A and others v National Blood Authority and another

QUEEN'S BENCH DIVISION

BURTON J

10–13, 16–20, 23–27, 30 OCTOBER, 1, 6–9, 13, 15, 16, 20, 21, 27–29 NOVEMBER, 1, 4–6, 8, 11–13 DECEMBER 2000, 9–12, 15–19, 26, 29, 30 JANUARY, 26 MARCH 2001

European Community – Consumer protection – Product liability – Whether unavoidability of risk relevant in determining whether product defective – Whether unavoidable risk falling within development risks defence if producer unable to discover defect in particular product by means of accessible information – Consumer Protection Act 1987 – Council Directive (EEC) 85/374, arts 6, 7(e).

The claimants had been infected with Hepatitis C (the virus) through blood transfusions which had used blood or blood products obtained from infected donors. They brought actions for damages against the defendants, the authorities responsible for the production of blood and blood products. During the period when most of the claimants were infected, the risk of such infection through blood transfusions, though known to the medical profession, was impossible to avoid, either because the virus itself had not yet been discovered or because there was no way of testing for its presence in blood. Accordingly, the claims were brought not in negligence, but under the Consumer Protection Act 1987 which implemented Council Directive (EEC) 85/374 (on the approximation of the laws, regulations and administrative provisions of the member states concerning liability for defective products). Under that directive, a producer was liable for damage caused by a defect in his product. By virtue of art 6(1)[a], a product was defective when it did not provide the safety which a person was entitled to expect, taking all circumstances into account, including the presentation of the product, the use to which it could reasonably be expected that the product would be put and the time when the product was put into circulation. Article 7(e)[b] provided the producer with a defence if he could establish that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable 'the existence of the defect' to be discovered. On the trial of the six lead cases, the defendants accepted that a producer's liability under art 6 was irrespective of fault. They nevertheless contended that, in assessing whether the infected blood was defective, the unavoidability of the risk was a circumstance to be taken into account, and that the most that the public was entitled to expect was that all reasonably available precautions had been carried out, not that the blood would be 100% clean. In so contending, the defendants submitted that the infected blood was to be regarded as an inherently risky standard product (ie one which performed as the producer intended) rather than a non-standard product (ie a product which was deficient or inferior in terms of safety from the standard product, and whose harmful characteristic, not present in the standard product, had caused the material injury

a Article 6(1) is set out at [16], below

b Article 7 is set out at [16], below

or damage). They also relied on the fact that they were obliged to produce blood and had no alternative but to supply it to hospitals and patients, as a service to society. Alternatively, the defendants sought to rely on the art 7(e) defence, contending that an unavoidable risk qualified for protection under it if the producer was unable to discover, by means of accessible information, the defect in a particular product.

Held – (1) Avoidability was not one of the circumstances to be taken into account under art 6, even in respect of a harmful characteristic in a standard product. In that provision, 'all circumstances' meant all relevant circumstances. Avoidability was not a relevant circumstance since it fell outside the purpose of the directive, which was intended to eliminate proof of fault or negligence. That was not simply a legal consequence. It was also intended to make it easier for claimants to prove their case, such that not only would a consumer not have to prove that the producer had not taken reasonable steps, or all reasonable steps, to comply with his duty of care, but also that the producer had not taken all legitimately expectable steps either. Even without the full panoply of allegations of negligence, the adoption of tests of avoidability or of legitimately expectable safety precautions would inevitably involve a substantial investigation. If it had been intended that avoidability would be included as a derogation from, or a palliation of, the directive's purpose, it would have been mentioned. It would have been an important circumstance, and it was intended that the most significant circumstances were those listed. In the case of a non-standard product, the circumstances specified in art 6 might obviously be relevant, as well as the circumstances of the supply. However, the primary issue might be whether the public at large accepted the non-standard nature of the product, ie whether they accepted that a proportion of the products was defective. That was not the end of the matter, because the question was one of legitimate expectation, and the court might conclude that the expectation of the public was too high or too low. Questions such as warnings and presentations would be in the forefront, but the avoidability of the harmful characteristic, the impractability, cost or difficulty of precautionary measures, and the benefit to society or the utility of the product (except in the context of whether, with full information and proper knowledge, the public had and should have accepted the risk) were not relevant. In the instant case, the infected blood products were non-standard products since they were different from the norm which the producer intended for use by the public. They were defective within art 6 because the public at large was entitled to expect that the blood transfused to them would be free from infection. There had been no warnings and no material publicity. The knowledge of the medical profession, not materially or at all shared with the consumer, was of no relevance. Nor was it material to consider whether any further steps could have been taken to avoid or palliate the risk that the blood would be infected (see [57], [58], [63], [65], [66], [68], [80], [82], below); *European Commission v UK* Case C–300/95 [1997] All ER (EC) 481 considered.

(2) The defence in art 7(e) of the directive did not apply where the existence of the generic defect was known or should have been known in the context of accessible information. Once the existence of the defect was known, there was the risk of that defect materialising in any particular product, and it was immaterial that the known risk was unavoidable in the particular product. It would be inconsistent with the purpose of the directive if a producer, in the case

of a known risk, continued to supply products simply because, and despite the fact, that he was unable to identify in which of his products that defect would occur or recur, or, more relevantly in a case where the producer was obliged to supply, he continued to supply without accepting the responsibility for any injuries resulting, by insurance or otherwise. Such a conclusion did not mean that non-standard products were incapable of coming within art 7(e). Such products might qualify *once*—ie if the problem which led to an occasional defective product was not known. However, once the problem was known by virtue of accessible information, the non-standard product would no longer qualify for protection under art 7(e). Accordingly, in the instant case, art 7(e) was of no avail to the defendants, and the claimants were therefore entitled to recover against them (see [74], [77], [78], [82], below).

(3) If, contrary to the court's primary conclusion, the issues of avoidability or discoverability of the defect in the particular donation of blood had arisen, precautions to prevent or make a material reduction in the transfer of transmitted infection through infected blood were available and not taken. From 1 March 1988 the blood was defective in all the circumstances and from 1 March 1990 the defect in the donations was discoverable (see [106]–[107], [173], [181]–[187], below).

(4) The damages recoverable by the claimants were not based upon loss of a chance. They could include, dependent upon the facts, provisional or final damages in respect of invasive or debilitating treatments, handicap in respect of employment and insurability, and the provision of gratuitous services. In the absence of any special evidence of exceptional circumstances, the proper recompense for gratuitous services in the instant cases would normally be commercial cost, less a deduction to allow at least for tax and national insurance (see [176]–[180], [211], [214]–[216], [219]–[225], [226]–[231], below).

Notes

For liability for defective products, see 41 *Halsbury's Laws* (4th edn reissue) paras 515–520.

For the Consumer Protection Act 1987, see 39 *Halsbury's Statutes* (4th edn) (1995 reissue) 150.

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Morris v West Hartlepool Steam Navigation Co Ltd [1956] 1 All ER 385, [1956] AC 552, [1956] 1 WLR 177, HL.
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Action

By writ issued on 1 May 1998, 114 claimants sought damages, pursuant to the Consumer Protection Act 1987, from the defendants, the National Blood Authority and Velindre NHS Trust, for damage suffered by them as a result of receiving blood or blood products infected with the Hepatitis C virus. By order dated 26 February 1999, Burton J required the identification of generic issues to be determined at the trial of the six lead cases, those of Ms T, Ms V, Mr U, Mrs X, Mr W and Mr S. The facts are set out in the judgment.

Michael Brooke QC, Stuart Brown QC, Ian Forrester QC and *Jalil Asif* (instructed by *Deas Mallen*, Newcastle upon Tyne) for the claimants on the generic issues.
Michael Brooke QC and *Jalil Asif* (instructed by *Deas Mallen*, Newcastle upon Tyne) for Ms T, (instructed by *Donne Mileham & Haddock*, Brighton) for Ms V, (instructed by *Evill & Coleman*) for Mr U, (instructed by *Freeth Cartwright*, Nottingham) for Mrs X and Mr W and (instructed by *Howard Cohen & Co*, Leeds) for Mr S.
Nicholas Underhill QC, Philip Brook Smith and *Louise Merrett* (instructed by *Davies Arnold Cooper*) for the defendants.

Cur adv vult

26 March 2001. The following judgment was delivered.

BURTON J.

CONTENTS

c Paragraphs [109]–[140] are not included in this report.

THE CLAIMANTS

[1] This trial has concerned the claims of 114 claimants for recovery of damages arising out of their infection with Hepatitis C from blood and blood products through blood transfusions from 1 March 1988. It has been the first and

d Paragraphs [147]–[169] are not included in this report.
e Paragraphs [233]–[283] are not included in this report.

main trial heard by me as the assigned judge within the Hepatitis Litigation, which was the subject matter of a Practice Direction issued by the Lord Chief Justice on 30 July 1998. This trial has been limited to consideration of the case brought by those claimants infected with Hepatitis C from blood and blood products who are making claims under the Consumer Protection Act 1987 (CPA). There is a small number of other claimants within the group action whose claims are not being dealt with by this trial, for example those not claiming under the CPA and/or claiming in relation to infection as a result of the transplant of body parts and/or with Hepatitis B: their claims are to be dealt with so far as possible later this year. The 114 claimants received blood transfusions or blood products usually in the course of undergoing surgery, whether consequent upon having suffered an accident or otherwise, or immediately after childbirth or in the course of treatment for a blood disorder. The earliest date of infection in respect of which claimants can make such claims is 1 March 1988, being the date when the CPA was brought into effect. Most of the claimants have been identified by the defendants' own admirable Look-Back programme, which began in 1995. There were, fortunately, relatively few such sufferers, and it should be said immediately that there is no question of their having received 'contaminated' blood, that is blood infected by some outside agent: the blood they received was 'infected' because, exceptionally, the donor's blood was infected by Hepatitis C.

CAUSE OF ACTION

[2] The claims the subject matter of this trial are not in negligence, but are put against the defendants by way of 'strict' or 'objective' liability by virtue of the CPA, which implemented in the United Kingdom the European Union (then the EEC) Product Liability Directive of 1985: Council Directive (EEC) 85/374 (on the approximation of the laws, regulations and administrative provisions of the member states concerning liability for defective products). The directive is not, in any event in this action, said to be directly enforceable against the defendants by the claimants, who rely for their cause of action on the CPA. However, as below appears, the European Commission complained, by application lodged at the Court of Justice of the European Communities on 20 September 1995, that the United Kingdom Government had not fulfilled its obligations under the directive and under the EC Treaty by implementing the CPA in the terms it had. Although the Court of Justice dismissed that application, it is apparent from the judgment of the Court of Justice, reported as *European Commission v UK* Case C–300/95 [1997] All ER (EC) 481, that, there not at that stage having been any decisions of the English courts, nor indeed any facts before the Court of Justice, the Court of Justice was concluding that, whatever be the precise terms of the CPA, the United Kingdom *would* so implement and construe the CPA as to be consistent with the directive—not least by virtue of s 1(1) of the CPA, which reads as follows: '[Part I] shall have effect for the purpose of making such provision as is necessary in order to comply with the Product Liability Directive and shall be construed accordingly.' Consequently both parties have during this trial almost exclusively concentrated on the terms of the directive, on the basis that, in so far as the wording of the CPA, in relation to matters which have been the subject matter of particular issue in this case, differs from the equivalent articles in the directive, it should not be construed differently from the directive; and consequently the practical course was to go straight to the fount, the directive itself. As will be seen, the arguments were directed mainly to the true and proper

construction of art 6 of the directive (the equivalent being s 3 of the CPA) and art 7(e) (the equivalent being s 4(1)(e)), and consequently it is with those articles, and not the relevant sections, with which this judgment will be primarily, if not exclusively, concerned. It is conceded for the purpose of these proceedings that the blood or blood products by which the claimants were infected are products within the meaning of the CPA and the directive, and that the defendants' production of blood was, for the purpose of the directive, an industrial process.

THE DEFENDANTS

[3] The National Health Service bodies responsible for the production and supply of blood and blood products prior to 1 April 1993 in England (and also covering northern Wales) were 14 regional blood transfusion centres (RTCs), controlled and administered by regional health authorities. From that date, by the National Blood Authority (Establishment and Constitution) Order 1993, SI 1993/583, the National Blood Authority (NBA) was established, with responsibility for the RTCs and both central blood laboratories (the Central Blood Laboratory Authority (CBLA), which itself had responsibility for the Blood Products (later Bio Products) Laboratory (BPL), and the Blood Groups Research Laboratory (BGRL)). Subsequently the National Blood Authority (Establishment and Constitution) Amendment Order 1994, SI 1994/589 provided that all rights enforceable by or against a regional health authority in respect of the exercise of functions which became exercisable by the NBA were to be exercisable against the NBA. So far as Wales is concerned, those parts of Wales not serviced by the Mersey RTC were covered by a transfusion centre in Cardiff operated by the South Glamorgan Health Authority. Responsibility for that, and for the provision of a blood transfusion service in Wales, was transferred not to the NBA but to the Welsh Health Common Services Authority, and as from 1 April 1999 was further transferred to Velindre NHS Trust, which is now the relevant defendant so far as any liabilities to the claimants in respect of the balance of Wales is concerned. I shall refer in this judgment to 'the defendants' without taking into account the various changes of identity and responsibility.

THE PROCEEDINGS

[4] The group action effectively commenced with a generic order for directions on 1 May 1998 made by Master Eyre, who was assigned master, which set out the basic rules for the conduct of the Hepatitis Litigation, gave leave to issue an omnibus writ and provided for the maintenance of a Hepatitis Register. The omnibus writ was issued on 1 May 1998. I was appointed as assigned judge in February 1999, and Master Eyre and I have made a number of orders since then, which have, with the considerable co-operation of those representing the parties, led to the identification and trial of generic issues and of six lead cases. Each claimant has been entitled to have his or her own solicitor, but the generic aspects of the action have been handled, and the individual cases co-ordinated, on the claimants' behalf by Messrs Deas Mallen, instructing Michael Brooke QC, Stuart Brown QC, Ian Forrester QC and Jalil Asif. The defendants' solicitors have been Messrs Davies Arnold Cooper, instructing Nicholas Underhill QC, Philip Brook Smith and Louise Merrett. They have together worked extraordinarily hard in order to achieve a miracle of good order and clarity, by slimming down the issues, where at all possible, and managing to contain a myriad of documentation within a relatively small compass and a relatively small number

of files. By the third generic order of 26 February 1999 I ordered that the generic trial of issues to be agreed and/or determined take place in October 2000, and by dint of the co-operation and hard work to which I have referred, this has occurred, and was more or less contained within the original time estimate of three months: I have been enormously assisted by the way the case has been both industriously prepared and skilfully, persuasively and economically argued and presented. The generic issues effectively amounted to whether the defendants are liable to the claimants under the CPA, ie whether the claimants as a whole can prove that (assuming injury, causation and loss can be proved in respect of each claimant) the defendants are liable under s 3 (art 6) and not exonerated within s 4(1)(e) (art 7(e)), to which I shall refer. I have also heard six lead cases, in which, on the assumption of having established liability generically under the CPA, such claimants have sought to prove individual liability and quantum, both on their own behalf and in order to resolve generic issues relating to quantum in such a way as to assist in the subsequent disposal of the other cases. All the claimants have, by an unopposed order in May 1998, been entitled to remain anonymous, and the six lead claimants have been known by the codes of Mr S, Miss T, Mr U, Ms V, Mr W and Mrs X. As will be seen, these six lead claimants have been carefully chosen (the equal balance of their sex is, I believe, a coincidence) to cover and illustrate a spread of consequences from their Hepatitis C infection: ranging from Mr S, now 17, who was infected by a blood transfusion after a road traffic accident at the age of 7, but had the good fortune that the virus spontaneously cleared his blood and has not recurred: through to Mrs X, a lady of 56, who at the age of 45 was infected by a blood transfusion in the course of routine surgery, and whose treatment for Hepatitis C was not successful, such that her condition progressed to cirrhosis of the liver (severe damage and/or scarring to liver tissue (fibrosis)), resulting in progressive deterioration in liver function, and a consequent liver transplant, which to date has been successful, although her Hepatitis C infection remains.

SETTLEMENT

[5] After the case started, I was informed that it had been agreed between the parties that the claims of almost all those claimants already then party to the action who were infected on or after 1 April 1991 would no longer be opposed, on the basis that they would each receive 90% of whatever sum I should find (in the case of those lead claimants falling within such category, being Mr S and Mr W), or as should thereafter be agreed or determined (in the case of the other claimants) in the light of my determination of the issues, and my resolution of the amounts otherwise due in respect of the lead cases. This agreement made the need for any detailed consideration of the facts relating to the period subsequent to 1 April 1991 very much reduced. Its effect, however, overall is that, subject to that somewhat foreshortened consideration of the timescale, in so far as I have had to consider the factual history, the issue of liability which I have to decide remains unaltered; but so far as concerns two of the lead claimants and 19 of the other claimants, their individual liability no longer being contested, their dispute has become one as to quantum only.

BLOOD TRANSFUSION

[6] Organised blood transfusion began in England and Wales in 1921. The practice (unlike in the United States, where donors were paid until the 1970s) was

of donation by unpaid volunteers. By 1970 the 14 RTCs (organised into three geographical divisions as from 1978) and the South Glamorgan Health Authority were responsible for the collection of blood from voluntary donors, the processing and testing of blood donations and the supply of blood to hospitals within their area, and on some occasions to other hospitals and bodies outside their region. Each RTC was managed by its own independent medically qualified regional transfusion director, but, although there were some central co-ordinating arrangements, there was no centralised administration until 1988, when the National Directorate of the National Blood Transfusion Service (NBTS) was formed, and Dr Harold Gunson was appointed as director. As set out in [3] above, this was replaced as from 1 April 1993 by the NBA, with full central authority, and Dr Gunson became national medical director, in which post he remained until his retirement in July 1994, since when he has been a part-time consultant to the NBA.

[7] Blood is traditionally donated two to three times per year, by voluntary donors. It is collected by encouraging the donor to bleed into a collection bag, where the blood is mixed with an anti-coagulant. Each donor's blood will be kept separate, and separately identifiable, though it may be retained and used as whole blood, to be transfused to those suffering serious life-threatening haemorrhages, or may be separated out into constituent parts, such as red cell concentrates, white cell concentrates, platelet concentrates, fresh frozen plasma or other blood products. Depending on how much blood or blood products a patient subsequently needs, he may derive such blood or blood products from a number of different donors. Blood is given to a patient in units, that is bags, each from a single donor. Rarely, a single unit is supplied to a patient, but for serious operations or illnesses many units, from different donors, may be necessary. Autologous transfusion, that is the use of a patient's own blood, which is a rare alternative method, though originally canvassed, did not materially feature in the trial.

HEPATITIS

[8] Hepatitis simply means 'inflammation of the liver'. It can result from a number of different causes, including self-inflicted substance abuse. It has been known since the 1940s that hepatitis can be transmitted by transfusions of blood and plasma. It quickly became apparent that there was a distinction between what was then called infectious hepatitis (now known as Hepatitis A) and serum hepatitis (now known as Hepatitis B). The Hepatitis A virus was identified by Feinstone and others in 1973, and is transmitted almost entirely from the oral and faecal routes, rather than by the transfusion of serum and plasma. The Hepatitis B virus (found in the serum of an Australian Aboriginal and called the 'Australia antigen') was identified by Blumberg and others in 1964. Tests to screen out Hepatitis B in blood were pioneered in 1971, and were introduced for all blood in the United Kingdom from December 1972. The combination of the exclusion of paid donors and of blood donors tested positive for Hepatitis B led in the United States to a substantial reduction in Post-Transfusion Hepatitis (PTH). However, by 1975 an agent other than Hepatitis A or B was recognised to be causing PTH, and it was found by Dr Harvey Alter (for many years the doyen of research in this field, based in the United States), of the National Institutes of Health in Maryland (NIH), that by 1985 PTH still occurred in 7% to 12% of blood transfusion recipients in the United States. The condition caused by this unknown agent was,

as Dr Gunson put it, 'for the want of a better term', described by Dr Alter and others as Non-A Non-B Hepatitis (NANBH). The virus which caused NANBH was eventually first identified within the research department of a US company called Chiron Corp (Chiron) by Houghton and others, in spring 1988, and was announced by a news release by that company on 10 May 1988 which stated:

> 'Scientists at Chiron Corporation have identified, cloned and expressed proteins from a long-sought blood-borne hepatitis non-A, non-B virus and have developed a prototype immunoassay that may lead to a screening test for hepatitis non-A, non-B antibodies.'

The virus was hurriedly itself christened, perhaps inevitably, as Hepatitis C. Its convenient shortening is Hep C. However, it has also been regularly known as HCV in the medical and blood professions, and the antibody to it, and hence the immunoassay subsequently developed, known as anti-HCV, and indeed Hepatitis B as HBV. This shorthand seems to me to be totally unnecessary and is responsible for a great deal of distress, embarrassment and indeed potentially for economic loss, because of the consequent association with the quite unconnected condition of HIV—the human immunodeficiency virus related to AIDS. The resultant confusion of sufferers themselves, of their relatives and friends, even of doctors and dentists, certainly of employers and insurance companies, has been natural and quite unnecessary. Though it is to be hoped that attitudes towards HIV sufferers change, and that a treatment for HIV is developed and expanded, nevertheless so far as Hepatitis C sufferers are concerned it is important to distinguish between the conditions. So far as concerns the source of infection by Hepatitis C, it can, on the evidence I have heard, almost never be transmitted sexually. In so far as its consequences are concerned, although it is and can be a serious condition, leading in rare cases to eventual death, many sufferers from Hepatitis C have few or no clinical symptoms, life expectancy is often unaffected and little if any change in lifestyle results, unlike the present position in relation to HIV sufferers. If this case and the publication of this judgment do any good at all to anyone, the one achievement that can be hoped for is the total and permanent abandonment of the shorthand of HCV, anti-HCV and indeed HBV.

