

# A personal (and selective) introduction to product liability law

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*"If you think you understand quantum mechanics, you don't understand quantum mechanics."*

(attributed to Richard Feynman)

*"Men in their forties are like the New York Times Sunday crossword puzzle: tricky, complicated, and you're never really sure you got the right answer."*

(*"Sex & the City"*, Carrie)

Product liability law, like quantum mechanics, can be impossible to understand. Like dealing with men in their forties (at least according to Candace Bushnell), applying the product liability directive<sup>1</sup> can leave you unsure whether you have the right answer. The problems arise, first, from the conceptual difficulties faced by tort lawyers in leaving far behind their homely concepts of breach of duty and "but for" causation and in entering the alien world of "no fault" liability and direct causation. Secondly — and remarkably for a law which has been in force for 26 years — there is little black letter law on the meaning and application of the key concepts of the product liability directive. Thirdly, much in a particular case ultimately will turn on the discretion of the deciding tribunal. Thus, this limited judicial interpretation of the law and the wide judicial discretion at its heart creates that terror for lawyers advising on any subject: lack of certainty.

Fourthly, coming relatively fresh to product liability law in 2006, I was initially intimidated by the vast array of analysis and exotic labelling applied to the concepts underpinning it. I was next struck, however, by the jarring discrepancy between the vast plethora of academic analysis and that dearth of solid legal precedent. Studying product liability law is like a disappointing pass-the-parcel game from my childhood: one enthusiastically tears away layer after interminable layer of prettily patterned academic papers finally to reveal the meagre "prize" of only one meaningful judgment at its centre.

There are, nevertheless, two plus points for new students of the topic. First, to get on top of the UK black letter law on the subject quickly one need only read that judgment — *A v National*

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<sup>1</sup> Product Liability Directive 1985/374 (purportedly) brought into English law by the Consumer Protection Act 1987

*Blood Authority*<sup>2</sup> (all the time noting that it is a non-binding first instance decision). Secondly, what is refreshing about the judgment itself is that it shows that the English judiciary can be both bold and intellectually rigorous in seeking to give real effect to the radically different – and alien – legal approaches at the heart of the product liability directive. It thereby skewered the conservative expectations and stereotypes expressed beforehand by the chattering commentariat.

This paper cannot hope to set out all the key aspects of product liability law nor — for the reasons set out above — can it even set out firm guidance on the applicable law it deals with. It is intended simply as a brief overview of the area with my personal and highly selective observations on certain aspects of the jurisprudence.

### **The balance struck between consumers and manufacturers: Uncertainty 28 years down the line**

After lengthy debate between 1976 and 1985 the Council Directive 85/374 on liability for defective products was adopted. The UK was the first member state to implement the Directive through the Consumer Protection Act 1987 (“CPA 1987”). Two – at times conflicting – principles lay behind the introduction of the Directive. The first was a desire to ensure that consumers could be afforded far easier legal protection from injury caused by defective products following disasters such as Thalidomide. The second was the desire to ensure that EU manufacturers operated on a level product safety playing field: there would be a unified standard so that products in one country were not judged by a lower – or higher – safety standard to those in another. This seems a legitimate price for manufacturers to pay for unhindered access to a unified market of over 500 million people.

Whilst (correctly) the Directive is often seen as introducing generally higher safety standards across the EU, the importance attached to ensuring a level economic playing field means that countries are prevented from imposing higher standards than required by the unifying Directive — and in fact may have to reduce the consumer protection afforded to their citizens prior to its implementation. France long tarried over introducing the Directive because of their legislators’ fear that it would lower consumer protection in the French market. Their fears were confirmed when the European court ruled that their initial attempt to implement the Directive was unlawful

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<sup>2</sup> [2001] Lloyd’s Rep Med 187, Burton J (“*A v NBA*”).

because it imposed wider liabilities than required by the Directive. The Directive was intended fully to harmonise the rules on liability for defective products across the European Union, so that national rules that hinder such an effect were not allowed.<sup>3</sup> It “*aims not only to avoid differences in levels of consumer protection, but also to ensure undistorted competition between traders and to facilitate the free movement of goods.*”<sup>4</sup>

The emotive and key driver for the consumer protection element of the Directive was the Thalidomide disaster: this led many to consider that workable protection for consumers could only be obtained through no fault laws which made recovering damages for defective products far simpler – and less costly.<sup>5</sup> Ironically, however, the Directive itself is silent on the appropriate legal protection of those injured in the womb: protection of those born with life-long disabilities is left to the vagaries of complex national legislation.<sup>6</sup> Further, the rosy hopes of the Directive’s progenitors that a low-cost regime with simple proof of product defect would emerge have been completely dashed. The machinations of parties to product liability cases have created some of the most complex litigation ever to hit the courts. The absence of clear statutory rules and a lack of decided case law have unfortunately led the Directive to be almost wholly ineffectual in key product areas. That key concepts such as “defect”<sup>7</sup> remain so shrouded in mystery is testament to the under-developed nature of the jurisprudence. It can no longer be hoped that adequate clarification of the Directive will come through litigation: for the Directive to secure its key objective of meaningful consumer protection will require EU legislators to act to fill the jurisprudential lacunae.

### Sources of the law

Although the CPA was in force from 1988, there have been few reported higher court decisions in relation to it. The key source of the law is the Product Liability Directive itself. Whilst the Consumer Protection Act 1987 (“CPA”) represents the UK implementation of the Directive, the approach of

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<sup>3</sup> *Commission of the European Communities v France* Case C-52/00 [2002] E.C.R. I-3827; *Commission v Greece* [2002] ECR I-3879 and Case C-183/00 *González Sánchez* [2002] ECR I-3901.

<sup>4</sup> *Somer v Dalkia France* Case C-285/08, paragraph 29

<sup>5</sup> For example, Germany in response to the Thalidomide tragedy introduced their own strict liability regime for the pharmaceutical industry: Drug Act (*Arzneimittelgesetz*) 1983

<sup>6</sup> See the concluding section below

<sup>7</sup> Discussed in detail below.

the European court in *European Commission v UK*<sup>8</sup> was to say that the UK Courts would have to interpret the CPA in line with the Directive. Burton J in *A v NBA* referred to the CPA only in passing and in deciding the case focused exclusively on interpreting the Directive itself. In analysing the Directive it should be noted that European jurisprudence permits – if not requires – that a liberal approach is taken to the assessment of its underlying purpose. Thus care must be taken to review the Recitals to the Directive and the *travaux préparatoires* in researching a particular approach to the interpretation of an Article.<sup>9</sup> Case law from other Member States can also assist. It may provide useful persuasive authority, as noted by Burton J. It is also consistent with the approach of the Directive of total harmonization and a unified pan-European approach.

### **Defect: Article 6**

Article 6 of the Directive sets out the test for “defect”:

*“a product is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account...”*

The Sixth Recital of the Directive states that

*“to protect the physical well-being and property of the consumer, the defectiveness of the product should be determined by reference not to its fitness for use but to the lack of the safety which the public at large is entitled to expect”.*

The Directive makes clear that:

*“A product shall not be considered defective for the sole reason that a better product is subsequently put into circulation.”*

The CPA (unhelpfully) sets out a more complicated two-stage definition for “defect”:

*3(1): “there is a defect in a product for the purposes of this Part if the safety of the product is not such as persons generally are entitled to expect”*

*3(2): “in determining for the purpose of subsection (1) above what persons generally are entitled to expect in relation to a product all the circumstances shall be taken into account...”*

I would propose, for the reasons set out above, that there should be a laser focus on the Directive’s definition of “defect” and that the CPA wording should be largely ignored. Nevertheless, the exact meaning of defect in the Directive — and its applicability in wide-ranging situations — has remained

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<sup>8</sup> [1997] AER (EC) 481 : the statute must be interpreted “in the light of the wording and the purpose of the Directive so as to achieve the result which it has in view” (paragraph 38).

