Neutral Citation Number: [2016] EWHC 3096 (QB)

Case No HQ15P02664

IN THE HIGH COURT OF JUSTICE
QUEEN'S BENCH DIVISION

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 06/12/16

Before :

MR JUSTICE HICKINBOTTOM

- -

Between :

ANTHONY FREDERICK WILKES

Claimant

- and -

DEPUY INTERNATIONAL LIMITED

Defendant

- -
- -

Timothy Trotman (instructed by **Sheldon Davidson Solicitors**) for **the Claimant**
David Myhill (instructed by **Kennedys Law LLP**) for **the Defendant**

Hearing dates: 21-23, and 25 November 2016
Further written submissions: 29 November 2016

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Approved Judgment

Mr Justice Hickinbottom :

Introduction

1. In January 2007, at the North Manchester General Hospital ("the NMG Hospital"), the Claimant underwent a surgical procedure to insert an artificial left hip made up of metal components manufactured by the Defendant, one of which was a steel femoral shaft called a "C-Stem". In January 2010, that stem fractured; and, when the artificial components were replaced, there was some evidence of metal debris having been shed around the joint.

2. In this claim, the Claimant alleges that the fracture and the metallosis were caused by the negligence of the Defendant: but a claim is also brought under the Consumer Protection Act 1987 ("the Act"), the Claimant contending that, when the C-Stem component was put into circulation by the Defendant, there was a "defect" in it, as defined in the Act, because its safety was not such as persons generally were entitled to expect. Damages are claimed on the basis of each cause of action.

3. On 28 April 2015, Master Cook ordered a trial of a preliminary issue, that was formulated in his Order of 16 December 2015, as follows:

> "Having regard to the failure of the C-Stem by fracture (but excluding considerations of metallosis… and negligence….), is the Defendant liable to the Claimant by reason of the matters set out in the Particulars of Claim pursuant to section 3 of the [1987 Act]?"

4. At the trial of that issue, Timothy Trotman appeared for the Claimant, and David Myhill for the Defendant.

5. In respect of lay evidence, I heard from the Claimant, and several employees of the Defendant. The Claimant served a statement by the consultant orthopaedic surgeon who performed the procedure at the NMG Hospital in 2007, Mr (now Professor) David Sochart, as evidence upon which he proposed to rely; but, unfortunately, Professor Sochart was not timeously asked by the Claimant to attend court for the trial, and, when he was asked very shortly before the trial, he was unable to attend because of clinical commitments in Ireland. Despite these unhappy circumstances, I allowed his evidence to be admitted; although, as Mr Myhill emphasised, the fact that there was no opportunity to cross-examine Professor Sochart upon it inevitably affects the weight I am able to give it.

6. The majority of the evidence was from two experts, Mr Miles Hammersley instructed on behalf of the Claimant, and Professor Christina Doyle instructed in behalf of the Defendant. Both are Chartered Engineers. Mr Hammersley is a general forensic engineer, with a background in aerospace engineering, who has considerable experience in mechanical engineering, metallurgic and materials-based investigations. Professor Doyle has both commercial and academic experience, with particular experience and expertise in implanted medical devices and instruments.

The Regulatory Background

7. Medicinal products have been regulated in the United Kingdom since the Therapeutic Substances Act 1925; but the inadequacies of regulation became apparent in the early 1960s. The failings in respect of thalidomide led to demands for greater regulatory control, which was recognised in the United Kingdom in the Medicines Act 1968 and, later, in regulatory systems driven by European legislation. As a result, every aspect of the design, testing, promotion and marketing of medicines and medicinal products, including medical devices such as prosthetic components, is now closely regulated; and regulated on the basis of the precautionary principle. Broadly, the relevant regulatory authority, applying its own scientific and medical expertise, will only allow a product to be put (and, thereafter, maintained) on the market if it is satisfied that the product meets appropriate standards of safety, efficacy and quality.

8. For the purposes of this claim, it is unnecessary to bore deeply down into the regulatory scheme that applies to prosthetic components such as the C-Stem; but it will be helpful to describe the main planks of the scheme.

9. The Medicines and Healthcare products Regulatory Agency ("the MHRA") is the designated and competent authority in the UK for assessing whether manufacturers and their medical devices meet the relevant legislative requirements.

10. The C-Stem falls within the scope of the EC Council Directive 93/42/EEC ("the Medical Devices Directive"), as effectively implemented in the United Kingdom by the Medical Devices Regulations 2002 (SI 2002 No 618) ("the 2002 Regulations"), around which the regulatory scheme applying to the C-Stem is based. The scheme comprises the following strands, with which I will briefly deal in turn:

    i) requirements for marketing approval (paragraphs 11-20 below);

    ii) information requirements (paragraphs 21-22); and

    iii) post-marketing surveillance obligations (paragraph 23).

11. By regulations 8 and 10 of the 2002 Regulations, a medical device cannot be marketed unless it meets the "Essential Requirements" set out in Annex I to the Medical Devices Directive, and has a CE (Conformité Européene) marking to that effect.

12. The General Requirements are set out in Part I of the Annex, and include, for example:

> "1. The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their intended use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.
>
> 2. The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety

> principles, taking account of the generally accepted state of the art.
>
> In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order:
>
> - eliminate or reduce risks as far as possible (inherent safe design and construction).
>
> - where appropriate take adequate protection measures including alarms, if necessary, in relation to risks that cannot be eliminated.
>
> - inform users of the residual risks due to any shortcomings of the protection methods adopted."

13. This requirement therefore involves an assessment of whether the "risks" of the medical device are "acceptable". "Risk" in this sense is the hazard or chance of the happening of a particular adverse event that will cause loss or damage: the greater the potential loss or damage, the smaller will be the acceptable chance of it occurring. The assessment of risks posed by a medical device involves the compound assessment of the chance of each such potential adverse event; but the acceptability of those risks taken as a whole can only be seen in the context of the potential benefits that the device will bring. As the text of this requirement makes clear, whether a product has an acceptable level of safety therefore necessarily involves some balancing of risks and potential benefits including, of course, potential utility. Given that no medicinal product is free from risk, and thus "safety" in this field is inherently and necessarily a relative concept, a medical device will only be allowed onto the market if the product is assessed as having a positive risk-benefit ratio, in this sense. In this judgment, otherwise required, I shall use the term "risk-benefit" rather than "risk-utility", on the basis that, for these purposes, "benefit" includes "utility".

14. Risk-benefit in this context is explained in the commendable consideration of the issues surrounding "Product liability for medicinal products" in the chapter of that name by Charles Gibson QC, Geraint Webb QC and James Purnell in "Clinical Negligence" (Michael Powers QC and Anthony Barton eds, 5th Edition (2015), Chapter 13) ("Powers & Barton"), at paragraph 13.29, as follows:

> "Underpinning the continuous process of review of medicinal products throughout their lifecycle, is the recognition that all medicines carry risks as well as provide benefits to the patients. No medicine is 100 per cent safe, and all medicines have side effects. A licence will only be granted or renewed if there is deemed to be a positive balance of risks and benefits (in other words, the benefits of the product outweigh the risks) or the product is, in the [MHRA's] own words, 'acceptably safe'. Determining the safety of a product is a holistic approach that calls for an integrated assessment of the clinical and laboratory adverse effects associated with the product in terms of their frequency, seriousness, severity, reversibility and outcome, and determining whether the risk can be mitigated by

> warnings on any risk factors. That assessment is complex and takes into account a range of factors including the nature of the disease or condition to be treated, the type of patient and the duration of treatment. It is important to appreciate that regulators approve or disapprove a drug on the basis of risk/benefit at a population level and not at an individual patient level…."

15. That passage is focused upon pharmaceutical products; but it applies to all medicinal products, including medical devices such as prostheses. As Professor Doyle explained, any medical device necessarily involves design compromises which seek to reduce symptoms and/or optimise utility, efficacy and functionality in appropriate patients. However, in respect of any particular patient, there is inevitably a risk of adverse effects including failure, often for a myriad of possible causes. The design of the product is intended to reduce that risk to one which is, in all the circumstances, considered appropriate by the MHRA, "appropriate" because the risk to some individual patients is outweighed by the benefits of the product overall.

16. Therefore, unless the manufacturer satisfies the MHRA as to that risk-benefit ratio, then a product will not be allowed on to the market. The way in which the 2002 Regulations achieve that goal is primarily through the European technique of a requirement for CE marking. By virtue of regulation 13, a device falling into defined classes of medical devices may bear a CE marking only if its manufacturer fulfils various specified obligations, ensures that the device meets the provisions of the Medical Device Directive that apply to it, and makes a declaration of conformity that it does so comply. At the relevant time, the C-Stem fell within category IIb of the Medical Devices Directive classification. As a result of EC Council Directive 2005/50/EEC, from 1 September 2007, it was reclassified from IIb to III; but nothing turns upon that.

17. Under the 2002 Regulations, responsibility for carrying out a conformity assessment falls upon the "UK Notified Body", which is BSI Assurance Limited ("the BSI"). The assessment involves the preparation of a design dossier by or on behalf of the manufacturer, which is then submitted to the BSI for review. To give some idea of the scope of such dossiers, the C-Stem Design Dossier included the following standard sections, (1) Executive Summary, (2) Declarations of Conformity, (3) Product Codes and Descriptions, (4) Front Cover and Essential Requirements Checklist, (5) Design Rationale, (6) Design Changes Summary, (7) Product Drawings, (8), Complaints/Sales Review, (9) Instructions for Use and labels, (10) Surgical technique, (11) Material Specifications, (12) Applicable Standards and Statutory Requirements, (13) Risk Management Reports, (14) Manufacturing Methods, (15) Design Verification, (16) Design Validation, (17) Pyrogenicity Statement, (18) Clinical Data, (19) Sterilisation Information and (20) Packaging and Shelf Life Information.

18. In practice, the assessment requires (amongst other things) evidence that the product complies with a raft of various European standards (often themselves international standards), which are simply adopted by technically equivalent British Standards ("BSs"). For example, BS 7252-9:1993 (the technical equivalent of ISO 5832-9:1992) defines, in the context of implants for surgery, the standard for wrought high nitrogen stainless steel (the material from which C-Stems are made).

