liability' 74 Brook L Rev 781, 791–9 (2009).

[348] The expectation test was held applicable, thus effectively introducing a no duty rule, in the context of simple product designs: *Scoby v Vulcan Hart Corp* 569 NE 2d 1147, 1151 (4th Dist, 1991) (risk–utility test inapplicable to simple but obviously dangerous products: deep fat fryer); *Todd v Societe Bic, SA* 21 F 3d 1402, 1412 (7th Cir, 1994). However, this rendering of risk–utility inapplicable to simple products with open and obvious dangers was rejected in *Calles v Scripto-Tokai Corp* 864 NE 2d 249, 257–60 (2007) (open and obvious danger of a product not a per se bar to manufacturer's liability nor a bar to application of risk–utility test; open and obvious danger 'is one factor that may be weighed in the risk utility test': ibid, 260).

jurisdictions have held that the open and obvious nature of the danger does not preclude liability for design defects'.[349] Thus the patent danger doctrine in design defect cases is essentially defunct. As the *Restatement, Third, Torts: Products Liability* § 2, comment d, observes:

> The fact that a danger is open and obvious is relevant to the issue of defectiveness, but does not necessarily preclude a plaintiff from establishing that a reasonable alternative design should have been adopted that would have reduced or prevented injury to the plaintiff.

Hence, if obviousness is now applied in a way which permits a claimant to establish that an alternative design could be adopted in the manner of the *Third Restatement*, the Consumer Protection Act 1987 will be able to avoid the difficulties associated with the patent danger rule.

(b) Regulations and equivalent safety standards

10.92 **(i) General observations** A further relevant non-specified factor, which is especially important in design defect cases, is whether or not the product complies with regulations concerning product safety and relevant safety standards, such as those laid down by the British Standards Institute. The matter is similarly relevant in the context of claims based on an allegation of negligence and is discussed further in that context.[350]

10.93 **(ii) Regulations** Non-compliance with regulations concerning product safety, such as those made under the Consumer Protection Act 1987, will constitute a criminal offence, leading to the imposition of appropriate penalties. Depending on the particular statute in issue, there may be a cause of action for breach of statutory duty.[351]

10.94 Conversely, compliance with regulations which cover a product in a relevant respect may be evidence that the product is not defective for the purposes of the product liability provisions in Pt I of the 1987 Act. Such evidence will be regarded as particularly cogent, and indeed often effectively dispositive of the matter, where the regulations are regularly updated and detailed.[352] Thus, as Hickinbottom J (as he then was) has put it: while the mere fact of regulatory approval is not an automatic defence or even a prima facie defence under the Act, 'such approval may be evidence (and, in an appropriate case, powerful evidence) that the level of safety of the product was that which persons generally were entitled to expect'.[353] A fortiori, 'where every aspect of the product's design, manufacture and marketing has been the subject of the substantial scrutiny, by a regulatory authority comprised of individuals selected for their experience and expertise in the product including its safety, on

[349] *Ogletree v Navistar Intern Transp Corp* 500 SE 2d 570, 571–2 (1998) (Sup Ct of Georgia).

[350] See paras 14.145–14.154.

[351] See para 14.153.

[352] The view expressed in the text was cited in *Wilkes v Depuy International Ltd* [2016] EWHC 3096 (QB), [2017] 3 All ER 589, [100] per Hickinbottom J. Miller, *Product Liability and Safety Encyclopaedia*, Div III, para 255. While compliance with regulatory requirements does not absolve a defendant from liability in negligence, in heavily regulated industries such compliance carries 'considerable but not decisive weight': *Lambson Aviation v Embraer Empressa Brasiliera de Aeronautica SA* [2001] All ER (D) 152 (Oct) (QBD, 11 October 2001), para 17 per Tomlinson J (noted in R Freeman, 'Assessing Manufacturers' Liability in Highly Regulated Industries', Lovells' *European Product Liability Review*, December 2001, Issue 5, 25), see paras 14.148–14.150.

[353] *Wilkes v DePuy International Ltd* [2016] EWHC 3096 (QB), [2017] 3 All ER 589, [101] per Hickinbottom J; *Gee v DePuy International Ltd* [2018] EWHC 1208 (QB), [176]; C Newdick, 'The Impact of Licensing Authority Approval on Pharmaceutical Product Liability: A Survey of American and UK Law' (1992) 47 Food & Drug LJ 41, 53–4.

the basis of full information, and that body has assessed that the level of safety is acceptable, then it may be challenging for a claimant to prove that the level of safety that persons generally are entitled to expect is at a higher level'.[354] This position is consistent with decisions from German courts which hold that while compliance with regulations and standards does not of itself preclude the finding of a design defect, such compliance is *indicative* of the fact that a product is as safe as could be legitimately expected.[355] That said, if the claim concerned a known danger that the licensing authority had not been notified of, or which had been misrepresented, a presumption might arise that the medicinal product was defective. This presumption could also apply to risks that became known at a post-marketing authorization stage, but which were not communicated to the licensing authority: such an approach could help to incentivize prompt and full disclosure on the part of the pharmaceutical manufacturer.[356]

10.95 An important factor in such cases is that a court would be reluctant to lay down standards higher than (and thus inconsistent with) those prescribed by Parliament. This was the position in *Albery & Budden v BP Oil*,[357] where the Court of Appeal dismissed the claims of children who had allegedly suffered physical injury through ingestion of quantities of lead from exposure to the defendant's petrol, on the grounds that BP had complied with the regulations prescribed by the Secretary of State and approved by Parliament. To hold them negligent would mean that the courts would be laying down limits lower and more demanding than those prescribed by Parliament, which would result in an unacceptable constitutional anomaly. Although a decision reached in the context of a claim in negligence, it is submitted that the same principles would be applicable under a strict liability regime.[358]

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[354] *Wilkes v DePuy International Ltd* (n 353), [101] per Hickinbottom J. Cf the Full Federal Court of Australia's emphasis in *Merck Sharp & Dohme (Australia) Pty Ltd v Peterson* [2011] FCAFC 128, [161]–[163] leave to appeal refused, [2012] HCATrans 105, upholding [2010] 184 FCR 1, [792]–[795], Jessup J on medicines legislation as establishing minimal and not optimal standards. As well as emphasizing that compliance with such standards does not foreclose the issues of reasonable safety and reasonable care in negligence, it may suggest that when one examines the question of whether compliance with medicines regulations or standards should preclude a medicinal product from being found defective, such standards would not necessarily reflect the optimum standard that persons generally would be entitled to expect. See further, M Mildred, 'Pharmaceutical Products: The Relationship between Regulatory Approval and the Existence of a Defect' [2007] 6 EBLR 1267, 1280 (where the approach is mooted whereby one would recognize the relevance of the regulatory decision as evidence before the judge, but would afford opportunity for the parties to comment upon, or contradict, such evidence).

[355] Decision of Cologne Court of Appeal, noted by S Lenze and D Vierheilig, 'Life tastes good: the German Coca-Cola and liquorice litigation' (2005) 21 European Product Liability Rev 34, 35–6; Hamm Court of Appeal, 27 January 2002, 311 116/00 ('Log Flame'); Düsseldorf Court of Appeal, 20 December 2002, 14 u/99/02 ('Mars Bar') (reported on the British Institute of International and Comparative Law Product Liability Forum database). Compare the decision of the Swiss Supreme Court that the owner of a building was liable for injuries caused by a malfunctioning elevator, despite compliance with the product's technical and safety standards: Case 4C 386/2005, noted in L Wyss, 'The Role of Product Safety Standards as a Defence to Product Liability Claims' (2006) 22 European Product Liability Rev 39.