<sup>9</sup> For example, see *Von Colson and Kamann* Case C-14/83 [1984] E.C.R. 1891

elusive. In 2003 Lovells in a report for the EU<sup>10</sup> noted that in light of the many “unresolved questions” about the concept of “defect”, it might be suggested that:

*“the concept could be more precisely defined in the Directive itself, so as to clarify the issues that remain controversial. Some would argue, however, that it is better not to attempt to define the concept with too much precision, not least because this could restrict the ability of judges to deal with matters on a case-by-case basis. It might be expected however, that, as experience of the Directive in litigation grows, there will emerge a body of case law that will provide a guide to the interpretation of this fundamental concept. It might be expected that some aspects of the concept of “defect” will come to be clarified in due course by the ECJ”.*

Unfortunately that clarification has not come. *A v NBA* provides the best starting-point for how English courts may approach the concept in the future, but it must be noted that Burton J’s decision was only first instance<sup>11</sup> and has since been the subject of some criticism by commentators<sup>12</sup> and sustained full frontal attack by defendants in product liability litigation.<sup>13</sup>

### **Defect: “standard” versus “non-standard” products**

Further, *A v NBA* identifies the appropriate definition to be applied in the context of non-standard blood products (that is, contaminated blood which caused Hepatitis C in recipients). There are many definitional labels proposed in product liability law commentaries: some can be forgotten or ignored as not being relevant to EU law; others are essential to understanding the actual jurisprudence. The “standard”/“non-standard” divide resides unequivocally in the latter category. A “standard product” is one “which is and performs as the producer intends”. A “non-standard product” was defined by Burton J as:

*“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*

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<sup>10</sup> Lovells, Product liability in the European Union, 2003 pp48-49

<sup>11</sup> At first instance in the oral contraceptive group litigation (*XYZ v Schering Health Care Ltd* [2002] EWHC 1420 (QB)) *A v NBA* was not mentioned because the case was decided on a preliminary causation issue. On appeal no reference was made to *A v NBA* in the following CPA cases: *O’Byrne v Aventis Pasteur MSD Ltd* [2008] UKHL 34 & [2010] UKSC 23 (limitation issue); *Tesco v Pollard* [2006] EWCA Civ 393 and *Piper v JRI (Manufacturing) Ltd* [2006] EWCA Civ 1344 and *Ide v ATB Sales Ltd* [2008] EWCA Civ 424). In the recent Scottish appeal in *McGlinchey v General Motors UK Ltd* [2012] CSIH 91, *A v NBA* was cited by the Inner House in reviewing the arguments of the pursuer, but was not explicitly approved by the court.

<sup>12</sup> For example, the considered review by Goldberg: “*Paying for Bad Blood: Strict Product Liability after the Hepatitis C Litigation*” (2002) 10 Med, L Rev 165

<sup>13</sup> But note Field J’s analysis of s3 and s4 of the CPA and articles 6 and 7 of the Directive: *B (A Child) v McDonald’s Restaurants Ltd* [2002] EWHC 490 (QB).

*in the non-standard product, but not in the standard product, which has or have caused the material injury or damage.”<sup>14</sup>*

The contaminated blood products in the *A v NBA* case were non-standard products: only a few bags of blood used for transfusion actually were contaminated with the Hepatitis virus. It can be – and has been – argued that a different approach must be taken with different categories of products (in particular, pharmaceuticals) and with all “*standard products*”. Burton J in *A v NBA* accepted that:

*“the resolution of the problem of the defective standard product will be more complex than in the case of a non-standard product....”<sup>15</sup>*

However, he did consider that the rubric laid out in *A v NBA* with its focus on safety and use, and clearly defined *permissible* circumstances would provide the bedrock for the determination of defect in subsequent cases concerning “*standard products*”:

*“It may be that, if I am right in my analysis, and if it is followed in other cases, problems may arise in the consideration of a standard product on such basis, but I do not consider any such problems will be insurmountable if safety, use and the identified circumstances are kept in the forefront of consideration”<sup>16</sup>*

### **“Triad of Defects” & “Risk/Utility”: Rejection of US concepts**

Much academic analysis has focussed on a triad of potential defects (manufacturing, design and information). This is an approach developed principally in US case law and set out in the *Restatements of the Law, Third, Torts: Product Liability* at section 2:

*“A product is defective when, at the time of sale or 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 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;*

*(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 by the seller or other distributor, or a predecessor in the commercial chain of*

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<sup>14</sup> paragraph 36

<sup>15</sup> paragraph 73

<sup>16</sup> paragraph 73

*distribution, and the omission of the instructions or warnings renders the product not reasonably safe.”*

In relation to prescription medicine and medical devices the Restatement goes on to clarify by stating that:<sup>17</sup>

*“(c) 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.”*

US case law supported the use of a risk/utility analysis when assessing whether a product should be deemed defective. Whether risk/utility should apply to the European definition of “defect” was central to the argument in *A v NBA*. Burton J was clear that Article 6 did not allow a “risk/utility” approach to be involved in the assessment of defect.<sup>18</sup> Further the defendant’s — and commentators’ — attempts to shoehorn the European concept of defect into a “*triad of defects*” should be rejected. The Directive made no attempt to categorise defects in that way and fitting a particular case into one of those “*boxes*” gave absolutely no assistance in performing the task required by Article 6 of determining whether the product was defective.<sup>19</sup> The manufacturing, design and information defect labels were consigned by Burton J to the EU definitional dustbin.<sup>20</sup>

### **Defect: “legitimate expectation of safety”**

Burton J brought the question of “defect” back to basics. The question to be posed was whether the product in question met the “*legitimate expectation of safety*” for that product. This was the consumer expectation of safety as objectively interpreted by the court under article 6 of the

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<sup>17</sup> Section 6

<sup>18</sup> Paragraph 35.i

<sup>19</sup> Paragraphs 39-41

<sup>20</sup> Nonetheless, the concepts of risk/benefit have surfaced in decisions of other European courts. For example, the first Civil Chamber of the French *Cour de Cassation* (26 Sept 2012 No. 11-17738, *consorts X*) appeared implicitly to accept that risk/benefit in the context of a vaccination for hepatitis was a permissible part of the relevant circumstances. In Germany, the Hamm *Oberlandesgericht* (equivalent to a court of appeal) held, in *NJW-RR 2003, 1382* (18 June 2003), another vaccine case, that the product was not defective by design due to (i) its positive risk/benefit analysis, (ii) a positive recommendation for use from the Commission for Vaccination at the Koch Institute, and (iii) the lack of any reasonable alternative.

Directive. The court was concerned with what legitimately was to be expected in terms of safety.

This is supported by the Sixth Recital which states:

*“Whereas to protect the physical well-being and property of the consumer, the defectiveness of the product should be determined by reference not to its fitness for use but to the lack of safety which the public at large is entitled to expect; whereas the safety is assessed by excluding any misuse of the product that is not reasonable in the circumstances.”*

This did not impose absolute safety or absolute liability.<sup>21</sup> The question of defect was in *Burton J’s* view resolved by determining the safety, or the degree or level of safety or safeness which persons generally are entitled to expect and that was not an individual assessment: it was the expectation of persons generally, or the public at large.

The term *“legitimate expectation”* adopted in *A v NBA* has been attacked by commentators<sup>22</sup> and defendants. Professor Stapleton has suggested that the focus should be on what the consumer is **entitled** to expect. She has used the term *“legal entitlement”*.<sup>23</sup>

In *Abouzaid v Mothercare*<sup>24</sup> the Court of Appeal considered the case of a claimant who had been injured when the buckle of an elasticated fastening system on a pushchair hit him in the eye. He was awarded damages at first instance on the basis that (i) there was a failure to provide instructions; (ii) the product was of an unsafe design because it could not be secured in safety; (iii) there was a risk that a person using the product quite properly, especially younger children, could suffer serious injury, as happened; and (iv) there was an obvious risk or danger which the defendant, as manufacturer, should have appreciated.