19. The most relevant standards for the purposes of this claim are BS 7251-5:1990 (the technical equivalent of ISO 7206-4:1989), which defines the test method (but not the loads) for determining the fatigue endurance properties of stemmed femoral components, read with BS 7251-12:1995 (the technical equivalent of ISO 7206-8:1995), which sets out the specific requirements for the loads under which the stem is to be tested. The test is performed by the repeated cyclic loading of the stem, in a machine, under laboratory conditions. Under the heading "Endurance performance", section 4 of BS 7251-12:1995 requires testing of 5m cycles of the application cyclic load of 2kN, where the minimum load is 300N and the maximum load is 2.3kN.

20. The BSI effectively audit the design dossier, to ensure that there is compliance with the relevant standards and thus the Essential Requirements of the Medical Device Directive. If satisfied, the BSI issues a Design Examination Certificate, which allows the product to be CE marked and marketed.

21. Turning to product information, in Part II, the Essential Requirements incorporate Requirements regarding Construction and Design, which include, in paragraph 13, requirements relating to "Information supplied by the manufacturer". Those, so far as relevant to this claim, provide:

> "13.1 Each device must be accompanied by the information needed to use it safely…, taking into account the training and knowledge of potential users….
>
> …
>
> 13.6 … The instructions for use must… include details allowing the medical staff to brief the patient on any contra-indications and any precautions to be taken…"

A product also has to comply with those requirements to obtain CE marking. These provisions require the manufacturer of a product to provide sufficient information to ensure that each device produced can be used "safely" – that word being used in the same, relative sense as it is used in paragraphs 1 and 2 of the General Requirements – taking into account the fact that, often, a healthcare professional will intervene between the producer and the person in whom the device is fitted; and that that healthcare professional will advise that patient as to (amongst other things) the relevant risks and benefits of using that product.

22. In respect of some medicinal products, there is an obligation under the Human Medicines Regulations 2012 (SI 2012 No 1916) to provide information for the patient direct, in the form of Patient Information Leaflets ("PILs"). There is, however, no such obligation in respect of prosthetic components such as C-Stems, which, for obvious reasons, are only available through medical professionals – notably, in this case, the relevant orthopaedic surgeon. Relevant information, including appropriate warnings, is provided to those professionals in the form of Instructions for Use ("IFU"). For C-Stems, the patient is therefore reliant upon the orthopaedic surgeon who advises upon the procedure to give him sufficient material to enable him to make an informed decision about treatment.

23. Finally, with regard to post-marketing surveillance, article 10 of the Medical Devices Directive, as effectively implemented by regulation 13 of the 2002 Regulations, requires Member States to take the necessary steps to ensure that information with regard to various adverse incidents is recorded, evaluated and brought to its attention. Compliance with those provisions is audited by the BSI as the Notified Body, and in practice the Defendant notifies all complaints and reported adverse events to both the MHRA and the BSI. In addition to those statutory obligations, (a) healthcare professionals have a professional (although not a legal) duty to report adverse events; and (ii) subject to patients' consent, data in relation to joint surgery (including hips) are collected by the National Joint Registry ("the NJR"), which publishes an annual report including data on numbers of procedures and indications for surgery.

The Product

24. The hip joint comprises a deep socket or cup in the hip bone of the pelvis (the acetabulum) into which the head of the thigh bone (the femur) fits. The joint is generally very stable; but it is susceptible to damage due to trauma or degenerative disease (osteoarthritis) which can be very painful and disabling. Surgical techniques have been developed which can both relieve symptoms and improve mobility, by replacing affected parts of the joint with prosthetic implants. The techniques include the resurfacing of the joint, replacing just the femoral head, and replacing both the femoral head and the acetabulum (i.e. total hip replacement, or arthroplasty).

25. The DePuy ASR Total Hip Replacement System is a modular arthroplasty system, comprising a large diameter femoral metal component and an acetabular metal component, each in various sizes. The head is compatible with a variety of stems, including the C-Stem with which this claim is concerned. The shaft of the C-Stem fits into the hollow of the thigh bone (the medulla of the femoral diaphysis), and it too is flexible: it can connect to a variety of prosthetic femoral heads by way of a third component, a taper sleeve adapter. In the case of the ASR system, that head is metal; but the C-Stem is compatible with other systems and heads including those made of ceramic.

26. The C-Stem itself is made from high nitrogen austenitic stainless steel. The trunnion or neck of the stem – which fits into the taper sleeve adapter and head – has a machined thread around it, designed to increase the surface area of contact with a ceramic head, which evens out the stresses within the head that might otherwise cause the ceramic to fracture, with potentially serious adverse consequences for the patient. That is not a concern if the head is metal. The specification requires the root radius of the thread – in lay terms, the size of the "bottom" of each thread in profile – to be in the range 0.05-0.1mm.

27. In terms of its design, the C-Stem evolved from earlier models manufactured by the Defendant, notably the Charnley – Sir John Charnley being the modern pioneer of hip replacement design in the 1960s – and the Elite Plus models, both of which are still commercially available. The Charnley stem has an integral head, and is designed to pressurise the cement in the medullary cavity to reduce the risk of failure at that point. However, because the head is fixed to the stem, the physiology of some patients means that the surgeon has to compromise the fit of the stem in the bone and/or the biomechanics of the prosthesis. The Elite system has a head separated from the stem, allowing for a greater flexibility of size and a greater opportunity to improve both the

fit of the stem with the bone and the biomechanics. The Elite stem neck also has a thread to facilitate attachment of a ceramic head, although there is no evidence before me as to the nature or size of that thread. In the 1990s, the relationship between the extra-medullary biomechanics and the inter-medullary sizing was better recognised; and the C-Stem was designed to optimise the fit of the stem to the bone, primarily by changing the shape of the stem, with the aim of improving the load transfer between stem and bone by transferring the load from the stem to the cement mantle more evenly.

28. The Defendant's Design History Files ("DHFs") are intended to show the development history of any product, from conception to market launch. The basic design for the C-Stem size 1 was developed under DHF A021. The product line was later extended, and to an extent redesigned, with more sizes ("C-Stem Mk II") under DHF A124 (which is the current DHF), to include the C-Stem high offset model ("C-Stem HO") in various sizes, and also a redesigned stem with a different taper ("C-Stem AMT"). HO models have a head that is offset from the axis of the stem. The range became wide, with primary sizes 1-8, "Asian" sizes 0A-3A and HO sizes 2-5, designed to offer more options for surgeons, with a view to enabling them to choose a stem that would likely optimise fit and biomechanics in a particular patient.

29. Validation tests were performed upon successive models. Such tests were conducted comparing the (already existing) C-Stem size 2 with the (new) C-Stem HO size 2. For example, on 5 October 2000, a design validation test was performed which concluded that the new model was "acceptable", because the osteotomy plane of sections taken at 5mm intervals were identical within ± 0.3mm. Consequently, to a considerable extent, because the design was similar, the Defendant was able to rely upon work that had been done in relation to previous C-Stem models in support of the C-Stem HO models.

30. The C-Stems were subject to various fatigue tests, to show that they complied with the requirements of BS 7251-12:1995 (see paragraph 19 above). On 2 October 2000, six C-Stems HO size 2 were tested, with a 28mm diameter head and offset of either 3mm and 6mm, chosen so that the most severe offset with the smallest section thickness would be tested, i.e. the model with the least fatigue resistance. Two – one of each type – were subjected to 10m cycles, and the other four to 5m cycles, with a minimum load of 300N and a maximum load of 3.3kN. The development protocol to which the test was performed required the termination of the test only for fracture of the component or loosening of the stem. The result was that the cycles were run without failure.

31. The experts are agreed, and it is common ground, that the C-Stem HO withstood cyclic loading of at least 5m cycles of minimum 300N and maximum 2.3kN; and thus complied with the standard for fatigue. There is no evidence before me as to why the values of 10m cycles and 3.3kN load were used, rather than higher or lower figures over those required by the test criteria themselves. However, in taking the number of cycles to 10m (not merely 5m), and having a maximum load of 3.3kN (not merely 2.3kN), the parameters of the test were clearly more demanding than those required by the BS. For what it is worth, the yield strength of the steel from which the C-Stem is made was also found to be equal to its 0.2% proof strength, which, according to the British Stainless Steel Association paper, "Fatigue properties and endurance limits of stainless steels", "as a general rule" is equivalent to its fatigue limit. It is also

uncontroversial that the material used for C-Stems also satisfied the relevant standard (BS 7252-9:1993: see paragraph 18 above).

32. Turning to product information, in her evidence, Dr Mary Stewart (the Defendant's Senior Principal Engineer for Commercialised Product Development) said that the IFU for C-Stems was generated on the basis of the Defendant's design knowledge of, and its experience with, similar existing products. She explained:

> "The rationale for this is where a product contains the same design features as an existing product, then the expectation is that it will perform in the same manner and, by extension, the same risks as previously identified and set out in an IFU will apply to that product."

In other words, because of the similarity of product, the Defendant was able to use its experience with existing products in formulating appropriate IFU for the C-Stem.

33. The IFU that was packaged with the C-Stem HO size 3 supplied and implanted in the Claimant, was IFU-0902-00-701 Rev G (although the evidence was that earlier revisions did not materially differ). That IFU was, of course, approved by the relevant regulator, and it continues to be approved.

34. So far as relevant to this claim, the IFU said (all emphasis etc in the original):

> **"WARNINGS AND PRECUATIONS**
>
> …
>
> **CAUTION:** The following conditions, singularly or concurrently, tend to impose severe loading on the affected extremity, thereby placing the patient at higher risk for failure of the hip replacement:
>
> *1.* Obesity or excessive patient weight.
>
> *2.* Manual labour.
>
> *3.* Active sports participation.
>
> *4.* High levels of patient activity…
>
> …
>
> WHEN THE SURGEON DETERMINES THAT THE HIP REPLACEMENT IS THE BEST MEDICAL OPTION AVAILABLE AND DECIDES TO USE THIS PROSTHESIS IN A PATIENT WHO HAS ANY OF THE ABOVE CONDITIONS OR WHO IS SIMPLY YOUNG AND ACTIVE, IT IS IMPERATIVE THAT THE PATIENT BE INSTRUCTED ABOUT THE STRENGTH LIMITATIONS OF THE MATERIALS USED IN THE DEVICE AND FOR IMPLANT FIXATION, AND THE RESULTANT NEED TO

> SUBSTANTIALLY REDUCE ANY OF THE ABOVE CONDITIONS.
>
> …
>
> Excessive physical activity or trauma to the replaced joint may contribute to the premature failure of the hip replacement by causing a change in position, fracture and/or wear of the implants. The functional life expectancy of prosthetic hip implants is, at present, not clearly established. The patient should be informed that factors such as weight and activity levels may significantly affect wear.
>
> …
>
> **ADVERSE EVENTS AND COMPLICATIONS**
>
> The following are generally the most frequently encountered adverse events and complications in hip arthroplasty:
>
> **General**
>
> *1.* Change in position of the prosthetic components, often related to the factors listed in WARNINGS AND PRECAUTIONS.
>
> *2.* Early or late loosening of the prosthetic components, often related to the factors listed in WARNINGS AND PRECAUTIONS.
>
> *3.* Fatigue failure of the femoral stem, often related to the factors listed in WARNINGS AND PRECAUTIONS…."