[356] C Newdick, 'The Impact of Licensing Authority Approval on Pharmaceutical Product Liability: A Survey of American and UK Law' (1992) 47 Food & Drug LJ 41, 57.

[357] (1980) 124 Sol Jo 376, CA.

[358] See further, *Buckley v Henkel Ltd* (unreported, 25 November 2013, St Helens County Court, [82](f) (noting that compliance with legislation one factor to be considered in assessing what persons are entitled to expect and not necessarily determinative, but also noting that, as with the BP case, the nature of the legislation and the potential risk of creating a constitutional anomaly could be a relevant consideration).

10.96 The related, but limited, defence of the defect being attributable to compliance with mandatory regulations is explored elsewhere.[359]

10.97 The current state of European law does not allow for a regulatory compliance defence. However, efforts have been deployed in favour of the adoption of a broader defence of regulatory compliance under the European product liability regime. In essence it is argued that regulatory compliance interfaces directly with the legitimate expectations test in the sense that the safety which consumers are entitled to expect is that encapsulated in the regulatory procedures, for instance in the pharmaceutical sphere that the marketing authorization process and post-marketing obligations (eg pharmacovigilance) have been adhered to. In the Lovells report on the application of the Directive of 2003,[360] it was observed in the executive summary that study respondents had raised the regulatory compliance defence: 'A number of participants (from the pharmaceutical industry in particular) suggested that the Directive should provide a defence for producers in industries where the safety of a product is closely regulated, if products comply fully with applicable regulations.'[361] Moreover, it was noted in the 2006 review of the Directive by the European Commission, that:

> stakeholders, and in particular representatives of the pharmaceutical industry, have argued strongly for the introduction of a defence of regulatory compliance, which would apply to a product whose safety was closely regulated, provided that the product complied fully with the applicable regulations.[362]

In the conclusions of its report, the Commission included in the list of areas where close and regular monitoring should take place 'the defence of regulatory compliance'.[363] However, no view was expressed on the merits of such arguments or the legislative means by which such change to the Directive might be implemented.[364] In the Fourth Report, there was implied reiteration of support for a regulatory compliance defence from representatives of the pharmaceutical industry in Europe, who opined that the Directive 'does not sufficiently take into consideration that the medical products sector is very strictly regulated'.[365] Continuing interest in such arguments has been fuelled by the recent US

[359] See Dir 85/374/EEC, Art 7(d) and s 4(1)(a) of the 1987 Act (paras 13.03–13.05).

[360] Lovells, *Product Liability in the European Union* (2003), available at http://ec.europa.eu/enterprise/regulation/goods/docs/liability/studies/lovells-study_en.pdf.

[361] ibid, p vii.

[362] European Commission, Third Report (n 38), 11.

[363] ibid.

[364] M Mildred, 'Pharmaceutical Products: The Relationship between Regulatory Approval and the Existence of a Defect' [2007] European Business Law Rev 1267. Since the Directive is one of maximum harmonization, amendment of it would be required: ibid; see Case C-183/00 *Gonzalez Sanchez v Medicinia Asturiana SA* [2002] ECR I-3901, [24]; Case C-52/00 *Commission v France* [2002] ECR I-3827, [24] and Case C-154/00 *Commission v Greece* [2002] ECR I-3879, [20]; Case C-402/03 *Skov v Bilka* [2006] ECR I-199, [22], [23], [44].

[365] European Commission, Fourth Report (n 38), 8. The Fourth Report betrays a misunderstanding of Art 7(d) of the Directive, which provides a defence on proving 'that the defect is due to compliance of the product with mandatory regulations issued by the public authorities' (see para 13.03–13.07), by classifying Art 7(d) in a heading as a 'defence of regulatory compliance': ibid. The Fourth Report also noted the pharmaceutical industry's view that the fact that use of a medicinal product is generally subject to external examination by health professionals (including doctors, nurses, or pharmacists) and that the producer does not have any control over the way in which medicines are prescribed or administered, 'should be taken into account when analysing the defect of the product and the producer's liability': ibid. While these comments may relate to the question of whether the learned intermediary rule is applicable under the Directive, they seem to bear little relation to the question of a regulatory compliance defence: R Goldberg, *Medicinal Product Liability and Regulation* (n 291).

case law on the pre-emption doctrine.[366] However, the key concerns about the viability of a regulatory compliance defence continue to be the major role of the post-approval period in identifying new risks concerning drugs, the incorporation of that information into the drug's labelling, and the regulator's ability to monitor both manufacturer compliance and information provided by the adverse drug reaction process.[367]

10.98 (**iii**) **Standards** It is clear that failure to conform to mandatory standards in matters touching on the safety of a product will be evidence of defectiveness, since persons generally are entitled to expect conformity of products with such standards.[368] Conversely, conformity with such standards will provide evidence that, in respect of pure design or composition matters, the requisite level of safety has been satisfied and that the product is not defective.[369]

10.99 In *Richardson v LRC Products Ltd*,[370] in holding that it had not been proved that a particular condom was defective, Ian Kennedy J placed reliance on evidence which had demonstrated that in a large-scale trial in the United States, condoms had failed inexplicably under American standards, and also on evidence that the defendants' condoms were manufactured to a standard in excess of the relevant British standard.[371] In particular, however, whereas evidence of conformity with standards supports a finding that a product has achieved an acceptable level of safety it does not follow that the same is true of evidence of industry standards laying down failure rates within quality control systems which result in the production of a predictable number of defective products.[372] However, this is not to say that such general statistics point to there being a defect in any *given* product (whether a condom or a bottle or whatever) since the claimant must establish that this is so. It seems that in *Richardson* the likelihood was that the ozone cracking in the condom had occurred after the fracture and was not the cause of it.

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[366] See eg *Riegel v Medtronic Inc* 522 US 312, 128 S Ct 999, 1007–8 (2008) (US Sup Ct); and further R Goldberg, *Medicinal Product Liability and Regulation* (n 291), 145–58.

[367] MD Green, 'Statutory Compliance and Tort Liability: Examining the Strongest Case' (1997) 30 U Mich J of Law Reform 461, 495–6, 499. See further, R Goldberg, *Medicinal Product Liability and Regulation* (n 291), 158–67.

[368] *Wilkes v Depuy International Ltd* [2016] EWHC 3096 (QB), [2017] 3 All ER 589, [97] per Hickinbottom J. In the United States, breach of such standards may be effectively equated with defectiveness: *Elsworth v Beech Aircraft* 691 P 2d 630, 636–7 (Cal, 1984) (FAA standards). The *Restatement, Third, Torts: Products Liability* § 4(a) provides that the non-compliance of a product 'with an applicable product safety statute or administrative regulation renders the product defective [in design or by virtue of inadequate instructions or warnings] with respect to the risks sought to be reduced by the statute or regulation'. This rule is based on the policy that designs and warnings which fail to comply with applicable safety standards established by statute or regulation are defective. Since design and marketing decisions are made before distribution to users and consumers, the manufacturer can defer sale until statutory or regulatory compliance is achieved: see comment d.