TESTING IN RESPECT OF NANBH/HEPATITIS C

Surrogate tests

[9] As appears above, there was neither identification of the NANBH virus nor, consequently, development of any screening test or assay so as to eliminate such virus from blood donations prior to their use, in the years up to 1988. There was, however, as will appear in more detail below, considerable research and academic discussion in the medical journals about the problem of PTH, particularly in the United States, which was still suffering from the aftermath of paid donors, and at all times appears to have had a much higher incidence of PTH than Europe. There was discussion as to whether to introduce in the United States what became known as 'surrogate tests'; but after lengthy and detailed studies carried out and reported by two prestigious groups, the Transfusion Transmitted Virus Study ('TTVS') and the NIH Study (the latter including Dr Alter), published in 1981 and subsequent years, and, after considerable discussion in committees and in the medical journals, no surrogate tests were

introduced. The two tests that were being looked at by the two bodies were the ALT test and the anti-HBc test. These were as follows. (i) *ALT.* This test measures the level of an enzyme, ALT (Alanine Aminotransferase), in the blood. This was a test regularly used by hepatologists in the diagnosis and treatment of liver diseases. Raised ALT in the blood could suggest abnormality of liver function: it could indicate the presence of hepatitis; it could on the other hand, even where substantially raised, be an indicator of other liver conditions or simply of high alcohol intake and/or obesity. An ALT test therefore did not test for the presence of hepatitis or the NANBH virus; and a 'positive' test (about the marker for which there was in any event no unanimity, because different 'cut-offs' were adopted in different laboratories and in different countries) thus did not signify the presence of hepatitis, but was only a possible indicator of it. Hence a 'surrogate' test. (ii) *Anti-HBc.* A virus or antigen can have an envelope containing a core. Thus there is reference to surface antigen and core antigen. A healthy body develops antibodies, which hopefully resist the antigens, by binding on them. Some tests identify the antigen (whether the surface or the core) and some the antibodies. The screening test introduced for Hepatitis B identified the Hep B surface antigen (HBsAg). An additional test was also developed, but not used as the screening test for Hep B, which could identify, not the Hep B core antigen (HBcAg), but the antibody to the Hep B core antigen (anti-HBc). Such a test therefore, which was only identifying the antibody to Hep B, could plainly not identify (what had in any event not been itself discovered) the NANBH antigen or indeed antibody. However, it was contended that it could provide what was called a 'lifestyle marker'. Those who had had, but had recovered from, Hepatitis B in the past (and thus would no longer test positive for the Hep B antigen) would or could retain in their blood traces of the Hep B antibody. It could thus be identified by the use of the anti-HBc test whether someone had had Hepatitis B, and it was suggested that a donor with past exposure to Hepatitis B would be more likely to have been exposed also to the NANBH agent, eg by intravenous drug use. This was the other suggested 'surrogate test'.

[10] As will appear in more detail below, the United States did not introduce either of these surrogate tests after the detailed studies referred to above: ALT testing (but not anti-HBc) was introduced in Germany as early as 1965 and in Italy in 1970, but neither in the United Kingdom nor in any other country, so far as is known to the parties in this case, was either test then introduced. The United States, however, introduced both tests starting from September 1986. As will appear, albeit that discussion continued, those responsible for blood transfusion in the United Kingdom did not support, and did not introduce, the surrogate tests, notwithstanding their adoption in the United States, and, once Chiron had pioneered the assay in respect of Hepatitis C, they concentrated upon whether and when to introduce that test.

[11] *Anti-Hep C screening.* After the identification of the Hepatitis C virus, development speedily continued, as indeed was indicated in the Chiron news release, of an assay: well in the lead was a US company called Ortho Diagnostic Inc (Ortho) (Chiron's licensee) followed some time later by another US company, Abbott Laboratories Inc (Abbott) and, less successfully and later still, by others. Known as anti-HCV, but, for the reasons I have given, to be resolutely called, at any rate by me, anti-Hep C, this assay did not detect the antigen, but was a test for the antibody to the Hepatitis C virus (a test to identify the antigen took very much longer to develop, by means of polymerase chain reaction (PCR)—later

'NAT' (nucleic acid testing)—and is not relevant to the timescale which I am now considering). The anti-Hep C assay was an enzyme-linked immunoabsorbent assay (ELISA). The details of the Ortho Elisa were disclosed in April 1989 and were fully canvassed at a well-attended symposium organised by Ortho in Rome on 14–15 September 1989, when it was given backing by, among others, Dr Alter. Dr Gunson came away impressed, and reported back to the two high-powered committees on which he sat, the United Kingdom Advisory Committee on Virological Safety of Blood (ACVSB), and the United Kingdom Advisory Committee on Transfusion Transmitted Diseases (ACTTD), of which latter he was the chairman. The factual history will appear below in greater detail. At this stage it is sufficient to set out as follows. (i) At this time the Ortho Elisa had only just been developed. It was a 'first generation' test and there were concerns about its sensitivity (not catching all it should) and its specificity (catching those it should not). There was no supplementary or confirmatory test yet developed to verify or cross-check its findings and increase the specificity of the process. (ii) No export licence was obtained for export of the assay from the USA until the end of November 1989, and the approval by the US Food and Drugs Administration (FDA) for its use within the USA was not granted until 2 May 1990. (iii) Recommendations to proceed with the introduction of the anti-Hep C testing were made by the relevant United Kingdom committee, the ACVSB, in July and November 1990, subject to the holding of various trials. Ministerial approval was given on 21 January 1991 and a programme of implementation was then commenced for all RTCs. The tests (by now second generation tests, and with a supplementary test available for confirmatory purposes in place) were introduced throughout England and Wales on 1 September 1991. However, as set out above, the defendants have accepted that the relevant date for these proceedings is 1 April 1991 and most claimants who were infected on or after that date have received an admission of 90% liability. Since the introduction of the tests on 1 September 1991, the problem of PTH in the United Kingdom has been all but eliminated.

THE CLAIMS

[12] The claims in this trial have been that, pursuant to the CPA, those who received blood or blood products infected by Hepatitis C subsequent to 1 March 1988, when the Act came into effect, are entitled to recover damages: that is notwithstanding that: (i) the Hepatitis C virus itself had not been discovered or identified at the date when the claims commence on 1 March 1988; (ii) no screening test to discover the presence of such virus in a donor's blood was even known of, certainly not available, until Ortho's assay, first publicised in spring/summer 1989; and (iii) it is not sought to be alleged (at least not in this trial) that the United Kingdom blood authorities for whom the defendants are responsible were negligent in not introducing the screening tests until they did on 1 September 1991 (or now, as a result of the agreed concession, 1 April 1991) nor that they were negligent in not having introduced surrogate tests. The case which is put is that they are liable irrespective of the absence of any fault, under the directive and the CPA.

THE DIRECTIVE

[13] The directive, resolved by the Council on 25 July 1985, had taken a long time in coming. In the first instance this was because discussion of it, which had

begun in 1969/1970 in the light of the Thalidomide scandal, was held up largely due to the impending arrival of a number of new members of the Community, including the United Kingdom; but then because of the very lengthy processes of discussion and negotiation, and of intergovernmental and parliamentary discussion, which then took place. A number of matters appear to be common ground between the parties to these proceedings: (i) that its purpose was to increase consumer protection; (ii) that it introduced an obligation on producers which was irrespective of fault, by way of objective or strict liability, but not absolute liability; (iii) that its aim was to render compensation of the injured consumer easier, by removing the concept of negligence as an element of liability and thus of the proof of liability; and (iv) that it left an escape clause (in those Community jurisdictions, like the United Kingdom, where such provision was desired) for products otherwise found pursuant to the directive to be defective, if the producer could bring himself within what was, in the course of the 'travaux préparatoires', described as a 'development risks' defence.

[14] The parties before me agreed to number what are in the published directive an otherwise unnumbered set of 19 recitals. The significant ones for the purpose of these proceedings have been as follows:

> '[1] Whereas approximation of the laws of the Member States concerning the liability of the producer for damage caused by the defectiveness of his products is necessary because the existing divergences may distort competition and affect the movement of goods within the common market and entail a differing degree of protection of the consumer against damage caused by a defective product to his health or property;
>
> [2] Whereas liability without fault on the part of the producer is the sole means of adequately solving the problem, peculiar to our age of increasing technicality, of a fair apportionment of the risks inherent in modern technological production;
>
> [3] Whereas liability without fault should apply only to movables which have been industrially produced; whereas, as a result, it is appropriate to exclude liability for agricultural products and game, except where they have undergone a processing of an industrial nature which could cause a defect in these products ...
>
> [6] Whereas, to protect the physical well-being and property of the consumer, the defectiveness of the product should be determined by reference not to its fitness for use but to the lack of the safety which the public at large is entitled to expect; whereas the safety is assessed by excluding any misuse of the product not reasonable under the circumstances;
>
> [7] Whereas a fair apportionment of risk between the injured person and the producer implies that the producer should be able to free himself from liability if he furnishes proof as to the existence of certain exonerating circumstances ...
>
> [11] Whereas products age in the course of time, higher safety standards are developed and the state of science and technology progresses; whereas, therefore, it would not be reasonable to make the producer liable for an unlimited period for the effectiveness of his product; whereas, therefore, liability should expire after a reasonable length of time, without prejudice to claims pending at law ...

[13] Whereas under the legal systems of the Member States an injured party may have a claim for damages based on grounds of contractual liability or on grounds of non-contractual liability other than that provided for in this Directive; in so far as these provisions also serve to attain the objective of effective protection of consumers, they should remain unaffected by this Directive; whereas, in so far as effective protection of consumers in the sector of pharmaceutical products is already also attained in a Member State under a special liability system, claims based on this system should similarly remain possible ...

[16] Whereas, for similar reasons, the possibility offered to a producer to free himself from liability if he proves that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of a defect to be discovered may be felt in certain Member States to restrict unduly the protection of the consumer; whereas it should therefore be possible for a Member State to maintain in its legislation or to provide by new legislation that this exonerating circumstance is not admitted; whereas, in the case of new legislation, making use of this derogation should, however, be subject to a Community stand-still procedure, in order to raise, if possible, the level of protection in a uniform manner throughout the Community.'

[15] It is not in dispute between the parties that the directive can and must be construed by reference to its recitals and indeed to its legislative purpose, insofar as it can be gleaned otherwise than from the recitals. The following points are also not in dispute and are in any event clear: (i) that it is proper to look at travaux préparatoires to glean such purpose, but with caution, always chary of early discussions or disputations which may have been overtaken by later events, or of documents which may always have been internal or confidential and not reflected in the decisions; (ii) that it is important to bear in mind in construing a directive that there may be an 'autonomous' or Community meaning or construction for legislation intending to harmonise and to be of effect in diverse jurisdictions within the Community; and that some guidance can be obtained from other languages in which the directive was published, all of which are of equal weight, the more so if some appear clear and congruent; and to some extent also from the way in which a directive has been implemented or applied in other Community countries.

[16] The relevant articles are as follows:

'*Article 1*

The producer shall be liable for damage caused by a defect in his product ...

Article 4

The injured person shall be required to prove the damage, the defect and the causal relationship between defect and damage ...

Article 6

1. A product is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account, including: (a) the presentation of the product; (b) the use to which it could reasonably be expected that the product would be put; (c) the time when the product was put into circulation.

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

Article 7

The producer shall not be liable as a result of this Directive if he proves: (a) that he did not put the product into circulation; or (b) that, having regard to the circumstances, it is probable that the defect which caused the damage did not exist at the time when the product was put into circulation by him or that this defect came into being afterwards; or ... (d) that the defect is due to compliance of the product with mandatory regulations issued by the public authorities; or (e) that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered ...

Article 8

1. Without prejudice to the provisions of national law concerning the right of contribution or recourse, the liability of the producer shall not be reduced when the damage is caused both by a defect in product and by the act or omission of a third party.

2. The liability of the producer may be reduced or disallowed when, having regard to all the circumstances, the damage is caused both by a defect in the product and by the fault of the injured person or any person for whom the injured person is responsible.

Article 9

For the purpose of Article 1, "damage" means: (a) damage caused by death or by personal injury ...

Article 12

The liability of the producer arising from this Directive may not, in relation to the injured person, be limited or excluded by a provision limiting his liability or exempting him from liability ...

Article 15

1. Each Member State may ... (b) by way of derogation from Article 7(e) maintain or ... provide in this legislation that the producer shall be liable even if he proves that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of a defect to be discovered.'

THE CPA

[17] When the United Kingdom implemented the directive, it did so by way of the CPA, which came into force on 15 May 1987, but with effect from 1 March 1988. There have been few decisions under the CPA. I have been referred only to two—one unreported in the Court of Appeal, *Abouzaid v Mothercare (UK) Ltd* [2000] CA Transcript 2279 ('the Cosytoes case') and one a decision of Ian Kennedy J, which has been reported (*Richardson v LRC Products Ltd* [2000] Lloyd's Rep Med 280: I shall refer to them both. However, in neither case was there the need nor the opportunity for the kind of detailed consideration of the CPA, and in particular of all the issues raised by arts 6 and 7(e) of the directive (respectively ss 3 and 4(1)(e) of the CPA), that there has been in this case. Apart from the evidence and its analysis, and from the separate consideration of the lead cases, I have had the great benefit of detailed submissions in writing, and some ten days of exegesis and argument orally in opening and closing by leading counsel, just on the law, including authorities and academic writings from France, Germany, Spain, Portugal, Sweden, Denmark, Belgium, Italy, Holland, Australia and the United States, as well as the United Kingdom and the Court of Justice. In the light

of the concession in this case that blood is a product within the directive, and the nature of the issues for determination and the possible consequent knock-on effect of this judgment (subject always to any appeal to higher courts in this country or on reference to Europe), I note without surprise that Professor Stapleton, probably the most eminent and certainly the most prolific of the common law writers on the topic of product liability, refers to the fact that this case is pending in her introduction to the recent volume in the Butterworths Common Law Series *The Law of Product Liability* (2nd edn, 2000) edited by Professor Howells.

[18] The most authoritative consideration of the CPA has of course been in the case of *European Commission v UK*, to which I have referred in [2] above, and that was consideration in principle, not by reference to the facts of any case, and directed specifically to art 7(e) (and s 4(1)(e)). As I have set out in [2], the Commission contended that the section did not properly or lawfully reflect the article as it should. As will be seen below, it adopts different wording from the article, and this may result from the United Kingdom Government's own unilateral declaration that it made at the time of the adoption of the directive, namely—

> 'this provision should be interpreted in the sense that the producer shall not be liable if he proves that, given the state of scientific knowledge at the time the product was put into circulation, no producer of a product of that kind could have been expected to have perceived that it was defective in its design.'

This falls to be compared with the text of the article, which I have set out in [16] above. Section 4(1) of the CPA as enacted is as follows (I italicise the significant differences from the article):

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

[19] Whatever the content of a unilateral declaration may be, a Community government is obliged in law to enact the directive, and the Commission contended before the Court of Justice that the United Kingdom Government had not done so. The Court of Justice concluded that, notwithstanding that there was a difference of wording, it could not be satisfied that it was intended by the United Kingdom to interpret its statute differently from the directive, nor was the United Kingdom entitled to do so. The Advocate General (Tesauro) stated in his opinion ([1997] All ER (EC) 481 at 490–491 (para 25)):

> 'I consider that I am unable to share the Commission's proposition that there is an irremediable conflict between it and the national provision at issue. Indeed, there is no denying that the wording of s 4(1)(e) of the [CPA] contains an element of potential ambiguity: in so far as it refers to what might be expected of the producer, it could be interpreted more broadly than it should. Notwithstanding this, I do not consider that the reference to the "ability of the producer", despite its general nature, may or even must

(necessarily) authorise interpretations contrary to the rationale and the aims of the directive.' a

[20] After its own analysis of art 7(e), the Court of Justice concluded (at 495–496):

'32. The Commission takes the view that inasmuch as s 4(1)(e) of the [CPA] refers to what may be expected of a producer of products of the same b description as the product in question, its wording clearly conflicts with art 7(e) of the directive in that it permits account to be taken of the subjective knowledge of a producer taking reasonable care, having regard to the standard precautions taken in the industrial sector in question.

33. That argument must be rejected in so far as it selectively stresses c particular terms used in s 4(1)(e) without demonstrating that the general legal context of the provision at issue fails effectively to secure full application of the directive. Taking that context into account, the Commission has failed to make out its claim that the result intended by art 7(e) of the directive would clearly not be achieved in the domestic legal order. d

34. First, s 4(1)(e) ... places the burden of proof on the producer wishing to rely on the defence, as art 7 of the directive requires.

35. Second, s 4(1)(e) places no restriction on the state and degree of scientific and technical knowledge at the material time which is to be taken into account. e

36. Third, its wording as such does not suggest, as the Commission alleges, that the availability of the defence depends on the subjective knowledge of a producer taking reasonable care in the light of the standard precautions taken in the industrial sector in question.

37. Fourth, the court has consistently held that the scope of national laws ... must be assessed in the light of the interpretation given to them by f national courts ... Yet in this case the Commission has not referred in support of its application to any national judicial decision, which, in its view, interprets the domestic provision at issue inconsistent with the directive.

38. Lastly, there is nothing in the material produced to the court to suggest that courts in the United Kingdom, if called upon to interpret g s 4(1)(e), would not do so in the light of the wording and the purpose of the directive so as to achieve the result which it has in view and thereby comply with the third paragraph of art 189 of the Treaty ... Moreover, s (1)(1) of the [CPA] expressly imposes such an obligation on the national courts.

39. It follows that the Commission has failed to make out its allegation h that, having regard to its general legal context and especially s 1(1) of the Act, s 4(1)(e) clearly conflicts with art 7(e) of the directive. As a result, the application must be dismissed.'

[21] Although the United Kingdom Government has not amended s 4(1)(e) of the CPA so as to bring it in line with the wording of the directive, there is thus j binding authority of the Court of Justice that it must be so construed. Hence, although I shall in certain respects require to consider sections of the CPA, when dealing with the issues raised before me of causation and/or quantum of loss, to which I shall refer, the major discussions in this case, and all the areas of most live dispute, have concentrated entirely upon the wording of arts 6 and 7(e) of the

directive, and not upon the equivalent sections of the CPA, to which I shall make little or no further reference.

[22] In those circumstances there is no need for me to set out in full s 3 of the CPA which implements art 6, although it may be worth pointing out that the words in art 6(1)(a) 'the presentation of the product' are helpfully expanded and clarified in the CPA in the following way—'the manner in which, and purposes for which, the product has been marketed, its getup, the use of any mark in relation to the product and any instructions for, or warnings with respect to, doing or refraining from doing anything with or in relation to the product' (s 3(2)(a); and that the words with which s 3(2) ends are perhaps a cogent way of expressing art 6(2) which I have set out above, and in particular the reference in the article to 'a better product [being] subsequently put into circulation' namely: '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.'

[23] I shall set out below, when they fall for consideration, the two other sections of the CPA to which reference was made in the course of the trial, with respect to the issue which I have described as causation and/or quantification of loss, namely ss 2(1) and 5(1).

THE STRUCTURE OF THIS JUDGMENT

[24] I propose to adopt the following structure in this judgment. I shall begin with the most significant legal questions, arising out of the construction of the directive. I should at this point make it clear that because I have heard all the facts of the case upon which either side might wish to rely upon any of the issues, I shall make the necessary findings, irrespective of my conclusions in law. This is because both parties wish to take advantage of the very full consideration which there has been so that, if there were appeals or references leading to different conclusions of law in due course, there would be the factual material for the substitution of a different result. In particular, as will appear, if the claimants be right about their construction of the directive, then little if any of the evidence that I have heard relating to the factual history with regard to Hepatitis C and screening would be admissible or relevant. I shall, however, resist the temptation, nor am I in any event permitted by the approach of the parties, if I were to resolve such point of law in favour of the claimants, not to proceed to resolve the factual issues which would then have become irrelevant. Equally, at any rate until there was the 90% concession, which has meant that liability to some claimants is no longer in issue, it might have been that if I had found for the defendants on liability I would not have needed to go on to decide what I would have awarded to the claimants, had they been successful: but again, for similar reasons, this is not a course that I have adopted. Accordingly, whatever my decisions on the various issues, I have proceeded to decide the further issues, whether or not they continue to arise.

THE SIX ISSUES

[25] This raises the question of whether the defendants are liable to the claimants, without consideration of the history of testing. The claimants allege that, upon the basis of a proper construction of the directive and the agreed factual common ground, the blood was defective under art 6 and the defendants have no escape within art 7(e), without need for further consideration of the facts

(Issue I). This was described in the course of the hearing as the 'Forrester case' or the 'Brown short case' (which descriptions derogate from the role of Mr Brooke QC for the claimants who ably married together all the claimants' arguments).