The Factual Background

35. The Claimant was born on 31 October 1951. He is a general builder and plumber by trade.

36. In 2004, the Claimant began suffering from increasing pain in his hips; and, in July 2005, an X-ray revealed degenerative changes in both hips. The medical records indicate that he was over 120kg in weight, and had been substantially heavier in the recent past. He was advised to lose weight. In April 2006, he had injections; but these were not effective in reducing the pain in either hip for more than a couple of weeks. The Claimant described how this pain was considerable, and how it seriously reduced his mobility and ability to function in his everyday life.

37. He was referred to Professor Sochart who, on 10 August 2006, conducted a review and advised upon the implant options available. In a letter dated 23 August 2006, he recorded the presence of bilateral osteoarthritis in the Claimant's hips, and that his left leg was 2cm shorter than his right leg. He continued:

> "The pros, cons and risks of total hip replacement in general were discussed with Mr Wilkes and in particular the risk of infection, thrombosis, embolism, dislocation and leg length discrepancy. Following this we discussed the implant options available and it was felt that given Mr Wilkes' age, size and occupation then some form of metal on metal arthroplasty would be indicated, either resurfacing or an extra large head on a conventional stem.
>
> Following discussion Mr Wilkes was keen to proceed with a left sided resurfacing arthroplasty. He has therefore been listed for this and will be sent for in due course…."

38. The Claimant remembers Professor Sochart telling him that he was relatively young for a hip replacement, and that is why a metal-on-metal arthroplasty would be suitable, because of the movement it would give him. It would allow him to resume a normal life, and carry on working as a builder/plumber. In his statement, Professor Sochart says:

> "8. I explained to Mr Wilkes that the hip to be fitted should last him a long time, and that after the operation and an appropriate recovery period Mr Wilkes would be able to resume normal life and continue to work as a builder/plumber. I did not consider that Mr Wilkes' size would present a problem in respect of the operation that I was to perform and indeed confirmed this to Mr Wilkes when he asked the question.
>
> 9. I informed Mr Wilkes that following recovery he would be able to continue to work in his business and would be able to climb ladders and do roof work and that it should not affect his social life."

39. The Claimant said that he understood that he was being admitted for a resurfacing procedure; but that, if technical difficulties with that were encountered during the course of the procedure, a total hip replacement would be performed. That was confirmed at his pre-operative assessment, as evidenced by the letter from the Specialist Registrar to the Claimant dated 13 December 2006.

40. The Claimant was admitted to the NMG Hospital on 3 January 2007, under the care of Professor Sochart. He is recorded as weighing 123kg. The operation was performed that day, using the DePuy ASR Total Hip Replacement System with a C-Stem. Professor Sochart says that it was straightforward, although, in the event, a full hip replacement was required.

41. The Claimant's recovery was longer that he had hoped and expected, because his left leg was numb and stiff for some time, and he required considerable physiotherapy. However, by mid-2007, he was back at work; although only doing small jobs, and generally taking care of himself. It was only in 2008 that he started to do ladder-work again, and then only at low heights of no more than eight feet or so. His son helped him with heavier and higher work.

42. During 2008, the Claimant said that he got very much better, although parts of his left leg continued to be numb. It was, he said, generally a good time so far as his mobility and hip pain were concerned. However, by early 2009, his right hip was very painful. In April of that year, he recalls "really struggling" to do a guttering job on a single storey building.

43. On 26 May 2009, he was admitted to the NMG Hospital once more for right hip replacement surgery, which was again performed by Professor Sochart and again with a C-Stem. The surgery was uneventful, and successful; and the recovery went well.

44. That year, although he said he undertook no strenuous activity, he went caravanning. He was planning to return to work as a builder/plumber in early 2010. In the meantime, he found a job as a caretaker at a firm of solicitors, for 15 hours per week. There, he did such jobs as empty the bins, mop and lock up. In late 2009, he went on holiday to Florida for two weeks, and started to do some small plumbing jobs. He had by this time, lost some weight. He was about 110kg.

45. On 5 January 2010, as he was walking out of his kitchen at home, the Claimant felt his left hip "give way". Subsequent investigations at the NMG Hospital showed that the C-Stem had suffered a fracture, in the neck region. On 21 January 2010, the left hip components were removed and replaced with components of a different model, including an Exeter V40 short cemented stem and a wide ceramic V40 head. The Claimant was off work until 7 May 2010, when he resumed as a caretaker with the same hours, and he also began doing small building and plumbing jobs for about five hours per week.

46. Unfortunately, on 13 August 2015, when he was in the kitchen at work, he felt his left hip suddenly "go", in much the same way as it had in January 2010. Examination showed that the Exeter stem had fractured; and, on 17 August 2015, a further revision procedure was performed, using a C-Stem AMT HO size 4 stem.

C-Stems: Other Fracture Reports

47. As I have explained, fatigue failure is noted in the C-Stem IFU as one of the "generally… most frequently encountered adverse events" associated with the product (see paragraph 34 above)

48. Gordon Taylor is the Defendant's Complaints Manager. He said that the most recent sales information, to the end of June 2016, shows that nearly 133,000 C-Stems Mk II have been sold, of which 10,275 were HO size 3. In respect of the 133,000, there have been 26 complaints of stem fracture, in six of which the complaint related to a fracture in the neck/taper region, one of which was the Claimant's case. That equates to a stem fracture failure rate of 0.195%, and a stem neck fracture rate of 0.004%. Of the 26 cases, four were in respect of HO size 3; one of which was again, of course, the Claimant's case. Two of these four cases concerned a fracture in the neck/taper region, the Claimant's case and one other. Sales figures for the earlier "Mk I" design are not available, but there have been an additional three complaints of stem fracture in respect of those.

49. When the Claimant's prosthetic hip failure was reported on 12 March 2010, the Defendant gave it the identifying reference DINT 13179; and, later, under its new system, COM-0161250.

50. There is a note on the report "Link to DINT 14530". That is one of two other specific reports upon which Mr Trotman focused. That report was first received by the Defendant on 7 October 2010. It concerned a C-Stem ASR XL, which had suffered a neck fracture, the fracture face and positioning of the break indicating fatigue of the stem. However, on the basis of the available information and the failure of the patient to agree to destructive testing, it was concluded that the root cause was "undetermined". On 5 December 2011, the complaint was closed with an "indetermined [sic] conclusion", on the basis that, if further information came to light or the patient agreed to destructive testing, then it would be investigated further.

51. The other report upon which Mr Trotman focused was DINT 3427, apparently first made to the Defendant on 1 December 2004, i.e. prior to the Claimant's left hip procedure in 2007. It again concerned a fracture at the neck of a stem that was supplied in 1999 (and was thus clearly not a Mk II model). Again, this was closed on 14 March 2005 with an "indetermined conclusion", on the basis that, without further information about the patient:

> "The root cause could not be confirmed. If patient weight and activity level information is received then investigation could be progressed further."

It was entered on the complaints database, and was to be "monitored through trend analysis". A review in April 2006 found that there was no new information available.

52. However, the evidence extends beyond the Defendant's own experience. As I have already described (paragraph 23 above), the NJR publish an annual report on the data in relation to various joint procedures which it has collected. Although the release of data depends upon the patient's consent, the returns are high, e.g. at least 77% of all procedures in 2005, and 81% in 2006. The NJR's Third Report (for the year 2005), reported that, of a total of 5,348 recorded hip revision procedures that year, the indication for surgery in 88 cases (to the nearest round number, 2%) was stem fracture. The Fourth Report (for the year 2006), reported that, of a total of 5,355 recorded hip revision procedures that year, the figure was 80 (1%). By far the highest number and percentage of cases gave an indication of failure of "aseptic loosening", i.e. loosening of the stem in the femoral bone (3,352 (63%) and 3,338 (60%) in 2005 and 2006 respectively).

The Consumer Protection Act 1987

53. Part 1 of the Consumer Protection Act 1987 implements EC Council Directive 85/374/EEC ("the Directive"). The Directive is not directly applicable, and the Claimant's cause of action is derived from the Act. For the purposes of this claim, the focus is therefore on the Act, not the Directive. However, it was not suggested that the Act failed to implement the Directive in any material way; and, section 1(1) of the Act requires the statutory provisions to be construed on the basis that it is intended to comply with the Directive, providing:

> "This Part shall have effect for the purpose of making such provision as is necessary in order to comply with the [Directive] and shall be construed accordingly."

54. One main purpose of the Directive and Part 1 of the Act is, of course, to protect the interests of consumers, hence the title of the Act. However, as Powers & Barton emphasise (at paragraphs 13.55 and following), importantly, the Directive is not driven solely by those interests: its aim is, rather, to "solve the problem, peculiar to our age of increasing technicality, of a fair apportionment of the risks inherent in modern technological production" (the Second Recital). It does so, not by imposing absolute liability or a warranty of performance (see Tesco Stores v Pollard [2006] EWCA Civ 393 ("Tesco Stores") at [17] per Laws LJ); but by imposing "liability without fault on the part of the producer". Thus, under article 4 of the Directive, although an "injured party" does not have to prove negligence or fault, he "shall be required to prove the damage, the defect and the causal relationship between defect and damage".

55. Whilst there has been considerable academic discussion about the proper approach to a claimant's task in proving these elements, there are few authorities which have considered the relevant issues. However, Mr Trotman relied upon the monumental judgment of Burton J in A v National Blood Authority [2001] 3 All ER 289 ("A v NBA") in this regard. The claimants had been infected with the hepatitis C virus through blood transfusions which had used blood ultimately obtained from infected donors. At the time when the relevant blood products were supplied, the virus had not been discovered or, at least, there was no screening test for it. Nevertheless, the claimants claimed damages against the authorities responsible for the production of blood products under the Act. They claimed, broadly, that the infection of the blood resulted from a manufacturing defect. The defendant submitted that, if there was a defect in the blood, then it was a design defect.