[369] *Wilkes v Depuy International Ltd* (n 368), [97] per Hickinbottom J. In the United States, compliance with a relevant government standard is generally regarded as probative of non-defectiveness: *Miller v Lee Apparel Co* 881 P 2d 576, 583–5 (Kan App, 1994) (product complying with federal flammability standards is presumed non-defective unless plaintiff rebuts presumption by proving reasonably prudent manufacturer could and would have taken additional safety standards); *Kaufman v Meditec, Inc* 353 NW 2d 297, 301 (ND, 1984) (statutory rebuttable presumption that a product is non-defective where the alleged defect or designs were in conformity with government standards established for that industry). See also paras 14.148–14.151.

[370] [2000] Lloyd's Rep Med 280 (para 10.09).

[371] ibid, 285.

[372] Miller, *Product Liability and Safety Encyclopaedia*, Div III, para 255.

10.100 Whilst compliance with mandatory standards is relevant, it does not provide an automatic defence.[373] This is consistent with the position in the United States, where the *Restatement, Third, Torts: Products Liability* § 4(b), provides that compliance of a product with an applicable product safety statute or administrative regulation 'is properly considered in determining whether the product is defective with respect to the risks sought to be reduced by the statute or regulation, but compliance does not preclude as a matter of law a finding of product defect'. Subsection (b) reflects the view that the majority of product safety statutes or regulations set only minimum standards, establishing a floor of safety below which product sellers fall only at their peril. They leave open, however, the question of whether a higher standard of public safety should be applied.[374] Thus mere compliance with warning standards or regulations as to warnings, such as those issued by the United States Food and Drug Administration (FDA), may not be sufficient to protect the manufacturer from a claim based on an inadequate warning, if a finder of fact concludes that a more effective warning was necessary. As the Californian Supreme Court stated in *Stevens v Parke, Davis & Co*, 'The warnings required by such agencies may only be minimal in nature and when the manufacturer or supplier knows of, or has reason to know of, greater dangers not included in the warning, its duty to warn may not be fulfilled.'[375]

10.101 It has been suggested that persons generally may be entitled to expect that goods conform with voluntary standards, where they have been widely accepted as establishing an industry norm.[376] This is consistent with the position which would be adopted where the claim is based on negligence.[377] Also, the General Product Safety Directive provides that a product shall be presumed safe when it conforms to voluntary national standards transposing European standards, the references of which have been published in the Official Journal of the European Communities.[378] In addition, in respect of other circumstances, the conformity of a product to the general safety requirement is to be assessed by taking into account, in particular:

(a) other voluntary national standards transposing relevant European Standards;
(b) standards drawn up in the Member State in which the product is marketed;
(c) Commission recommendations setting guidelines on product safety assessment;
(d) product safety codes of practice in force in the sector concerned;
(e) the state of the art and technology; and
(f) reasonable consumer expectations concerning safety.[379]

While such provisions do not apply directly to the Product Liability Directive, it is arguable that they are relevant by analogy, not least because of the explicit reference to reasonable consumer expectations concerning safety.[380] However, it should not be assumed that there is necessarily a complete symmetry between the definition of a 'safe' or non-dangerous

[373] G Howells in Howells (ed), *The Law of Product Liability*, para 4.172, citing the view of an Austrian Court, KG Ried in Innkreis, 17 March 1992, R 51/92.
[374] Comment e.
[375] 507 P 2d 653, 661 (1973).
[376] Howells (n 373), para 4.1724
[377] See para 14.146.
[378] Dir 2001/95/EC [2002] OJ L1 1/4, Art 3(2), paras 19.21–19.59.
[379] Art 3(3), para 19.38.
[380] Art 3(3)(f).

product under Directive 2001/95/EC[381] and that of a defective product under the Product Liability Directive. This lack of complete symmetry is illustrated by the approach taken by the Court of Appeal in *Tesco Stores vPollard*[382] to the role of voluntary safety standards in determining the level of safety persons are entitled to expect. In that case, Laws LJ rejected arguments that a child-resistant closure 'CRC' cap on a dishwasher bottle should comply with a British Standard torque measure, since that standard was not referred to on the product and members of the public could not be supposed to have appreciated that any public authority would have pronounced on the matter.[383] This decision, however, has been subject to some critique due to the perceived failure of the court to give an explanation of its approach to the notion of defect and the emphasis in the decision on the actual perception of the individual claimant in the case, at the expense of an objective test of entitled expectation.[384]

(c) Cost and practicability of a safer design and risk–utility analysis

10.102 As is the case where a claim is based on alleged negligence,[385] the standard of safety which persons generally are entitled to expect will depend in part on the costs and practicability of producing an equivalent product without the characteristic which is alleged to constitute the defect.[386] This is no more than a reflection of the fact that safety is inevitably a relative concept. Thus, and to take an extreme example, no doubt it is the case that a car would be safer for its occupants if the strength of its shell were such that it would not buckle in a high-speed crash and even safer if it were built with bullet-proof glass lest it be driven through areas with a drug-fuelled gun culture. However, it would never be seriously suggested that an ordinary passenger car would be regarded as defective by virtue of the fact that it lacked such characteristics.[387] Obviously, the position would be different if the producer of a toy were seeking to argue that its dangerous condition was justifiable since it was cheap and mass-produced. For similar reasons, in the approach adopted in this work, an analysis of the benefits and disadvantages associated with a product (or risk–utility) cannot realistically be avoided. An

[381] Art 2(b) and (c).

[382] *Tesco Stores v Pollard* [2006] EWCA Civ 1393, [2006] All ER (D) 86.

[383] ibid, [16]. For criticism of this as a 'relatively weak interpretation of consumer expectations', focusing on actual expectations of consumers rather than the legal test that requires consideration of what persons generally are entitled to expect, see G Howells in Howells (ed), *The Law of Product Liability* (2nd edn), para 4.151 and further, M Mildred [2006] J of Personal Injury Law C130–3; cf the argument that the court in *Pollard* should have reasoned that the public were not entitled to expect compliance with British Standards because the CRC was not a regulatory requirement, and therefore failure to comply with the British Standard was not a breach of the regulatory regime: C Webber, 'The Role of Voluntary Safety Standards in Determining the Level of Safety a Person is Entitled to Expect Under the Product Liability Directive' (2006) 23 European Product Liability Rev 21, 22. Cf violation of mandatory safety standards, which can constitute conclusive evidence of a product's defectiveness under the Product Liability Directive: District Court of Düsseldorf Landgericht Düsseldorf, 30 November 2005, 100 144/04, NJW-RR 2006, 1033 ff, noted in S Lenze, 'Product Safety Regulations and Defect' (2006) 24 European Product Liability Rev 20, 21 (who observes that there was nothing in the Düsseldorf court's decision to suggest that the case would have been decided differently in the context of voluntary standards, and that in German and Austrian courts violation of voluntary standards is proper, though not conclusive evidence of a product's defectiveness). Accordingly, Lenze submits that there is a seeming divergence between the national courts of Member States on the role of safety standards under the Product Liability Directive: ibid.

[384] M Mildred [2006] JPIL C130–3.

[385] See paras 14.10, 14.22–14.23.

[386] *Wilkes v DePuy International Ltd* [2016] EWHC 3096 (QB), [2017] 3 All ER 589, [83] per Hickinbottom J.