[26] *Factual case*: legitimate expectation (Issue II). Whether or not I find the defendants so liable, for the reasons I have set out above, I must proceed to resolve the factual questions which the claimants assert to be unnecessary—the 'Brown case'. The claimants assert, if they need to, that, in the light of the factual history relied upon by the defendants, the blood was defective within art 6. I shall also make sufficient findings to resolve any factual issues under art 7(e), as to which see [28] below.

[27] I must then resolve the issue of the nature and measure of damages under art 6 in the event that the defendants were found liable (and in any event, for the reasons given above): (i) on the basis of my conclusions on Issue I (Issue IIIa) and (ii) on the basis of my conclusions on Issue II (Issue IIIb).

[28] I must decide whether the defendants escape any such liability under art 7(e): (i) in the light of my conclusions on the construction of art 7(e) on Issue I (Issue IVa) and/or (ii) in the light of my conclusions on Issue II (Issue IVb).

[29] I shall turn then to the six lead cases. Subject always to the outcome of Issue I, I may have made, in my consideration in respect of Issue II, findings as to the date when tests could legitimately have been expected to be implemented which might mean that, depending upon their date of infection, only certain claimants succeed, ie those infected after such and such a date, while others do not. That apart, I have heard a good deal of evidence about Hepatitis C and its prognosis and consequences generally, and in addition all the evidence relating to the individual circumstances of the six lead claimants (two of whom, as previously discussed, will in any event receive compensation in accordance with my conclusions on quantum, by virtue of the 90% concession agreement).

[30] I shall, again even if I shall have found that some or all of the claimants fail (apart from those covered by the concession): (i) make findings on the generic issues raised relating to quantum arising out of and by reference to the particular circumstances of the six lead claimants, including such matters as recoverability or otherwise of damages in respect of alleged social or insurance or employment stigma resulting from their Hepatitis condition, past or present (Issue V); and (ii) assess damages, in the case of five of the lead claimants by way of provisional damages, on the basis of what have now, after considerable discussion and argument, become agreed triggers for any potential future entitlement to additional damages pursuant to s 32A of the Supreme Court Act 1981, and in the case of one of them, Mr W, at his request, final damages (Issue VI).

ARTICLE 6

The common ground

[31] I turn then to consideration of art 6. There is a foundation of common ground. (i) Article 6 defines 'defective', and hence a defect. A harmful characteristic in a product, which has led to injury or damage, may or may not be a defect as so defined, and thus within the meaning of the directive. It is common ground that the liability is 'defect-based' and not 'fault-based', ie that a producer's liability is irrespective of fault (Recitals 2, 6). (ii) The purpose of the directive is to achieve a higher and consistent level of consumer protection throughout the Community and render recovery of compensation easier, and uncomplicated by

the need for proof of negligence. Both these propositions are expressed by Christopher Newdick in two published articles, first in the Law Quarterly Review 'The Future of Negligence in Product Liability' [1987] 103 LQR 288:

> '... liability for defective products is no longer to be dependent on fault, but rather on the mere fact of defectiveness. The broad reasons of policy for the change continue to be articulated by the injuries suffered by the thalidomide children. By the attention it devotes to consideration of the alleged fault of the defendant, the law of Negligence is unable to consider the interests of the person for whom the action has been brought.'

and also in 'The Development Risk Defence of the Consumer Protection Act 1987' [1988] CLJ 455 where, before going on to deal with art 7(e) as a possible exception, he states:

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

(iii) The onus of proof is upon the claimants to prove the product to be defective. (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 injury caused by the 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. At one stage Mr Forrester QC contended that the process was to discover what the expectation was, and then see if it was legitimate; but, not least for the reasons set out in the next following subparagraph, he no longer actively pursued that contention. The common ground is that the question is what the legitimate expectation is of persons generally, ie what is legitimately to be expected, arrived at objectively. 'Legitimate expectation', rather than 'entitled expectation', appeared to all of us to be a more happy formulation (and is analogous to the formulation in other languages in which the directive is published); the use of that expression is not intended to import any administrative law concepts. (vii) The court decides what the public is entitled to expect: Dr Harald Bartl in *Produkthaftung nach neuem EG-Recht* (1989) described the judge (as translated from the German) as 'an informed representative of the public at large'. Mr Brown did not like this, and preferred to suggest simply that the judge is determining what level of safety the public is entitled to expect, but I do not consider the two descriptions inconsistent. Such objectively assessed legitimate expectation may accord with actual expectation; but it may be *more* than the public actually expects, thus imposing a higher standard of safety, or it may be *less* than the public actually expects. Alternatively the public may have no *actual* expectation—e g in relation to a new product—the word coined in argument for such an imaginary product was a 'scrid'. (viii) There are some products, which have harmful

characteristics in whole or in part, about which no complaint can be made. The examples that were used of products which have obviously dangerous characteristics by virtue of their very nature or intended use, were, on the one hand knives, guns and poisons and on the other hand alcohol, tobacco, perhaps foie gras. The existence of such products was recognised in an exchange of question and answer by Mrs Flesch MEP to the European Commission, answered by Viscount Davignon on behalf of the Commission in June 1980. The question read in material part as follows:

> 'This provision ought apparently to be interpreted in the sense that nobody can legitimately expect from a product which by its very nature carries a risk and which has been presented as such (instructions for use, labelling, publicity, etc.) a degree of safety which this product does not and cannot possess, with the result that this product would not therefore be defective within the meaning of the future directive.'

The answer was:

> 'The Commission agreed with the Honourable Member that nobody can expect from a product a degree of safety from risks which are, because of its particular nature, inherent in that product and generally known, e.g., the risk of damage to health caused by alcoholic beverages. Such a product is not defective within the meaning of ... the ... Directive.'

This does not of course amount to an exemption for such a product from the article, but simply an explanation of how the article operates. Such obvious danger or risk of injury is, not very felicitously, described by a Danish writer, Borge Dahl, as 'system' damage. Professor Howells in *The Law of Product Liability* at para 1.19 refers to this as a description of:

> 'The risks which are inherent within a product which it is nevertheless considered justifiable to market. Examples include the risk of being cut by a sharp knife and the risk of illness associated with such otherwise pleasure giving products [as] alcohol and tobacco ... The emphasis on the autonomy of the individual and his free choice to expose himself to risks has generally relieved the producer of ... liability. However this free choice must be an informed choice and so there has been a need to define which types of system damage users can be expected to be aware of from their general life experience (i.e., that knives can be sharp) and those that they have to be warned about (i.e., risks associated with drinking and smoking).'

Drugs with advertised side-effects may fall within this category. The defendants point out that, with other such products also, the known dangerous characteristics need not be the desired ones—eg carcinogenicity in tobacco. (ix) Article 6(2) means that such test must be applied as at the date when the product is put into circulation, ie tested against the safety then to be expected. It is apparent that a product may be compared with other products said to be safer, but will not be condemned simply because another safer product is subsequently put into circulation. (x) There is also important factual common ground. It has, as set out in [8] above, been known, at least since the 1970s, by blood producers and the medical profession, primarily blood specialists, hepatologists and epidemiologists, that there was a problem of infection by Hep C (formerly NANBH) in transfused blood, and that a percentage of such blood—in the United

Kingdom thought to be between 1% and 3%—was infected with NANBH/Hep C. The claimants say that such knowledge by the medical profession and blood producers is on the one hand irrelevant to art 6, and to the public's expectation, and legitimate expectation, and on the other rules out the producers from the protection of art 7(e). The defendants say that such risks so known, which they allege to be impossible to avoid or prevent, affect the legitimate expectation of the public, such as to exclude art 6, and, because they were unavoidable, qualify them, if necessary, for art 7(e).

The differences between the parties

[32] Having set out what is common ground, I now summarise briefly the difference between the two parties, some of which is already apparent from my setting in context of the factual common ground. (i) As to art 6, the claimants assert that, with the need for proof of negligence eliminated, consideration of the conduct of the producer, or of a reasonable or legitimately expectable producer, is inadmissible or irrelevant. Therefore questions of avoidability cannot and do not arise: what the defendants could or should have done differently; whether there were any steps or precautions reasonably available; and whether it was impossible to take any steps by way of prevention or avoidance, or impracticable or economically unreasonable. Such are not 'circumstances' falling to be considered within art 6. In so far as the risk was known to blood producers and the medical profession, it was not known to the public at large (save for those few patients who might ask their doctor, or read the occasional article about blood in a newspaper) and no risk that any percentage of transfused blood would be infected was accepted by them. (ii) The defendants assert that the risk was known to those who mattered, namely the medical profession, through whom blood was supplied. Avoiding the risk was impossible and unattainable, and it is not and cannot be legitimate to expect the unattainable. Avoidability or unavoidability is a circumstance to be taken into account within art 6. The public did not and/or was not entitled to expect 100% clean blood. The most they could legitimately expect was that all legitimately expectable (reasonably available) precautions—or in this case tests—had been taken or carried out. The claimants must therefore prove that they were legitimately entitled to expect more, and/or must disprove the unavoidability of the harmful characteristic. There would need to be an investigation as to whether it was impossible to avoid the risk and/or whether the producers had taken all legitimately expectable steps. In so far as there was thus an investigation analogous to, or involving similar facts to, an investigation into negligence, it was not an investigation of negligence by the individual producer and was necessary and, because it was not an investigation of fault, permissible. If, notwithstanding the known and unavoidable risk, the blood was nevertheless defective within art 6, then it is all the more necessary to construe art 7(e) so as to avail those who could not, in the then state of scientific and technical knowledge, identify the defect in a particular product so as to prevent its supply. (iii) The claimants respond that art 7(e) does not apply to risks which are known before the supply of the product, whether or not the defect can be identified in the particular product; and there are a number of other issues between the parties in respect of art 7(e) to which I shall return later.

All circumstances

[33] Article 6 must then be considered against the background of this summary of the issues. In the establishment of the level of safety, art 6 provides

that the court (on behalf of the public at large) takes into account *all circumstances*, including the following. (i) *Presentation*, ie the way in which the product is presented, eg warnings and price. As set out above, the expanded wording of s 3(2)(a) of the CPA is helpful. (ii) The *use* to which the product could reasonably be expected to be put, eg: (a) if the product is not a familiar or usual one, such as a scrid, it will be necessary to find out what its expected or foreseeable use is; (b) if it is expected and required to be dangerous in respect of its expected use, eg a gun, then complaint cannot be made of that dangerousness; but complaint could still be made of a different dangerousness, such as if it exploded on the trigger being pulled; and (c) if it is not expected to be dangerous in respect of its expected use, but the use to which it is put is unexpected, then it may not be defective. (iii) The *time* when the product is circulated, for example when the product is out of date or stale.

[34] The question arises as to the status of the *circumstances* enumerated in art 6. Are they exclusive? Neither side, rightly, now suggests that they are. Indeed Mr Forrester, who had, at an interlocutory hearing, seemingly run a contention to that effect, no longer pursued this, and indeed suggested that some *circumstances* not specifically mentioned in the article, such as the circumstances of the supply of the product, may be relevant. That the *circumstances* are not exclusive obviously seems right. Are they then unlimited? There are various possibilities. (i) That they are to be construed ejusdem generis. This is asserted by Professor Taschner, the leading European expert on the directive, in his 1990 book *Produkthaftungsgesetz und EG-Produkthaftungsrichtlinie* p 297; but, despite diligent research, the claimants' team was unable to find any support for the proposition that such a rule of construction could be exemplified in European law. (ii) That they are to be construed as the most significant examples of the *circumstances*. There was some support for this proposition, both by way of some exemplars in European legislation—from which it could be suggested that European draftsmen had considered that the matters actually set out as examples were the ones most worthy of mention—and also by reference to the French language version of art 6, which used the word, before the list of the circumstances, 'notamment', and the German, which used 'insbesondere', both of which I take to mean 'in particular' or 'especially'—although other language versions use phraseology more similar to the English 'including'. (iii) That they are to be construed as unlimited. Even Mr Underhill, I think, did not so contend, but accepted that the *circumstances* would have to be 'relevant' circumstances. Mr Forrester of course submits that *circumstances* which are inconsistent with the purpose of the directive would not be 'relevant'. He also refers to Professor Rolland of Halle University, who, in his 1990 book *Produkthaftungsrecht* p 131 cites Professor Taschner in concluding (translated from the German) that, in relation to the art 6 circumstances, 'only such considerations are relevant which do not alter the meaning of the safety expectations of the public at large, which are assessed on the basis of objective criteria, but not the subjective necessities of the producer, and also not those of the user of the product'.

[35] The dispute therefore is as to what further, if anything, falls to be considered within 'all circumstances'. There is no dispute between the parties, as set out in para 31(i) and (ii) above, that consideration of the fault of the producer is excluded; but does consideration of 'all circumstances' include consideration of the conduct to be expected from the producer, the level of safety to be expected from a producer of that product? The parties agree that the starting point is the

particular product with the harmful characteristic, and if its inherent nature and intended use (e g poison) are dangerous, then there may not need to be any further consideration, provided that the injury resulted from that known danger. However, if the product was not intended to be dangerous, that is the harmful characteristic was not intended, by virtue of the intended use of the product, then there must be consideration of whether it was safe and the level of safety to be legitimately expected. At this stage, the defendants assert that part of the investigation consists of what steps could have been taken by a producer to avoid that harmful characteristic. The defendants assert that conduct is to be considered not by reference to identifying the individual producer's negligence, but by identifying and specifying the safety precautions that the public would or could reasonably expect from a producer of the product. The exercise is referred to as a balancing act; the more difficult it is to make safe, and the more beneficial the product, the less is expected and vice versa, an issue being whether a producer has complied with the safety precautions reasonably to be expected. This is contended by the defendants to be appropriately analogous to the 'risk/utility' consideration familiar from United States law, particularly as summarised in the US Second Restatement on Torts (1965). However—(i) the claimants point out that, although the Advocate General in *European Commission v UK* Case C–300/95 [1997] All ER (EC) 481 at 488 (para 17) records that the Commission's original proposal in 1976 drew its inspiration from the US model, it is clear from the travaux préparatoires that when submissions were made that a United States style formulation should be adopted, it was not: the rejected suggestions including (from a body called UNICE in 1980) that 'the fact that a product conforms with generally accepted standards should be prima facie evidence that the product is not defective' and, from the American Chamber of Commerce in Belgium in the same year, that the proposed article 'should be amended to include specific language concerning unavoidably unsafe but useful products ... In drafting this amendment regard should be paid to the wording of Comment K to Section 402a of [the Second Restatement]'. (ii) Although the concept of 'unavoidably unsafe' has meant that producers have been found not liable in many states of the United States in respect of infected blood (see e g *Brody v Overlook Hospital* (1974) 317 A (2d) 392 (subsequently affirmed by the Supreme Court of New Jersey (1975) 332 A (2d) 596), the US Second Restatement has led to, or allowed for, a result, at least in Illinois, whereby there was strict liability imposed on the supplier of blood unavoidably infected with hepatitis (*Cunningham v McNeal Memorial Hospital* (1970) 47 Ill (2d) 443, Supreme Court of Illinois): which decision was dealt with statutorily, as a matter of public policy, by the giving of immunity to blood banks—a so-called 'blood-shield statute', passed in most states of the United States. (iii) The defendants themselves accept that the *risk/utility* model adopted in the United States cannot be applied in its entirety, because of the express exclusion, so far as the directive is concerned, of any question of liability for negligence. Nevertheless the defendants assert that there is a 'basket' of considerations: the likelihood of injury resulting and the seriousness of it if it results, the cost and the quality of the product, the efficacy of the product (with and without safety precautions), none of which would necessarily be contentious from the claimants' point of view. For if it were to be asserted by a producer that a product was very cheap, and thus might have been expected to have been less safe, that might, on the claimants' case, be part of the *presentation*, if it were simply a question of an alleged lowering of expectations by virtue of the

cheapness; while on the defendants' case the questions would arise in their own right as to what could have been practicable (or not) by way of safety precautions, and/or then perhaps as to the cost of such precautions, and perhaps the effect on the profitability of a producer. What would, on any basis, be contentious would be the further contents of the defendants' basket, namely the avoidability or unavoidability of the danger, and the availability or unavailability of alternatives. The contentions proceed as follows. *The defendants* assert that, in looking at the product, it is essential to consider, in deciding what level of safety could reasonably have been expected, what more if anything could have been done: what precautions or tests could be used/should have been used/were available to be used/can legitimately be expected to have been used. If, the defendants contend, the producer did not use obviously available safety processes or precautions, then that itself must be a factor to be taken into account against him, just as it would be in his favour if all available safety precautions were adopted. They accept that the investigation of what level of safety the public is entitled to expect may involve consideration of factual issues which would also be relevant in a negligence inquiry, but they say that this would be a matter of overlap rather than duplication, and inevitable and acceptable. *The claimants*, however, assert that, given that it is common ground that the article imposes liability irrespective of fault, the exercise of considering what could or should have been done by the producer is an impermissible and irrelevant exercise, which lets questions of fault back in by the back door. They say that the consideration of what safety precautions should have been expected to have been adopted simply amounts to the introduction of a standard of legitimate expectability, rather than a standard of reasonableness, against which the conduct of a producer must be set: while the defendants may be asserting that they accept that the consideration of the conduct of the individual producer is not relevant, nevertheless by the very consideration of what steps could legitimately have been expected to have been taken (against which what did occur inevitably has to be set) the same result is achieved. The claimants contend that any consideration of the method or processes of production, including the safety precautions taken or not taken, is irrelevant. They assert that it is necessary only to look at the product itself (including comparison with similar or identical products on the market), which would involve its expected or intended use, without considering what more could have been done (and how easy or difficult or cheap or expensive it would have been to have done it). The safeness even of a scrid must be considered by reference to examination of such a product and its intended or foreseeable use, *not* its method of manufacture. *The defendants* counter that it would be impossible to carry out any comparative exercise without understanding what steps were taken, and why certain steps could or could not have been taken. If such comparison is with a later and safer product, the producer would then rely on art 6(2), to assert that the greater safety offered by a subsequent model was not to be held against him, pursuant to art 6(2): to which a claimant could inevitably seek to respond that, although the safer product was five years later, the producer could have taken the same steps five years earlier.

Non-standard products

[36] In any event, however, the claimants make a separate case in relation to the blood products here in issue: namely that they are what is called in the United States 'rogue products' or 'lemons', and in Germany 'Ausreisser'—escapees or

'off the road' products. These are products which are isolated or rare specimens which are different from the other products of a similar series, different from the products as intended or desired by the producer. In the course of Mr Forrester's submissions, other more attractive or suitable descriptions were canvassed, and I have firmly settled on what I clearly prefer, namely the 'non-standard' product. Thus 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. Some Community jurisdictions in implementing the directive have specifically provided that there will be liability for 'non-standard' products, ie that such will automatically be defective within art 6: Italy and Spain have done so by express legislation, and Dr Weber, in *Produkthaftung im Belgischen Recht* (1988) at pp 219–220, considers that that is now the position in Belgium also as a result of the implementation of the directive.

[37] Were the infected bags of blood in this case non-standard products? The claimants say Yes—99 out of 100 are safe and uninfected as intended. The defendants say No—all blood, derived as it is from a natural raw material, albeit then processed, is inherently risky. But the claimants assert that persons generally are entitled to expect that all blood and blood products used for medical treatment are safe, and that they will not receive the unsafe one in 100. The claimants say that this will only not be the case if the public does know and expect that blood, like cigarettes or alcohol, is or may be defective, not because the public's expectation is limited to an expectation that legitimately expectable safety precautions will have been taken.

[38] In a jurisdiction where, unlike Spain and Italy, and perhaps Belgium, no legislative distinction has been drawn between standard and non-standard products, the distinction, even if I were to conclude that the blood bags in this case are non-standard products, would not be absolute. Non-standard products would not be automatically defective. A product may be unsafe because it differs from the standard product, *or* because the standard product itself is unsafe, or at risk of being unsafe. It may, however, be easier to prove defectiveness if the product differs from the standard product.

Boxes

[39] United States tort law has developed a difference between manufacturing defects, design defects and instruction defects (the last category being irrelevant for our purposes). This was worked through in case law, though it did not appear in the Second Restatement, published in 1965, but it has been expressly incorporated into the Third Restatement, published in 1998 (s 2(a)(b)(c): Categories of Product Defects). There is almost a separate jurisprudence for manufacturing defects as opposed to design defects. A manufacturing defect is defined as being 'when the product departs from its intended design even though all possible care was exercised in the preparation and marketing of the product' and a design defect as—

> 'when the foreseeable risks of harm imposed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller or other distributor, or a predecessor in the commercial chain of

distribution, and the omission of the alternative design renders the product not reasonably safe.'