The Court of Appeal dismissed the defendant’s appeal. The case turned on whether a product was *‘defective’* and it was held that the product was to be judged by the standard persons were generally entitled to expect in all the circumstances and those expectations were to be determined by the court. The term *“legitimate”* expectation was not used. The product was considered defective however as it was supplied with a design that permitted the risk to arise

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<sup>21</sup> Paragraphs 31 (i), (iv)-(vii)

<sup>22</sup> However other commentators have praised the use of ‘legitimate expectation’: see Howells et al, *The Law of Product Liability* (2<sup>nd</sup> Ed), p.338. It also accords most closely with several other language versions of the Directive which as official versions can be used as a guide to interpretation.

<sup>23</sup> Professor Stapleton, *Restatement (Third) of Torts: Products Liability, an Anglo-Australian Perspective* 39 Washburn LJ 363, 377 (2000) and *Liability for Drugs in the US and EU: Rhetoric and Reality*, (2007) 26 Rev.Litig. 991-1033 at 1008

<sup>24</sup> LTL 21/12/2000



without warning making it impossible for the user to position himself so as to avoid the risk. Whether the product was defective was to be judged by the expectations of the public at large and there was no suggestion that that expectation had changed since the pushchair was brought to market in 1990. Pill LJ noted that, as in the words of the Recitals to the Directive, the defectiveness of the product should be determined “*by reference not to its fitness for use but to the lack of the safety to which the public at large are entitled to expect*”.<sup>25</sup> Chadwick LJ stressed that it was irrelevant whether the hazard which caused the damage had come, or ought reasonably to have come, to the attention of the producer before the accident occurs. Implicitly adopting the rationale adopted by Burton J he stated:

*“To hold otherwise is, to my mind, to seek to reintroduce concepts familiar in the context of a claim in negligence at common law into a statutory regime which has been enacted in order to give effect to the product liability directive.”*<sup>26</sup>

The determination of “*defect*” was in his view “*a question of fact*”.<sup>27</sup>

Again in *Piper v JRI (Manufacturing) Ltd*<sup>28</sup> the term “*legitimate expectation of safety*” was not used. Thomas LJ in the Court of Appeal noted in the context of a hip replacement that a person 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...”*<sup>29</sup>

The “*expectation of safety*” test – whether phrased as “*legitimate expectation*” or not — can produce a higher standard than manufacturers generally apply or even find scientifically possible to obtain. It may conversely impose a lower standard than that required by the design standard to which it was manufactured: *Tesco Stores v Pollard*<sup>30</sup> concerned a 13 month old child who had ingested dishwasher powder from a plastic bottle. It was alleged that the plastic cap was defective

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<sup>25</sup> paragraph 22

<sup>26</sup> Paragraph 44

<sup>27</sup> Paragraph 40

<sup>28</sup> [2006] EWCA Civ 1344

<sup>29</sup> Paragraph 34

<sup>30</sup> [2006] EWCA Civ 393

as it did not function properly as a child resistant cap. The Court of Appeal overturned a first instance finding that Tesco was liable. They held that there had been no breach of the CPA 1987. Applying the test of what persons generally were entitled to expect, in the instant case a consumer was generally entitled to expect that a bottle of dishwasher powder that had a child resistant closure cap would be more difficult to open than if it had an ordinary screw top. Since the bottle was more difficult to open than an ordinary screw top there was no breach regardless of whether or not it met a particular British Standard. Laws LJ commented that:

*“Members of the public... are unlikely to have the faintest idea to what safety standard the product they are buying has been designed, if it has been designed to any.”*

It was impossible therefore to construe the CPA as requiring that there was some form of contractual warranty as to the safety standard to which the product had been designed.

The Court of Appeal’s focus in the *Tesco* case appears to have been on the **actual** expectation of the public. However, according to Burton J in *A v NBA* what the objective “*legitimate expectation of safety*” standard required (a) may accord with actual expectation, (b) may be more than the public actually expects, or (c) **less** than the public actually expects.<sup>31</sup> Yet again a definitive ruling on this question is awaited.<sup>32</sup>

### **Defect: No need to prove “avoidability”**

In *A v NBA* reference was made to *the German bottle case*<sup>33</sup> in which the German Federal Supreme Court held that it was correct to determine that a consumer expected a mineral water bottle to have no obvious or even microscopic damage which might lead it to explode. Importantly they stressed that:

*“The fact that it is not technically possible to detect and repair such defects in the bottle does not alter the consumer's expectations.”*

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<sup>31</sup> Paragraph 31(vii)

<sup>32</sup> The recent Scottish case of *McGlinchey v General Motors UK Ltd* [2012] CSIH 91 unfortunately offered little clarity on this point. *A v NBA* was cited in argument and by the court in reviewing the submissions made. In the operative reasoning, however, reliance was instead placed on *Abouzaid v Mothercare* and the test applied appeared to be what ‘the public are entitled to expect’ (see at §37 of the judgment) albeit that no significant analysis of defect was required as “The court does not understand there to be any dispute with the proposition that a car would have a defect if its handbrake mechanism was such that it did not, upon proper application, engage at least the rear brakes of the car.”

<sup>33</sup> Paragraph 44(ii)

Burton J accepted this approach, concluding that avoidability was irrelevant when assessing defect. To permit an assessment of whether the defect was avoidable in his opinion was to introduce a fault standard by the back door. Thus whether or not it was technically feasible to detect or avoid the defect was neither here nor there. What mattered in the assessment of defect was the legitimate expectation of safety of the product and what was therefore required evidentially was a description of the “*composition or construction of the product*” and its “*effect and consequence in use*” but it was not appropriate in this context to “*consider what could or should have been done, whether in respect of its design or manufacture, to avoid the problem*”. Thus the claimant did not have to prove that there was some hypothetical alternative universe in which the defect could have been avoided. Avoidability was irrelevant.<sup>34</sup>

English commentary<sup>35</sup> is available – but as yet no translated judgment – on an important case heard by the German Supreme Court snappily titled “*VI ZR 107/8*”<sup>36</sup>. The Court concluded that the subjective safety expectation of a harmed consumer was not decisive. Following more closely the Burton’s “*legitimate expectation*” approach (again implicitly not explicitly), a product was determined to have a design defect if, at its conception, it did not meet the “*necessary*” safety level.

*“Thus, as early as the designing and planning stages of a product, the manufacturer must take into consideration **all measures** that are objectively necessary and objectively reasonable to avoid possible danger originating from the product.*

*“‘Necessary’ measures are those safety measures that are **constructively possible** according to the state-of-the-art science and technology available at the time that the product is placed on the market, which are sufficient and able to prevent damage. The court pointed out that **the applicable “state-of-the-art science and technology” standards must not be considered to be those which are customary in the respective trade**, as the safety measures applied in the industry can lag behind technical developments and thus fall below the legally required measures.”<sup>37</sup>*

Thus customary measures were not sufficient as they could “lag behind”. As stated in the commentary the implications of this decision are “*astonishing*” putting enormous pressure on

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<sup>34</sup> This contrasts sharply with the Dutch decision of the Amsterdam district court *Rb. Amsterdam, 3 February 1999, NJ 1999, 621*. This case also involved contaminated blood. Whilst a verified translation of the decision does not appear to be available, the court appears to have decided that because it was not scientifically possible to detect the contamination (HIV virus) during the screening window, the defendant could avail itself of the developmental risk defence.