[387] The example noted in the text was specifically cited by Hickinbottom J to support the potential relevance of cost of a safer design as a circumstance to be taken into account in determining defectiveness: ibid.

obvious contemporary example is in the case of litigation involving the MMR (mumps, measles, and rubella) triple vaccine. Thus even if it were accepted that the vaccine was capable of having severe side effects this should not mean that it is automatically to be adjudged defective. The risks would have to be balanced against the serious risks involved in not immunizing children and in all probability a court would conclude that the benefits of vaccination outweigh the perceived risks. This is equally so whether the issue arises in the context of a dispute between parents as to whether a child should be vaccinated[388] or in product liability litigation.[389] The relevance of such factors is predominant in the area of design defects and is discussed in the following chapter.[390] While an element of doubt may have been cast on them by the decision of Burton J in the hepatitis C litigation, to which we now turn, this has been dispelled by the landmark decision of *Wilkes v DePuy International Ltd* in its establishment that risk–benefit may be a central part of the question of determining defectiveness in strict product liability for the purposes of the 1987 Act[391] This was reaffirmed by Mrs Justice Andrews in *Gee v DePuy International*.[392] She agreed that risk–benefit may sometimes play a legitimate part in in determining defectiveness,[393] particularly in the context of medicinal products. She observed:

> As Hickinbottom acknowledged in *Wilkes*, a pharmaceutical product that is highly beneficial to most patients but in a minority causes death or serious injury for a reason unascertained and unascertainable, may nevertheless be held to lack the appropriate level of safety. Yet in my judgment it would be wrong in principle to exclude from consideration of what level of safety the public is entitled to expect, the benefits that the product could confer, or to confine the relevant benefits to safety benefits, in cases in which those wider benefits might properly have a bearing on that assessment.[394]

Further, in discussing counsel's example of a new chemotherapy drug which had proven advantages over all others on the market, but a rare and serious side effect, she concluded that 'the additional benefit is plainly a relevant circumstance that would assist in the evaluation of safety by reference to the test set out in s.3 of the Act'. For the reasons discussed earlier, this must surely be an unavoidable conclusion in practice.

(4) Apparently irrelevant circumstances

10.103 Although the list of circumstances specified in s 3(2) of the 1987 Act is non-exhaustive, the relevance or otherwise of other suggested circumstances was one of the main issues

[388] As in *Re C (Welfare of Children: Immunisation)* [2003] EWCA Civ 1148, [2003] 2 FLR 1095, where the Court of Appeal strongly supported the decision of Sumner J ([2003] EWHC 1376 (Fam), [2003 2 FLR 1054) holding in favour of the parent advocating immunization; followed in *F v F* [2013] EWHC 2683 (Fam), [9] per Theis J; *LCC v A, B, C and D* [2011] EWHC 4033 (Fam), [15] per Theis J.

[389] *Wilkes v DePuy International Ltd* [2016] EWHC 3096 (QB), [2017] 3 All ER 589, [66] (where Hickinbottom J opined that a particular medicinal product (eg a vaccine) might require consideration of a wider range of risks and benefits, including the public interest). See also *Gee v DePuy International Ltd* [2018] EWHC 1208 (QB), [152].

[390] See paras 11.19–11.31.

[391] *Wilkes v DePuy International Ltd* (n 389), [69]. For criticism that Hickinbottom J focused on the specific patient in discussing the risk-benefit assessment as opposed to balancing 'the global potential benefits and risks of the product', see D Nolan, 'Strict product liability for design defects' (2018) 134 LQR 176, 180. But note that comparing a drug's overall benefits and risks has also been subject to criticism: see R Goldberg, *Medicinal Product Liability and Regulation*, pp 47–8.

[392] [2018] EWHC 1208 (QB).

[393] ibid, [152]–[153].

[394] ibid, [161].

addressed in *A v National Blood Authority*.[395] The background to the case, which involved some 114 claimants, was both complex and tragic. The claimants had been infected with hepatitis C through blood transfusions or blood products from 1 March 1988, usually in the course of undergoing surgery. The source of the infection was not contamination by an outside agent but was, rather, within the donor's blood. The National Blood Authority was legally responsible for the obligations arising from its supply. It was a central feature of the case that during the period of infection the risk was known to the medical profession in general terms, but impossible to avoid either because the hepatitis C virus itself had not been discovered or identified or, at a later stage and until April 1991, because it was undetectable through a screening test in any individual case. Liability under the Product Liability Directive and hence the 1987 Act was, in principle, strict and not dependent on negligence but the issue was whether it extended to a case of this type.

10.104 Although, as noted earlier,[396] there was much common ground between counsel for the opposing sides as to the way in which the test was to be formulated and applied, there were also important differences. According to the claimants, with the elimination of the need to prove negligence questions of avoidability and of what the defendants could and should have done differently did not arise. Neither was it relevant to inquire whether there were any steps or precautions reasonably available or whether any such steps were impracticable or economically unreasonable.[397] The defendants responded by submitting that whereas the conduct of the individual producer was irrelevant, it remained relevant to identify and specify the safety precautions that the public could or would reasonably expect from a producer of such products. So, the submission went, in as much as avoiding the risk was at the time impossible and unattainable, avoidability was a circumstance to be taken into account as the public did not and/or were not entitled to expect 100 per cent clean blood. The most they could legitimately expect was that all legitimately expectable (reasonably available) precautions—or in this case tests—had been taken or carried out.[398]

10.105 After a detailed examination of the issues, which included both citation of academic literature and consideration of the limited assistance to be gained from the case law of other jurisdictions, Burton J concluded, in the context of discussing what he termed 'non-standard' products,[399] that the following circumstances were *not* relevant and so could not be taken into account:[400]

> (i) avoidability of the harmful characteristic—i.e. 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).

He added, in the context of discussing 'standard products', that there was no room in the basket of relevant circumstances for consideration of '(i) what the producer could have done differently; and (ii) whether the producer could or could not have done the same as

[395] [2001] 3 All ER 289. The other main issue was the scope and application of the development risk defence: see paras 13.43, 13.45, 13.104, and 13.113–13.125.

[396] See para 10.59.

[397] [2001] 3 All ER 289, para 32.

[398] ibid.

[399] See further, paras 10.111–10.120.

[400] [2001] 3 All ER 289, para 68 (emphasis in original).

the others did'.[401] On the facts of the case there was no evidence to suggest that the patients knew that there was a risk that blood was, or was likely to be, infected with hepatitis C and the conclusion was that the blood products were defective.[402]

10.106 There is no doubt that the conclusion on this issue is controversial.[403] The following observations may be advanced. First, at least in the generality of cases, there are sound reasons for not considering the avoidability of the harmful characteristic and the practicability of taking such measures where the product is, in Sir Michael Burton's terminology, 'non-standard'.[404] If it were otherwise there would be room for an argument to the effect that it was impossible to screen out the occasional rogue product (car tyre, exploding bottle, contaminated food, etc) even under the most advanced quality control system available. The line between strict liability and liability based on negligence would be obliterated or at least further blurred.[405] Secondly, Sir Michael does not deny the relevance or possibility of a risk–utility analysis even in the case of 'non-standard' products. He postulates, rather, that it operates only where the public has 'full information and proper knowledge' of the benefits to society of the product and then accepts and ought to accept the risk.[406] However, this is a high hurdle to overcome since in such matters the public at large may well have no such information and knowledge.[407] Indeed, while increasing consumer information may be a positive objective in the blood context, 'it is not at all clear that informing the public of the risk is helpful or actually enhances the consumer's choice'.[408]

10.107 It is also entirely possible that with such community-used natural resources as blood a previously uninformed and representative cross-section of the public would agree, after the event and having acquired such knowledge, that a low, but inevitable, risk was consistent with the standard of safety which was legitimately to be expected, albeit that this would not be so in the case of an equivalent risk of exploding bottles or car tyres. It may be objected that basing conclusions as to legitimate public expectations as to safety where there is no pre-existing knowledge of the dangers associated with a product would be unsatisfactory. However, the

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[401] ibid, para 71.