The claimants say that, in terms of that dichotomy, the infected blood here is a manufacturing defect—an error in production has led to a one-off. The defendants say that, if a defect at all, it is a design defect, because the process as designed leads inevitably to the occasional failure as a result of an inherent defect in the raw material. In this context, so far as the academics are concerned, the claimants appear to have the better of it. Professor Sole Feliu in his book *El Concepto de Defecto del Producto en la Responsabilidad Civil del Fabricante* (1997) p 525, when addressing the question of whether blood with hepatitis is to be considered a design or manufacturing defect, following the view of American Professors Phillips and Pryor (*Products Liability* (1993) vol 1, p 392), concludes (as translated from the Spanish) 'since the defects occur only occasionally and since there is no design whatsoever, and since the blood as such is processed and used for the transfusion, these are rather manufacturing defects'. Professor Howells (*The Law of Product Liability*, para 1.14) considers that 'manufacturing defects are caused by an error in the production process or by the use of defective raw materials'. However, notwithstanding that there was some use of these American terms in the travaux préparatoires, there is no place for them in the directive. After some discussion in the course of the hearing, I am satisfied, and indeed neither counsel contended to the contrary, that no assistance can be gained from what Mr Underhill 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, for the following reasons among others: (i) as referred to above, there are no such boxes or categories in the directive, unlike the Third Restatement; (ii) in order to define whether the defects are manufacturing or design defects, in most cases it would be inevitable that there would require to be consideration of the precise processes adopted in production, which both sides accept to be inappropriate; and (iii) consequently, whatever may be the position in US jurisprudence, art 6 directs consideration of whether the *product* is defective, and as to what legitimate expectation is as to the safeness of the product. Whether it is appropriate to define the one infected bag of blood in 100 as a manufacturing defect, or as an inevitable result of a chosen design process which cannot guarantee uniformity of product, the issue is still the same, namely whether the safety was provided which the public was entitled to expect in respect of that product.

[40] The significance to my mind only arose at all in our discussions because, by virtue of the fact that many European experts in product liability, both academics and practitioners, have been steeped in the US jurisprudence, 'rogue products', or rather what I now call 'non-standard products', have been almost automatically defined by them as manufacturing defects. Given that there is a dispute between the parties in this case as to what is meant by a manufacturing defect, it seems to me sensible to concentrate simply on the concept of a standard or non-standard product. As will appear, this does appear to me to make easier the understanding of those few European decisions which there have been arising out of the directive. In the criminal field, the United Kingdom courts have responded stringently to manufacturing errors: this appears clearly from the House of Lords decision in *Smedleys Ltd v Breed* [1974] 2 All ER 21, [1974] AC 839, where, notwithstanding non-negligent quality control, there was strict liability at

criminal law where a caterpillar identical in colour, size, density and weight to the peas in a tin survived the process in one out of three million tins: but that too would be a non-standard product.

[41] If the distinction is between a standard and non-standard product, the critique of a non-standard product will be the same, namely by virtue of its difference from a standard product, whether it is treated as a one-off manufacturing defect or as a design defect resulting from a way in which the producer's system was designed, which led to all the producer's product being subject to the same risk. The approach to whether non-standard and standard products are defective may, however, be different, primarily because non-standard products fall to be compared principally with the standard product, while standard products, if compared at all, will be compared with other products on the market.

The status of the defendants

[42] One final point with which I should deal is the fact that the defendants are required to produce the product, in this case blood, pursuant to the obligations of the NBTS, and thus, it is said, had no alternative but to supply it to hospitals and patients, as a service to society. The defendants submit that this is a factor to be taken into account in the 'basket', not least because, unlike commercial producers, they have no option to withdraw it from the market rather than incur liabilities. Quite apart from the claimants' overall objection to the basket if it brings in a concept anything close to a *risk/utility* test, the claimants contend that, if art 7(d) does not apply ('that the defect is due to compliance of the product with mandatory regulations issued by the public authorities'), as it is not suggested to do, then there is no automatic reason why the public's expectation of safety should be lowered, *unless* such product is known to be defective, or at risk of being defective. Further there is, in any event, no necessary reason why a public authority or a non-profit making organisation should be in any different position if the product is unsafe (which proposition accords with the opinion of the Advocate General (Colomer) in *Henning Veedfald v Arhus Amstkommune* Case C-203/99 (14 December 2000, unreported) at para 27 (the 'Danish Kidney case'), which has not yet been considered by the Court of Justice[f]). There is of course no 'blood-shield' statute in the United Kingdom.

Travaux préparatoires

[43] There is nothing much to assist in the travaux préparatoires, save for: (i) the rejection of the express US approach and *risk-utility* analysis (see [35] above); (ii) the fact that the strength of the contentions in support of a defence of state of the art, and of protection for producers in the context of inevitable risks, was directed first to the introduction into the drafts, and then the expansion and exposition, of art 7(e). It might well be said that if those lobbying for extra protection for the producer had considered that there was already substantial protection under art 6 itself (which is not mentioned in this context in the documents in evidence) they might not have needed to fight so hard to introduce and retain art 7(e). This probably inadmissible approach is better expressed simply as the fact that in the documents before me (and that in itself is an important caveat) there is no discussion of whether the availability (or not) or adoption (or not) of safety

f Editor's note: the Court of Justice delivered judgment in this case on 10 May 2001.

precautions by a producer is relevant, or a *circumstance*, in the context of art 6 (nor of course is such listed at any time among the *circumstances* which are set out in the article, 'notamment' or otherwise).

Court decisions

[44] I turn to consider the few court decisions in Europe in which the directive, or these issues under the directive, have been considered or touched upon. As indicated above, these have not been many, notwithstanding the fact that the directive and implementing legislation within the Community countries (save in France, which delayed its implementation, although its own local laws were and remained in some respects more stringent) have been in force for 10 to 15 years. Leaving aside any English decisions, to which the ordinary rules of precedent would apply, so far as relevant, I would of course pay particular attention to any European decisions, not because they are binding upon me, but because not only does respect have to be paid, on the usual principles of comity, to reasoned decisions of competent foreign courts considering the same or similar issues, whatever the nature of the legislation, but particularly so where Community courts are applying the directive. In such a case, even though Community courts are entitled to come to different views, particularly on the facts, by reference to national and local conditions, and even though the Court of Justice can resolve and give a final opinion upon issues where different views have been taken in different Community countries on the same legislation, nevertheless harmony is desirable, particularly where it can be said that an autonomous or Community approach or meaning is required. (See most recently the Advocate General's opinion in the 'Danish Kidney case' at para 30.)

(i) *United Kingdom.* On the art 6 issues which I have to decide, *Richardson's* case is unclear. Ian Kennedy J concluded in relation to a condom, the teat end of which became detached during sexual intercourse, resulting in the pregnancy of the claimant, that 'naturally enough the users' expectation is that a condom will not fail'. But he does not then appear to have gone on to consider the actual question, being whether they were entitled so to expect. He appears to have concluded that he could not identify a harmful characteristic, either occurring in the factory (art 7(b)) or at all. Whether that resulted from too much concentration during the trial by both parties on the method of manufacture, or whether there was an implicit finding that the fracture was caused by misuse by the claimants, is not clear, but in any event he concluded, without consideration of the issue of legitimate expectation, that the claimants' claim failed. In the 'Cosytoes case', the claimant was successful, where an elastic strap for attaching a buckle to a baby's sleeping bag sprang back, causing the buckle to hit the baby's brother in the eye. So far as concerns the claim under the CPA, and hence for our purposes under art 6, the claim succeeded. Chadwick LJ (at para 44) emphasised that fault of the producer is irrelevant:

> 'It is irrelevant whether the hazard which causes the damage has come, or ought reasonably to have come, to the attention of the producer before the accident occurs. To hold otherwise is to my mind to seek to reintroduce concepts familiar in the concept of a claim in negligence at common law into a statutory regime which has been enacted in order to give effect to the ... directive.'

But he does not appear to address in terms whether the conduct of *any* producer would be relevant. Pill LJ left the position unclear (at para 27) when he concluded 'Members of the public were entitled to expect better from the appellant': but Chadwick LJ (at para 45) does address himself towards the level of safety to be expected 'in relation to child care products'. In neither of these two cases, however, does it appear that there was any or any full argument on the points now in issue.

(ii) *Germany*. In what has been called the 'German Bottle case' (9 May 1995) NJW 1995, 2162), the Bundesgerichtshof (BGH), the German Federal Supreme Court, gave judgment on 9 May 1995, allowing an appeal by a claimant injured as a result of an exploding mineral water bottle, resulting from a very fine hairline crack, not discovered notwithstanding what was found to be a technical and supervisory procedure in the defendant's factory in accordance with the very latest state of technology (including seven different inspections). Although the BGH dealt at some length with the questions under art 7(e), to which I shall refer below, it had no difficulty, after what was obviously detailed consideration, in concluding that the harmful characteristic was a defect within art 6 (or the German statute implementing it). The BGH concluded (translated from the German):

> 'The Court of Appeal [was] correct in law to assume that pursuant to [Article 6] a product is defective if it does not guarantee the degree of safety which may be expected when taking all circumstances into account. The Court of Appeal also [assumed] correctly that a consumer expects a mineral water bottle to have no obvious or even microscopic damage which might lead it to explode. The fact that it is not technically possible to detect and repair such defects in the bottle does not alter the consumer's expectations.'

The defendants accept that the crack in that case was plainly a manufacturing defect, capable of being described, as the BGH expressly did, as a rogue product ('Ausreisser') and do not contend that the decision of the BGH was wrong. They submit, however, that this logic does not apply to a bag of blood, which they submit to share the same characteristics as all blood, namely in that all blood bears—or bore—the 1% risk of being infected. (The BGH also rejected the producer's arguments under art 7(e), to which I shall return.)

(iii) *Holland*. The County Court of Amsterdam (not an appellate court) gave a judgment on 3 February 1999 in the case of *Scholten v Foundation Sanquin of Blood Supply* (unreported). In this case the claimant received blood infected with HIV, after the introduction of HIV screening tests in that country, because of the (infinitesimal) risk in that case from blood which had been so screened but must have been given by a donor who had only just contracted HIV, such that his infection could not be detected by a test during what has been called 'the window period'. The court appears to have looked at the facts in that case with some care. The claimant was pointing out that the foundation's leaflet suggested that the chance of being infected with HIV was so small that one should consider that one would not be infected. The defendants pointed out that the media had paid a great deal of attention to the fact that blood products always carried a risk of transmitting infections, and the defendants contended that (para 6, as translated from the Dutch)—

> 'the foundation carefully carried out investigations of the blood and followed the correct and relevant guidance, so that one is not able to expect

a greater safety of the blood product than that which can be offered by the proper compliance with the relevant regulations.'

The court concluded, in finding for the claimant in respect of art 6 (or the Dutch implementing equivalent), as follows:

'The court agreed with Scholten that, taking into account the vital importance of blood products and that in principle there is no alternative, the general public expects and is entitled to expect that blood products in the Netherlands have been 100% HIV free for some time. The fact that there is a small chance that HIV could be transmitted via a blood transfusion, which the foundation estimates at one in a million, is in the opinion of the court not general knowledge. It cannot therefore be said that the public does not or cannot be expected to have this expectation. The fact that the foundation acted in accordance with the relevant guidance, and that the use of an HIV-1 RNA test at the time could not have detected the HIV virus does not have any bearing on this.'

The defendants contend that this decision of the County Court of Amsterdam, which is obviously not in any way binding upon me, was wrong: but further or in the alternative they contend that the decision which the court then went on to make which resulted in Scholten's claim failing by reference to art 7(e) (to which I shall return below) was right.

(iv) *France.* There are no decisions directly under the directive in France, first because in any event the directive was not implemented until 1998, and secondly because, as referred to above, the French national laws of product liability are in some respects more favourable to claimants. In those circumstances, although I have been referred to decisions severally in the Conseil d'Etat (1995), the Lyon Administrative Court of Appeal (1997) and the Cour de Cassation (1998) (in the last of which the court said that they were interpreting the relevant articles of the Code Civil in the light of the directive), in which claimants succeeded in product liability claims in respect of infected blood, it is not helpful to consider them in any detail.

Academic literature

[45] As I have indicated above, my attention has been drawn to a large number of learned and perceptive academic writings, much of which has been relevant to the issue before me, but upon which of course I must make up my own mind. I shall summarise what seem to me to be the most relevant. (i) Professor Henderson (of Boston University), writing of the US law in (1973) 73 Columbia LR 1531ff ('Judicial Review of Manufacturers' Conscious Design Choices: The Limits of Adjudication'), doubts in US terms the role for a judge in adjudicating design decisions. However, this seems to me not inconsistent with—and may support—the conclusion that the only question should be whether the product—as designed—is unsafe, given its use and presentation and the injuries that have occurred—and not whether any other design could have been adopted to improve the safeness of the product. (ii) Simon Whittaker (now of St John's College, Oxford) in the early days of consideration of the directive, and before the CPA, raised, in an article in (1985) 5 Yearbook of European Law 233ff ('The EEC Directive on Product Liability'), the question as to whether safety standards arise for consideration within art 6, and concludes that they

perhaps do; but he rewrites the directive to represent that it is asking whether the product was 'reasonably safe', rather than using the words of legitimate expectation. It is in that context that he considers that it may 'look as though there is no practical difference between liability in the tort of negligence and liability under the Directive' (at 246). He postulates the possibility, at 257, of evidence of compliance with safety standards being 'admissible but not conclusive' under art 6, while asserting that such 'would not avail the defendant of a defence under Article 7(e)'. On that basis, it seems to me illogical if the escape route provided should be narrower than that which it is suggested may be a main defence: for a producer would not need reliance on art 7(e) if he had already succeeded on art 6. I return to this further below. (iii) Christopher Newdick, to whom I have referred above, of the University of Reading, appears to support the claimants' case in articles in (1987) 103 LQR 288 and [1988] CLJ 455); in the former (at 296–297) where he concludes:

> 'To excuse all ... production defects ... on the ground that they were undiscoverable would be to emaciate the potential of the directive. In this respect there may be sufficient grounds for strict liability to be applied in the absence of cogent reasons of policy to the contrary.'

and in the latter (at 455) in the passage which I have already quoted in [31] above. (iv) Professor Stoppa of Rome University appears to do so also, in an article on the CPA ('The Concept of Defectiveness in the Consumer Protection Act 1987: a critical analysis') in (1992) 12 Legal Studies 210, where he states (at p 212) (following Professor Alistair Clark of Strathclyde University, at p 168 of his book *Product Liability* (1989)): 'The solution most consistent with the spirit of the Directive would seem to suggest that all products which are unsafe because of a flaw in the production process be considered defective, unless there exist statutory provisions to the contrary.' Stoppa, however, appears to suggest that the position may be different in relation to what he is encouraged by US jurisprudence to consider as a design defect (pp 214–217). Thus he writes:

> '... in relation to sophisticated or innovative design cases, it could be argued that actual consumer expectations, which could be non-existent, are not at issue, in that the Act refers to the safety which persons generally are "entitled" to expect. But what are persons generally entitled to expect? It would probably be a fair assumption to say that consumers are entitled to expect, generally speaking, that all products be designed carefully and intelligently in the light of all foreseeable circumstances, with a view to manufacturing a product which is as safe as possible. Yet, the questionability of such a standard, or of a similarly worded one, is self-evident ... Indeed, it is submitted, a dual approach might also prove a workable solution under the [CPA]. In many design defect simple cases, as where the failure of the product [ensues] from its normal and intended use, the consumer expectations test seems to be an appropriate test. A product which causes injury when put to its core uses clearly disappoints consumer expectations and liability should be imposed accordingly. On the other hand, in more complex cases, where a consumer expectations test is but a semantic veneer concealing each court's own subjective assessment, a more structured balancing process of some kind seems necessary. In these cases, a risk-utility analysis would seem to be permitted by the wording of the [CPA], according

to which, for the purpose of determining what ordinary consumers are entitled to expect, "all the circumstances" should be taken into account.' a

(v) Christopher Hodges of Cameron McKenna, in his book *Product Liability: European Laws and Practice* (1993) does not appear to support Professor Stoppa's approach in relation to design defects. At para 3.019 he states:

'Strict liability is likely to have a significant impact on design defect claims. b
A claimant no longer has the difficult task of proving faulty conduct by a manufacturer ... The emphasis of the directive is shifted to a judgment about the safety to be expected of the product itself ... Liability is now imposed if something is unacceptably dangerous without it being anyone's fault.'

His subsequent para 3.023 appears not to contradict this, but simply to amount to c
advice to manufacturers and designers with a view to avoiding a defective design.
(vi) Professor Stapleton, to whom I have referred above, now of Australian National University, asserts that the directive does not in practice achieve strict liability. She said so in her book *Product Liability* (1994) at p 236:

'Despite the "strict liability" rhetoric in its Preamble the directive rarely d
imposes more than a negligence regime on manufacturers. The origin of this surprising and not obvious result is worth pursuing in detail because of the widespread assumption in business and the legal profession that the directive imposes strict liability on manufacturers.'

and again at pp 271–272. At the passage at p 236, she refers to the view of the then e
Lord of Appeal, Lord Griffiths (in extra-judicial capacity), together with two members of the staff of the Law Commission, prior to the implementation of the directive in the United Kingdom by the CPA, in an article in (1988) 62 Tulane LR 353ff. The latter there opine (at p 382) that 'some element of balancing is necessary to any proper analysis of the concept of a defective product', recite the various elements which American courts include in the *risk-utility* analysis f
(including (footnote 122) 'the manufacturer's ability to eliminate the unsafe character of the product without impairing its usefulness or making it too expensive to maintain its utility') and conclude that 'it does not seem likely that English judges would overtly adopt [a risk-utility analysis], albeit they would as an educated response to the facts of a particular case undertake a balancing g
exercise of an analogous kind'. Professor Stapleton simply concludes at p 236 of her book, by reference to Lord Griffiths' suggestion:

'... in other words the core of the "defect" enquiry will substantially parallel the issue which underlies the negligence standard ... Practitioner h
handbooks fleshing out the standard in the directive will therefore look remarkably like current handbooks on the substance of the duty in negligence. The only really important question to which manufacturers will need an answer concerns the strictness of the behavioural standard'.

(vii) Such a handbook in German, however, by Count von Westphalen of j
Bielefeld University, *Produkthaftungshandbuch* (1990), at paras 23–24 states as follows, in relation to the German implementation of art 6 (as translated from the German):

'Since product liability ... is liability irrespective of fault ... the criterion of Zumutbarkeit [translated as "reasonableness" and by Mr Forrester as "what

> the producer could be expected to do"] is irrelevant. In contrast to product liability in tort ... the producer cannot rely on the fact that he could not be expected to produce a safe alternative construction, possible according to the state of science and technology. The same applies if the producer wanted to rely on the fact that the market did not accept a more expensive but safer product, or that his competitors do not respect the required, higher safety standard either. In extreme cases, the producer must stop producing the insufficiently safe product. This makes it clear that the cost-benefit analysis plays no role in determining defectiveness of a product.'

Summary

[46] I summarise the position. (i) The first question of law which I have to resolve in the light of my construction of arts 6 and 7(e) is whether I need to consider and determine the issues raised by the evidence, which I have in fact heard over more than 20 days (including consideration of documents), from the claimants and the defendants, at the defendants' instance, on the 'Brown case'; namely as to whether in fact the defendants did everything that could be legitimately expected of them (what might be called their 'Zumutbarkeit' evidence). If I consider that I do not in law need to do so, then I resolve the question of defectiveness without such evidence (the 'Forrester case'). If I conclude that in law the evidence is admissible (but, as it happens, in any event, for the reason set out in [24] above, of possible appeals or references) then I must proceed to decide whether the claimants have shown that the defendants failed to do what was legitimately expected of them (the 'Brown case'). If I find that the product was defective on the 'Forrester case', the defect is, on any basis, infection by Hepatitis C. If, however, I find it defective on the 'Brown case', on the basis that the defendants failed to test or screen early enough, then the claimants would say the defect is the same, but the defendants would then say that the defect is the 'unscreenedness' of the blood. This dispute as to the precise description of the defect is only relevant for the purposes of the issues of causation and/or quantification of loss, to which I come below, and I shall return to it and resolve it only in that context. (ii) The onus of proof on art 6 is on the claimants. The defendants submit that if the claimants were right about art 6, because 'unavoidability' would not then assist them to avoid liability, art 7(e) should certainly then be so construed as to exclude them from liability: and conversely if art 7(e) is too limited to enable them to be exonerated, all the more should art 6 be construed in their favour. I turn therefore to consider art 7(e) before I reach my conclusions.

ARTICLE 7(e)

[47] I repeat, for the sake of convenience at this stage, art 7(e):

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

[48] This defence, for such it is, being an escape clause for the producer, the onus being upon the producer, has been called by the claimants (as it is in most academic literature) the *development risks* defence, which is how it was usually described during the working through of the directive, as is apparent from the

travaux préparatoires; and by the defendants the 'discoverability' defence, both because that concept is certainly an express and significant part of the defence, whatever it relates to, as will be seen, but also because it aids, as the defendants see it, their construction of the article. I propose, neutrally, simply to call it the 'art 7(e) defence'. Once again there is a great deal of common ground, not least because in relation to this article there is in certain respects binding authority and guidance from the Court of Justice (*European Commission v UK*).