<sup>35</sup> Product Liability – Germany Overview (June 2011) ILO Caroll Burdick & McDonough June 30 2011

<sup>36</sup> Supreme Court Decision VI ZR 107/ 08, June 16 2009

<sup>37</sup> Product Liability – Germany Overview : *ibid*: my emphasis

manufacturers. Proof of common safety standards adopted for a long time by all in the same industry will not provide a defence. What was required to avoid a “defect” finding in relation to a harmful effect was that all “*constructively possible*” science and technology had been brought to bear to prevent the harm.<sup>38</sup>

It remains to be seen whether the ECJ, UK courts or other jurisdictions will follow the radical lead set by the German Supreme Court.<sup>39</sup>

### **Defect: Defence: Full information and social acceptance “sozialadäquat”**

A product may be known to cause harm. A knife poses a risk of injury. Cigarettes are known to cause cancer. They are not however defective in law. The German courts (unsurprisingly) rejected a consumer’s argument that chocolate bars were defective in composition and by reason of a lack of warnings. The consumer had eaten at least two chocolate bars a day since 1994 and claimed damages for diabetes and tooth decay. The Court observed that the dangers of cocoa were “*well known with respect to obesity and dental damage, especially when frequently consumed*”. The manufacturer could not be made liable for failing to inform the consumer about information which fell within the average “*knowledge and expectations of the consumer for whom the product is intended*”<sup>40</sup>

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<sup>38</sup> A mere suspicion of defectiveness has been held to be sufficient by the German Hamm *Oberlandesgericht* in its judgment of 26 October 2010, Case No. I-21 U 163/08. The manufacturers of a pacemaker were held liable for the removal of a pacemaker. After implantation, it was realised that a component was possibly defective, which slightly increased the risk of the pacemaker failing prematurely. It was not possible to determine whether it was, in fact, defective without explanting the device. It was held that that suspicion was enough to render the device defective within the meaning of the Directive. This case is to be contrasted with the conflicting decision of the *Oberlandesgericht* of Frankfurt and Main (judgment of 20 May 2010, Case No. 1 U 99/09) which held that only an actual defect in the explanted pacemaker would suffice. The French courts to date have tended to focus on the state of scientific knowledge, rather than industry standards. In an unpublished decision of the *Cour de Cassation* (1ère Ch. Civ, 19 March 2009, No. 08-10143), it was held that clinical trials undertaken by the defendant drug manufacturer were inconclusive, meaning they did not have the requisite knowledge at the time the product was put into circulation. Similarly, in a vaccine case (Cass., 1ère Ch. Civ, 9 July 2009, No. 08-11073) the fact that a side effect was listed in a medical dictionary was enough that the manufacturer should have drawn the risk to the patient’s attention, rendering the product defective due to inadequate labelling.

<sup>39</sup> One simple practical step the European Commission could undertake would be to ensure rapid promulgation of official translations of judgment from Member States’ Higher Courts in product liability cases.

<sup>40</sup> *Brinkman v Masterfoods*, Court of Appeal Dusseldorf 20/12/02 quoted in *Cases, Materials and Text on Consumer Law* ed. Droushout (Hart Publishing, 2010), pg470. A similar finding was reached in the first-instance decision of the Bonn *Landgericht* (19 April 2004, Case No. 9 O 603/03): the claimant sued the sweet manufacturer Haribo on the basis that

Burton J in *A v NBA* addressed the issue of side effects of treatment, in that case blood transfusions. He accepted that a product with a harmful effect may be considered **non-defective** if (and only if) the side effects were fully known **and** socially accepted (referring to the term “*sozialadäquat*”<sup>41</sup>) — although at the same time noting that consideration would have to be given to Article 12 of the Directive which prevents waiver from the effect of the Directive itself.<sup>42</sup>

Thus in Burton J’s analysis information might — and only might — provide a defence if there was both (a) full information provided to the public about the nature of the product’s harmful effect and (b) social acceptance of that harm (with the judge acting as arbiter for society). A prime example – albeit not one referred to in the judgment – would be chemotherapy drugs which are known to cause harmful side effects but whose curative benefits render the drugs socially accepted.

The difficulty posed by Burton J’s formulation, however, is **who** needs to be provided with full information. If, for example, a medicine is only used by one patient group, information “made public” is in fact only going to be received by a very small section of the public. Does that constitute full information such as to render a useful product non-defective? Does the “agreement” of that small section that the drug is socially useful amount to *sozialadäquat*?

### **Defect: Informational defect in other EU Member States**

Other Member States have on occasions treated lack of information as the defect itself. As the Directive makes clear, the circumstances to be taken into account in assessing defect include the presentation of the product and any labelling or instructions.<sup>43</sup> In France, two appellate decisions are illustrative of the general approach in the medical context.<sup>44</sup> In a *Cour de cassation*<sup>45</sup> case the

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the pack should have contained a warning that excessive consumption of liquorice could lead to high blood pressure and heart disorders due to the release of glycyrrhizin. The court rejected the claim, holding that although manufacturers had the general obligation to warn consumers of product risks “where this was necessary for clear and sufficient information”, where the public was aware of the inherent risks of a product there was no such necessity.

<sup>41</sup> Term used by Professor Taschner and Count von Westphalen: see paragraph 55.

<sup>42</sup> Article 12 states: “*The liability of the producer arising from this Directive may not, in relation to the injured person, be limited or excluded by a provision limiting his liability or exempting him from liability.*”

<sup>43</sup> Directive 85/374 article 6(1)(a).

<sup>44</sup> Two other cases illustrate the approach more generally: C.Cass (1ère Ch. Civ., 7 November 2006, No. 05-11604) and the decision of the *Cour d’appel de Paris*, 10 October 2003 *SARL société oasis des serres de bon pain v. SA société Algavi*. In the first case, the claimant was mixing concrete. Although the instructions warned of the risk of skin burns and advised gloves and eye protection, they did not also warn of the need to wear waterproof clothing. On that basis, the

claimant had developed multiple sclerosis after receiving a vaccine for hepatitis B. The court held that since the risk of multiple sclerosis was listed in the Vidal medical dictionary as a side effect, it should have been included on the product label. Thus, the vaccine was determined to be defective due to inadequate labelling. In another<sup>46</sup> a plastic surgery patient had a product called “Dermalive” injected. It led to inflammation. The instructions provided to the doctor mentioned side-effects including those which were suffered, but the same information was not included in the leaflet provided to the patient. Again, the court held that the information given to the end-user was insufficient and held the manufacturer liable.

In Germany, a similar approach to the French courts has been applied in medical cases. The Hamm *Oberlandesgericht*<sup>47</sup> exonerated a vaccine manufacturer on the basis that the leaflet adequately represented the state of medical knowledge at the time of vaccination. In Austria, the standard that has been applied by the *Oberster Gerichtshof* (the supreme court) is that a product manufacture must issue warnings capable of protecting the “least informed” of an average group of users, albeit that the duty does not extend to uses that are “unforeseeable or downright absurd”.<sup>48</sup> A Dutch court came to a very similar conclusion, holding that instructions should be clear enough even for first-time users, but that on the facts they were clear, since the use (and risk) in question was not foreseeable.<sup>49</sup>

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*Cour de cassation* upheld the finding that the defendant was liable. In the second case, a pond purifying product caused the deaths of the claimant’s fish. The defendant argued that an excessive dose of the product had been applied. The Paris court of appeal held that the manufacturer was liable because although the instructions gave details of appropriate dose in respect of the surface area of water, it said nothing about water depth.

<sup>45</sup> 1ère Ch. Civ, 9 July 2009, No. 08-11073

<sup>46</sup> Cass., 1ère Ch. Civ, 22 November 2007, No. 06-14174

<sup>47</sup> 18 June 2003, Case No. NJW-RR 2003, 1382

<sup>48</sup> *Re Room Dividers* (30 Sep 2002, 1 OB 169/02 P) [2004] ECC 20, and see also *Re Defective Instructions on Oven Cleaner* (22 February 2011, 8 Ob 14/11h) [2012] ECC 10, where the *Oberster Gerichtshof* held that where the product was associated with risks, the warning had to identify the type of risk and make apparent why the product was dangerous.