56. Mr Myhill submitted, with force, that A v NBA is readily distinguishable from the Claimant's case on a number of grounds – to some of which I shall refer later in this judgment – but Mr Trotman considered that Burton J's approach to the matters which a claimant is required to prove was broadly correct, and this court should follow it. His closing submissions attempted to follow that approach, namely:

    i) the identification of "the harmful characteristic which caused the injury" (see A v NBA at [67]);

    ii) the determination of whether the product was "standard" (i.e. whether it performed as the producer intended), or "non-standard" (i.e. whether it did not perform in that manner) (see [36] and [67]); and then

    iii) the application of an approach to circumstances which bear upon the definition of "defect", dependent upon whether the product was found to be "standard" or "non-standard" (see [68]-[73]).

57. However, I have some substantial difficulties with each stage of that analysis.

58. Burton J said (at [67]) that "[t]he first step must be to identify the harmful characteristic which caused the injury". Thus, in the words of Christopher Miller and

Richard Goldberg in their book "Product Liability" (2nd edition) ("Miller & Goldberg"), at paragraph 10.92, Burton J appears to have "[identified] the primacy of causation before any investigation of defect can take place". Leaving aside the practical problems to which the approach gives rise, to which Miller & Goldberg refer, in my respectful view, the approach is self-evidently circular: 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. In any event, concentration at this early stage on causation is a distraction from the true focus of the Directive and the Act, which is on defect. It is to that which I shall immediately turn, after clearing the decks. I shall return to the other elements of the analysis in A v NBA, in due course.

59. Clearing the decks can be done very briefly. Section 2(1) of the Act provides that "subject to the following provisions of this Part, where any damage is caused wholly or partly by a defect in a product, every person to whom section 2(2) below applies shall be liable for the damage". It is common ground that, for the purposes of the Act, the C-Stem is a "product": and the Defendant comes within section 2(2) as a producer of the C-Stem.

60. And so to "defect". "Defect" is defined in section 3 of the Act, as follows:

> "(1) Subject to the following provisions of this section, there is a defect in a product for the purposes of this part if the safety of the product is not such as persons generally are entitled to expect; and for those purposes 'safety', in relation to a product, shall include safety with respect to products comprised in that product and safety in the context of risks of damage to property, as well as in the context of risks of death or personal injury.
>
> *(2)* In determining for the purposes of subsection (1) above what persons generally are entitled to expect in relation to a product all the circumstances shall be taken into account, including –
>
> > *(a)* the manner in which, and purposes for which, the product has been marketed, its 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."

This reflects, but also expands upon, article 6 of the Directive. In particular, section 3(2)(a) is substantially more detailed than its direct equivalent of article 6(1)(a), which refers to merely "the presentation of the product".

61. Thus, in short, for the purposes of the Act, there is a defect in a medicinal product if the safety of the product is "not such as persons generally are entitled to expect", taking into account "all the circumstances".

62. Few would demur from the learned authors of Miller & Goldberg, at paragraph 10.13, when they say:

> "It is arguable that the definition of a 'defect' is the single most difficult part of the… Directive and Part I of the… Act".

However, whilst some of the mountains in the distance are formidable, this claim does not require us to climb them all; and some of the foothills are relatively gentle. With regard to "defect" in this context, some clear and uncontroversial propositions can be made.

63. First, whilst, in relation to a product, negligence focuses upon the acts and omissions of those involved in production etc, the Directive and the Act focus rather upon the condition or state of the product itself. This is fundamental to the move away from fault-based liability, heralded by the Directive.

64. Second, the condition of the product required by the Directive and Act is not put in terms of (e.g.) fitness for purpose or efficacy, but rather in terms of safety and only in terms of safety, the required hallmark of defect being a lack of safety.

65. Third, although Mr Trotman was reluctant to accept the point, safety is inherently and necessarily a relative concept. Certainly, as I have indicated (paragraphs 13-14 above), no medicinal product, if effective, can be absolutely safe. Whilst I fully appreciate the debate between consumer expectations and risk-benefit (admirably described in Section C of Chapter 10 of Miller & Goldberg), however consumer expectations are defined and gauged, there cannot be a sensible expectation that any medicine or medicinal product is entirely risk-free. As I have described, the potential benefits (including potential utility) of such a product have to be balanced against its risks.

66. Of course, that is not done (or not only done), with the benefit of hindsight, by considering the benefits actually obtained by a specific patient, and the adverse effects actually suffered by him: for a patient who suffers a severe adverse reaction or failure of a product, then of course that may overwhelm any therapeutic benefit he personally gains from it. Medicinal products are prescribed and used to alleviate symptoms and/or improve the patient's condition and functionality. The potential benefits of a medicinal product for a particular patient are often very substantial. Properly informed patients will often wish to accept risks posed by such a product, rather than continue to bear the symptoms and/or lack of functionality that attaches to the conditions for which the product is prescribed and from which they suffer. I have described the difficulties that the Claimant had with his left hip, which resulted in Professor Sochart advising (and the Claimant accepting) that a hip replacement operation should be performed. The potential benefits from the operation for the

Claimant were considerable. What have to be balanced are, or at least include, the potential benefits of the medicinal product for the specific patient against the risks for that patient, at the time the product is used. I say "include" because a particular medicinal product (such as a vaccine) may require consideration of a wider range of risks and benefits, including the public interest.

67. Of course, the fact that risk-benefit may lie at the heart of the question of appropriate level of safety of a medicinal product for the purposes of the Act does not mean that the detailed specific aspects of the doctrine of risk-utility as formulated in the United States will apply – or that the approach of our courts will, or should, be the same.

68. The Directive and Act set a standard of safety for virtually all products supplied to consumers, i.e. "every 'movable' which is commercially supplied" (Powers & Barton at paragraph 13.84), or, as Mr Myhill said, from an electric heater to a bottle top, from a car to a medicine. The standard of safety which people are entitled to expect across the whole range of these products is incapable of precise definition in a framework document such as the Directive; but, of course, more assistance and guidance could have been given than is found in that document. As Professor Stapleton has said, as it is left, the definition of "defect" used is at best circular, and at worst empty, because "what a person is entitled to expect is the very question a definition of defect should be answering" (J Stapleton, "Product Liability" at page 234: quoted in Miller & Goldberg at paragraph 10.18). However, those responsible for the Directive clearly, and deliberately, declined to do give better particulars. Indeed, in the report commissioned by the European Union in 2003 (J Meltzer, R Freeman and S Thompson, "Product Liability in the European Union: A Report for the European Commission the Report on Product Liability"), the possibility of defining "defect" to clarify controversial issues was mooted; but, the authors of the report understood that this might fetter the ability of judges to deal with such matters on a case-by-case basis. The report envisaged that a body of case law would develop that would give guidance with regard to the concept. However, no such body of law has yet developed.

69. The reference to judges being able to deal with matters on a case-by-case basis reflects the fact that – as is rightly common ground before me – the test for safety in this context requires an objective approach. Therefore, the relevant level of safety is not that which a particular patient considers the product should provide; nor even the level of safety which members of the public generally may consider it ought to provide. The level of safety is not assessed by reference to actual expectations of an actual or even a notional individual or group of individuals. Section 3(1), reflecting article 6 of the Directive (which refers to "the safety which a person is *entitled* to expect"), defines "defect" in terms of "the safety of the product is not such as persons generally are *entitled* to expect…" (emphases added). That can only be a reference to an entitlement as a matter of law, not actual individual or even general expectation. As Burton J put it in A v NBA, at [31]:

> "(iv) 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 harm caused by a harmful characteristic.

> (v) In the assessment of that question the expectation is that of persons generally, or the public at large.
>
> (vi) The safety is not what is actually expected by the public at large, but what they are *entitled* to expect…" (emphasis in the original).

70. The fact that "expectation" in this context is objective in that sense is vitally important; because "expectation" can be (and, in common parlance, is often) used in a different way. Mr Myhill gave an example. A person undergoing spinal surgery with a 1% chance of being rendered paraplegic as a result of his operation due to a non-negligent complication, of which he is appropriately warned, if asked, would not say that he "expected" that complication to occur. It could be said that he does not expect it to occur. However, the patient is not *entitled* to expect that it will not do so, or that paraplegia will not happen to him, because there is a known (if very small) risk that it will, about which he was properly informed. The surgeon does not guarantee the aspired outcome. It is a risk that the patient bears.

71. In A v NBA, the parties had agreed that the question raised by the definition of "defect" under the Directive and Act concerned the "legitimate expectation" of persons generally; a formulation to which Burton J assented (at [31(vi)]). However, Mr Myhill submitted that the use of the phrase "legitimate expectation" in this context was an unnecessary and unhelpful gloss on the Act, particularly as it is used as term of art elsewhere, e.g. in public law. I agree. If by "legitimate expectation" here is meant simply "expectation as a matter of law", it would be unobjectionable; but, in my respectful view, a test of what persons generally are "entitled to expect" requires no gloss, and does not benefit from being re-described.

72. Therefore, in considering whether a product suffered from a defect, the court must assess the appropriate level of safety, exercising its judgment, and taking into account the information and the circumstances before it, whether or not an actual or notional patient or patients, or indeed other members of the public, would in fact have considered each of those factors and all of that information.

73. Fourth, although a claimant must prove causation in the sense of showing a causal link between the defect and damage, and it may be helpful to one side or another to show the cause of the lack of safety that amounts to defect, a claimant is not required to prove the cause of that lack of safety or why the product failed (see, e.g., Ide v ATB Sales Limited [2008] EWCA Civ 424 at [19]-[22] per Thomas LJ, as he then was). The issue as to the degree of specificity with which the defect (i.e. lack of safety) has to be described and proved (which has been the subject of considerable academic debate, on the basis of such cases as Richardson v LRC Products Limited [2000] PIQR P163 which, on one reading, suggest that considerable specificity might be required) is not in issue in this claim, and therefore I need say little about it; but one can imagine 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 for the Act, and therefore be defective.