[49] Such common ground is as follows. (i) The *state of scientific and technical knowledge* referred to is the most advanced available (to anyone, not simply to the producer in question), but it must be 'accessible'. In response to a more extreme position being taken by the Commission, the Advocate General answered as follows, in his opinion in *European Commission v UK* Case C–300/95 [1997] All ER (EC) 481 at 490 (paras 22–24), which, although not expressly approved in the judgment of the Court of Justice, is taken to be the state of the law:

> '22. ... Where in the whole gamut of scientific opinion at a particular time there is also one isolated opinion (which, as the history of science shows, might become with the passage of time opinio communis) as to the potentially defective and/or hazardous nature of the product, the manufacturer is no longer faced with an unforeseeable risk, since, as such, it is outside the scope of the rules imposed by the directive.
>
> 23. The aspect which I have just been discussing is closely linked with the question of the availability of scientific and technical knowledge in the sense of the accessibility of the sum of knowledge at a given time to interested persons. It is undeniable that the circulation of information is affected by objective factors, such as, for example, its place of origin, the language in which it is given and the circulation of the journals in which it is published. To be plain, there exist quite major differences in point of the speed in which it gets into circulation and the scale of its dissemination between a study of a researcher in a university in the United States published in an international English-language international journal and, to take an example given by the Commission, similar research carried out by an academic in Manchuria published in a local scientific journal in Chinese, which does not go outside the boundaries of the region.
>
> 24. In such a situation, it would be unrealistic and, I would say, unreasonable to take the view that the study published in Chinese has the same chances as the other of being known to a European product manufacturer. So, I do not consider that in such a case a producer could be held liable on the ground that at the time at which he put the product into circulation the brilliant Asian researcher had discovered the defect in it. More generally, the "state of knowledge" must be construed so as to include all data in the information circuit of the scientific community as a whole, bearing in mind, however, on the basis of a reasonableness test the actual opportunities for the information to circulate.'

It is not entirely clear what in practice is meant by the 'Manchuria exception'. I put to counsel, in the course of argument, that if in fact the product in question were a product for which Manchuria was renowned, perhaps yoghurt or fabric, then Manchuria itself would be a bad example: if, however, it were a product of particularly high technology then it might well be wholly unlikely that Manchuria would have thought something up. It seems to me that the right

approach is to look at 'accessibility' and to regard as *Manchuria* perhaps an unpublished document or unpublished research not available to the general public, retained within the laboratory or research department of a particular company. Fortunately the issue does not arise in this case. (ii) The article is not concerned with the conduct or knowledge of individual producers. As the court made clear (at 495 (para 29)):

> '... the producer of a defective product must prove that the objective state of scientific and technical knowledge, including the most advanced level of such knowledge, at the time when the product in question was put into circulation was not such as to enable the existence of the defect to be discovered.'

It is clear from the passage which I have already quoted, in [20] above, at 495 (para 36) of the court's judgment that 'the availability of the defence [does not depend] on the subjective knowledge of a producer taking reasonable care in the light of the standard precautions taken in the industrial sector in question'. (iii) The relevant time to assess the state of such *scientific and technical knowledge* is the time when the product was put into circulation. (iv) Whether or not the defect for the purposes of art 6 should be defined as 'unscreenedness' as discussed in para 46(i) above, there is no dispute that the defect for the purposes of art 7(e) is its infection by Hepatitis C (and of course the claimants rely on this, when this dispute becomes relevant, as a further argument, based on consistency in the construction of the directive, why the defendants' such definition of defect in art 6 is wrong).

The issues between the parties

[50] Must the producer prove that the defect had not been and could not be discovered in the product in question, as the defendants contend, or must the producer prove that the defect had not been and could not be discovered generally, ie in the population of products? If it be the latter, it is common ground here that the existence of the defect in blood generally, ie of the infection of blood in some cases by Hepatitis virus notwithstanding screening, was known, and indeed known to the defendants. The question is thus whether, in order to take advantage of the escape clause, the producer must show that no objectively assessable scientific or technical information existed anywhere in the world which had identified, and thus put producers potentially on notice of, the problem; or whether it is enough for the producer to show that, although the existence of the defect in such product was or should have been known, there was no objectively accessible information available anywhere in the world which would have enabled a producer to discover the existence of that known defect in the particular product in question. The crux of the dispute therefore is as follows. (i) The claimants say that once the defect in blood is known about, as it was, it is a known risk. A known but unavoidable risk does not qualify for art 7(e). It *may* qualify for art 6, not because it was unavoidable (see their contentions set out in [35] above) but if it could be shown that, because the risk is known, it was accepted, and lowered public expectations—like poison and alcohol. But otherwise once it is *known*, then the product cannot be supplied, or is supplied at the producer's risk and has no protection from art 7(e). Hence an art 7(e) defence is, as was intended, a development risks defence; for if it is not known that a particular product, perhaps a pioneering such product (such as a scrid), has or can

have a harmful characteristic, whether by virtue of its inherent nature, its raw materials, its design or its method of manufacture, and then the defect materialises, or is published about, for the first time, it has *prior to that time* been a true development risk, and protection is available under art 7(e). However, once the risk is known, *then* if the product is supplied, and if the defect recurs, by then it is a known risk, and, even if undiscoverable in a particular example of the product, there is no escape. There is only one stage of consideration, and if there be 'non-Manchurianly accessible' knowledge about the product's susceptibility to a defect, be it a manufacturing or design defect, there is no availability of art 7(e). As it is common ground in this case that there was such knowledge, the defendants cannot avail themselves of art 7(e). (ii) The *defendants* say that if a risk is unavoidable, it falls within art 6 (see their contentions in [35] above) but, if not, then it can still qualify for protection under art 7(e), if non-Manchurianly accessible information cannot enable a producer to discover the defect *in the particular product*. There may be no 'stage one'—ie knowledge of the risk—but, even if there is, there is a 'stage two'—namely consideration as to whether any accessible knowledge could have availed the producer to take any steps which he did not take. The defendants say there were none such here, or at any rate that such a conclusion could only be reached after resolution of the 'Brown case'.

[51] Nothing much can be gained by simply looking at the words of art 7(e). The claimants assert that to establish the defendants' construction the words 'in the product [in question]' needs to be inserted after the words 'the existence of the defect', while their construction does not need any additional words. The defendants assert that the words 'existence of the defect' are more apt to apply to the existence of a particular defect in a particular product, and for the claimants' construction to serve there should have been the use of the word 'risk' such as '[risk of] the existence of the defect to be discovered'. Neither argument is to my mind determinative or would stand in the way of either construction. The following points should be recorded. (i) The claimants rely heavily upon purposive construction, that is that the directive and this article must be construed in order to further the purpose of the directive, namely consumer protection and ease of recovery of compensation. (ii) The defendants counter that this is an express escape clause, specifically so as to allow a level of protection for producers who are non-negligent. There is provision for a member state to exclude art 7(e) from its legislation if (Recital 16) it was—'felt ... to restrict unduly the protection of the consumer', so this is what the clause was aimed at: and they refer also to Recital 7, whereby a 'fair apportionment of risk between the injured person and the producer implies that the producer should be able to free himself from liability if he furnishes proof as to the existence of certain exonerating circumstances'. (iii) The claimants contend that it is clearly apparent from *European Commission v UK* (to which I shall refer further below) that art 7(e) is intended to be construed restrictively: and in any event there is as much a concept of Community law as of the common law that a proviso, exception or escape clause should be construed restrictively. (iv) The defendants rely on the fact that in art 7(b), another of the exonerating circumstances, namely whereby a producer can show that the defect did not exist when the product left his factory etc, the defect being there referred to must be a defect in the product in question, rather than in the population of products. They assert that, at least by reference to English rules of construction, such a usage in a neighbouring sub-clause throws light on the meaning of art 7(e). (v) The knowledge in art 7(e) must be such as

to 'enable' the existence of the defect to be discovered. The claimants submit (and refer to other languages of the directive to support the proposition) that this simply means 'permit' or 'give the opportunity for' this to occur: and that this is less consistent with knowledge leading to the discovery of the defect in a particular product than with knowledge enabling the existence of the defect to be discovered generally, so that the risk of its being in the particular product is thus known of, as opposed to being an unknown development risk for which the producer could be excused. The claimants also rely on the fact that the passive voice is used: 'to enable the existence of the defect *to be* discovered' generally, rather than the issue being whether it enables 'the producer to discover' the defect in a particular product.

Travaux préparatoires

[52] When the Commission first proposed a directive, its suggestion was for the complete reverse of how it eventuated, namely that there should be an express *inclusion* of development risks, that is it should be made clear that the producer should be made expressly liable even for the 'inconnu'. The proposed article (then art 1) then provided that—

> 'the producer of an article shall be liable for damage caused by a defect in the article, whether or not he knew or could have known of the defect. The producer shall be liable even if the article could not have been regarded as defective in the light of the scientific and technological development at the time when he put the article into circulation.'

There is no addressing there of the question as to whether the defect was discoverable in the particular product, but the reference appears clearly to be to there being no knowledge of the defect at all. The contest thereafter by those seeking to introduce some protection for producers was first for the successful deletion of the express inclusion of liability for the unknown defect, and then, as set out in [43] above, the introduction of what eventually became art 7(e). There was, so far as I have seen from what has been put before me, no consideration specifically of whether the availability of knowledge in art 7(e) related to the discoverability of the defect in the particular product. But at almost every stage the reference is to the 'development risks' defence: 'Inclusion of development risks could have an inhibiting effect on innovation, because the cost of insuring such unforeseeable risks is likely to be quite high' (opinion of the Economic Social Committee, 7 May 1979). 'If liability for damage occasioned by development risks was excluded ... the effect would be to require the consumer to bear the risk of the unknown' (explanatory memorandum by the Commission dated 26 September 1979); and other such references.

Court decisions

[53] Clearly the most significant of these is the decision of the Court of Justice of *European Commission v UK*, although, as discussed above, it was not in terms addressing the particular issue here.

(i) *European Commission v UK*. While clarifying that the knowledge to be imputed to a producer must be accessible, ie not restricted within Manchuria, the Court of Justice none the less plainly intended to limit the escape clause. The fuller consideration was in the Advocate General's opinion. So far as there could be said to be passages relevant to the issues now before me, consideration

centred, in the course of argument, upon para 20, the material part of which reads as follows ([1997] All ER (EC) 481 at 489):

> '20. It should first be observed that, since [Article 7(e)] refers solely to the "scientific and technical knowledge" at the time the product was marketed, it is not concerned with the practices and safety standards in use in the industrial sector in which the producer is operating. In other words, it has no bearing on the exclusion of the manufacturer from liability that no one in that particular class of manufacturer takes the measures necessary to eliminate the defect or prevent it from arising, if such measures are capable of being adopted on the basis of the available knowledge.'

It has first of all to be emphasised that the context in which the Advocate General was setting out his opinion was one in which the form adopted by the United Kingdom Government in implementing art 7(e), ie s 4(1)(e) of the CPA, seemed clearly to suggest a much more subjective and more negligence-orientated defence than was provided for in art 7(e); and the Advocate General, and in due course the court, while content to give the United Kingdom Government the benefit of the doubt as to its intentions in implementation, was anxious to stamp upon such a prospect. The aim of the Advocate General's para 20 was obviously to emphasise that it could not excuse a manufacturer from liability if he complied with the safety measures (or lack of them) prevalent in the relevant industry. At first blush, the passage from para 20 which I have quoted could be construed to mean 'it has no bearing on the exclusion of the manufacturer from liability that no one in that particular class of manufacturer takes the measures necessary to eliminate the defect or prevent it from arising provided that such measures are capable of being adopted'. If this were right then it could be argued that it is a matter of significance as to whether there *could* be such measures, and if there are not, ie if the defect is unavoidable, then the producer might escape liability. However, I do not consider that that is the right construction of this paragraph. (a) I have taken note of the fact that the opinion was given by Advocate General Tesauro in Italian, and I have been shown the Italian version, where the subjunctive is used ('se ... siano') in respect of the last clause, so that in fact the translation should read 'if such measures were to be capable of being adopted'. With or without that clarification, however, I am satisfied that what the Advocate General is in fact saying, by way of summation in this sentence beginning with the words 'in other words', is that 'it has no bearing on the exclusion of the manufacturer from liability that no one takes the measures ... even if there were any such measures available'. I also do not see any significance, such as Mr Underhill suggests there to be, in the reference to 'elimination' of the defect, particularly when the alternative of preventing it from arising is also used: if a problem is known, as a result of non-Manchurianly accessible information, then one would expect the one or the other, elimination or prevention, and what is *not* being referred to is 'measures to inspect, or discover the defect in, the particular product'. (b) Paragraph 22 of the opinion is, however, of assistance. The Advocate General there states (at 490) that—

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

The Advocate General is there concentrating on foreseeability of risks rather than the discoverability of particular defects, and the measures which the producer can take are not limited to greater efforts to discover the defect in the particular product. Thus, whether or not he can take preventive measures, the producer can still be liable (and protect himself by insurance). In the paragraph of its judgment (26) in which para 20 of the opinion is referred to, there is not specific approval by the court of the whole of it (nor any mention of para 22), but reference is once again made then and throughout to 'knowledge', and not to the ability, as a result of the knowledge, to discover the defect in a particular product.

(ii) *The United Kingdom.* In *Richardson's* case, Ian Kennedy J, albeit having dismissed the claimants' claim, continued (obiter) to consider the art 7(e) defence and would have rejected it. He states ([2000] Lloyd's Rep Med 280 at 285) in a passage which, albeit obiter, is obviously relied upon by the claimants: 'This provision is, to my mind, not apt to protect a defendant in the case of a defect of a known character merely because there is no test which is able to reveal its existence in every case.'

(iii) *Germany.* The BGH in the 'German Bottle case' concludes (and is referred to by the recent Commission Green Paper dated 28 July 1999 at p 23 as having concluded) that art 7(e) applies only to design defects, and not manufacturing defects. Interestingly, this is what the unilateral declaration by the United Kingdom at the time of the passage of the directive had originally suggested (I have quoted it in [18] above). But, as made clear at [39]–[41] above, in my judgment there is no need nor call for differentiation between manufacturing and design defects in the construction of the directive, and the BGH appears to have been working on the assumption, not an uncommon one, as discussed, that rogue or non-standard products are always manufacturing defects. It is not perhaps surprising that Professor Stapleton in her recent article in the Washburn Law Journal ([2000] Wash LJ 3R/BL) at 381 described as *extraordinary* that 'the [BGH] merely asserted that the development risk defence in the ... Directive does not apply to manufacturing errors'. But I do not consider either that the question of 'boxing' was central to the decision of the BGH, or that that is all that the BGH decided, on a careful reading of the judgment. I have already set out, in [44](ii) above, that, in relation to the claim in respect of the exploding mineral water bottle, the court rejected the defence under art 6. It is right to say that the BGH categorised the undiscoverable crack in the bottle as a rare and inevitable production defect, but they did so, with reference to the word 'Ausreisser', as a rogue product or non-standard product, as it seems to me, irrespective of the categorisation as a production defect; and the relevant conclusion, as I see it, was that set out at II(bb) in the judgment (as translated from the German) namely—

> 'such rare and inevitable [production] defects ("Ausreisser") are not defects for the purposes of Article 7(e) of the ... Directive ... *simply because they are inevitable despite all reasonable precautions.* The purpose of the [Directive] is merely to exclude liability for so called development risks.' (My emphasis.)

This proposition plainly supports the claimants. The BGH continues (again in translation) 'Liability should only be excluded when the potential danger of the product could not be detected because the possibility to detect it did not (yet) exist at the time of marketing'. As 'the potential danger of re-usable bottles filled with carbonated drinks has been known for a long time' the art 7(e) defence was not available. In those circumstances the perhaps unnecessary repetition by the

BGH of the words 'unavoidable production risks do not constitute development risks' seems to me to be set into context. What the BGH was primarily saying is that if the risks are known, unavoidability of the defect in the particular product is no answer.

(iv) *Holland.* In *Scholten*'s case, after resolving the art 6 defence in favour of the claimant, the County Court of Amsterdam reached a conclusion supportive of the defendants on art 7(e). The court's conclusion on art 7(e) at pp 7–8 (as translated from the Dutch) is based upon the submission by the Foundation that it was not liable because it was impossible to detect the infection of the blood with HIV in the window phase, and that the new PCR test was technically not yet fully developed to achieve such detection; it stated:

> 'Given the state of scientific and technical knowledge at the time of the blood donation and the transfusion to Scholten, this leads to the conclusion that it was, practically speaking, not possible to use the [PCR] test as a screening test in order to detect HIV contamination in blood products. This could therefore not have been expected of the foundation.'

The claimants, while supporting the court's decision on art 6, do not agree with its decision on art 7(e), and the defendants' position is the reverse. It does seem to me, however, on consideration of the judgment alone that: (a) reference by the court in that passage to 'expectation' seems to me inapt. The expectation test is relevant only to art 6, which had been resolved in favour of the claimant; and (b) it is not clear whether the point in issue before me, and resolved against the producer in the 'German Bottle case', was argued.

(v) *Australia.* I touch briefly upon this jurisdiction. The wording of s 75AK(1)(c) of the Trade Practices Act 1974, which is to the same effect as art 7(e), is slightly different. In relevant part, the section reads as follows:

> '(1) In a liability action, it is a defence if it is established that: (a) the defect in the action goods that is alleged to have caused the loss did not exist at the supply time; or ... (c) the state of scientific or technical knowledge at the time when they were supplied by their actual manufacturer was not such as to enable that defect to be discovered.'

Such wording allows more clearly for the defendants' submission being made before me, namely that the issue is discovery of the defect in the 'action goods', ie the product in question, to be put forward. Even on that form of words, however, it seems to me that the claimants' construction, namely that the reference to the defect was generic, could be argued. But we are not faced with the Australian statute. The reason why reference was made to Australia is the existence of a decision of the Federal Court of Australia, *Graham Barclay Oysters Pty Ltd v Ryan* (2000) 177 ALR 18 (Lee, Lindgren, Kiefel JJ), which was referred to by Mr Underhill. In that case the court concluded that the judge below was right to construe the question as being whether the state of scientific or technical knowledge was such as to enable the presence of Hepatitis A virus to be discovered in the particular oysters being sold, notwithstanding that it was or appears to have been common ground that the risk of hepatitis in oysters generally was known. The judge found that there was no way of discovering the defect in the particular oysters, and consequently dismissed the claim. Clearly this is an example of an apparently strict liability statute resulting in the consumer failing. However, in so far as I am to draw any further help than that from the

case, I am not convinced, because (a) the wording is different, as I have pointed out (b) on a reading of the judgment it does not in fact appear to me that the issue before me, and before the BGH, was being canvassed by counsel: the issue appears to have been whether discovery in the individual product could *only* be done by a physical verification of each and every oyster, and it seems to have been assumed (it may well be rightly, on the basis of the Australian statute) that it was indeed discovery in the individual product which was necessary, which would beg our question.

Academic literature

[54] I turn again to consider the learned, persuasive and interesting contributions of various distinguished academics which have been put before me. (i) Newdick's article in [1988] CLJ 455 was written before the rejection by the Court of Justice in *European Commission v UK* of the United Kingdom Government's arguments (apart from those on accessibility, which he powerfully supports). He appears to have thought that those arguments might be right, although, in the event of course, apart from accessibility, they were not accepted. But that apart, his conclusion (at 472) after setting out the arguments appears to support the claimants:

> 'The argument against such a view is that the defence is not available once the possibility of the defect has been appreciated. If it were otherwise, this reforming Act would simply repeat in statutory form that which is thought to be inadequate in Negligence. Though the defence may inevitably protect the case of the entirely unforeseeable defect, it ought not to be extended further to cover problems of quality control. Rather than defending producers who knowingly, but without negligence, put into circulation defective products, a no-fault regime would commit itself to imposing liability ... The [argument] is further assisted by comparing the position of those with rights in contract. There, liability has never depended on the fault of the manufacturer or supplier. Once the buyer has shown goods to be defective, strict liability arises for their consequences. In the absence of clear words to the contrary, [a] no less generous approach should be adopted on behalf of the consumer by the no-fault regime of product liability.'

(ii) Professor Clark in his 1989 book *Product Liability* at pp 166–168 appears to come to a similar conclusion in relation to known but undiscoverable risks, that is 'a risk that is known or suspected to be present in the product, but, effectively, both the presence of the danger in particular samples of the product and the means of elimination of the danger are undiscoverable'. (iii) Professor Freiherr von Marschall of Friedrich Wilhelms University, Bonn, citing Professor Taschner, states in his 1991 article 'Deutschland: Bedenken zum Produkthaftungsgesetz' (PH 1 5/91 at 169) (as translated from the German) that:

> 'Contrary to an occasionally voiced view, it is irrelevant whether the producer in question was in a position to recognise the defectiveness in his product. The decisive question is whether, on the basis of scientific and technical knowledge which was accessible at the time the product was put on the market, it was objectively possible to recognise the defectiveness, i.e., its potential danger.'

(iv) Professor Stoppa, in his 1992 article ((1992) 12 Legal Studies 210 at pp 212–213), concludes that 'the defence should only be available in the case of entirely unknown and unforeseeable risks and should not allow the manufacturer to avoid liability in respect of defects which are known to be potentially present, but are still ineliminable'. (v) Howells *The Law of Product Liability* at para 4-242, in a short and unexpanded footnote briefly supports the claimants' proposition: 'Both the directive and the [CPA] refer to the defect, but in fact what is crucial is knowledge of risks which lead one as part of the overall assessment of the product to determine that it is defective.' (vi) Whittaker in his 1985 article states ((1985) 5 Yearbook of European Law 233 at 257–258):

> 'A situation covered by "present knowledge" would be where a drug could not be tested for a certain effect, because there was no reason to believe that it *could* have such an effect. Similarly, a producer would not be liable for impurities in his product, such as a virus in blood products, which could not be detected at the time of putting it into circulation.' (Author's emphasis.)