<sup>49</sup> The case involved a 16-year-old girl who incorrectly inserted a mini-tampon into the urethra and not the vagina. The incorrect insertion involved a lot of effort and pain and, on her mother’s advice, Vaseline. She was unable to remove the tampon after insertion and suffered toxic shock syndrome. She argued that the instructions were inadequate.

## Attacks on A v NBA

As highlighted above the Court of Appeal has considered “*defect*” post-*A v NBA* and appears on occasion to have steered clear of some of Burton J’s formulations in particular in relation to “*legitimate expectation of safety*”. However, not too much should be read into this as the differing potential interpretations have not been central to the appellate decisions and the cases can in no way be seen as casting appellate doubt on Burton J’s approach.

The potential key areas of attack for defendants on the *A v NBA* decision appear to be: the test for expectation of safety, the true scope of “circumstances” and hence the role for risk/utility. As to the first, a wide defendant attack may be made which would be to say that simply the *actual* expectation of the public should be determined as a fact: the route apparently taken in the *Tesco* dishwasher powder decision discussed above.<sup>50</sup> Actual expectation does however seem a step too far. One can imagine a public which is excessively jaundiced about the safety standards of a particular industry. That realistic actual expectation should not be the benchmark, otherwise EU uniform safety standards could plunge to an appalling lowest common denominator.

A narrower, more subtle — and potentially more successful — attack would be to contend that Burton J was wrong to conclude that the court should assume the role of an informed representative of the public at large: the court should instead determine the safety which a person is entitled to expect having regard to all the circumstances.<sup>51</sup> The test therefore would not turn upon either the actual knowledge/expectations of the public at large as to the product in question or as to the safety which it should provide. The focus would be on what the public *should* expect if they had all the available information and were aware of all the circumstances. It requires placing the judge in a near omniscient position about all the available information concerning a product and its manufacture thereby significantly complicating the evidential position at trial. For defendants this usually has the benefit of ensuring that the impossibility of detecting a defect *will* be taken into account (contrary for example to the *German bottle case* discussed above) and that wider circumstances than would in fact be apparent to the consumer can be taken into account (for example, that the harm *should* be socially accepted even if it in fact is not currently accepted by the public at large). However, rejection of Burton J’s “*legitimate expectation*” approach would probably

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<sup>50</sup> *Tesco Stores v Pollard* [2006] EWCA Civ 393 – discussion above under [Defect: “legitimate expectation of safety”](#)

<sup>51</sup> Entitled expectation or “legal expectation” as coined by Stapleton – see above.



enable manufacturers to introduce fault standards by the back door and would ensure that the current — very over-complicated — evidential approach to product liability cases was entrenched for the foreseeable future.<sup>52</sup>

Secondly, defendants are likely to attack Burton J's determination that certain "circumstances" are beyond the Pale. In *A v NBA* it was concluded particularly that avoidability and risk/utility were impermissible factors and could not go into the basket of circumstances the judge took into account when determining whether a product was defective or not. Defendants will argue that **all** circumstances should go into the basket. In the relation to pharmaceutical litigation this is of great significance because importing *all* the circumstances — and including "avoidability" and risk/utility — could render nearly all product liability litigation in relation to drugs with beneficial therapeutic effects a non-starter. The absence of information about side-effects could, for example, be rendered peripheral to a defect finding: a court could determine that a drug was **not** defective in *all the circumstances* because (1) the drug satisfied the required risk/utility analysis and (2) such information about side-effects would not have prevented the drug being taken or prescribed. The logic of *A v NBA* is powerful on this score: if the Directive had intended to include risk/utility it would have stated it. The *travaux préparatoires* indicate that the US approach was rejected. Nevertheless, in the field of pharmaceuticals or medical devices it may be difficult to resist the push for some form (however attenuated) of risk/utility analysis. In fact as noted by Goldberg<sup>53</sup> Burton J's social acceptability test ("*sozialadäquat*") does include an assessment of risk/utility: society's determination that a harmful product is acceptable must entail — in part at least — a weighing up of the risk from the product against its benefits (for example, the therapeutic benefits of chemotherapy drugs are seen to outweigh their nasty side-effects). Goldberg gives the example of the AZT drugs used in the treatment of AIDs:

*"Although Burton J. has rejected the risk-utility test for hepatitis C, the irony in respect of such community-used natural resources would seem to be that the circumstances in which the expectation is not one hundred per cent are going to be situations where the public are aware that a risk-benefit assessment has been made to put the product on the market, e.g. the AIDS drug AZT. It is thus submitted that the public expectation in these circumstances is shaped by risk-benefit assessment."*

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<sup>52</sup> It would also be inconsistent with the majority of decisions in other Member States, such as those cited above, which have tended to focus on the legitimate expectation of the public at large (as in France), the typical consumer (Germany) or on the lowest objectively reasonable user (Austria and the Netherlands).

<sup>53</sup> *Paying for bad blood: strict product liability after the hepatitis C litigation* Richard Goldberg, Med. L. Rev. 165



Whilst Burton J implicitly confined risk/utility to the full information/social acceptability defence, it remains to be seen whether appellate courts or other first instance judges will preclude risk/utility considerations from coming into play particularly in the context of pharmaceuticals and medical devices. Miller & Goldberg have commented that *“There is no doubt that the conclusion on this issue is controversial”*.<sup>54</sup>

### **An underlying principle: Fair apportionment of risk**

The Recitals to the Directive indicate that the balance between manufacturer and consumer struck by the Directive comprised a fair apportionment of the risks:

*“[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;*

*[7] Whereas a fair apportionment of risk between the injured person and the producer implies that a producer should be able to free himself from liability if he furnishes proof as to the existence of certain exonerating circumstances”*.

The EU explanatory memorandum<sup>55</sup> noted:

*“Where a producer is liable irrespective of fault, the damage suffered by the user of the defective article is passed on to him. The compensation paid forms part of the general production costs of the product. This increase in costs is reflected in the pricing. The damage is thus, from an economic point of view, spread over all the products which are free from defects. Before any claims are made, the producer will make allowance for possible compensation payments, and form a reserve or attempt to cover himself by effecting insurance...*

*Liability irrespective of fault does not burden the producer to an unjustified extent. Normally he can divide the costs of damage passed on to him as a result of liability being made independent of fault amongst all users or consumers of products free of defects from the same range, or of his production as a whole, by including the expense incurred (payment of damages or payment of insurance premiums) in his general production costs and in his pricing of the goods. Thus all consumers bear the costs of the damage to a reasonable extent. ”*

John Rawls argued that:

*“ ... There are striking cases of public harms, as when industries sully and erode the natural environment. These costs are not normally reckoned with by the market so that commodities are sold at much less than their marginal social costs. There is a divergence between private and social accounting that the market fails to register. One essential task of law and government is to institute the necessary corrections”<sup>56</sup>*

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<sup>54</sup> Professor Miller and Dr Goldberg, *Product Liability* (2<sup>nd</sup> Edition), paragraph 10.86, page 385.

<sup>55</sup> [1976] OJ C2241/9; EC Bull Sup 11/79

<sup>56</sup> John Rawls: *‘A Theory of Justice’* (p268) 1971

The balance was later explained in the Advocate-General's opinion in *the Commission –v- UK*<sup>57</sup> as follows:

*“the producer has to bear the foreseeable risks, against which he can protect himself by taking either preventive measures by stepping up experimentation and research investment or measures to cover himself by taking out civil liability insurance against any damage caused by defects in the product.”*

In the *FAC case*<sup>58</sup> Burnett J was called to consider both an application by the claimants to admit expert evidence of a forensic accountant in support of their interpretation of the “*fair apportionment of risk*” principle and a counter-application by the defendant to strike out the part of the claimants’ statement of case which raised the issue. Burnett J both rejected the application for accountancy evidence and the application to strike out. Whilst declaring that the proper interpretation of the Directive for a drug with “*unavoidable adverse, as well as therapeutic effects*” was best carried out at trial, he noted that evidence about “*the sales and pricing structure*” of the drug in issue and the profit made from it “*cannot sensibly inform the question whether this product was defective at the time it was supplied to the any of the claimants’ mothers.*”<sup>59</sup>

Thus, whilst Burnett J limited the potential evidential significance of the principle, the precise impact – if any – of the “*fair apportionment of risk principle*” on the interpretation of the Directive is unclear. The “*principle*” could mean no more than that the Directive was simply intended to achieve a balance between the consumer and manufacturer (as argued by the defendant in *FAC*) and this is reflected in the substantive “*defect*” provisions. It could conversely mean – adopting the European purposive approach to interpretation — that there should be a greater “*pro-consumer*” shift in how “*expectation of safety*” is interpreted. Like so many other areas of product liability law this awaits further clarification by the courts.<sup>60</sup>

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<sup>57</sup> C-200/95 [1997] All ER (EC) 481

<sup>58</sup> *Claimants Registered in the GLO v Sanofi-Synthelabo Limited* [2009] EWHC 95 QB.