74. Fifth, it is common ground and uncontroversial that the court must consider the level of safety at the time the product was first put out onto the market by the relevant

producer (derived from section 3(2)(c) of the Act, reflecting article 6(1)(a) of the Directive).

75. Having dealt with the uncontentious, we must now consider the potentially controversial, namely the circumstances which should (and any which cannot properly) be taken into account in making this assessment of safety. It is uncontroversial that the weight to be given to a relevant circumstance will, of course, be a matter for the court.

76. In determining the level of safety which the public is entitled to expect in this sense, section 3 of the Act, directly reflecting article 6 of the Directive, requires "all circumstances" to be taken into account, "including" three specific matters. "All circumstances" must mean "all relevant circumstances": there can be no place for a requirement to consider the irrelevant, nor any basis for demanding less than all relevant circumstance be taken into account.

77. The circumstances which are relevant in a particular case is itself a matter of law; but it is to be noted that neither the Directive nor the Act imposes any restriction on the considerations that may be taken into account. The three specific matters set out in section 3(1)(a) are circumstances which must be considered ("… shall be taken into account…"); but they are clearly not intended to be an exhaustive list of relevant circumstances, nor are they such that any other circumstance, to be relevant, must be shown to be *eiusdem generis*.

78. There has been a great deal of consideration, before me and in the cases and the academic texts, as to the circumstances which are or are not relevant, and therefore can or cannot be taken into account. However, by whatever criteria "acceptability" is gauged, assessment of whether the safety of a product is at an acceptable level requires a holistic approach (see paragraphs 13-15 above), involving the application of judgment to the exercise of balancing all relevant considerations. Given the wide range of products (and their intended use) to which the Directive and Act apply, the court must maintain a flexible approach to the assessment of the appropriate level of safety, including which circumstances are relevant and the weight to be given to each, those factors being quintessentially dependent upon the particular facts of any case. That was the intention – and, certainly, the effect – of the Directive (see paragraphs 65-66 above). As it is put in Powers & Barton (at paragraph 13.87):

> "Within these broad horizons, however, the open-textured character of the prescribed safety standard provides the court with a very considerable degree of flexibility in relation to the matters to which it can properly have regard to as to enable it to perform its duty, on a case-by-case basis, of ensuring that the appropriate safety standard is set on as fully an informed basis as possibly having regard to the facts pertaining to the specific product in question."

79. Accordingly, whilst over time cases may indicate which characteristics may be relevant in particular sets of circumstances (e.g. where the product is a prescription-only medicine), in my view, any attempt at formal rigid categorisation of products for these purposes is in conflict with the inherent flexibility of the Directive, and is likely to be both difficult and unwise. The issue raised by the Act in terms of defect is

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

80. Before me, the following circumstances came under particular scrutiny:

i) risk-benefit;

ii) the "avoidability" (or "non-avoidability") of the defect;

iii) whether the product is "standard" or "non-standard", in accordance with the distinction drawn by Burton J in A v NBA (see paragraph 56(ii) above);

iv) the compliance (or non-compliance) with appropriate standards;

v) the compliance (or non-compliance) with any relevant regime under which the product is regulated; and

vi) warnings and other IFU, and the role of any intermediary.

I will deal with those in turn.

Risk-benefit and Avoidability

81. These two matters can conveniently be taken together.

82. Section 3(2)(a) requires "the purposes for which the product has been marketed" to be taken into account. Primary amongst the purposes for which a medicinal product is marketed is the relief of a patient's symptoms and/or betterment of his condition and/or increase in his ability to function. Given that such a product will inevitably have some risks attached, as I have explained, any assessment of its safety will necessarily require the risks involved in use of that product to be balanced against its potential benefits including its potential utility. As such a product will almost always involve design compromises, the effect of eliminating or reducing a particular risk can only be seen in the context of any adverse consequences of doing so, in the form of increased risks of a different sort or reduced benefit and utility. Consequently, the practicability of producing a product of risk-benefit equivalence must therefore potentially be a relevant circumstance in the assessment of a product's safety. It is inherent in the relative nature of "safety".

83. Although not relevant in this case – because the Defendant does not suggest that cost was a factor in its design decision-making – in my view, without inappropriately

moving the focus from the product to the acts and omissions of the producer and/or others, cost too must be potentially relevant. This is illustrated by an example given in Miller & Goldberg at paragraph 10.82(c):

> "… [N]o 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 should 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."

84. With regard to "avoidability", Mr Trotman adduced considerable evidence (notably from Mr Hammersley) to persuade me that the defect in the C-Stem implanted in the Claimant was avoidable, and simply so. I will deal with the suggestions as to how that could have been done in due course (see paragraph 121 below). But in any event, Mr Trotman submitted that the avoidability or non-avoidability of the defect was not a circumstance that was relevant to the issue of defect.

85. I accept that, in considering avoidability, there is a danger of unduly focusing upon the acts and omissions of the designer/producer of the product, rather than the product itself. However, I consider that whether, and the ease with which and extent to which, a risk might be avoided, may, in appropriate cases, be a circumstance that is relevant to the question of level of safety and therefore defect under the Act; although, in respect of a medicinal product such as a prosthesis, I consider a detailed consideration of the discrete question of whether a particular risk is or is not "avoidable" is unlikely to be fruitful.

86. As I have explained, there is a small but recognised risk of stem fatigue in a hip implant at some stage in its life (see paragraphs 48 and 52 above). Mr Trotman accepts as much. Although Mr Hammersley said that the risk of stem neck fracture could be designed out altogether, as I understand it, Mr Trotman accepted that the public generally were not entitled to expect that a C-Stem would last, or even remain without fracture, for ever. However, in this case, he contends that persons generally were entitled to expect that the C-Stem would last, say 10-15 years, and certainly longer than it did last in the Claimant's case. In other words, the C-Stem ought to have been designed so that it lasted longer than it did implanted in the Claimant. On the basis of this contention, it is not suggested that the stem should not have failed at all, but rather that it failed earlier than it should have done. The issue of "avoidability" in these circumstances is therefore at best a matter of degree, rather than a simple binary issue.

87. On this issue, the cases are not of any great assistance. In A v NBA, although there are ambivalent passages, Burton J appears to have closed the issue of "avoidability" in the case of what he termed "non-standard" products (see [68]), but probably left it open for "standard" products (see [73]).

88. The nuanced nature of the issue was apparent in Bogle v McDonald's Restaurants Limited [2002] EWHC 490 (QB), a case concerning injures caused by the spillage of hot drinks served by the defendant in fast food outlets. Field J purported to adopt

Burton J's approach to avoidability; although, expressly, he adopted the proposition that "the avoidability of risk of harm is not a relevant circumstance" in respect of even "standard" products (see [73(d)]). However, he proceeded to consider the issue of safety, as the Directive required, in the context of the purposes for which the product had been sold. Clearly, the risk of scalding could be avoided by serving drinks cold; but he noted that the public want to be able to buy tea and coffee served hot. That is indisputable. Although phrased in terms of expectations, in substance, Field J appears to have considered avoidability as a soft-edged concept in the context of (effectively) a risk-benefit analysis, albeit, because of the facts of that case, very different factors bore upon the analysis in that case compared with this. He concluded (at [80]) that people expect (I think he meant, "want" or "require") tea and coffee to be served hot, and some prefer to drink those beverages in an open cup. They are aware of the risk involved in that. He continued:

> "They expect precautions to be 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 with a lid off."

In other words, although the risk of scalding was avoidable in absolute terms, the cost of avoiding it in terms of utility was unacceptably high. Thus, avoidability as seen in the broader context of the risk-benefit balance was, in substance, taken into account.

89. In my judgment, that is the correct approach. Whether a particular risk is "avoidable" is not an issue that will often be capable of being considered discretely, in a vacuum. In any event, it will not in itself be determinative of the issue of defect. However, in my view, in an appropriate case and without inappropriately moving the focus of the exercise, the ease and extent to which a risk can be eliminated or mitigated may be a circumstance that bears upon the issue of the level of safety that the public generally is entitled to expect.

Standard/Non-standard

90. Section 2(a), (b) and (c) of the United States Third Restatement on Products Liability classifies defects by reference to traditional types, namely manufacturing, design and warnings; and, as Burton J indicated in A v NBA at [39], in the United States, "there is almost a separate jurisprudence for manufacturing defects as opposed to design defects".

91. The Directive singularly does not seek to impose this taxonomy; and, at [39], Burton J, noting that to be the case, said that he considered "there is no place for [these American terms] in the Directive". He continued:

> "… I am satisfied, and indeed neither Counsel contended to the contrary, that no assistance can be gained from what Mr Underhill [Counsel for the defendants] called the 'boxing', or categorisation, of defects in this regard for the purpose of construction of the Directive, or the determination of any of the issues before me…."

92. Nevertheless, he proceeded to identify two categories of product, namely "standard" and "non-standard". He defined them in the following way (at [36]):

> "… [A] standard product is one which is and performs as the producer intends. A non-standard 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."

93. In Burton J's view, this categorisation, at least to an extent, then determines the approach to the circumstances which bear upon the definition of "defect" (see [68]-[73]). For example, as I have said (see paragraph 87 above), Burton J expressly excluded the relevance of risk-benefit in the case of a non-standard product, whereas he appeared to consider that that might be properly relevant in the case of a standard product.

94. In my respectful view, the categorisation of defects into "standard"/"non-standard", as a classification, is unnecessary and undesirable. It is not, of course, a classification deriving from the Directive or Act. In my judgment, whether a particular product is within the producer's specification, and is compliant with relevant standards (see paragraphs 97-98 below), may be relevant circumstances in relation to whether the level of safety is that to which persons generally are entitled to expect; but to raise the distinction to a rigid categorisation is positively unhelpful and potentially dangerous.

95. For example, in this case, Mr Trotman sought to persuade me that the C-Stem the subject of the claim was "non-standard" on the definition of Burton J, because, although the exact root radius of that stem is unknown, it might have been as low as 0.05mm, whereas, given that the specification required a root radius in the range 0.05-0.1mm, other such products (and, potentially, all other such products) might have had a root radius of 0.1mm (or, at least, more than 0.05mm). The C-Stem implanted in the Claimant might, therefore, have been a non-standard product; and, thus, he sought to argue, I should proceed on the basis that this was a non-standard product, and omit consideration of risk-utility.