This passage is, however, unclear to me. Although, on the face of it, his statement about a virus in blood products is unconditional, nevertheless he does not seem to address the point in terms as to whether (by analogy with his drugs example) art 7(e) will only be available if 'there was no reason to believe that' the virus *could* be in the blood. (vii) The most favourable to the defendants appears to be Professor Stapleton in ch 10 of her 1993 book, at p 237. She there states, as part of her proposition, that the directive 'rarely imposes more than a negligence regime on manufacturers' (p 236), that 'the defence ... seems to shield a defendant in situations in which the risks of a product are well known at the relevant time (such as the risk of Hepatitis infection in donated blood)', although I do not follow the rest of her sentence where she continues 'but where, given available substitutes, it is regarded as not defective at the relevant time'. I do not follow this, first because I do not see how there being an available substitute is relevant in the case of blood, and, secondly, if in fact the product is not regarded as defective at the relevant time, then the claim will not have passed the threshold of art 6, and art 7(e) does not arise, as she herself points out later in the paragraph. By her acceptance, and assertion, that the words 'to enable the existence of the defect to be discovered' were not intended to imply 'to be discovered by him' (p 238) and that 'the Article 7(e) defence only requires a defect to be discoverable by someone' (p 238), she seems perhaps to negate a suggestion that the test is whether a defect could have been discovered in the particular product (produced by the producer). Yet her consideration of the Australian case of *Graham Barclay Oysters* (then only reported in the court below) in her 2000 article at p 382 suggests that she construes the Australian statute no differently from the directive (and she is of course an Australian professor) and is therefore influenced by the result of that case in her construction of the directive.

CONCLUSIONS ON ARTICLE 6

[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 is 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), as Professor Taschner and Count von Westphalen would describe such risks: Taschner and Riesch *Produkthaftungsgesetz und EG Produkthaftungsrichtlinie* (1990) at p 291 and von Westphalen *Produkthaftungshandbuch* at 27. Thus blood was not, in my judgment, the kind of product referred to in the Flesch/Davenant question and answer in the European Parliament ie 'a product which by its very nature carries a risk and which has been presented as such (instructions for use, labelling, publicity, etc.)', 'risks which are ... inherent in [a] product and generally known': nor as referred to by Professor Howells at para 1.17 as being risks which 'consumers can be taken to have chosen to expose themselves to in order to benefit from the product'.

[56] I do not consider that the legitimate expectation of the public at large is that legitimately expectable tests will have been carried out or precautions adopted. Their legitimate expectation is as to the safeness of the product (or not). The court will act as what Dr Bartl called the *appointed representative of the public at large*, but in my judgment it is impossible to inject into the consumer's legitimate expectation matters which would not by any stretch of the imagination be in his actual expectation. He will assume perhaps that there are tests, but his expectations will be as to the safeness of the blood. In my judgment it is as inappropriate to propose that the public should not 'expect the unattainable'—in the sense of tests or precautions which are impossible—at least unless it is informed as to what is unattainable or impossible, as it is to reformulate the expectation as one that the producer will not have been negligent or will have taken all reasonable steps.

[57] In this context I turn to consider what is intended to be included within 'all circumstances' in art 6. I am satisfied that this means all *relevant* circumstances. It is quite plain to me that (albeit that Professor Stapleton has been pessimistic about its success) the directive was intended to eliminate proof of fault or negligence. I am satisfied that this was not simply a legal consequence, but that it was also intended to make it easier for claimants to prove their case, such that not only would a consumer not have to prove that the producer did not take reasonable steps, or all reasonable steps, to comply with his duty of care, but also that the producer did not take all legitimately expectable steps either. In this regard I note para 16 of the Advocate General's opinion in *European Commission v UK* [1997] All ER (EC) 481 at 487 where, in setting out the background to the directive, he pointed out that:

> 'Albeit injured by a defective product, consumers were in fact and too often deprived of an effective remedy, since it proved very difficult procedurally to prove negligence on the part of the producer, that is to say, that he failed to take all appropriate steps to avoid the defect arising.'

[58] The Court of Justice in its judgment perhaps refers implicitly to this when it states (at 494 (para 24)): 'In order for a producer to incur liability for defective products under art 4 of the directive, the victim must prove the damage, the defect and the causal relationship between defect and damage, but not that the producer was at fault.' It seems to me clear that, even without the full panoply of allegations of negligence, the adoption of tests of avoidability or of legitimately expectable safety precautions must inevitably involve a substantial investigation.

What safety precautions or tests were available or reasonably available? Were they tests that would have been excessively expensive? Tests which would have been more expensive than justified the extra safety achieved? Are economic or political circumstances or restrictions to be taken into account in legitimate expectability? Once it is asserted that it is legitimately expectable that a certain safety precaution should have been taken, then the producer must surely be able to explain why such was not possible or why he did not do it; in which case it will then be explored as to whether such tests would or could have been carried out, or were or would have been too expensive or impracticable to carry out. If risk and benefit should be considered, then it might be said that, the more beneficial the product, the lower the tolerable level of safety; but this could not be arrived at without consideration as to whether, beneficial or not, there would have nevertheless been a safer way of setting about production or design. As Mr Brown pointed out, even if an alleged impracticability is put forward by a producer, it would still be possible to go back further, and see why it was impracticable, and whether earlier or different research and expenditure could not have resolved the problem.

[59] Mr Underhill submitted that he accepted that liability was irrespective of fault and that investigation of negligence was inappropriate, and that that was not the exercise he submitted the court was involved in. No criticisms were being made of the defendants on the basis that they were negligent. The investigation that was being carried out was not, as it would have been in a negligence action, as to what steps actually taken by these defendants were negligent, so that their individual acts and omissions were not being investigated. However, many of Mr Underhill's submissions were indistinguishable from those that he would have made had a breach of a duty of care—albeit one with a high standard of care, so that breach of it might not carry any stigma or criticism—been alleged against him. Did the defendants act reasonably in doing, or not doing, may often have been carefully replaced by 'can it be legitimately expected that ...?': but often the language of reasonableness—or Zumutbarkeit—crept in. I quote from his closing submissions:

> 'The exercise necessarily involves concepts such as proportionality and reasonableness which are encountered in the law of negligence, and in particular in relation to the *standard* of care in a duty-situation. But it remains a fundamentally different exercise, addressed to a different question. The claimant does not have to be concerned with the producer's conduct at all. He does not have to adduce, or rebut, evidence about *how* the process or choice which led to the product having the characteristic complaint. He has only to persuade the court that a product with that characteristic fell below the level of safety that persons generally are entitled to expect as the Community standard. English law traditionally distinguishes between different degrees of reasonableness (typically characterised as "ordinary reasonableness" and "*Wednesbury* reasonableness") (see *Associated Provincial Picture Houses Ltd v Wednesbury Corp* [1947] 2 All ER 680, [1948] 1 KB 223). Such distinction should not be pressed too far in the exercise of judgment required by the directive. But it will be entirely legitimate for a court in deciding the correct standard in a given case to recognise that views may legitimately differ as to exactly where the line is to be drawn and there may be a range of reasonable responses (both as to substance and as to the timing of the introduction of any safety feature).'

[60] Even from this carefully argued passage it can in my judgment be seen that there is no sufficient distinction between what Mr Underhill accepts is impermissible and what he is inviting the court to do. As Mr Brown pointed out, certain of Mr Underhill's formulations differ hardly at all from that enunciated by Lord Reid as being the issue in negligence in *Morris v West Hartlepool Steam Navigation Co Ltd* [1956] 1 All ER 385 at 399, [1956] AC 552 at 574, namely:

> '... it is the duty of an employer, in considering whether some precaution should be taken against a foreseeable risk, to weigh on the one hand the magnitude of the risk, the likelihood of an accident happening and the possible seriousness of the consequences if an accident does happen, and on the other hand the difficulty and expense and any other disadvantage of taking the precaution.'

[61] What is more, I have the inestimable advantage of not addressing this hypothetically, for the proof is in the pudding. In the 20 days or so evidence that I have heard, it is clear to me that I am being invited to conclude what the legitimately expectable (reasonable) producer would have been legitimately expected to do (should have done) in relation to the safety of blood between 1988 and 1991: then I am being invited to set against what happened (no surrogate tests and no screening until September 1991) the legitimately expected scenario, albeit that would be the same, as the defendants would assert, or would be different and earlier, as the claimants would assert. As was inevitable, the carefully constructed distinctions occasionally blurred in the course of a long trial and lengthy submissions, such that for example Mr Underhill would perfectly understandably submit (day 7, p 105 of the transcript): 'I think it would be unusual to have a situation in which you held that everything we had done was reasonable, but nevertheless the public was entitled to expect a different outcome.' Having heard the evidence of Zumutbarkeit over some 20 days, I pay tribute to the fact that both parties were careful never to address head on the issue of negligence, the claimants noteworthily eschewing any such suggestion, and I am well aware that the investigation would have been wider and longer if it had expressly been based in negligence.

[62] As will be clear when I consider Issue II below, it is by no means easy to settle on a test for what is to be legitimately expected in the way of safety precautions, or extra or alternative safety precautions, assuming that to be appropriate. Must they be taken if they are available, or reasonably available, or not if there are two 'schools of thought', or only if as Mr Underhill put it, it was 'plainly the right thing for a blood transfusion service to do'? It has been quite clear to me that the claimants have had, on the trial of the facts before me, to prove, on the 'Brown case', that the defendants ought to have acted differently from the way they did: not on a day by day, or month by month basis, assessing their individual conduct, but simply on the basis that tests ought to have been introduced differently and earlier. I am satisfied that Mr Forrester was right to refer to Senator Huey Long's duck: namely 'If it looks like fault, and it quacks like fault then [to all intents and purposes] it is fault.'

[63] I conclude therefore that *avoidability* is not one of the *circumstances* to be taken into account within art 6. I am satisfied that it is not a *relevant* circumstance, because it is outwith the purpose of the directive, and indeed that, had it been intended that it would be included as a derogation from, or at any rate a palliation of, its purpose, then it would certainly have been mentioned; for it would have

been an important circumstance, and I am clear that, irrespective of the absence of any word such as 'notamment' in the English-language version of the directive, it was intended that the most significant circumstances were those listed.

[64] This brings me to a consideration of art 7(e) in the context of consideration of art 6. Article 7(e) provides a very restricted escape route, and producers are, as emphasised in *European Commission v UK*, unable to take advantage of it, unless they come within its very restricted conditions, whereby a producer who has taken all possible precautions (certainly all legitimately expectable precautions, if the terms of art 6, as construed by Mr Underhill, are to be cross-referred) *remains* liable unless that producer can show that 'the state of scientific and technical knowledge [anywhere and anyone's in the world, provided reasonably accessible] was not such as to enable the existence of the defect to be discovered'. The significance seems to be as follows. Article 7(e) is the escape route (if available at all) for the producer who has done all he could reasonably be expected to do (and more); and yet that route is emphatically very restricted, because of the purpose and effect of the directive (see particularly [1997] All ER (EC) 481 at 494–495, 495, 496 (paras 26, 36 and 38)). This must suggest a similarly restricted view of art 6, indeed one that is even more restricted, given the availability of the (restricted) art 7(e) escape route. If that were not the case, then if the art 7(e) defence were *excluded*, an option permitted (and indeed taken up, in the case of Luxembourg and Finland) for those member states who wish to delete this 'exonerating circumstance' as 'unduly restricting the protection of the consumer' (Recital 16 and art 15), then, on the defendants' case, an even less restrictive 'exonerating circumstance', and one available even in the case of risks known to the producer, would *remain* in art 6; and indeed one where the onus does not even rest on the defendant, but firmly on the claimant.

[65] Further, in my judgment, the infected bags of blood were non-standard products. I have already recorded that it does not seem to me to matter whether they would be categorised in US tort law as manufacturing or design defects. They were in any event different from the norm which the producer intended for use by the public. (i) I do not accept that all the blood products were equally defective because all of them carried the risk. That is a very philosophical approach. It is one which would, as Mr Forrester pointed out, be equally apt to a situation in which one tyre in one million was defective because of an inherent occasional blip in the strength of the rubber's raw material. The answer is that the test relates to the *use* of the blood bag. For, and as a result of, the intended use, 99 out of 100 bags would cause no injury and would not be infected, unlike the 100th. (ii) Even in the case of standard products such as drugs, side-effects are to my mind only capable of being 'socially acceptable' if they are made known. Mr Underhill submitted in his closing submissions that blood products—

> 'are drugs; they are given only by doctors; they are given typically in life-or-death situations; they are a natural product derived from the blood of another person and *known* therefore *inevitably* to carry the risk of transmitting pathogenic agents from the donor. The known risk of the presence of a virus in a BP does not represent a falling below intended manufacturing or production standards: it is inherent in the nature of the product.'

But I am satisfied, as I have stated above, that the problem was not *known* to the consumer. However, in any event, I do not accept that the consumer expected,

or was entitled to expect, that *his* bag of blood was defective even if (which I have concluded was not the case) he had any knowledge of any problem. I do not consider, as Mr Forrester put it, that he was expecting or entitled to expect a form of Russian roulette. That would only arise if, contrary to my conclusion, the public took that as socially acceptable (sozialadäquat). For such knowledge and acceptance there would need to be at the very least publicity and probably express warnings, and even that might not, in the light of the no-waiver provision in art 12 set out above, be sufficient.

[66] Accordingly I am quite clear that the infected blood products in this case were non-standard products (whether on the basis of being manufacturing or design defects does not appear to me to matter). Where, as here, there is a harmful characteristic in a *non-standard* product, a decision that it is defective is likely to be straightforward, and I can make my decision accordingly. However, the consequence of my conclusion is that 'avoidability' is also not in the basket of *circumstances*, even in respect of a harmful characteristic in a *standard* product. So I shall set out what I consider to be the structure for consideration under art 6. It must be emphasised that safety and intended, or foreseeable, use are the lynchpins: and, leading on from these, what legitimate expectations there are of safety in relation to foreseeable use. (i) I see no difficulty, on that basis, in an analysis which is akin to contract or warranty. Recital 6 ('the defectiveness of the product should be determined by reference not to its fitness for use but to the lack of the safety which the public at large are entitled to expect') does not in my judgment counter-indicate an approach analogous to contract, but is concerned to emphasise that it is safety which is paramount. (ii) In the circumstances, there may in a simple case be a straightforward answer to the art 6 question, and the facts may be sufficiently clear. But an expert may be needed (and they were instructed in *Richardson*'s case, the 'Cosytoes case' and the 'German Bottle case'). For art 6 purposes, the function of such expert would be, in my judgment, to describe the composition or construction of the product and its effect and consequence in use: not to consider what could or should have been done, whether in respect of its design or manufacture, to avoid the problem (that may be relevant in relation to art 7(e), if that arises). (iii) In the following analysis I ignore questions that may obviously arise, either by way of 'exoneration' in respect of other heads of art 7 or in respect of misuse or contributory negligence (art 8, set out in [16] above).

[67] The first step must be to identify the harmful characteristic which caused the injury (art 4). In order to establish that there is a defect in art 6, the next step will be to conclude whether the product is standard or non-standard. This will be done (in the absence of admission by the producer) most easily by comparing the offending product with other products of the same type or series produced by that producer. If the respect in which it differs from the series includes the harmful characteristic, then it is, for the purpose of art 6, non-standard. If it does not differ, or if the respect in which it differs does not include the harmful characteristic, but all the other products, albeit different, share the harmful characteristic, then it is to be treated as a standard product.

Non-standard products

[68] The *circumstances* specified in art 6 may obviously be relevant—the product may be a second—as well as the circumstances of the supply. But it seems to me that the primary issue in relation to a non-standard product may be

whether the public at large accepted the non-standard nature of the product—ie they accept that a proportion of the products is defective (as I have concluded they do not in this case). That, as discussed, is not of course the end of it, because the question is of *legitimate* expectation, and the court may conclude that the expectation of the public is too high or too low. But manifestly questions such as warnings and presentations will be in the forefront. However, I conclude that the following are not relevant: (i) avoidability of the harmful characteristic—ie impossibility or unavoidability in relation to precautionary measures; (ii) the impracticality, cost or difficulty of taking such measures; and (iii) the benefit to society or utility of the product (except in the context of whether—with *full information* and *proper knowledge*—the public does and ought to accept the risk).

[69] Lord Griffiths et al in their 1988 article appear to accept (62 Tulane LR 353 at 382) that an *overt* approach by English judges to consider these latter factors would not be likely, but I do not conclude that they enter into the exercise at all. This is obviously a tough decision for any common lawyer to make. But I am entirely clear that this was the purpose of the directive, and that without the exclusion of such matters (subject only to the limited defence of art 7(e)) it would not only be toothless but pointless.

[70] The submissions of Mr Underhill threw up an anomaly. As part of his submission that unavoidability is material, he contended that there may be a situation in which a claimant might wish to suggest that a harmful product, supplied with a warning, could yet have been manufactured or designed in other ways in order to *avoid* the harmful characteristic of which the warning was given. Mr Forrester eschews this opportunity on behalf of consumers. It seems to me that is right. The issue of *avoidability* is as immaterial at the instance of the consumer as it is of the producer (though of course the consumer could always put forward an alternative claim in negligence if he wished to shoulder the burden both of proof and evidential investigation). The problem is most unlikely to arise in any event in relation to a non-standard product, where the other, standard, products will in any event be pointed to, and the warning would itself have to point out the risk of deviation from the norm. However, in relation to a standard product, the problem may again not arise if there is an alternative product without the defect, with which the product with the warning can then be compared, and the question of acceptance of the risk or legitimate expectation of safety can be assessed, once again without going into any questions of avoidability. However, even where no such comparability is available, it seems to me clear that, whether or not there could have been some other way of manufacturing or designing the product, the social acceptability of the actual product, as it in fact was, must be tested against the background of the warnings that were in fact given. Warnings can never in any event amount to a waiver, because of art 12.

Standard products

[71] If a standard product is unsafe, it is likely to be so as a result of alleged error in design, or at any rate as a result of an allegedly flawed system. The harmful characteristic must be identified, if necessary with the assistance of experts. The question of presentation/time/circumstances of supply/social acceptability etc will arise as above. The sole question will be safety for the foreseeable use. If there are any comparable products on the market, then it will obviously be relevant to compare the offending product with those other

products, so as to identify, compare and contrast the relevant features. There will obviously need to be a full understanding of how the product works—particularly if it is a new product, such as a scrid, so as to assess its safety for such use. Price is obviously a significant factor in legitimate expectation, and may well be material in the comparative process. But again it seems to me there is no room in the basket for: (i) what the producer could have done differently; and (ii) whether the producer could or could not have done the same as the others did.

[72] Once again there are areas of anomaly. The first is the same as I have discussed in respect of non-standard products, where the *claimant* might have wished to allege unavoidability. The second area arises out of art 6(2), which I repeat for convenience: 'A product shall not be considered defective for the sole reason that a better product is subsequently put into circulation.' In the comparative process, the claimant may point to a product which is safer, but which the producer shows to be produced five years later. Particularly if no other contemporary product had these features, this is likely to be capable of being established, and insofar as such product has improved safety features which have only evolved later in time, they should be ignored, as a result of art 6(2). The claimant might, however, want to allege that the later safety features *could* have been developed earlier by the producer. That would obviously amount to the *claimant* running the evidence of 'should have done', to which the producer would no doubt respond 'could not have done'. This would, however, once again go to the issue of *avoidability*, which I have concluded to be outside the ambit of art 6, and so once again if the claimant really wanted to do so he could run the point, but only in negligence.

[73] I can accept that resolution of the problem of the defective standard product will be more complex than in the case of a non-standard product. This trial has been in respect of what I am satisfied to be a non-standard product, and I see, after a three-month hearing, no difficulty in eliminating evidence of avoidability from art 6. It may be that, if I am right in my analysis, and if it is followed in other cases, problems may arise in the consideration of a standard product on such basis, but I do not consider any such problems will be insurmountable if safety, use and the identified *circumstances* are kept in the forefront of consideration. Negligence, fault and the conduct of the producer or designer can be left to the (limited) ambit of art 7(e), to which I now turn.

CONCLUSIONS ON ARTICLE 7(e)

[74] As to construction: (i) I note (without resolving the question) the force of the argument that the *defect* in art 7(b) falls to be construed as the defect in the particular product; but I do not consider that to be determinative of the construction of art 7(e), and indeed I am firmly of the view that such is not the case in art 7(e); (ii) the analysis of art 7(e), with the guidance of *European Commission v UK*, seems to me to be entirely clear. If there is a known risk, ie the existence of the defect is known or should have been known in the light of non-Manchurianly accessible information, then the producer continues to produce and supply at his own risk. It would, in my judgment, be inconsistent with the purpose of the directive if a producer, in the case of a known risk, continues to supply products simply because, and despite the fact that, he is unable to identify in which if any of his products that defect will occur or recur, or, more relevantly in a case such as this, where the producer is obliged to supply, continues to supply without accepting the responsibility for any injuries

resulting, by insurance or otherwise; and (iii) the *existence of the defect* is in my judgment clearly generic. Once the *existence of the defect* is known, then there is then the *risk* of that defect materialising in any particular product.

[75] The purpose of the directive, from which art 7(e) should obviously not derogate more than is necessary (see Recital 16) is to prevent injury, and facilitate compensation for injury. The defendants submit that this means that art 7(e) must be construed so as to give the opportunity to the producer to do all he can in order to avoid injury: thus concentrating on what can be done in relation to the particular product. The claimants submit that this will rather be achieved by imposing obligation in respect of a known risk irrespective of the chances of finding the defect in the particular product, and I agree.