<sup>59</sup> [2009] EWHC 95 (QB) at paragraph 16(i).

<sup>60</sup> Although the case law surrounding the Unfair Contract Terms Act 1977 (UCTA) and exclusion clauses may offer some guidance in interpreting the concept of a “*fair apportionment of risk*”. Applying “*reasonableness*” under UCTA, courts regularly consider factors such as (1) the availability of insurance to one or both parties, (2) the pricing of the product, (3) resources available to supplier to meet liabilities (4) the practical consequences of failure to meet risk (i.e. who would bear the loss instead). For example *St Albans City & District Council v International Computers Ltd* [1996] 4 All ER 481. Similarly, what is reasonably in contemplation of the parties – conceptually similar to the idea of the public’s legitimate expectation of safety – may point in favour of liability to be borne by the producer: *Britvic Soft Drinks v Messer UK Ltd* [2002] 2 All ER (Comm) 321

## Proof of Defect & Causation

A claimant will need to prove that the defect has on balance caused or materially contributed to his/her injury. There is controversy about the extent to which the claimant must prove the **exact** cause of the injury or nature of the defect. As the Directive was intended to ensure matters of proof were easier for consumers, it is not surprising that, at least in some European countries, courts “*have been flexible*”<sup>61</sup> in their willingness to infer defectiveness. The excellent *Cases, Materials and Text on Consumer Law* identifies cases in which European national courts have readily found defect despite the absence of clear proof of the nature of that defect and/or mechanism of injury (for example, a Belgian case concerning a soft drinks bottle which exploded and a French case involving a car which was destroyed by fire which started in the engine but which could not be explained).<sup>62</sup> The authors note however that:

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<sup>61</sup> *Cases, Materials and Text on Consumer Law* ed. Droushout (Hart Publishing, 2010), pg 468

<sup>62</sup> Consider also the following cases.

France:

- *Cour de cassation* (1<sup>ère</sup> Ch. Civ, 26 September 2012, No. 11-17738). The claimant developed MS following a hepatitis vaccination. The court of appeal held the objective defect had not been established. This was quashed by the court on the grounds that failing to consider whether the claimant’s positive medical antecedents did not in the circumstances constitute “serious, precise and concordant presumptions of such a nature as to establish the defective character of the three doses of vaccine administered to the interested party”. N.b. this decision revoked earlier case law which held that no presumption of defect could exist.
- *Cour d’appel de Toulouse*, 7 November 2000, involving an exploding car tyre. The court of appeal adopted an abstract notion of defect and considered that 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 ... nor subject to the proof... that no other external cause had played a role in the defectiveness of the product, since three successive examinations by two different experts had not been able to explain the explosion of the tyre in such a way as to exculpate the distributor nor establish the sole fault of the client.”
- *Cour d’appel d’Aix-en-Provence*, 10 April 2003, *Kyocera Electronics France v Mme Videau Gilli & Mr Duval*. A photocopier overheated and started a fire. Court held that overheating (such as to cause a fire) constituted the necessary defect under the Directive, it being established on the expert evidence that the overheating was the cause of the fire.

Austria:

- *Oberster Gerichtshof*, 22 October 2002 (10 Ob 98/02 P). A coffee machine on standby caught fire and caused a domestic fire. The court held that given the rarity of the event, a coffee machine on standby causing a domestic fire because of a technical defect is clearly defective. It did not live up to reasonable safety

*"In contrast to this willingness by several continental courts to infer defect UK judicial practice requires courts there to give a more detailed explanation for why a defect exists"*<sup>63</sup>

Nevertheless the Court of Appeal in *Ide v ATB Sales Ltd*<sup>64</sup> considered a case in which the judge had before him contentions about two or more competing explanations as to how the damaging event occurred, which though they might be uncommon, were not improbable. In such cases it was held to be 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. This indicates that there will be a degree of allowance made for the difficulties of establishing defect causation. Further, if one defines defect as not the physical defect of the product as such but in fact the *"defeating of the expectations of safety"*<sup>65</sup> as required by the Directive the problems of proof – and disparity between UK and continental practice – can melt away.

The other key aspect of defect causation has been flagged above: Burton J rejected *"avoidability"* as being one of the relevant circumstances. This has importance to lawyers versed in the language of *"but for"* causation. In negligence once fault is established it is necessary (although

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expectations. The claimant did not have to prove which part of the machine was defective as in the circumstances a there was a presumption of defectiveness which satisfied the burden of proof.

- *Oberster Gerichtshof (406 94/04H)* [N.B. There is no full translated judgment of this case at the present time] The claimant sued the manufacturer of a ground level aerial firework which exploded whilst on the ground causing a serious eye injury. The court held that in order to establish defectiveness under the Directive it was not necessary to show the precise product flaw.

Spain:

- *Tribunal Superior de Barcelona*, 21 February 2003. A lemonade bottle exploded when the claimant placed it in a shopping basket, and a splinter caused eye damage and vision loss. Reversing the normal burden of proof, the court held that the bottle was defective, as the *"explosion of a glass bottle occurred neither by manipulation of the same by the consumer, nor by its abusive or inappropriate use"*. Moreover, *"nothing indicated that the product was not defective when it was put into circulation"*; it fell to the manufacturer *"to prove the suitability of the product or other grounds which could exonerate him"*

<sup>63</sup> Note the higher UK standard in *Foster v Biosil* [2001] 59 BMLR 178 decision involving a breast implant where Cherie Booth QC ruled that it was insufficient to show *"merely that the product failed in circumstances which were unsafe and contrary to what persons generally expected"* and the contrast drawn by the *Cases, Materials* authors to the French approach in a toy safety case in which it was stated that defectiveness was based on what *"could be legitimately expected and did not necessarily require a design or manufacturing defect."*(page 467)

<sup>64</sup> [2008] EWCA Civ 424 (issue whether handlebars of bicycle were defective)

<sup>65</sup> *Ibid* page 469

not always sufficient) to show that but for the fault the injury would not have occurred. Thus it must be shown that in a hypothetical world in which the defendant was competent the claimant would not have been harmed. In product liability all that needs to be shown is that the defect (however defined) caused the injury. It is not necessary to prove that there could be some alternative hypothetical world in which the injury would have been avoided. Thus in the French case noted above it was not necessary for the claimant to prove that there could have existed a car factory which could have created an engine which did not explode: also it was not a defence for the manufacturer to prove the converse; that is, despite a perfect production system the engine would still have gone on fire. Another example is the *A v NBA* case: it appears clear that there was no system in existence which could have prevented most – if not all – of the recipients from being transfused with infected blood. Thus, all that need be proved is the harmful characteristic, that is the defect, caused the injury and no more.