[402] ibid, para 55.

[403] For comment, see eg R Goldberg, 'Paying for Bad Blood: Strict Liability after A v National Blood Authority' (2002) 10 Med L Rev 165; J Stapleton, 'Bugs in Anglo-American Product Liability' 53 SC L Rev 1225, 1249–54 (2002); S Whittaker, *Liability for Products: English Law, French Law, and European Harmonisation* (OUP, 2005), 489–92; G Howells and M Mildred, 'Infected Blood: Defect and Discoverability, A First Exposition of the EC Product Liability Directive' (2002) 65 MLR 95; C Hodges, 'Compensating Patients' (2001) 117 LQR 528.

[404] cf the entirely plausible argument that avoidability is 'is properly relevant to the assessment of a product's defect whether or not it is known to people generally, but it will not conclude it': Whittaker (n 403), 501; and further R Goldberg, 'Paying for Bad Blood: Strict Liability after A v National Blood Authority' (2002) 10 Med L Rev 165, 183; R Goldberg, *Medicinal Product Liability and Regulation* (Hart Publishing, 2013), 28. Both Fairgrieve and Howells concede that Burton J 'may even have gone too far in his concern to avoid slipping back into a negligence-type analysis by totally excluding factors such as avoidability from the list of relevant circumstances and rejecting any scope for the application of the risk:utility analysis': D Fairgrieve and G Howells, 'Rethinking Product Liability: A Missing Element in the European Commission's Third Review of the European Product Liability Directive' (2007) 70 MLR 962, 968.

[405] Not least because the standard of care required by the law of negligence is very high: see eg *Grant v Australian Knitting Mills Ltd* [1936] AC 85 (paras 14.03 and 14.132).

[406] [2001] 3 All ER 289, para 68 (para 10.105).

[407] Indeed, as in other areas, perceptions may be based almost entirely on impressions formed from reading incomplete or simply inaccurate accounts in the press—or reliance on 'junk science' as Sedley LJ described the evidence against immunization advanced in *B (A child)* [2003] EWCA Civ 1148, [36].

[408] Whittaker (n 403), 490–1. See further, R Goldberg, *Medicinal Product Liability and Regulation* (Hart Publishing, 2013), 29.

overall conclusion of Burton J would have been more convincing if he had given some explanation as to why the knowledge of the medical profession treating the patients was not in point. As to this he said no more than that: 'Doctors and surgeons knew, but did not tell their patients unless asked, and were very rarely asked. It was certainly, in my judgment, not known and accepted by society that there was such a risk, which was thus not "sozialadäquat" (socially acceptable) …'[409] He later added: 'There were no warnings and no material publicity, certainly none officially initiated by or for the benefit of the defendants, and the knowledge of the medical profession, not materially or at all shared with the consumer, is of no relevance.'[410]

10.108 There are obvious comparisons to be drawn here with the learned–intermediary rule which operates against the background of a general expectation that doctors and others will explain the nature and extent of risks involved in any given course of action.[411] In general, it is right to confine the rule to this type of case. Yet with infected blood there is an element of unreality in (it seems) requiring the knowledge of the medical profession to be typically shared with consumers before it becomes relevant. The patient may well be unconscious and, in any event, in life-threatening circumstances the choice between running a very small risk of infection and a highly probable death is hardly a meaningful one. It may be that in this respect blood is in a category of its own and that the position would be different where other products such as semen used in artificial insemination[412] and vaccines are concerned. The test is, of course, what persons generally are *entitled* to expect and in the case of blood it can be argued that the entitlement should not depend on the danger having been widely publicized in advance. Nor would it make sense to distinguish between the conscious patient who is warned and an unconscious accident victim for whom no warning is possible.

10.109 *A v National Blood Authority* was considered by Field J in *B v McDonald's Restaurants Ltd*[413] who agreed that the avoidability of the risk of harm through scalding was not a relevant circumstance for the purposes of s 3 of the 1987 Act[414] and that the court was concerned with the safety of the product and not what considerations the producer gave to its safety.[415] Nonetheless, in holding that the hot drinks met the expectation of persons generally, he clearly treated as relevant the fact that serving staff were trained to cap hot drinks securely and were warned in McDonald's Health and Safety Manual that hot drinks could be very dangerous, especially to young children, and were instructed to advise customers if they thought drinks could be a hazard. The overall conclusion that the product was not defective was largely linked to an acceptance of the view that persons generally expect drinks purchased to be consumed on the premises to be hot, but elements of a risk–utility analysis clearly formed at least part of the basis for this conclusion.[416] As Field J stated: '[Persons generally] expect precautions to be

[409] [2001] 3 All ER 289, para 55.

[410] ibid, para 80. Cf *Wilkes v DePuy International Ltd* [2016] EWHC 3096, [106]–[108] (learned intermediary is a relevant circumstance), approved in *Gee v DePuy International Ltd* [2018] EWHC 1208 (QB), [169].

[411] See also Hodges (n 293). For discussion of learned-intermediaries, see paras 12.51–12.66 (strict liability) and paras 14.109–14.114 (liability in negligence).

[412] As in *Kobe ter Neuzen v Korn* (1995) 127 DLR (4th) 577 (para 13.123).

[413] [2002] EWHC (QB) 490.

[414] ibid, para 73.

[415] ibid, para 78.

[416] ibid, paras 77–8, 80. The warnings resulted from a risk assessment of hot drinks causing serious burns which had been undertaken by McDonald's Health and Safety Manager. Yet the omission of any such

taken to guard against this risk but not to the point that they are denied the basic utility of being able to buy hot drinks to be consumed on the premises from a cup with the lid off.' The question of avoidability of the risk of harm was reviewed in *Wilkes v DePuy International Ltd*.[417] While conceding that in considering avoidability there was a danger of unduly focusing on the designer/producer of the product, as opposed to the product itself, Hickinbottom J considered that 'the ease and extent to which a risk can be eliminated or mitigated' was a potential circumstance in the assessment of a product's safety, and thus defect under the 1987 Act.[418] He viewed the approach to avoidability in *B v McDonald's Restaurants Ltd* as being one where it was correctly in the broader context of the risk–utility balance.[419]

F. Application of the Defectiveness Standard to the Alternative and Traditional Defect Taxonomies

(1) General observations

10.110 The definitions of defect in Article 6 of the Directive and s 3 of the Act do not distinguish explicitly between manufacturing or production defects and defects in a product's design or through a failure to warn.[420] Section 9 of Sch 2 to the Competition and Consumer Act 2010 (Cth) (previously s 75AC of the Australian Trade Practices Act 1974 (Cth)) also does not distinguish between these categories of defects. Nonetheless, the Explanatory Memorandum to the Trade Practices Amendment Bill 1992[421] makes this distinction by using the traditional categories of design defects, which relate 'to matters such as the form, structure and composition of the goods', manufacturing defects, relating 'to matters such as the process of construction and assembly', and instructional defects, that is, 'those caused by incorrect or inadequate warnings and instructions'.[422] The Memorandum explains that all these categories of defect are deemed to fall within the meaning ascribed to a defect in s 75AC.[423] The American *Third Restatement* on Products Liability has abandoned the doctrinal labels of strict liability and negligence and established separate functional definitions of liability for the traditional three types of defect taxonomy, namely a manufacturing defect,[424] a design defect,[425] and a warning defect.[426] Notwithstanding the absence of such functional definitions in the Directive and the Act, it has been said that the traditional

assessment would not have been regarded as relevant as the concern was with the safety of the product and not the defendant's conduct: ibid, para 78.