[76] The purpose of art 7(e) was plainly not to discourage innovation, and to exclude development risks from the directive, and it succeeds in its objective, subject to the very considerable restrictions that are clarified by *European Commission v UK*: namely that the risk ceases to be a development risk and becomes a known risk not if and when the producer in question (or, as the CPA inappropriately sought to enact in s 4(1)(e) 'a producer of products of the same description as the product in question') had the requisite knowledge, but if and when such knowledge were accessible anywhere in the world outside Manchuria. Hence it protects the producer in respect of the unknown (inconnu). But the consequence of acceptance of the defendants' submissions would be that protection would also be given in respect of the known.

[77] The effect is, it seems to me, not, as the BGH has been interpreted as concluding (or perhaps as it did conclude, but if it did then I would respectfully differ) that non-standard products are incapable of coming within art 7(e). Non-standard products may qualify *once*—ie if the problem which leads to an occasional defective product is (unlike the present case) not known: this may perhaps be more unusual than in relation to a problem with a standard product, but does not seem to me to be an impossible scenario. However, once the problem is *known* by virtue of accessible information, then the non-standard product can no longer qualify for protection under art 7(e).

THE RESULT IN LAW ON ISSUE I

[78] *Unknown risks* are unlikely to qualify by way of defence within art 6. They may, however, qualify for art 7(e). *Known risks* do not qualify within art 7(e), even if unavoidable in the particular product. They may qualify within art 6 if fully known and socially acceptable.

[79] The blood products in this case were non-standard products, and were unsafe by virtue of the harmful characteristics which they had and which the standard products did not have.

[80] They were not ipso facto defective (an expression used from time to time by the claimants) but were defective because I am satisfied that the public at large was entitled to expect that the blood transfused to them would be free from infection. There were no warnings and no material publicity, certainly none officially initiated by or for the benefit of the defendants, and the knowledge of the medical profession, not materially or at all shared with the consumer, is of no relevance. It is not material to consider whether any steps or any further steps could have been taken to avoid or palliate the risk that the blood would be infected.

[81] I am satisfied that my conclusions, if not all of my reasoning, are consistent with the decision of the BGH, and with the views of the majority if not all of the academic writers. Insofar as they are inconsistent with the views of Professor Stapleton as to the effect of the directive, I rather consider that I have confounded her pessimism than disappointed her expectations.

The consequence

[82] In those circumstances the claimants recover against the defendants because their claim succeeds within art 4, the blood bags being concluded to be defective within art 6, and art 7(e) does not avail.

[83] But I must, as set out above, proceed in any event to consider the Zumutbarkeit or avoidability arguments (Issue II), which I have found to be immaterial and unnecessary. The main issue is whether the public at large would legitimately expect that different steps would have been taken by way of safety precautions and in particular that: (i) the anti-Hep C assay would be introduced earlier than it was and/or as early as January 1990, as the claimants assert; and (ii) surrogate tests would be introduced in the United Kingdom by March 1988 and would continue until at least April 1991: continuing alongside the assay if and in so far as the assay were itself introduced prior to that date.

[84] In the light of my construction of art 7(e), and the conclusion that the risk of Hepatitis C infection was known, the art 7(e) defence does not arise. However, I must on a similar basis also nevertheless address art 7(e), and decide, in the light of the same evidence, Issue IV, namely whether the defendants can prove that they would not have been enabled to discover the existence of the infection in the particular product by virtue of the scientific and technical knowledge at the time, ie the assay, as the claimants would assert as from 1 December 1989 (when Japan had introduced it), or surrogate testing as from 1 March 1988.

ISSUE II

[85] In order to resolve the issues of fact, I have heard a number of impressive, experienced and conscientious witnesses and read, with the assiduous guidance of counsel, a very substantial number of articles, reviews, papers, surveys and reports in learned medical journals and from high-powered and distinguished medical conferences and symposia, in the fields of blood transfusion medicine, hepatology, virology, microbiology and epidemiology.

[86] I set out first the defendants' witnesses, as, by agreement, the defendants led their evidence first, as they were most easily able to lay the factual position before the court.

The defendants' factual witnesses

[87] Dr Harold Gunson CBE, to whom I have referred to above, as can be seen by reference to his career, is certainly the most experienced expert in blood transfusion in the United Kingdom, but perhaps also in Europe. Dr John Barbara has been the lead scientist in Transfusion Microbiology at the North London Blood Transfusion Centre, and Microbiology Consultant to the NBA, and has recently been appointed Principal of the National Transfusion Microbiology National Laboratories and a member of the Advisory Panel on Blood Transfusion Medicine of the World Health Organisation (WHO). He too is a man of the greatest distinction and experience in the field of transfusion medicine. They were the main witnesses of fact called by the defendants, although it was difficult

to distinguish them from expert witnesses, save that Dr Barbara did not seek to disguise his own well-publicised position of lack of support for the introduction in the United Kingdom of routine surrogate testing. As will appear below, Dr Gunson gave measured evidence of great authority, and was able, to the admiration of, I suspect, both claimants and defendants, to admit, in retrospect, to his concern that in the event routine screening for Hepatitis C was not introduced in the United Kingdom until September 1991. The publications of these two distinguished doctors are numerous. Apart from his 70 other publications in this field since 1955, Dr Gunson was co-author of *Fifty Years of Blood Transfusion* (1996). Dr Barbara has authored or co-authored some 500 relevant publications since 1973.

[88] The other live factual witness was Dr Garwood, now the national processing, testing and issue director of the NBA, who was called to give evidence of the requirements and problems of the BTS in the implementation of the new assay. Statements were also read, under the Civil Evidence Act, which were made by three witnesses whose statements were originally served on behalf of the claimants, but, after a decision not to call them, were adopted by the defendants. These were Dr Reesink, Associate Professor in Hepatology in Amsterdam, and an experienced Dutch blood transfusionist, dealing with the history of Hepatitis C screening in the Netherlands, and two witnesses, Professor Stirrat and Mr Wright, respectively clinician and consultant surgeon, whose evidence dealt, as did that of another witness, whose statement was also read, Dr Wolff, a consultant anaesthetist, with the extent of the knowledge of surgeons and practitioners about the risks of transfusions, to which I have made general reference above.

The defendants' expert witnesses

[89] I deal at this stage in my judgment only with those experts who gave evidence on the generic issues, as opposed to the lead cases. Professor Zuckerman is the doyen of UK microbiologists and virologists. He is Professor Emeritus of Medical Microbiology at the University of London and Honorary Consultant in Medical Microbiology and Clinical Virology at the Royal Free, Hampstead, NHS Trust and the National Blood Authority. He has been a member of the WHO Expert Advisory Panel on Viral Diseases since 1974 and is Director of the WHO Collaborating Centre for Research on Viral Diseases. He was Principal and Dean of the Royal Free University College Medical School of University College, London, effectively from 1989 to 1999, and an adviser to the Department of Health continuously for 30 years on matters concerning hepatitis and microbiology. His expertise in the field of viral hepatitis is further apparent from his having been the author of some 18 textbooks and over 1,000 publications in learned journals. Although called as an expert witness, he, like Dr Gunson and Dr Barbara, was intimately involved at committees and working groups, symposia and conferences and in the presentation of papers, concerning the topic of screening for hepatitis at the material time. He, like Dr Barbara, has not been a supporter of the introduction in the United Kingdom of surrogate testing. I heard also from Professor Högman, retired Director of the Department of Clinical Immunology Transfusion Medicine at University Hospital, Uppsala, in Sweden, as to the history of screening in Sweden.

[90] In addition, I heard from two further expert witnesses live, whose evidence was hardly at all in the event contested by the claimants, who indeed

adopted much of what they had to say. Dr Peter Simmonds, who is Reader in Virology at the University of Edinburgh, has, like the others to whom I have referred, an extraordinary publication list, of some two hundred learned publications in this field. A particular expertise which he brought to the trial was to explain the nature of genotypes, for the development of learning about which, and research into which, he has, as I understand it, been substantially responsible. There are now known to be at least six major genotypes, or sub-species, of Hepatitis C. The differences between these genotypes depend upon variations in their epitopes, which I understand to be stretches of amino acids with different sequences. From the result of this research it can now be appreciated that there are certain differences in effect, discoverability and indeed, as will be seen later, treatability (genotypes 2 and 3 responding better) in relation to these different genotypes, depending upon which genotype of the virus it is by which the blood in question, and hence the recipient of it, is infected. It is now clear that the most frequent genotype of Hepatitis C virus, at any rate found in the United Kingdom, (about 40% of all, according to the guidance paper issued in 2000 by the NHS National Institute for Clinical Excellence (the 'NICE guidance')) is genotype 1: coincidentally as it happens, none of the six lead case claimants has that genotype (although the majority of the cohort of claimants, I am informed, does). As a result of genotype testing carried out for the purposes of this litigation in respect of the various claimants, it has been identified that there are examples among them not only of genotype 1, but also of genotype 2 (itself subtyped into 2a and 2b), 3 (also subtyped 3a and 3b), 4 and I believe also 5. Genotype 1 was, as will be seen, the subspecies of the virus most easily discoverable by the first generation screening test: indeed it was not controversial between the parties that the finding of research carried out by Dr Simmonds and a Dr McOmish was that the first generation test picked up about 90% of donations infected by genotype 1, but only some 30% of those infected by the other genotypes.

[91] The other expert witness called by the defendants was Mr Andre Charlett, who is also the distinguished author of a substantial number of publications: he is an experienced medical statistician, employed by the Public Health Authority Service. He gave substantially unchallenged evidence which indeed met with approval by Professor MacRae, the claimants' statistical expert, by taking the court through a number of the relevant published articles relating to research into, and surveys of, the results of first generation screening and of surrogate tests ALT and anti-HBc. He explained and exemplified, by reference to those results, the adjusted efficacy of various tests. This is a method of assessment of the tests, by reference to their specificity, and after the making of certain established adjustments, so as to calculate statistically how successful the tests would be in identifying the blood that is infected with virus. Hence, in the context of this case, adjusted efficacy of 75% would mean that for every 100 donations of blood infected with Hepatitis C screened by a test, the test would identify 75 of them: ie had the test been operated, 75 out of 100 infected donations would have been screened out and would not have infected recipients. Mr Charlett identified certain biases and caveats, none of which were controversial, in the assessment of such efficacy by reference to published studies; and, subject to making generous allowance for those factors, and for the fact that the science of statistics can never be more than a helpful guide, both parties and I have relied upon his figures.

[92] In addition to these live witnesses, the helpful and enlightening evidence of Dr Hay, a consultant haematologist, and Dr Heptonstall, a consultant microbiologist, was agreed and read, as was that of Dr Taylor, a consultant in transfusion medicine (to whom I refer briefly below).

The claimants' factual witnesses

[93] Professor Dusheiko was described as a factual witness, but, to all intents and purposes, as he did not play a personal role in any of the events to which primary attention has been directed (save that he attended at the Ortho symposium in Rome, as did Dr Gunson and Dr Barbara), he was really an expert witness. His expertise also is very substantial. He is professor of medicine and honorary consultant of the University of London, based at the Royal Free Hospital, an expert hepatologist, and the author of lectures and papers presented at a substantial number of national and international meetings and of more than 200 learned publications in the field.

[94] The evidence of three other factual witnesses was agreed and read. Dr Ward had made a statement about the practice and procedure of the development and regulation of drugs manufactured by pharmaceutical companies, which was only of marginal relevance by way of background: the evidence of Dr Kay, to which Dr Taylor, to whom I have referred above, replied on the same issue, related to the marginal topic, not in the event developed, as I have indicated, of autologous transmission: the evidence of Mr Hardiman, Marketing Director of Ortho for Northern Europe, was produced during the hearing, and agreed, explaining so far as he could the procedures of the United States Food and Drug Administration (FDA) in so far as they related to the grant of an Export Licence and a Full Product Licence, thus giving the court some understanding, by way of very general background, to the grant of such licences in respect of the Ortho assay in this case.

The claimants' expert witnesses

[95] Dr Caspari, another distinguished expert in transfusion medicine, was employed between 1986 and 1991 by the German Red Cross Blood Transfusion Service, in Lower Saxony, and is now Research Fellow at the Department of Transfusion Medicine in Greiswald in Germany. He has also published widely on blood transfusion and hepatitis. He was able to tell the court about the position in Germany, where, although it has never adopted the anti-HBc test, which he personally has not supported, there has been compulsory routine ALT testing of blood since 1965, of whose benefits he spoke highly: Germany introduced anti-Hep C screening, alongside ALT testing, by the beginning of July 1990. The claimants also called Professor MacRae, Professor of Medical Statistics at the European Institute of Health and Medical Sciences at the University of Surrey, and again a very substantial author in his field, who explained and developed a number of statistical issues.

The oral evidence

[96] This has not seemed to me to be a case in which I have needed, or was indeed qualified, to disbelieve or reject any evidence given by these highly experienced and knowledgeable witnesses. What I have endeavoured to do, with the aid of counsel, and, in the fulfilment of my task as I have concluded it to be in law, is to arrive at my conclusions by assessing that evidence, making allowances

as I have considered necessary for any over-enthusiasms and also both matching the oral evidence with, and fitting it into, the substantial literature by them and by others which I have endeavoured, again with the very considerable assistance of counsel, to assimilate.

The literature

[97] For the purpose of the generic issues, there has been, as I have previously indicated, a massive slimming-down exercise by both legal teams to arrive at a comprehensible and manageable amount of documentation. Publications in this field over the last 30 years about Hepatitis, and in particular NANBH or Hepatitis C, have, I am told, run into four, or even five, figures. After considerable additions, and deletions, during the course of the trial we have ended with four (very fully filled) core files of learned publications: in addition, some fairly frequent reference has been made to a number of minutes of, and papers from, conferences, working groups and committees and other relevant documentation in another 16 files or so. Much time has been spent during the hearing in which I have been taken through these publications and documents first by counsel, and then, as appropriate, by the witnesses, in order that I should become sufficiently educated to understand the issues. In the end, much of what I have learned, all of which I believe has been necessary, has not had to be spelt out in this judgment. However, I am satisfied that it was essential for me to seek to understand as much as possible of the very complex matters underlying the decisions I have to reach, in order for me to be in a position to grapple with my conclusions. With the assistance of counsel and the witnesses, I have not had to read in detail every publication, but I feel that I have had a very considerable education, and one sufficient for my task.

[98] As for those publications, many of them were, as would be expected, written by the distinguished witnesses themselves. In addition I have already mentioned Dr Harvey Alter from the United States, and his influential writings have been heavily represented. I have had the benefit of publications, elucidated before me, by other highly qualified and experienced authors of learned books and articles from around the world. Apart from those whom I have mentioned, they included publications from the United Kingdom (including those by Dr, now Professor, Contreras, and Drs Cash, Dow, Follett, Garson, Gillon, Kitchen, McClelland, Mitchell, Polokaff and Collins and Bassendine), the United States (Drs Aach, Miriam Alter (no relation), Bayer, Dienstag, Donahue, Holland, Houghton, Stevens, Seeff and Ms Koziol): and from Australia (Drs Cossart, Morgan, Young), Canada (Drs Blajchman, Steinbrecher), Finland (Drs Eberling, Leikola), France (Drs Aymard, Chataing, Janot, Jullien, Richard), Germany (Drs Kühnl, Müller, Sugg,), Italy (Dr Tremolada), Netherlands (Drs Katchaki, Van der Poel), New Zealand (Dr Woodfield), Spain (Drs Esteban, Hoyos), and Sweden (Dr Widell).

The background facts

[99] A number of facts should be set out which I believe to be common ground, or which in any event I find to be the case. (i) The brief history of NANBH has been set out in [8] above. It is clear that, from the introduction of screening of Hepatitis B at the beginning of the beginning of the 1970s, NANBH was responsible for most if not all of the infection of blood by hepatitis, and it is common ground that in the 1970s and 1980s the infection by NANBH was the

major complication in blood transfusion. (ii) There is still no immunisation discovered for Hepatitis C: it is not yet possible to grow the virus in tissue, and, since the virus is highly resistant to antibodies, the present prospects for an effective vaccine are not bright. In the 1980s it was believed, as Professor Zuckerman confirmed in evidence, that no one ever recovered from it. It is now known that there can be recovery, and treatments have been pioneered in the 1990s, to which reference will be made later. As will appear in more detail below, apart from those who spontaneously clear or are (now) successfully treated, a substantial number suffers chronic liver disease, of which a considerable proportion progresses to cirrhosis. (iii) In the 1970s and 1980s, the vast majority of NANBH sufferers were not diagnosed as a result of clinical symptoms made known to hepatologists or practitioners, but as a result of discovery by testing in laboratories. The most frequent if not only symptom or indicator of NANBH was raised ALT in the blood. It is common ground that there was substantial under-reporting of the condition (and this was known at the time). (iv) Even on the basis of what was reported, the prevalence (that is prevalence of the virus amongst the donor population) and the incidence (that is the incidence of the infection among recipients) were higher in the United States (assessed by Dr Alter in the 1970s at between 7–12%) and, particularly, Japan, which had an even higher incidence, than in the United Kingdom and Europe. The United States' position improved during the 1980s for a number of reasons: the abolition of paid donors; the introduction of screening tests for HIV, which excluded a number of donors who would also have been at risk of NANBH; more effective monitoring and self-exclusion of drug users etc. The incidence in the United Kingdom, which Dr Gunson believed to be the case at the material time in 1986 and following, and which was generally accepted and was reported by him to the Council of Europe, was 3%. (In fact when screening was introduced, and more accurate assessment was thus able to be made, the incidence became or was—and still remains—between 0·05 and 1%.) There are approximately 2·5m donations per year (each donor donating approximately twice per year).

The approach to be adopted

[100] If, contrary to my conclusions of law set out above, the question of *avoidability* is a *circumstance*, then it must be introduced into what Mr Underhill has called the basket. Although the evidence has largely concentrated on the factual issue of avoidability, it is obviously essential that, after I make the necessary findings of fact on that issue, it must be fitted together with all the other matters or *circumstances* and weighed together in the basket. I shall set out what seem to me to be the material factors. (i) *The position of recipients/consumers.* As has eloquently been put by Mr Brown, they go to hospital for treatment, or resuscitation, but leave the hospital, albeit cured or improved in respect of their original condition, now significantly disabled as a result of the very treatment they received, leading (unless they be one of the few very lucky ones) to a life with a permanent need for medical oversight and at least a risk of serious deterioration and resultant death. (ii) *The position of donors.* They are volunteers, who altruistically donate blood. Their interests must certainly be carefully fostered, not only in order not to put off them and other potential donors, and thus put the blood supply at risk, but also because of the duty on the BTS to look after them: if for example they are simply told that their blood has been rejected, they may be frightened or distressed, or may be stigmatised by the possible

presence of some uncertain and undiagnosed infection. (iii) *The possible shortened lifespan of the recipients*. Set against the risk of infection (3% incidence as then believed) is the statistic (which was not controverted) that, with regard to those who received transfusions, either 50% of the patients, or patients who received 50% of the blood (which it was unclear to Dr Gunson, although it was recorded as being the former in his October 1986 paper to the United Kingdom Working Party on Transfusion-Associated Hepatitis (WPTAH), which he set up) die in any event of their original condition within one year of the transfusion. (iv) *The interests of patients generally*: to secure the blood supply, so that there is no risk of there being no reserves of blood available in an emergency. (v) *The defendants' own determination to give priority to NANBH/Hep C*, particularly given that it was, as set out, a major complication for them. By a letter dated 7 February 1979 the senior medical officer of the Medical Research Council (MRC) confirmed that the chief scientist of the Department of Health and Social Security had informed the MRC that NANBH was being given high priority by the department. The department confirmed to Dr Gunson on 8 March 1989, when it set up the ACVSB, that the United Kingdom Health Ministers believed that it was of the utmost importance that the United Kingdom Blood Transfusion Services acted in unison on the subject, and Dr Gunson in response confirmed that he too thought the committee very important and had thus set up his own committee, the ACTTD. (vi) *The fact that no warnings* were given to the public or to patients or recipients about the risk from the receipt of transfused blood or in particular about the risk in question. I have already referred to the fact that I am satisfied that neither the defendants nor the government nor the Press, in so far as either of the latter were relevant, gave any or any sufficient warning to the public of the risks: and that although medical practitioners knew of them, and would advise patients if asked, they were rarely asked, and unless asked, did not inform. (vii) In fact, a substantial number of *donors who had used drugs* and who were thus the most likely to be carriers of NANBH did escape the net of self-exclusion and give blood: many of these might have experimented briefly with drug use many years before and forgotten or put it from their mind. Dr Barbara estimated that 10% of those who gave blood should not have been giving blood. Dr Gunson accepted that intravenous drug users had become donors, and Professor Zuckerman accepted that the problem that amongst those giving blood were those who had been drug users in the past was known at the time. In subsequent research carried out after the introduction of screening, it was found that, in that cohort, 50% of infected blood donations had been given by those who subsequently accepted that they had been at one time or another intravenous drug users. According to the NICE guidance, the prevalence of Hepatitis C among intravenous drug users is said to be up to 50%. (viii) The last ingredient must, on these assumptions, be *avoidability*: which has a number of sub-categories. (a) What is the risk?—seen as 3% incidence at the time. (b) How foreseeable?—known. (c) What is the priority for avoidance?—see sub-para (v) above. And then the factors to be addressed by reference to the evidence. (d) What is the seriousness of the consequence to the claimants if the steps are not taken? (e) What is the seriousness of the consequence to others if the steps are taken? (f) As to the precautions themselves—in this case the tests: (i) what steps are said to be available; (ii) how reliable are they; (iii) how efficacious (sensitivity: specificity: adjusted efficacy); (iv) how expensive are they to implement/continue; and (v) what are the logistics for implementing them? (g) What is the proper

analysis that should be adopted to conclude whether tests/precautions are available? I turn to this.