96. However, even leaving aside the burden of proof (which, in respect of defect, is upon the Claimant, and which, in my view, alone prevents this argument leaving the ground), this appears to me to be an arid exercise, is 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. I appreciate that, where a particular specimen of a product is out of specification (or otherwise "non-standard"), then risk-benefit of an in-specification product is unlikely to have much, if any, weight: but I would not advocate a rule of law that it must have none. In assessing the safety of a product, the court should consider the relevant circumstances, in a suitably flexible way: no more and no less.

Standards

97. It was, rightly, common ground that non-compliance with any appropriate mandatory standards will provide evidence of defect; and that compliance with such standards,

whilst not providing a complete defence, will provide evidence that, in respect of the matters to which those standards go, the level of safety required by the Act has been satisfied and the product, in those respects, is therefore not defective. I do not consider that Laws LJ in Tesco Stores at [15] intended to suggest otherwise.

98. In an appropriate case, compliance with such standards will have considerable weight; because they have been set at a level which the appropriate regulatory authority has determined is appropriate for safety purposes.

Regulatory regime

99. The same is true, as is again common ground before me, with regard to compliance or non-compliance with regulations which apply to a product.

100. As such regulations are made by Parliament – or those to whom Parliament has delegated the function, because of their particular expertise and experience in the field – it has been said that "[s]uch evidence [of compliance] will be regarded as particularly cogent, and indeed often effectively dispositive of the matter, where the regulations are updated and detailed" (Miller & Goldberg at paragraph 10.77). Certainly, where every aspect of the product's design, manufacture and marketing has been the subject of the substantial scrutiny, by a regulatory body comprised of individuals selected for their experience and expertise in the product including its safety, on 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. That is the view of the learned authors of Benjamin on Sale of Goods (9th Edition) at paragraph 14-099, with which I agree. The challenge is compounded where, as here, the standards for the product are set on a European-wide basis, such that CE marking hallmarks a product as one which has satisfied the relevant standards (including safety standards) so that it can be marketed throughout Europe.

101. Of course, the simple fact of regulatory approval is not an automatic defence under the Act – nor even a prima facie defence, as in the United States. However, in my view, 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.

Warnings and Other IFU

102. Although article 6(1)(a) of the Directive merely refers to "presentation of the product" as a circumstance which must be taken into account, section 3(2)(a) expands that to include:

> "… 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."

That includes information provided in respect of the product's use, and warnings.

103. Clearly, warnings given in relation to a product will qualify the expectation that the public generally are entitled to expect of a particular product, and thus go to the issue of whether that product is defective. That appears to be the unanimous conclusion of the authorities (see, e.g., Worsley v Tambrands [1999] EWHC 273 (QB); [2000] PIQR P95 at page P104), and academic texts (see, e.g., Clerk & Lindsell on Torts (21st Edition) at paragraph 11-62, and Miller & Goldberg at paragraph 12.65)

104. Where a product, such as a C-Stem, is available to a patient only via a professional healthcare intermediary, the position is more complex.

105. The learned intermediary issue was not directly considered in A v NBA, but, in relation to knowledge of the risk of infection with hepatitis C, Burton J said this (at [55]):

> "I do not consider it to be arguable that the consumer had an actual expectation that blood being supplied to him was not 100% clean, nor do I conclude that he had knowledge that it was, or was likely to be, infected with hepatitis C. It was not seriously argued by the defendants, notwithstanding some few newspaper cuttings which were referred to, that there was any public understanding or acceptance of the infection of transfused blood by hepatitis C. 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)…."

106. Read in its proper context, I am not sure that Burton J there intended to convey the impression that the presence of a learned intermediary in the chain between producer and patient was not a relevant circumstance for the purposes of informing the scope of safety, and thus of defect, under the Act – although I accept that other parts of the judgment suggest that he may have done so. However, Mr Trotman appears to have accepted (as Mr Myhill submitted) that an intervening healthcare professional is a relevant circumstance; and, insofar as Burton J concluded differently, I respectfully but firmly disagree.

107. In this case, as Mr Myhill emphasised, there was no interaction between the Defendant as producer and the Claimant – the Defendant having no statutory duty to provide the Claimant with a patient information leaflet or any information, because Parliament has determined that, in relation to such products, information about risks is best relayed to, considered by, and applied and passed on to the patient by the treating surgeon, who must advise that patient as to intervention choices, and seek and obtain that patient's informed consent the particular chosen implant procedure.

108. Again, the fact that there is a learned intermediary does not provide a complete or automatic defence for a producer of a medicinal product. However, particularly in respect of a product such as a prosthesis (in respect of which there is no obligation upon a producer to give any information direct to the patient), it seems to me unarguable that the fact that there is a learned intermediary (who has chosen a particular prosthesis for a particular patient and has available, not only his general professional knowledge, but also the specific IFU including warnings) is other than a

relevant circumstance for the purposes of section 3 of the Act. That, again, appears to be the unanimous view of academic writers (see, e.g., Clerk & Lindsell (ibid), and Miller & Goldberg (ibid)).

The Stem Fracture

109. The experts, Mr Hammersley and Professor Doyle, were agreed about much.

i) As concluded by the BSI as the Notified Body, subject to one issue to which I shall return (see paragraphs 110(i) and 115 below), they agreed that the C-Stem met all Essential Requirements imposed by the Medical Devices Directive including the strength safety requirements (paragraph 9 of their Joint Statement dated 2-3 August 2016). Indeed, Mr Hammersley considered that "[t]he fact that the number of C-Stems that fail by fatigue is statistically very small indicates very strongly that the C-Stem had been designed to withstand loading in excess of that specified by ISO 7206-4 endurance testing standard" [i.e. the relevant standard set out in BS 7251-5:1990 read with BS 7251-12:1995 (the technical equivalent of ISO 7206-4:1989 read with ISO 7206-8:1995 (see paragraph 19 above)]. Professor Doyle agreed; and the test parameters described above (see paragraphs 30-31) show that the C-Stem was tested to criteria more demanding than those in the relevant BS.

ii) The offset nature of the stem had no effect on the bending-induced stresses at the neck, i.e. where the stem fractured (paragraph 25 of the Joint Statement).

iii) Mr Hammersley and Professor Doyle agreed on the process whereby the C-Stem fracture occurred. Examination of the fracture faces of the stem revealed ridge-like features created at crack initiation ("ratchet marks") and crack progression marks ("beach marks"), characteristic features of fatigue fractures. As to the way in which the fracture had occurred, they agreed as follows (paragraph 8 of their Joint Statement):

> "… [T]he process of the fracture in the index case, leading to the event of January 2010, was as follows:
>
> (i) Fatigue crack growth from opposite sides of the circular cross-section of the neck of the C-Stem,
>
> (ii) due to the application of repeated fully reversed bending loads,
>
> (iii) that gave rise to fluctuating tensile stresses at the point of fracture.
>
> (iv) Fatigue cracks gradually extended through the neck from opposite sides,
>
> (v) until eventually a narrow ligament of uncracked material [agreed between the experts to be about 13% of the whole stem cross-section: paragraph

10(a) of their Joint Statement] was all that separated them.

(vi) This narrow, uncracked ligament then fractured, probably under a single load application, at which point complete separation of the C-Stem occurred."

iv) The thread at the C-Stem neck was formed by machining, not rolling (paragraph 31 of the Joint Statement).

v) The root of the grooves of the thread at the neck of the stem would act as a preferential site for fatigue crack initiation, because stresses created by loading would be concentrated there (paragraph 30 of the Joint Statement).

110. However, there were some areas of disagreement.

i) Mr Hammersley focused on the fatigue test of 5m cycles at between 300N and 2.3kN, suggesting that, in the three-year period between the implant and its failure, the Claimant could not have imposed the equivalent loading upon the hip. On various assumptions, he calculated that it would require about 7,000-plus steps per day, every day, to be equivalent to that test: and, given the Claimant's periods of inactivity because of his two hip operations, on the balance of probabilities, the Claimant did not perform anything like that number of steps. Mr Hammersley also referred to the Claimant's prosthetic right hip – which also has a C-Stem shaft – which has not failed in seven years of use. He said that it was unlikely that the variation in loading between left and right hips would be so great as to explain why two notionally identical C-Stems would perform so very differently in the same patient (paragraph 23 of the Joint Statement). He was not impressed by the suggestion that the Claimant's weight and/or the number of steps that he in fact took were such as to explain why the C-Stem failed when it did. Mr Hammersley thus suggested that the C-Stem with which the Claimant was fitted fell below the fatigue strength level of the C-Stems tested (i.e. it was outside specification).

ii) Although the experts agreed that stress would be concentrated at the root radius of the thread groove, they were not agreed on the extent of that concentration. Using the formula set out in "Stress concentration formula useful for all notch shape in a round bar" (Noda N-A and Takase Y, International Journal of Fatigue 28 (2006) 151-163 ("Noda et al")), and particularly the graph at Fig 14 of that article, together with a mathematical formula to reflect the fact that in this case there was a thread not a single groove (the "gamma correction factor"), Mr Hammersley suggested that the stress concentration at the root groove in this case would have been in the region of 3.72 if the root had been 0.05mm (and somewhat less if the root radius had been higher). Mr Hammersley performed calculations that suggested that, had the neck of the C-Stem been smooth when subject to a load of 3.3kN the tensile stress would be about 18% of the Ultimate Tensile Strength ("UTS") (i.e. the strength at which the stem would fail and fracture with the application of that single load), whilst at the bottom of the thread grove radius that stress would have been about 68% of UTS, i.e. it would have a margin of only 32% rather than 82%.

iii) Mr Hammersley considered that the problem lay with the thread at the stem neck, which create concentrations of stress, and thus areas of particular weakness, in the root radii or groove valleys. That thread was entirely unnecessary for use with a metal head; but, if it was to be used, then the nature of the groove could be altered so that the concentration of stress was eliminated or reduced, by (i) increasing the size of the cross-section of the stem neck, and/or (ii) changing the groove profile to increase the root radius and/or to make the profile sinusoidal, and/or (iii) rolling, rather than machining, the thread.

iv) He was critical of the absence of any record of any calculations of the fatigue endurance limit of the austenitic stainless steel used in the C-Stem (i.e. the stress level below which fatigue cracking will not occur). In his view, that limit could and should have been calculated. Having calculated that, it would be possible to design out the risk of fatigue so that there would be no inherent tendency for (i.e. risk of) failure by way of fatigue, even at the thread groove, by ensuring that stresses in the component when in use will always remain below that limit or will only exceed that limit at a frequency and/or by an amount that would be immaterial (paragraph 37 of the Joint Statement).