417 *Wilkes v DePuy International Ltd* [2016] EWHC 3096 (QB).

418 ibid, [85], [89], approved in *Gee v DePuy International Ltd* [2018] EWHC 1208 (QB), [166].

419 ibid, [88], approved in *Gee v DePuy International Ltd* [2018] EWHC 1208 (QB), [165].

420 Taschner has noted that: 'When the Product Liability Directive was drafted, there was discussion as to whether or not to differentiate between manufacturing and design defects over liability. The overwhelming opinion in the Council was not to do so' (H-C Taschner, 'Product Liability: Basic Problems in a Comparative Law Perspective' in D Fairgrieve (ed), *Product Liability in Comparative Perspective* (CUP, 2005), 161.

421 Pt VA of the Trade Practices Act 1974, which is concerned with the liability of manufacturers for defective goods, was inserted into the Act by the Trade Practices Amendment Act 1992.

422 Explanatory Memorandum to the Trade Practices Amendment Bill 1992, para 15.

423 ibid.

424 *Restatement, Third, Torts: Products Liability* § 2(a).

425 ibid, § 2(b).

426 ibid, § 2(c).

distinction between manufacturing defects, design defects, and failure to warn defects is 'probably how the courts would tackle the problem in practice'.[427]

(2) An alternative to the classification of defects: Burton J's standard/non-standard product dichotomy in *A v National Blood Authority*

10.111 In line with the traditional taxonomy of product defects,[428] the claimants in *A v National Blood Authority* submitted that the infected blood was a manufacturing defect and that the blood products were thus 'rogue products' or 'lemons', whereas the defendants submitted that if the infected blood were a defect, it was a design defect.[429] However, Burton J concluded, that no assistance could be gained from the 'boxing' or categorization of defects in this way.[430] He preferred the distinction between a 'standard' and a 'non-standard' product which he drew as follows:[431]

> [A] *standard* product is one which is and performs as the producer intends. A *nonstandard* product is one which is different, obviously because it is deficient or inferior in terms of safety, from the standard product: and where it is the harmful characteristic or characteristics present in the non-standard product, but not in the standard product, which has or have caused the material injury or damage.

On the basis of this taxonomy, the claimants submitted that the infected bags of blood were non-standard products. The defendants disagreed, and submitted that they were standard products since 'all blood, derived as it is from a natural raw material, albeit then processed, is inherently risky'.[432] Burton J regarded the latter approach as 'very philosophical', and concluded that the infected bags of blood were 'non-standard' products[433] and went on to develop his own steps for consideration of Article 6 of the Directive, which were related to his standard/non-standard distinction.

10.112 The first step was to identify the harmful characteristic which caused the injury.[434] Since it was clear that the hepatitis C virus in the whole blood was the harmful characteristic which caused the patients to contract hepatitis, there was no difficulty. But it seems that one would have to ascertain the factual causal link between defect and damage before the first step could be satisfied. Burton J is thus identifying the primacy of causation before any investigation of defect can take place.[435] This could result in a vigorous contest of

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[427] A Stoppa, 'The Concept of Defect in the Consumer Protection Act 1987: a Critical Analysis' (1992) 12 Legal Studies 210, 211.

[428] This section is based on the second-named author's commentary in R Goldberg, 'Paying for Bad Blood: Strict Product Liability after A v National Blood Authority' (2002) 10 Med L Rev 165, 179–87.

[429] *A v National Blood Authority* [2001] 3 All ER 289, paras 36, 39.

[430] ibid, para 39.

[431] ibid, para 36 (emphasis in original).

[432] ibid, para 37.

[433] ibid, para 65. Cf GW Conk, 'The True Test: Alternative Safer Designs for Drugs and Medical Devices in a Patent-Constrained Market' 49 UCLA L Rev 737, 772–3 (2002) who argues in an analogous context involving haemophiliacs that such cases involve design and not manufacturing defects since: 'Every batch of the concentrated blood proteins was made without departure from its intended design.'

[434] [2001] 3 All ER 289, para 67. Dir 85/374/EEC, Art 4, provides that: 'The injured person shall be required to prove the damage, the defect and the causal relationship between the defect and the damage.'

[435] The view expressed in the text was noted by Hickinbottom J as demonstrating a self-evidently circular approach: 'proof of a causal connection between defect and damage cannot rationally, or even conceptually, be attempted without ascertainment of whether there is a defect, and, if so what that defect might be': *Wilkes v DePuy International Ltd* [2016] EWHC 3096 (QB), [58].

the causation issue at a preliminary stage and could also involve a requirement that the claimant prove the respect in which the product is alleged to be defective with a relatively high level of specificity. The problems of adopting any such approach have already been noted.[436] Accordingly, such an early focus on causation has thus been judicially criticized as 'self-evidently circular' and 'a distraction from the true focus of the Directive and the Act, which is on defect'.[437] This criticism was affirmed in *Gee v DePuy International Ltd*,[438] where the claimants had sought to adopt Burton J's approach in *A* to characterize a potentially harmful characteristic of a product during normal use (there, the propensity of a metal-on-metal prosthesis to shed metal debris) as a defect.[439] As Mrs Justice Andrews put it: 'It involves reasoning backwards from the harm (or incidence of harm) to find a defect in a normal characteristic of the product, even though the harm may have occurred without the product being defective. It ignores entirely the central question of the expectation of safety that persons were entitled to have of the product.'

10.113 Burton J then stated that to establish whether there was a defect within the meaning of Article 6, 'the next step will be to conclude whether the product is standard or non-standard'.[440] He adopts this taxonomy, notwithstanding the absence of such an approach in European Community or American law. In the absence of admission by the producer, he said that this would be done 'by comparing the offending product with other products of the same type or series produced by that producer'.[441] If the respect in which the offending product differs from the series includes the harmful characteristic, then it is a non-standard product. Conversely, if the offending product does not so differ, or if the respect in which it differs does not include the harmful characteristic, but all the other products, albeit different, share the harmful characteristic, then it is to be treated as a standard product.[442] Thus, for example, in the case of thalidomide, the harmful characteristic would appear to be the drug structure itself, and since the drug as a whole shared the harmful characteristic, it would appear to be a standard product. On the other hand, hepatitis C-infected blood is to be treated as a non-standard product since the harmful characteristic was not present in all bags of blood.

10.114 There are several points to be made about this attempt to shift away from the type of defect (manufacturing, design, or a failure to warn) to the type of product (standard or non-standard). First, as with any such distinction it may lead to difficulties of application in practice. Suppose that, as in a leading American case,[443] a bread delivery van collides with another vehicle and that an aluminium safety hasp breaks, releasing bread trays, which, in turn, propel the driver through the windscreen. On such facts the application of the standard or non-standard distinction would presumably turn on whether the hasp's lack of tolerance to the force of a collision was attributable to the use of an insufficiently strong type of metal (standard) or a flaw within the metal used in the individual van in question

[436] See paras 10.06–10.15.
[437] *Wilkes v DePuy International Ltd* (n 435), [58].
[438] *Gee v DePuy International Ltd* [2018] EWHC 1208 (QB), [106]–[108],
[439] ibid, [101]–[103].
[440] [2001] 3 All ER 289, para 67.
[441] ibid.
[442] ibid.
[443] *Cronin v JBE Olson Corp* 104 Cal Rptr 433, 501 P 2d 1153 (1972) (Cal Sup Ct).