The manifold evidential issues in relation to proof of causation of damage from pharmaceuticals or medical devices are beyond the scope of this paper, but one should note in particular the oral contraceptive group litigation<sup>66</sup> and tobacco litigation<sup>67</sup>. In *Loveday v Renton*<sup>68</sup> Stuart-Smith LJ noted:

*"I do not think there is any generally accepted standard of scientific proof, nor is it clear who has to be satisfied to such a standard. The addition of the words "95% confidence" is a confusion of thought derived from the statistical concepts of 95% confidence intervals and probability values... they are not concerned with standards of proof, but the probability of chance. Secondly, the expression "clinical proof" appears to be used to mean two different things. First, it is used in the sense of making a diagnosis in a particular case. Quite clearly if a clinician is to make a diagnosis in a given case that a child is suffering from permanent brain damage caused by pertussis vaccine, he can only do so on the basis that he has already reached the conclusion that pertussis vaccine can cause brain damage... The decision then depends upon the clinician's judgment as to whether or not the clinical signs and symptoms and the history relating to the patient meet certain criteria determined by the clinician in question. It also appears to be used as the standard of proof in determining to the clinicians' satisfaction whether the vaccine can cause brain damage. Ultimately this is the question for the court and in my mind the only significance of this topic is that when considering a witness's assertion that he is or is not satisfied of a certain fact, the court must bear in mind that he may be applying too low or too high a standard of proof."*

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<sup>66</sup> *XYZ v Schering Health Care Ltd* [2002] EWHC 1420 (QB) : The Court held that the claimants could not prove that third generation combined oral contraceptives carried an excess risk of venous thromboembolism which was twice that carried by second generation combined oral contraceptives.

<sup>67</sup> For example the Scottish case of *McTear v Imperial Tobacco Ltd* [2005] CSOH 69, [2005] 2SC 1 with the comment "*The fallacy of applying statistical probability to individual causation has already been recognised judicially*" in *Hotson*

<sup>68</sup> [1990] 1 MLR 117 (the Pertussis vaccine case).

The *Fairchild*<sup>69</sup> authorities and in particular the recent *Sienkiewicz –v- Greif*<sup>70</sup> case should also be reviewed.<sup>71</sup>

### Sweep up

This paper has focussed on highly selective aspects of the product liability regime. Even Miller & Goldberg's almost 1,000 page über-text on the subject<sup>72</sup> cannot cover all the difficult points connected to the subject. I would stress the value to those new to the topic of dipping into that book, but probably only after reading the succinct chapter in *Cases, Materials and Text*<sup>73</sup> and I will retreat from the product liability commentariat battlefield by flagging the following points in shorthand and noting one final area of concern.

- **“Regulatory compliance”** represents a further defect defence proposed by defendants. It is contended that in fields in which products are highly regulated (such as pharmaceuticals or medical devices) proof that the manufacturers have complied with the relevant regulatory standards either means that the product should not be considered defective or — at very least — the fact of that regulatory compliance should be seen as a very important factor to be considered by a judge looking in the basket of relevant circumstances. No such defence is apparent on the face of the Directive or the CPA.<sup>74</sup> Whether English courts will import such a defence or consider it to be importing fault standards by the backdoor awaits decision.<sup>75</sup>

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<sup>69</sup> [2002] UKHL 22

<sup>70</sup> [2011] UKSC 10 referred to in Heidi Knight's Legal Update paper

<sup>71</sup> *Reay v British Nuclear Fuels plc* [1994] 5 Med LR 1 particularly at 10 should be considered.

<sup>72</sup> Product Liability, see above.

<sup>73</sup> *Cases, Materials and Text on Consumer Law* ed. Droushout (Hart Publishing, 2010), Chapter 7

<sup>74</sup> However some German courts have made findings in respect of regulatory compliance, as mentioned above: *VI ZR 107/8* and the *Oberlandesgericht Düsseldorf*, 20 December 2002 (14 U 99/02). In the latter case, involving chocolate bars, the court reiterated the view that compliance with product safety legislation did not in and of itself preclude the finding that the product was defective.

<sup>75</sup> Note the extensive arguments which have been considered in the US under the rubric of “pre-emption”: for example, *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008)

- **Development risks defence (“DRD”):** Article 7(e) of the Directive provides a defence for manufacturers that:

*“The producer shall not be liable ... if he proves that the state of scientific and technical knowledge at the time when he put his product into circulation was not such as to enable the existence of the defect to be discovered.”*

This is, however, the most advanced state of knowledge available to a manufacturer at the time and does **not** require that the manufacturer in fact had that knowledge.<sup>76</sup> As stated by the Advocate-General in *Commission v United Kingdom*<sup>77</sup>:

*“First,... since that provision refers to ‘scientific and technical knowledge at the time when [the producer] put the product into circulation, Article 7(e) is not specifically directed at the practices and safety standards in use in the industrial sector in which the producer is operating, but, unreservedly at the state of scientific and technical knowledge, including the most advanced level of such knowledge, at the time when the product in question was put into circulation...”*

*“Second, the clause providing for the defence in question does not contemplate the state of knowledge of which the producer in question actually or subjectively was or could have been appraised, but the objective state of scientific and technical knowledge of which the producer is presumed to have been informed.”<sup>78</sup>*

The Advocate went on to note that:

*“...the ‘state of knowledge’ must be construed so as to include all data in the information circuit of the scientific community as a whole, bearing in mind, however, on the basis of a reasonableness test the actual opportunities for the information to circulate.”*

and hence gave the example that knowledge would not be assumed if the defect in question had only been discovered by a researcher in Manchuria whose work had not been promulgated to the wider world. (This leads to – yet another – product liability label: “*non-Manchurianly accessible knowledge*”.<sup>79</sup>) What is required, however, is that manufacturers will be judged by the highest common factor in the industry and not the lowest. Further and

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<sup>76</sup> Although in one case decided by the French *Cour de cassation* (1ère Ch. Civ, 19 March 2009, No. 08-10143), the court appeared to accept that the actual knowledge of the manufacturer was relevant. The case involved a drug which caused a cardiac arrest and left the claimant in a coma. The court of appeal held that some findings in the clinical trials were inconclusive. The court upheld that finding, and ruled that merely pointing out the link between the medicine and heart problems was not sufficient to show that the manufacturer had the requisite knowledge at the time.

<sup>77</sup> [1997] ECR I-2649

<sup>78</sup> Paragraph 27

<sup>79</sup> *A v NBA*, paragraph 50(i)



importantly – according to AG Tesouro at least — practicability and the expense of the measures suitable for eliminating the defect from the product fall outside the scope of Article 7(e). There remains a live debate, particularly in the context of pharmaceutical litigation, (a) whether and the extent to which in the context of DRD a claimant can allege that, whilst the industry did not have actual knowledge available, scientific tests and experiments were available which could/should have produced that knowledge and (b) what level of suspicion/information about side-effects comprises “knowledge” within Article 7(e) to preclude operation of the DRD defence.

It should be noted that this Article was an optional part of the Directive and not all countries have imported it. The UK included it via CPA section 4(1)(e).<sup>80</sup>

- **“Learned intermediary defence”:** This defence repeatedly floated by defendants derives not from the wording of the Directive but from US jurisprudence. *Restatements of the Law, Third, Torts: Product Liability* section 6(d) states:

*“A prescription drug or medical device is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to:*

*(1) Prescribing and other health-care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings; or*

*(2) the patient when the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings.”*

The rationale is explained thus:

*“The obligation of a manufacturer to warn about risks attendant to the use of drugs and medical devices that may be sold only pursuant to a health-care prescription traditionally has required warnings directed to health-care providers and not to patients. The rationale supporting this ‘learned intermediary’ rule is that only health-care professionals are in a position to understand the significance of the risks involved and to assess the relative advantages and disadvantages of a given form of prescription-based therapy...”<sup>81</sup>*

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<sup>80</sup> “In any civil proceedings by virtue of this Part against any person (“the person proceeded against”) in respect of a defect in a product it shall be a defence for him to show ... (e) that the state of scientific and technical knowledge at the relevant time was not such that a producer of products of the same description as the product in question might be expected to have discovered the defect if it had existed in his products while they were under his control...”