111. Professor Doyle took a different view.

i) She said that, in any individual case, the exact load on a prosthetic stem was informed by a substantial number of variables, including, for example, the anatomy of the patient (which is unique), his gait including stride length (which may be altered by other physical disabilities, such as problems with the other hip), the extent of any arthritis, any pre-existing conditions, surgical technique and the precise positioning and alignment of the C-Stem (whether within or outside the boundaries of the surgeon's duty of care), and the amount of micromovement between the stem and the surrounding cement. She was not convinced by the calculations produced by Mr Hammersley as to weight, steps and load; but, in any event, weight and number of steps performed were only two of many relevant variable criteria. They could not be considered the only relevant variables, simply because information on other possible variables (such as the Claimant's anatomy) was thin, so that no positive conclusions as to their impact in this case could be drawn.

ii) There were no calculations available of the theoretical fatigue failure level. However, Professor Doyle emphasised that the design of the C-Stem included all of the available data, including those from the tests, the post-marketing surveillance data and the other data from the marketing of this and other similar products. She said that the fatigue failure test (which was on a C-Stem with thread) was designed to ensure that the strength of the component was adequate in practice, i.e. that the risk of fatigue failure was acceptably small. It passed – and surpassed – that test. Furthermore, in this case, there is a considerable body of post-marketing surveillance data, shared with the MHRA and the BSI, which has satisfied those authorities that the risk remains acceptable. Those data do not suggest that the rate of failure is anything other than very low, in line (or lower) than the rates of failure of other equivalent products, and "acceptable" in the context of the general risk-benefit balance for the product.

112. In respect of these issues, I found the evidence of Professor Doyle generally the more persuasive. Mr Hammersley, understandably given his background, approached the issues from the perspective of a general forensic engineer, and focused upon theoretical mechanical calculations based upon limited criteria, notably weight/load and number of cycles/steps. But there are considerably more variables in the field of biomechanics than there are in (e.g.) the mechanics of an entirely artificial construction such as an aeroplane. Human bodies are infinitely variable, and, as Professor Doyle stressed, there are very many variables at work when consideration is given to the differential load that a prosthetic hip, in all its aspects, bears.

113. In particular, I do not agree with Mr Hammersley's analysis (and Mr Trotman's submissions to like effect) that, because there is no proof that other particular factor or factors are involved, it is appropriate to focus exclusively on general loading weight and number of cycles or steps. If matters were that simple, then medics could confidently predict when a femoral stem will fail by way of fatigue in a particular patient. Unfortunately, they cannot do so, precisely because of the variables involved. This means that, whilst the risk of failure by stem fracture is small, it is unpredictable: it is impossible to identify precisely the patients in whom fracture (or early fracture) will occur. The same is true for other modes of failure, in respect of some of which the risk of failure is much higher (e.g. by failure by loosening of the stem within the femoral cement, which in itself can lead to stem failure).

The Alleged Defects

114. In the Particulars of Claim, drafted by Mr Trotman, it was alleged that the C-Stem implanted into the Claimant suffered from manufacturing defects and/or design defects.

115. I can deal with the former shortly. Paragraphs 6 and 7 of the Particulars of Claim set out various defects that were alleged to arise from the manufacture, as opposed to the design, of the product. One – that the thread at the neck was formed by machining rather than rolling – was in fact a design feature, and can best be dealt with as such. With regard to the rest, by the time of closing submissions, Mr Trotman had abandoned reliance upon all except one, i.e. the alleged defect dealt with above (see paragraphs 95-96). For the reasons I have given, there was no force in the submissions in relation to that. The abandonment of the other "manufacturing" grounds was, in my view, entirely appropriate and wise. There is no evidence of any manufacturing defect, or other defect in the sense of the C-Stem implanted into the Claimant being outside the design specification. I did not see any force in any suggestion made by Mr Hammersley that, on the basis of his calculations, this particular stem could not have complied with the standard tested in accordance with BS 7251-5:1990 read with BS 7251-12:1995. That ignored the other variables to which I have referred. In any event, Mr Trotman, in my view rightly, did not pursue such a case.

116. In his closing submissions, Mr Trotman essentially relied upon a single formulation of defect. He submitted that the C-Stem was defective in design, because persons generally would not have expected the stem to suffer from early fracture arising out of a known stress concentration factor, when simple design measures could have removed the same (paragraph 39 of his closing submissions). In another iteration of what I understood to be in substance a similar formulation, in paragraphs 21-27 of his

written opening, he submitted that persons generally would be entitled to expect that the design of the C-Stem gave a greater margin on testing than the effectively 32% of the UTS that occurred here (see paragraph 109(ii) above), in circumstances in which the design could easily have been changed to give a much greater margin.

117. As forcefully as those submissions were made, I am unpersuaded by them. In my judgment, the C-Stem did not fall below the safety persons were generally entitled to expect at the time it was put into circulation, on the grounds put forward; and thus it was not defective for the purposes of the Act. In coming to that conclusion, I have taken into account, particularly, the following.

118. First, Professor Doyle was sceptical of Mr Hammersley's conclusion that the C-Stem neck thread concentrated stress within the bottom of each groove such that, when subject to a test load, the tensile stress there would be 68% of UTS. At one point in his evidence, Mr Hammersley said that, working at that level of UTS, there must have been "a high risk of failure", although he later retreated from that to merely "a risk of failure". But Mr Trotman picked up the point in his closing submissions, when he said that, by allowing a design specification tolerance that enabled the root radius of the thread groove to lie between 0.05 and 0.1mm, "[t]here was a failure [by the Defendant] to appreciate that such a margin brought *a high level of hazard*" (paragraph 20 of his closing submissions: emphasis added), which would have been avoided, he said, if the minimum specified radius had been 0.1mm, 0.2mm giving an even safer margin. Allowing a root radius of below 0.1mm, "invited fatigue failure in certain circumstances" (ibid).

119. Indeed, Professor Doyle accepted that routinely working at 68% of UTS would reduce the fatigue life of any component. However, as I have indicated, she was sceptical about that figure. In my view, that scepticism was justified. The figure was calculated by reference to a graph in Noda et al – which relates to a single notch and from which, as Mr Hammersley accepted, it is difficult to read off at the 0.05mm end – and a gamma correction factor to which Mr Hammersley did not refer until a point towards the end of his oral evidence. In any event, I accept Mr Myhill's submission, supported by the evidence of Professor Doyle, that, if the margin was in fact that fine, the absolute numbers and proportion of failures would be much higher than they are. As I have indicated (paragraph 48 above), the failure rate as a result of fatigue fracture at the stem is just 0.004%, much less than the rate of such failures elsewhere in the stem.

120. Professor Doyle – in evidence I accept – said that testing and clinical results were a key part of the design process and establishing the safety of the device. She considered that the fatigue level was not best proved on the basis of theoretical calculations, but rather by way of consideration of other criteria, notably the performance of the C-Stem against the standard in BS 7251-5:1990 read with BS 7251-12:1995 which was specifically designed to ensure that there was an appropriate fatigue failure, and the performance of the product on the market as shown by post-marketing surveillance data. In relation to the former, because the test was by way of a mechanical load evenly and monotonously applied, given that in practice it would inevitably be the subject of biomechanical variations, the test criteria must have had built in a margin regarded by the regulators as being sufficient for safety purposes. In any event, as I have explained, the Defendant tested to significantly higher levels. Although we do not know why the Defendant adopted the precise testing criteria that

it did (see paragraph 31 above), I do not agree that the selection of those criteria was necessarily "arbitrary"; and, in any event, they set a standard substantially higher than that set by the relevant BSs. As to the latter, the C-Stem had been developed from the Elite stem, and the clinical experience of that stem was therefore relevant to the assessment of its safety. But, in any event, as I have described, the failure rate as a result of fatigue failure at the C-Stem neck was very small indeed; and none of the individual reports suggested a design "problem" in practice.

121. Second, whilst Mr Trotman was ambivalent about whether avoidability was a relevant circumstance, on the basis of Mr Hammersley's evidence, he submitted that the problem with the C-Stem was with the neck thread, and that problem could have been simply and easily avoided by (i) increasing the size of the cross-section of the stem neck, and/or (ii) changing the groove profile to increase the root radius and/or to make the profile sinusoidal, and/or (iii) rolling, rather than machining, the thread. However, I am unpersuaded as to the force of that submission, which focuses upon one, small aspect of the design of the stem thread, whereas design is necessarily holistic. Mr Hammersley had not considered the possible design disbenefits of such changes. Professor Doyle's evidence was that, for example, by increasing the size of the stem cross section, that could increase the need to remove more femoral bone and the risk of the stem impinging on the bone, which could, at least, make the prosthesis more uncomfortable if not more prone to failure.

122. On the basis of a short article presented at the Combined Orthopaedic Research Societies Meeting, San Diego 6-8 November 1995 (M Zimmermann et al: Modular Hip Prosthesis: Effect of Superficial Taper Structure on the Corrosion Behaviour of Different Material Combinations), Professor Doyle faintly suggested that a stem thread assists in producing efficient locking of components and reduces micromotion and corrosion. I consider that article is thin evidence for the proposition that the thread gives some engineering advantage over a smooth stem where it is attached to a metal head. However, it is uncontroversial that some form of roughened neck surface is essential if it is to be fitted to a ceramic head, because of the risk of the ceramic head otherwise fracturing, which is a serious complication. Professor Doyle said that, by having a stem with which metal or ceramic heads can be used interchangeably, has significant benefits in practice. It has an economic benefit for hospitals, because it reduces their inventory requirement. It also gives flexibility; and, importantly, eliminates the possibility of mismatching, which could be disastrous if a ceramic head were to be fitted on a smooth necked stem. Mr Trotman submitted that these were benefits that were "outside scope" so far as any risk-benefit analysis is concerned: but I disagree. I accept that they might appear to be relatively modest; but they are benefits to be set against any increased risk of stem neck fracture resulting from the incorporation of a thread when a metal head is used.

123. It is perhaps noteworthy that:

i) Whatever the level of risk of stem failure at the thread root, it is a risk that is – and has to be – taken by patients who are fitted with a ceramic head.

ii) The C-Stem is not the only femoral stem component that has a grooved neck. The evidence before me was the Defendant has four other brands that do so; and at least three other manufacturers also have brands that do so.