(non-standard).[444] The same type of distinction has to be drawn in the more traditional distinction, now formally enshrined in the *Third Restatement*.

10.115 Secondly, although Burton J was at pains to avoid the traditional 'boxing' or categorization of defects, it is difficult to see how his own classification differs from it, other than in terminology. Thus 'non-standard' products are substituted for manufacturing defects, 'standard products' are associated with design defects, 'non-standard' products appear to be essentially the same as products which have manufacturing defects, and 'standard products' are those with inherent design flaws. Possibly he was reluctant to describe as a manufacturing defect a situation where the defect was not positively created by a manufacturing process, but involved, rather, a failure to eliminate an infection in a 'natural' product.[445] However, the expression 'manufacturing defect' would usually be regarded as a convenient shorthand for describing both situations.[446]

10.116 Thirdly, it is possible that the suggested terminology was adopted in an attempt to avoid the terminology of § 2 of the *Third Restatement*, with its avowed emphasis on a risk–benefit approach, and its rejection of the consumer expectation approach of § 402A of the *Second Restatement*, in assessing defectiveness.[447] Unfortunately, no guidance is to be gained from the *Third Restatement* in respect of blood or blood products, other than the fact that they are expressly excluded from the rules of the *Restatement* under § 19(c). In any event, it seems clear that, at least in respect of non-standard products, he was seeking to minimize the extent to which a risk–benefit analysis could enter into the assessment of defectiveness. Thus he rejects the view of Lord Griffiths et al that although English judges would not overtly adopt a risk–benefit approach, they would 'as an educated response to the facts of a particular case undertake a balancing exercise of an analogous kind'.[448] In Sir Michael's judgment this would, it seems, be a permissible exercise only in the context of deciding 'whether—with full information and proper knowledge—the public does and ought to accept the risk'.[449] It is only with such information and knowledge that legitimate public expectations would be shaped by a risk–benefit assessment.

10.117 Fourthly, in addressing his approach to 'standard' products and the assessment of defectiveness, Burton J said:[450]

> If a standard product is unsafe, it is likely to be so as a result of alleged error in design, or at any rate as a result of an allegedly flawed system. The harmful characteristic must be

[444] The latter appears to have been the position since the hasp was made from porous and 'a very, very bad piece of metal': ibid, 437.

[445] The distinction is seen as important by Prof Stapleton in her illuminating discussion of pre-manufacture generic infection cases: see 'Bugs in Anglo-American Products Liability' 53 SC L Rev 1225, esp 1232–4 (2002).

[446] See eg *Tarling v Nobel* [1966] ALR 189 (ACT Sup Ct) (chicken bone in sandwich). Consider also such examples as fish contaminated by a heavy metal, worms in a tin of spinach, or slugs in a bag of lettuce. For criticism of the distinction between standard and non-standard products as problematic, see S Whittaker, *Liability for Products: English Law, French Law, and European Harmonisation* (OUP, 2005), 491.

[447] For discussion of the *Third Restatement*, see J Stapleton, 'Restatement (Third) of Torts: Products Liability, an Anglo-Australian Perspective' 39 Washburn LJ 363, 376 (2000).

[448] Rt Hon The Lord Griffiths, P de Val, and RJ Dormer, 'Developments in English Product Liability Law: A comparison with the American System' 62 Tulane L Rev 353, 382 (1988). For Burton J's rejection of the approach, see [2001] 3 All ER 289, para 69.

[449] ibid, para 68, cited above, para 10.105.

[450] ibid, para 71.

> identified, if necessary with the assistance of experts. The question of presentation/time/circumstances of supply/social acceptability etc will arise as above. The sole question will be safety for the foreseeable use. If there are any comparable products on the market, then it will obviously be relevant to compare the offending product with those other products, so as to identify, compare and contrast the relevant features. There will obviously need to be a full understanding of how the product works—particularly if it is a new product, such as a scrid,[451] so as to assess its safety for such use. Price is obviously a significant factor in legitimate expectation, and may well be material in the comparative process. But again it seems to me there is no room in the basket: for: (i) what the producer could have done differently; and (ii) whether the producer could or could not have done the same as the others did.

The above passage is of interest for a number of reasons. It links the notion of a 'standard' product to alleged errors in design and acknowledges the obvious need to compare the product with 'comparable products on the market', thus pointing to a reasonable alternative design approach to design defects, as in § 2(b) of the *Third Restatement*.[452] However, in the *Restatement*, and probably more generally in the United States, the 'reasonable alternative design' approach is accorded primacy and at the expense of an approach based on consumer expectations.[453] Price is also seen as a significant factor in legitimate expectation and may be material in the comparative process.[454] However, there is, in Burton J's judgment, no room for consideration of (a) what the producer could have done differently, and (b) whether the producer could or could not have done the same thing as the others did.

10.118 An important question which arises from the above is what is envisaged as being excluded from consideration. Clearly, it cannot be a comparison with the relevant safety features of comparable products. Indeed, these are expressly included, as is price. Nor, in the case of standard products, is there any *expressly*[455] any exclusion of a risk–utility analysis as an element shaping legitimate consumer expectations.[456] Hence the answer must be a

[451] The word 'scrid' was coined to describe a new product of which the public had no actual expectation: ibid, para 31.

[452] S 2(b) provides that: '[A product] is defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the alternative design renders the product not reasonably safe.'

[453] See J Stapleton, 'Restatement (Third) of Torts: Products Liability, an Anglo-Australian Perspective' 39 Washburn LJ 363, 376 (2000). The adoption of the 'reasonable alternative design standard' in 'classic design defect cases' reflects the consensus view, and consumer expectation is regarded as an inappropriate standard for defectiveness in such cases: JA Henderson Jr and AD Twerski, 'Achieving Consensus on Defective Product Design' 83 Cornell L Rev 867, 872, 879, 901, 920 (1998). Classic design defect cases are 'the majority of design cases that do not involve product malfunctions, violations of safety regulations or egregiously dangerous products': JA Henderson Jr and AD Twerski, 'What Europe, Japan and other Countries can learn from the new American Restatement of Products Liability' 34 Texas Int LJ 1, 17 (1999). Prof Stapleton, however, regards the classic design defect category as a residuary one, which has been overemphasized by its primacy in § 2(c): Stapleton, 386.

[454] cf the conclusion that the sales and pricing structure of the medicinal product Epilin and profit made from it could not 'sensibly inform the question' whether the product was defective at the time of supply: *Claimants Registered in the GLO v Sanofi-Synthelabo Ltd* [2009] EWHC 95 (QB), [16]i per Burnett J. Accordingly, an application by the claimants to adduce expert evidence of a forensic accountant concerning the worldwide value of sales of Epilim and its profitability since it first went onto the market, together with evidence of the pricing structures in place which governed sales to the NHS, was rejected: ibid, [28].

[455] R Goldberg, *Medicinal Product Liability and Regulation* (Hart Publishing, 2013), 36.