<sup>81</sup> Restatement (n 5), commentary, at page 146.



The learned intermediary defence existed in the English common law and it has been argued that it survived the passing of the Directive and the CPA.<sup>82</sup> Christopher Hodges has argued that Burton J in *A v NBA* summarily dismissed the possibility of the operation of the learned intermediary defence as a defence to a strict liability action. He contends that it should have been given greater consideration:

*“There is surely no reason in principle why it could not be a relevant Article 6 circumstance to be taken into consideration, that the product was used, and was intended to be used, only where learned intermediaries would interpose between producer and consumer, and that it was generally recognised to be the function of such intermediaries to warn consumers as fully as should be necessary of the risks involved in the selection for use of a particular product, often from a number of other products. It might be that in particular circumstances where particular consumers were incapable of giving consent (e.g. unconscious patients), those further circumstances might tip the balance of circumstances back towards holding that the product was defective. But there seems considerable force behind the general proposition that in the “learned intermediary circumstances” the product should not be defective. (This is a quite different issue from the question of whether ‘avoidability’ is an Article 6 circumstance.) The result is that it should be a question of clinical negligence, and not producer strict liability if learned intermediaries fail to pass on appropriate warnings to their patients.”<sup>83</sup>*

- **Limitation:** It is vitally important that advisers are aware of the 10 year long stop provision in the Directive. This bars subsequent claims and does not protect those under a disability. Time is deemed to run from when the manufacturer put the product into circulation. This can be difficult if not impossible to prove exactly. For example, very few patients retain the boxes in which their medicine is supplied. The strictness of the long-stop was shown in a series of judgments in *O’Byrne v Aventis Pasteur*<sup>84</sup>. Hence extreme caution should be exercised to ensure claims are launched in time.

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<sup>82</sup> In France, however, the courts have implicitly excluded the defence, through the established principle that warnings must be given to the end-user or patient; it is not sufficient to merely warn the doctor. See the *Cour de cassation* judgments of 9 July 2009 and 22 November 2007, cited above under informational defect.

<sup>83</sup> Hodges L.Q.R. 2001, 117(Oct), 528 at page 532

<sup>84</sup> [2010] UKSC 23. The issue was whether it was possible to substitute as defendant the parent manufacturing company in circumstances where an action had been started against a wholly-owned subsidiary. The action against the subsidiary was brought in time, but the application for substitution was brought only after ten years had expired from the time the parent first transferred the product to the subsidiary. After two references to the ECJ, the test to be applied was “look[ing] at the circumstances ... whether, despite appearances, in fact, it was the manufacturing parent company which had determined that the product should be put into circulation”. Thus it is the date at which the product is supplied to an entity which is sufficiently removed from the manufacturer’s control and processes that it can

### Concluding thoughts: Harming babies in the womb: the remarkable lacunae

The Thalidomide disaster prompted a radical re-think in the approach to consumer safety. Other countries' governments responded more rapidly and more sensitively to the victims than the UK government. As Bryant and Stevens observed in *Dark Remedy* the “battle for the Thalidomide victims of Great Britain lasted longer than the Trojan War.”<sup>85</sup> The Directive and the UK CPA were meant to ensure that victims of a similar disaster did not face such an epic struggle to achieve compensation. However, the “development risks defence” which was included in the UK legislation<sup>86</sup> could provide a defence to such a Thalidomide-type claim – or at least ensure such complicated litigation that redress could be long deferred. As noted by Howells and Weatherill:

*“Given the presence of the development risks defence it is likely that thalidomide would not be labelled defective because the state of scientific knowledge would not have revealed the defect.”*<sup>87</sup>

Miller and Goldberg in the seminal text *Product Liability*, whilst adopting a slightly more nuanced approach, essentially agree, contending that it is “strongly arguable” that for Thalidomide one would have had to identify:

*“some standard or general acceptance within the advanced sectors of the relevant scientific community that there was a need for ... testing on pregnant animals.”*

Given the absence of such a standard at the time they suggest that the manufacturers of Thalidomide may well have succeeded in a development risks defence if the Directive had been in force at that time.<sup>88</sup>

Another remarkable lacuna is the failure of the Directive to include any direction or proposed mechanism for ensuring recovery for those injured in the womb. The protection of those damaged in the womb is left to national legislation, in the UK this is the Byzantine Congenital Disability (Civil Liability) Act 1976 (“CDCLA”). Thus, for a claimant injured in the womb to succeed in

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be considered to be “put into circulation” that matters for the 10-year long-stop. When suing groups that include separate manufacturing and distributing entities, it is necessary to carefully examine the intra-group circumstances in order to ensure that limitation is not missed.

<sup>85</sup> Basic Books, 2001, page 79,

<sup>86</sup> Countries could decide whether to opt in or opt out of this defence.

<sup>87</sup> Consumer Protection law, (Ashgate Publishing, 2005) , page 249

<sup>88</sup> Product Liability, Second Edition, (Oxford, 2004), page 520

a CPA claim requires him/her to negotiate the causation traps interwoven between the CPA and the CDCLA. The issue is too complex to address properly within the confines of this paper but two examples may suffice.

A claimant needs to prove whether he/she has suffered a pre- or post-conception “*occurrence*”. A defendant may argue that the commencement of a mother on treatment by a drug was the “*occurrence*” and hence a **pre**-conception occurrence. It would follow, if this was correct, that if parents knew prior to conception of the risk of their child being born disabled then no claim could be mounted under the CDCLA.<sup>89</sup> Thus fault questions in relation to the provision of information to non-injured parties (the parents) could, on this analysis, determine whether the injured parties (the babies) recovered — parties who had had absolutely no say on the ingestion of the drug in question and no say on whether they consented to the risk of life-long disability.

Another additional layer of complexity is imposed on a party injured *in utero* in relation to causation. The CDCLA — on one reading at least — requires the claimant to prove that but for the “*occurrence*” he could have been born uninjured. Section 1(2) provides that:

*“An occurrence to which this section applies is one which —*

*(a) affected either parent of the child in his or her ability to have a normal, healthy child; or*

*(b) affected the mother during her pregnancy, or affected her or the child in the course of its birth, so that the child is born with disabilities which would not otherwise have been present.”*

Thus, it can be argued that damage considered to be post-conception — which thereby falls under section 1(2)(b) and avoids the consent issues of section 1(2)(a) (and which is in fact the natural way to analyse damage from teratogenic drugs) — requires the claimant to prove that he has been “*born with disabilities which would not otherwise have been present*”. In the context of teratogenic drugs ingested in the womb, the defendant could maintain that, even with proof that parents had been provided with inadequate information about the risks, the claimant child still has to go on to prove that with adequate information the occurrence would not have happened; that is, that the drug would not have been taken and he would have been born uninjured. This analysis may mean that either there is a wrongful birth claim by the parents or there is no claim at all.

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<sup>89</sup> Relying on section 1(4) “*In the case of an occurrence preceding the time of conception, the defendant is not answerable to the child if at that time either or both of the parents knew the risk of their child being born disabled (that is to say, the particular risk created by the occurrence): but should it be the child's father who is the defendant, this subsection does not apply if he knew of the risk and the mother did not.*”

Whilst a purposive approach to interpretation could avoid the difficulties raised by the intricacies of the CDCLA, the great uncertainty about its application creates another substantial barrier to the commencement and progression of litigation. The very type of fetal injuries which drove product liability reform in the first place currently present one of the biggest challenges to proof. This provides a final and poignant example of the failure of the Directive to achieve its stated aims. The goal of simple low-cost redress to babies injured *in utero* has proven to be a chimera of the worst kind: a betrayal of thalidomide sufferers who may have thought that others caused lifelong damage by a product, like themselves, would in the future not have to engage in lengthy trench warfare to achieve redress. The time for further reform to ensure easily established no fault recovery for such people is long overdue.

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