124. Third, it is uncontroversial that the C-Stem complied with all relevant mandatory standards – and was tested to a higher level than the fatigue failure standard – and satisfied all of the regulatory requirements, including those imposed to ensure that the product was "acceptably" safe. Mr Trotman submitted that, generally, risk-benefit was an irrelevant consideration for the purposes of assessing the level of safety that people generally are entitled to expect; but in his closing submissions, referring to the judgment of Burton J in A v NBA at [68], he conceded that it would or might be relevant if "there has been a full public discussion of risk and benefit so that the public understands the risk it accepts for the benefit it gains" (paragraph 31(iv) of his closing submissions). For the reasons I have given above, the assessment of safety under section 3 of the Act is objective; but it is in my view important that the relevant regulators, acting in the public interest and on the basis of full information, have assessed the C-Stem to be acceptably safe. I stress that, as indicated above (paragraph 101), that does not mean that the Defendant has an automatic defence to this claim – nor even that there is a prima facie presumed defence, as in the United States – but, in my view, in this case, the fact that the regulator has made such an assessment is powerful evidence that the level of safety of the product was that which persons generally were entitled to expect.

125. Fourth, as I have described, there is a small risk of fatigue failure at the neck of the C-Stem. There is no evidence to suggest that any other model has no such risk, or indeed that the risk posed by the C-Stem in this regard is in practice higher than any other model. Professor Doyle referred to such a risk as "inherent", by which, as I understand it, she meant, not that it could not in theory be designed out, but that in practice it could not, because to eliminate the risk would result in disbenefits that would outweigh the benefits. In other words, it would not be appropriate to design out entirely that single risk, without regard for other design features.

126. In any event, as is made clear by the last part of section 3(2) of the Act (which provides that a defect need not be inferred from merely the fact that a later product is safer), the fact that a safer design can be envisaged does not mean that a current product is defective.

127. The risk of stem fracture is small. Furthermore, the C-Stem IFU expressly warned of that risk (see paragraph 34 above): as Mr Hammersley conceded, that warning is in respect of a risk of precisely the adverse event from which the Claimant unhappily suffered. It also cautioned that various conditions tended to impose severe loading on the prosthetic joint "thereby placing the patient at higher risk of failure of the hip replacement", including "obesity or excessive patient weight" and "high levels of patient activity".

128. Mr Trotman mounted an exegetical attack on the IFU. For example, he suggested that, later in the IFU text, it was said that only "excessive physical activity or trauma to the replaced joint may contribute to the premature failure of the hip replacement by causing… failure" – there was no reference there to weight – and Mr Trotman sought to show that the Claimant did not engage in "excessive physical exercise" during the period from his procedure until the failure of the C-Stem. However, I did not consider that there was any force in the suggestion – it never quite amounted to an overt submission – that the IFU was inadequate. It clearly and unambiguously warned that "fatigue of the femoral stem" was "generally" one of "the most frequently encountered adverse events". It said that such an event was "often related to the

factors listed…", which included obesity/overweight and high levels of activity. Most of the stem fatigue failures do not occur at the neck, but elsewhere in the stem. The IFU was, of course, aimed at orthopaedic surgeons. In my judgment, it is simply not arguable that that warning inadequately prepared such a surgeon for advising a patient with regard to the risk of fracture, to enable that patient to make an informed decision about the procedure. It did not fall short (as Mr Trotman suggested it might) in not suggesting that the risk was high: or in making that warning more prominent: or in failing to give more detail about the risk, e.g. how, as a matter of mechanics, the stem might fail at the neck thread.

129. In his statement, Professor Sochart says (at paragraph 34):

> "… [B]etween 2005 and 2007…., there was no general awareness of fatigue fracturing risks affecting artificial hip products currently in circulation at that time. The expectations were that a specialist medical component like a femoral C-Stem would not fracture from metal fatigue."

130. For the reasons I have explained (see paragraph 5 above), Professor Sochart was not cross-examined upon that evidence. However:

i) In support of the proposition that the relevant medical professionals (notably, orthopaedic surgeons who performed hip replacement procedures) were not aware of a risk of stem fracture, Mr Trotman relied upon a statement of the Claimant's solicitor who had diligently performed a web-based search of the Bone and Joint Journal from 2003 to 2007 inclusive, which makes no mention of the phenomenon of stem fatigue fractures. However, given the low risk of such events, it is not necessarily surprising that researchers had not dedicated time and effort to them, particularly if the small risk was well-established. In my view, this evidence provides no support of any substance to the Claimant's case. Professor Doyle's evidence was essentially to that effect.

ii) I do not understand why Professor Sochart says that there was at the relevant time no general awareness of the risk of stem fracture amongst orthopaedic surgeons who performed hip replacements. That risk was the subject of a specific warning in the IFU, which accompanied every C-Stem. It was also recorded in the NJR annual reports (see paragraphs 23 and 52 above). As I understand it, Professor Sochart was a regional representative for the NJR. Although perhaps not in the area of his core expertise, Mr Hammersley accepted that there would have been such awareness amongst orthopaedic surgeons.

iii) When Professor Sochart refers to "expectations", he seems to mean aspirations rather than the proper expectations which orthopaedic surgeons were entitled to have, given the evidence of risk to which I have referred.

iv) Professor Sochart's statement was prepared upon a false premise, in that he appears to have been told that the Defendant's Defence to the claim included an averment that there was an express warning (or contraindication) that the C-Stem should not be used if the patient was over a particular weight or BMI (paragraph 32 of his statement). He denies that there was such a warning

(paragraph 33). But it was never suggested in the Defence that there was, the Defence relying upon the express warning of the risk of fracture, with excessive weight being simply one factor with which such an event had been related.

v) Professor Sochart says he selected the C-Stem as an appropriate component having considered the Claimant's "age, *size* and occupation" (see paragraph 37 above: emphasis added). He says (in paragraph 8 of his statement) that, in addition to considering that the Claimant's weight in itself did not contraindicate the use of the C-Stem (which is uncontroversial):

> "I did not consider that Mr Wilkes' size would present a problem in respect of the operation that I was to perform and indeed confirmed this to Mr Wilkes when he asked the question."

vi) At the time of his procedure, it is clear that the Claimant was carried excessive weight, whether or not he was clinically obese. On the evidence available, it is unclear whether Professor Sochart considered the issue of the Claimant's weight and decided that he need not refer to it as a factor with which increased risk of failure was associated; or whether he did not consider the factor in that context at all. In any event, on the basis of the IFU, Professor Sochart was sufficiently well-informed that weight was such a reported factor to enable him to give any specific warning to the Claimant that he considered appropriate.

vii) It is also unclear on the evidence whether Professor Sochart took the view that it was unnecessary to give a specific warning about the risk of fracture – he appears to have discussed the risk of failure in other ways (see, again, paragraph 37 above) – but, in any event, in my view, on the basis of the IFU, he was sufficiently well-informed as to the risk of stem fracture to give any specific warning to the Claimant that he considered appropriate, and clearly so.

131. Fifth, as I have already indicated, whilst Mr Hammersley focused almost exclusively upon mechanical calculations relating to the loading at the stem thread grooves, Professor Doyle emphasised – in my view, rightly – the variables in the biomechanics of hip prostheses (which are set out in paragraph 111(i) above). Mr Hammersley went as far as suggesting that stem fatigue failure could be predicted by computer modelling. But I agree with Professor Doyle's evidence, that the biomechanical variables make reliable prediction impossible. What can be done, as the IFU in this case did, is to identify factors which are associated with such failure.

132. Sixth and finally, in assessing the risk of stem fracture in the context of safety generally, both the chance or hazard of the adverse event happening, and the consequences if the adverse event occurs, have to be taken into account. As I have indicated, the chance of a fracture (particularly at the stem) is small. In respect of consequences if it occurs, whilst a revision operation is of course unpleasant and debilitating (and I accept the evidence that, generally, there are more likely to be complications with a revision than with a prime replacement), the consequences are relatively limited. If a stem fails as a result of fatigue fracture, the patient will have to undergo another operation to replace the artificial hip.

Defect: Conclusion

133. In this case, the loading to which the Claimant's C-Stem was exposed was clearly greater than the C-Stem could withstand, and for which it had been tested in accordance with the relevant BS. However, in my judgment, that was the result of a constellation of factors, each variable, which came together in a manner such that the neck of the stem fractured. That was rare, unpredicted and unpredictable; and it was a risk that was expressly warned in the IFU. The Claimant was made expressly aware of other, much higher, risks of failure of the hip replacement, each of which, had it occurred, would have resulted in a revision procedure. It seems that he was not warned of this specific way in which failure might occur.

134. The failure of the C-Stem – earlier than was predicted – was unfortunate, and one can only have sympathy for the Claimant who was required to have a revision procedure, certainly earlier than he had hoped. However, the Defendant is only liable under the Act if the C-Stem had a defect, as defined in the Act, at the time it was put onto the market. For the reasons I have given, the Claimant has failed to satisfy me that the C-Stem supplied to him suffered from such a defect, i.e. that its safety was not such as persons generally were entitled to expect.

Causation

135. Given my conclusion on defect, it is unnecessary for me to consider causation; and I decline to do so.

136. Mr Myhill submitted that, where (as in this case) a claimant's case was based upon a defect causing an increased risk, then the general principle set out in cases such as XYZ v Schering Health Care Limited [2002] EWHC 1420 (QB) should apply, i.e. the Claimant is required to prove that the risk of the adverse event had more than doubled. Mr Trotman, referring to cases such as Fairchild v Glenhaven Funeral Services Limited [2002] UKHL 22, submitted that that was unnecessary, and that, having been satisfied that the level of safety was less than it ought to be, the court should readily find causation proved on the basis of material contribution.

137. In my judgment, where defect is defined in terms of an inadequate level of safety (and, thus, in effect, in terms of risk), causation requires careful consideration. A fractured prosthetic femoral stem is not the same thing as the risk of such a fracture. In my view, consideration of those issues is better left to a case in which they are or might be determinative.

Conclusion

138. For those reasons, I would answer the question posed by the preliminary issue, "No": having regard to the failure of the C-Stem by fracture, in my judgment, the Defendant is not liable to the Claimant under the provisions of the 1987 Act.