[456] This is mentioned only as an item (number (iii)) under the heading 'Non-standard products', but it does not appear under the heading 'Standard products': see, respectively, [2001] 3 All ER 289, paras 68 and 71.

comparison with what might have been done differently in a respect which would otherwise have been relevant in the discovery of the condition which gave rise to the danger. This was, of course, the very issue in the hepatitis C litigation itself and it was seen by Burton J as being the province of the very narrow development risk defence afforded by Article 7(e) of the Directive and s 4(1)(e) of the 1987 Act.[457] In other respects, evidence as to what the producer could or could not have done differently in designing the product should be capable of being adduced both by the producer and by the claimant.[458]

10.119 Finally, the point should be made that it is doubtful whether a reasonable alternative design approach could be of assistance in respect of medicinal products or whole blood products. As Professor Michael Green has noted: 'Unlike durable goods, drugs cannot be designed in an alternative fashion, at least not in the light of current technological capabilities.'[459] In a similar style, Professor David Owen submits that a drug's design 'normally' cannot be changed to improve its safety.[460] The *Restatement, Third, Torts: Products Liability* avoids the reasonable alternative design test of § 2(b) and adopts a so-called net benefit test for pharmaceuticals and medical devices in § 6(c).[461] Nevertheless, in Green's view, it is arguable that there are two exceptions to the rule that drugs are not amenable to design modification to build in more safety.[462] The use of bioengineering to design drugs to improve their benefit–risk ratio is a further possible exception.[463] However, there appears to be no reasonable alternative to whole blood.[464] So-called recombinant anti-haemophilic globulin (AHG) for the treatment of haemophiliacs is no substitute. Moreover, there remains no

[457] [2001] 3 All ER 289 para 64. For discussion of the defence, see paras 13.33–13.110.

[458] The position of the claimant who wishes to adduce evidence of 'avoidability' is discussed in paras 70 and 72 of the judgment. Again, it is not entirely clear what evidence is excluded. In principle, however, on Burton J's approach, evidence which goes to discoverability is outwith the scope of s 3(2) of the Act and can be used only in negligence or presumably to negate a development risk defence. But, on the position adopted in the text, the claimant may lead evidence of alternative safer designs, etc to show what was practicable.

[459] MD Green, 'Statutory Compliance and Tort Liability: Examining the Strongest Case' 30 U Mich J L Reform 461, 471 (1997); MD Green, 'Prescription Drugs, Alternative Designs and the Restatement (Third): Preliminary Reflections' 30 Seton Hall L Rev 207, 208–11 (1999).

[460] DG Owen, 'Dangers in Prescription Drugs: Filling a Private Law Gap in the Healthcare Debate' 42 Connecticut L Rev 733, 739 (2010).

[461] S 6(c) provides: 'A prescription drug or medical device is not reasonably safe due to defective design if the foreseeable risks of harm posed by the drug or medical device are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for any class of patients.'

[462] MD Green, 30 U Mich J L Reform 461, 474 (1997); MD Green, 30 Seton Hall L Rev 207, 210–12 (1999). The first exception is that of combination drugs. Since they contain multiple active ingredients they can be designed differently by removing or adding active ingredients. Green gives an example of Fiorinal, a prescription drug for headaches, which originally contained a barbiturate, aspirin, caffeine, and phenacetin (an analgesic). In 1981, the phenacetin was removed from the market because of safety concerns. Fiorinal was redesigned without the phenacetin component. The second exception is that of recommended dose. Experience with a drug, eg an oral contraceptive, may reveal that the same therapeutic benefits could be obtained with a lower dose, and that reducing the dose decreases the risk of adverse effects: see *Brochu v Ortho Pharmaceutical Corp* 642 F 2d 652 (1981), where absence of reference in a package insert to finding a 'positive correlation … between the dose of oestrogen and the risk of … cerebral thrombosis' was held to be a ground for upholding a jury finding that the manufacturer's warnings were factually inaccurate and that the pill was defective and unreasonably dangerous: ibid, 655, 658–9.

[463] MD Green, 30 Seton Hall L Rev 207, 210–12 (1999).

[464] Any biotechnologically produced blood products, such as recombinant AHG (anti-haemophilic globulin) only concern plasma products.

effective method of inactivating the hepatitis C virus or AIDS virus in whole blood or non-plasma products, for example red blood cells, white blood cells, and platelets, despite the fact that physical heat or chemical detergents can inactivate the virus in plasma products.[465] It has therefore been argued that it is difficult to see how Burton J's standard/non-standard product dichotomy adds to any clarity in establishing a taxonomy of defects in the context of medicinal products.[466] The standard/non-standard product dichotomy was disapproved of as an 'unnecessary and undesirable' classification by Hickinbottom J in *Wilkes v DePuy International Ltd*.[467] Whether a particular product was within the producer's specification, and compliant with relevant standards, could be relevant circumstances in determining the level of safety persons generally are entitled to expect, but 'to raise the distinction to a rigid categorization' was 'positively unhelpful and potentially dangerous'.[468] This rejection of the standard/non-standard dichotomy was affirmed by Mrs Justice Andrews in *Gee v DePuy International Ltd*.[469] In her view, the problem with the standard/non-standard dichotomy was its inherent rigidity.[470] Such a rigid characterization 'dictates what circumstances are and are not to be considered when making the assessment of safety'.[471]

10.120 In the light of the problems associated with the standard/non-standard product dichotomy, and the disapproval of it in recent case law,[472] it is important to examine the application of the defectiveness standard in the context of the traditional defect taxonomy of manufacturing or production defects, design defects, and defects arising through a failure to warn. Both manufacturing or production defects and design defects are discussed in the following chapter and defects associated with a failure to warn are discussed in chapter 12.

[465] See GW Conk, 'Is there a Design Defect in the Restatement (Third) of Torts: Products Liability?' 109 Yale L Rev 1087, 1109 (2000), citing Institute of Medicine, *HIV and the Blood Supply: An Analysis of Crisis Decisionmaking* (National Academy Press, 1995), 5, 81.

[466] R Goldberg, *Medicinal Product Liability and Regulation* (Hart Publishing, 2013), 37. Cf D Nolan, 'Strict product liability for design defects' (2018) 134 LQR 176, 177, 180-181 (supporting the standard/non-standard distinction) and J Eisler, 'One step forward and two steps back in product liability: the search for clarity in the identification of defects' (2017) 76 CLJ 230, 235.

[467] *Wilkes v DePuy International Ltd* [2016] EWHC 3096 (QB), [94].

[468] ibid. In terms of the subject of the claim, Hickinbottom J noted that counsel for the claimant had sought to persuade him that the C-stem was non-standard in terms of Burton J's definition, and that he should thus omit any consideration of risk–utility. He considered this to be 'an arid exercise, … a distraction from the exercise that the court is required to undertake, namely consideration of the appropriate level of safety taking into account all relevant circumstances': ibid, [95]. While a particular specimen of a product was out of specification (or otherwise 'non-standard'), the risk–benefit of an in-specification product was unlikely to have much if any weight, but he would not advocate a rule of law that it must have none: ibid.

[469] *Gee v DePuy International Ltd* [2018] EWHC 1208 (QB), [154]–[160].

[470] ibid.

[471] ibid, [160].

[472] *Wilkes v DePuy International Ltd* [2016] EWHC 3096 (QB), [94]; *Gee v DePuy International Ltd* (n 469), [154]–[160]. Previously, there had been uncertainty as to whether the dichotomy would be followed. While the basic principles of legitimate expectation in *A* were applied in *B (A Child) v MacDonald's* [2002] EWHC 490 (QB), no reference was made to the standard/non-standard product dichotomy.