The proper analysis

[101] The starting point is of course the difficulty that I inevitably have in finding a distinction between negligence and the question of *avoidability*: even if I be wrong in my conclusion that the very consideration of conduct, or of what could or should have been done, is a subversion of the object of the directive, nevertheless to tread the tightrope which Mr Underhill has laid out for me is not easy. Subject to that, a number of tests have been suggested, largely by Mr Underhill, or in the course of my exchanges with him, as he is the proponent of the issue to which the 'Brown case' is put forward by the claimants as their answer. Not least of course of the problems is that, in addressing the legitimate expectation of the public in respect of the taking of precautions or the holding of tests, I have already indicated that it is clear that the public itself would have had no such expectation, might not have known of the need for any test, or, if they did, would simply have assumed that all steps had been taken, so that the matter is left to me as objective assessor.

[102] It is clear to me that the analysis does *not* involve the following. (i) As indeed Mr Underhill has always made clear, the process does not involve a detailed analysis of each act or omission of the defendants. (ii) Equally however, I am satisfied that this is not an exercise by way of '*Wednesbury* unreasonableness', or considering whether the defendants came to a reasonable conclusion, or made reasonable management decisions, or examined, or came to proper conclusions in the light of, available expert opinion. (iii) Whereas the conduct of other similar authorities in other countries may be of some relevance, it plainly cannot be determinative, or an inhibition upon the conclusion I otherwise reach. (iv) There is no question of a conclusion that the public is legitimately entitled to every marginal improvement.

[103] I do on the other hand take into account, as an important part of the factual context and *circumstances* within which I reach the decision, the attitude and objectives of the defendants, and the priority of NANBH to which I have referred. In this regard Mr Brown referred to Dr Gunson's paper to the Council of Europe in May 1987, reporting conclusions of a distinguished working group of the Committee of Experts on Blood Transfusion and Immunohaematology on which he served, in which the following statement (among others) was recorded: 'If a stance is taken that blood should have maximum safety, then the tests [in this case surrogate tests] would be introduced but the benefits derived from testing would not be uniform throughout every country.'

[104] There was some considerable discussion as to whether indeed it was the stance or objective of the defendants that blood should have 'maximum safety', and indeed as to what that meant or would mean in any event. In the *Guidance for the Blood Transfusion Services in the United Kingdom 1989* at para 1.10 it was recorded, in the context of the United Kingdom BTS achieving and maintaining 'the highest standard of operations', that there should be 'some uniformity ... in the determination of those procedures that will ensure maximum safety of blood', and Dr Gunson confirmed that this concept was not newly introduced in 1989, but had antedated it, as far as he was concerned. A significant example can perhaps be given by reference to a study which he initiated in 1988, and which reported in draft in October 1989, intended to study raised ALT in recipients of

blood at three RTCs (which has become known as the 'Multi-Centre Study'). The draft report submitted to the ACVSB in October 1989 concluded as follows: 'In the meantime, the desirability of ALT testing or otherwise remains an issue of health economics.' Dr Gunson's response to this, when asked about it by Mr Brown in cross-examination, was: 'As I said to you earlier, Mr Brown, I was never one for going on health economics. I would like to know the cost of what we are doing, but not necessarily the benefit related to it, because I felt that, if you had to do it, you had to bear the cost.' In its final form in March 1990, the report concluded 'The subject of cost-effectiveness has recently been reviewed, but if the desire to ensure a "minimum risk" product overrides the economical and logistic considerations, ALT testing then becomes a serious contender' (as a matter of fact by this time the question of introduction of ALT was being regarded as academic, because main concentration was now being dedicated towards the question of introduction of routine anti-Hep C screening). Dr Gunson preferred the concept of 'minimum risk' to 'maximum safety'. However, this became clarified when he was shown, or reminded of, a preliminary discussion paper for the ACTTD prepared by Dr Barbara and Dr Contreras dated 23 January 1992, which read: 'The attitude towards transfusion safety has veered away from the concept of "maximum benefit/minimal cost" towards the notion that if a procedure is shown to prevent transfusion-transmitted infection and disease is available, it should be introduced.' He responded as follows to Mr Brown's question about this: 'Q. Were you aware of that shift in culture or do you think that that had always been the position? A. I think it was probably always the position.'

[105] A number of formulations have been put forward. (i) Mr Brown was firm in his assertion of the inappropriateness of the test in *Bolam v Friern Hospital Management Committee* [1957] 2 All ER 118, [1957] 1 WLR 582, whereby, in a case of professional negligence, a professional acting in accordance with a practice accepted as proper by a responsible body of professional opinion is not negligent 'merely because there is a body of opinion that takes a contrary view' ([1957] 2 All ER 118 at 122, [1957] 1 WLR 582 at 587–588 per McNair J) (the '*Bolam* test'); and Mr Underhill dissociated himself from the case that the *Bolam* test was apposite to the directive. However, it seems clear to me that that was indeed the kind of formulation that he was articulating when he set out the following in his summary of his case, which I invited at an early stage of the hearing from both sides: '[Persons generally] would only be "entitled to expect" such screening if it was plainly the right thing for a blood transfusion service to do.' Another formulation by Mr Underhill was that the public was 'not entitled to expect safety precautions where there is a matter of such doubt and debate'. At another stage Mr Underhill put it that if some people think a precaution is advantageous and others think it disadvantageous—

> 'entitlement to expect must arise from, if not a universal view, a better view that a precaution should be adopted ... Where there is quite vehement controversy internationally as to whether there is a good idea or a bad idea, it is a heavy thing to say the public was entitled to expect this to be happening when, if the public had informed itself, it would know that controversy was raging across the world as to whether or not it was a good thing to do or a bad thing to do.'

(ii) Another formulation by Mr Underhill was that, in order for it to be legitimately expected that a safety precaution would be taken, a 'really substantial benefit [must be] demonstrated'. (iii) Mr Brown, with an eye on the 1989 guidance, and the evidence to which I have referred in [104] above, formulated a proposition that 'the public was entitled to expect (at least in the absence of compelling/high quality/local evidence) that, consistent with the objective of ensuring maximum safety, such tests would be introduced'. He explained this by indicating that there would have to be 'really clear evidence the other way'. This of course is almost the mirror image of the first of Mr Underhill's formulations, which I have recited at (i) above.

[106] The broadbrush question of course is what tests or precautions it is reasonable or appropriate or legitimate to expect that a defendant producer should have adopted. In the light of art 6, and the obvious emphasis on a weighing exercise, *taking into account all the circumstances*, I interpret the position as being that the judge (whether as the representative of the public or otherwise) simply weighs up the advantages and disadvantages, the pros and cons, without the benefit of hindsight, and reaches his own decision, neither reviewing the producer's decision, nor declaring that the producer's decision was negligent. Accepting, but somewhat adapting, another of Mr Brown's formulations, I would declare myself as prepared, while walking Mr Underhill's tightrope, to adopt a formulation as follows. If a precaution shown to prevent, or make a material reduction in, the transfer of transmitted infection through infected blood is available, it should be taken, unless the disadvantages outweigh the advantages.

[107] I shall now accordingly, informed by the evidence, consider the pros and cons on that basis. As indicated, there are two issues, first as to whether surrogate screening should have been introduced (when it never was) and secondly whether the anti-Hep C assay should have been introduced by way of routine screening before it was on 1 September 1991, or (as now conceded as part of the settlement agreement, to be the relevant date for consideration) 1 April 1991. I shall thus reach my decision on the basis of my conclusions as to 'legitimate expectation', as required by the need to resolve Issue II irrespective of the outcome of Issue I: but nothing that I shall say or decide can, or does, reflect in any way on the personal dedication, professionalism, integrity and conscientiousness of those in the NBTS, the ACVSB and the ACTTD who were involved in their own weighing exercise at that time.

SURROGATE TESTS

[108] I refer to the explanation of the two surrogate tests, which I have set out at [9](i) and (ii) above. By way of further introduction to the issue of surrogate tests, the following should be explained. (i) As will be seen, the question of surrogate screening really came to the fore in the early 1980s as a result of the debate in the United States, and particularly the thorough studies published, originally in 1981, by the NIH and the TTVS, to which I have referred. The case for the claimants is that the tests ought (and I shall use that verb, or alternatively the tense 'should', as shorthand for *legitimate expectation*) to have been introduced in the United Kingdom by 1 March 1988, when the CPA came into effect. This is the case which I shall primarily consider. It is clear that if the surrogate tests were not in place by that date, or shortly afterwards, it becomes progressively less arguable that they should have been introduced: as the discovery of the Hepatitis C virus is first of all announced (May 1988), then its scientific details

published (April 1989) and thereafter as from April 1989 the Ortho assay is publicised, evaluated and debated. The claimants do assert that, even if not introduced by March 1988, the surrogate tests should still have been introduced later, particularly if the introduction of the Ortho assay was to be delayed to as late as September 1991, but this is plainly a subsidiary issue. (ii) The USA introduced surrogate testing, as I have recounted, from September 1986, ALT followed soon after by anti-HBc, and it introduced routine anti-Hep C screening on 2 May 1990. The surrogate tests continued alongside the assay until 1995. Whether or not there is a case that the surrogate tests, if they had been introduced in the United Kingdom, should thereafter have been discontinued, this issue does not arise for me, where consideration has in the event been limited to the period up to 1 April 1991, and on any view, if introduced, they would not have been discontinued by that date. (iii) As will be seen, it was concluded by the US researchers, somewhat to their surprise, that the blood identified by the ALT test as having elevated ALT, and the blood identified by the anti-HBc test as containing Hepatitis B antibodies, did not materially overlap. This was, it would seem, one of the main reasons why in the event they introduced and retained both tests. It seems to be accepted (as Dr Barbara explained) that where blood was positive on both tests, it was the more likely to have been genuinely infected with Hepatitis C. (iv) Routine ALT testing was, as I have described, in effect in Germany from 1965. The threshold for the test was higher in Germany than in the United States. The cut-off in the United States test to indicate when ALT was elevated was 45 international units per litre (iu/l). Germany used a different system of measurement of international units. The cut-off there was also 45 iu/l, but that equated to 90 or 100 iu/l on the US scale. The cut-off for which the claimants contend, on the basis that surrogate testing should have been introduced in the United Kingdom, is that adopted by the USA, which was also the level which was adopted for the investigations carried out by the Multi-Centre Study in 1988–1989 referred to above. (v) Not many countries apart from the United States (both tests) and Germany (ALT only) introduced surrogate tests. The full picture is as follows:

Germany	1965	(ALT)
Italy	1970	(ALT)
USA	September 1986 onwards	(Both)
Luxembourg	October 1 1986 Mid 1987 (for new donors)	(ALT) (anti-HBc)
France	15 April 1988 3 October 1988	(ALT) (anti-HBc)
Switzerland	1 June 1988	(ALT)
Malta	Early 1989	(ALT)

There was some partial routine ALT testing in certain centres in Austria, Belgium and Spain, from about 1987, and Queensland (alone of the Australian states) introduced compulsory ALT testing in about April 1989. Dr Högman told the

Council of Europe in 1987 that Sweden was to introduce anti-HBc testing for first-time donors, but he explained in evidence that this was intended in fact as a supplementary Hepatitis B screening. No other countries, so far as is known, ever introduced either test. (vi) An important part of the background is the Council of Europe Working Group Paper to which I have referred, the conclusions of which were as follows:

> '1. The use of non-specific tests [the surrogate tests in question] for the purpose of reducing the incidence of transfusion association NANB Hepatitis and [their] possible value as a public health measure remain a controversial issue.
>
> 2. If a stance is taken that blood should have maximum safety, then the tests would be introduced; but the benefits derived from this testing would not be uniform throughout every country. Also there is no guarantee, in a given country, that there will be a significant reduction in the transmission of NANB Hepatitis.
>
> 3. The introduction of non-specific tests could lead in some countries to a severe depletion of blood donors, which may compromise the blood supply; and this is a factor that must be taken into account.
>
> 4. When non-specific testing is introduced in a country, provision must be made for the interviewing, counselling, and further medical examination and treatment which may be required for donors found to have a raised ALT or who are anti-HBc positive.
>
> 5. The committee cannot give a general recommendation on the introduction routinely of non-specific tests for evidence of NANB infectivity of blood donors. Individual countries will have to assess the situation locally and decide upon the appropriate action to take.'

It is of course the assessment of whether the United Kingdom as an individual country ought to have introduced the surrogate tests that is before me. As for other international or transnational bodies, introduction of the test was, Professor Zuckerman told the court, never recommended by the World Health Organisation (WHO), nor was it recommended, as Professor Högman explained, by the Council of Nordic Transfusion Services.

[In **[109]**–**[118]** his Lordship considered the literature on surrogate testing and its effect. He then set out, in **[119]**–**[140]**, the pros and cons of such testing. He continued:]

Conclusion on surrogate testing

[141] The pros and cons in respect of the introduction of surrogate testing must be assessed and weighed and then placed, together with the other *circumstances*, into Mr Underhill's art 6 basket. I have not found this an easy task and it has required very careful deliberation. After such thought, I am left in no doubt that what I have in the preceding paragraphs categorised in almost every case as a 'However' outweighs or neutralises the contrary arguments that have been set against the arguments in favour, and I am clear that the scales have come down in favour of the introduction of these surrogate tests, and indeed of both kinds of surrogate test, both ALT and anti-HBc. The United States and France, the major countries who introduced surrogate tests at that time, introduced them both, and I am clear that, notwithstanding the lesser expert support for the latter test, once ALT testing is to be introduced, the addition of anti-HBc adds little by

way of extra disadvantage, cost, blood loss or inconvenience, and may be of substantial advantage. It was, in my judgment, at least very likely to decrease the number of donors who were in any event unwanted, a factor which does not seem to have been discussed at any ACVSB or ACTTD or other meetings to which my attention has been drawn. Further, if the US research was right, the two tests did not, or not materially, overlap, and in any event the combined efficacy of the two together, on the basis of the predictive studies, was clearly greater, and there may additionally have been advantages, as discussed in [133](iii) above, in relation to counselling and diagnosis. It is both difficult, and, in my judgment, unnecessary, for me to decide a particular time for such introduction. I am, however, satisfied that it ought to have been at some stage after the introduction of the surrogate tests in the United States and the subsequent consideration given to them in the United Kingdom, and before, or at any rate by, 1 March 1988.

[142] No question therefore arises as to the subsidiary and alternative issue, whether surrogate tests, if not introduced by 1 March 1988, should have been introduced after that date. Certainly no different considerations would have applied if it were a matter of only a few months after that date, but, once it was apparent that a screening test had actually been pioneered, I would have thought it difficult to suggest that the United Kingdom ought then to have introduced the surrogate test, when the proper and inevitable concentration would have been at that stage had been upon when to implement the assay, to which I now turn.

THE ASSAY

[143] I set out first a timetable of when various countries which we have considered in this trial commenced anti-Hep C screening:

November 1989	Japan
February 1990	Australia
March 1990	France (1 March); Luxembourg (new donors only, 1 March)
April 1990	Finland (1 April - all donations: partially started 1 February)
May 1990	USA (2 May): Austria: Amsterdam (other Netherlands Centres later)
June 1990	Canada; Germany (by 1 July)
July 1990	Belgium (1 July)
August 1990	Switzerland (1 August)
September 1990	Luxembourg (all donors)
October 1990	Italy (many centres); Spain (all by 12 October, some started earlier)
1990/1991	Norway
January 1991	Sweden (legal requirement published 24 January to start as soon as possible)

March 1991	Portugal (mandatory, some earlier); Cyprus; Greece; Hungary; Iceland; Malta (all 'not before' March)
April 1991	Netherlands (mandatory 1 April)
June 1991	Denmark
August 1991	Italy (balance)
September 1991	UK (1 September)
September/ October 1991	Ireland

[144] The table of dates does to a certain extent speak for itself. Certainly in relation to this issue, unlike the surrogate testing, Mr Underhill was not assisted by drawing comparisons or contrasts with other countries. As a result of the 90% concession agreement, the defendants do not seek to support a date later than 1 April 1991, which would notionally push the United Kingdom to further up the table.

[145] I shall now set out a narrative of the most material events of what did occur in the United Kingdom with regard to implementation of the assay. This is recounted only to show what did occur, and not as a preface to any criticism with regard to each individual step. Although Mr Brown did indulge occasionally in what he called 'poison and prejudice', he recognised the limits of the ambit which Mr Underhill has himself laid down by virtue of his submissions (which I have primarily found to be unsuccessful) as to what a court can and should consider with regard to steps which a producer could or should have taken. As discussed in [102] above, this would not involve, as would what Mr Underhill would call a negligence inquiry, or Mr Brown a full-blooded negligence inquiry, a detailed critique of every incident. What is to be done is, as against what did occur, to set out what I may be persuaded should have occurred, in the round. This involves my looking realistically as to how much time it is legitimately to be expected that the producer should have taken to introduce the precaution which he did rightly introduce, but, as the claimants allege, later than he ought to have done had he taken all legitimately expectable steps.

[146] So far as my approach is concerned in arriving at this picture in the round, I shall look at the steps which it is legitimately expectable that a producer in the position of the defendants would have taken, and the period of time which it is legitimately expectable they ought to have taken. If there were any particular outside circumstances either affecting the United Kingdom generally, ie such as the Gulf War, or locally, such as to make it evident that either nationally or in one particular area it would not at a material time have been possible to have taken a particular step, then that would and should be taken into account. But in the event neither such eventuality arises.

[In [147]–[169] his Lordship considered those issues against the factual background. He continued:]

Conclusion on routine screening

[170] Mr Brown's date, albeit originally allowing for the possibility of December 1989, settled down in the end as 1 January 1990. Mr Underhill's date

was 1 April 1991. The basic requirements to be fitted in are, I am satisfied, the carrying out of pilot studies and evaluations, the planning for counselling and implementation, and the execution of that implementation in respect of equipment, staff and building works. I am satisfied that it was not appropriate or necessary, or legitimately expectable, that the screening should wait until after FDA approval if, as I am satisfied should have occurred, sufficient evaluation had taken place to allow for the United Kingdom's own decision to be made, like that of Australia and France and the other countries which started prior to FDA approval within the United States. I am also satisfied that it was not necessary to wait to implement until after the confirmatory test was in place, provided that, as Dr Gunson, and to a substantial extent Professor Zuckerman and indeed the members of the ACTTD allowed, it was known, as it was, that the RIBA test would be available very shortly afterwards.

[171] I have already referred to Dr Gunson's evidence, subject to the question of a confirmatory assay as to 'certainly early in 1990', in retrospect. Later in cross-examination, he said to Mr Brown: 'Mr Brown, I have now said three times—I think I did say to His Lordship yesterday—that in retrospect we should have done it a different way.' Mr Underhill, of course, points out what is in any event particularly relevant in cases of negligence, namely that the use of hindsight is dangerous, and very often introduces too stringent a test. But my task, on Mr Underhill's case, examining all the *circumstances*, is to conclude, looking back on the full picture, what the public was entitled to expect, and I conclude that in fact, Dr Gunson, a supremely fair man, is in fact looking back with my spectacles.

[172] Bearing in mind all the *circumstances*, including the priority given to the elimination or reduction of PTH. (i) My primary conclusion is that routine screening ought to have been introduced by 1 March 1990. That in my judgment would have allowed sufficient time for pilot studies and evaluation, particularly if, as I conclude should have been the case, rather more work had been done prior to Rome, but even if it had not been. If pilot studies had been more promptly carried out, even in the context of a wider evaluation, I am satisfied that a decision could have been taken which would have given at least three months lead time for implementation by the centres before the introduction of routine screening. This date would accord with Dr Gunson's 'certainly early in 1990'; would be slightly before the date of 'sometime after April 1990', which Dr Cash had gambled on on 3 August 1989, in the course of his own evaluation of the assay; and would accord with the date of implementation of routine screening by France and for new donors in Luxembourg, and would post-date Japan, Australia and much of Finland. This would mean that the RIBA test would be known to be relatively imminent and would in fact have followed some two months later. In that interim period, either there could have been deferment of donors, for what even Professor Zuckerman would have accepted to have been a short period of time, or for that short period of time an extra burden on the newly instituted counselling procedures. (ii) I have concluded that surrogate testing should have been in place by March 1988 and thus, like France, the United Kingdom would have run the new routine screening alongside the surrogate tests from 1 March 1990 onwards. However, balancing the various *circumstances* and applying so far as I can Mr Underhill's test, which I have already found to be inappropriate in law on the proper construction of the directive, if, but only if, surrogate tests had been in place, then I might have been prepared to find that, in those circumstances only, the scales might have come down in favour of a delay

of the assay until May 1990 with the RIBA test actually in place. But I am satisfied that, with the position as it was, with no surrogate tests in place, and indeed with the deliberate decision made by the ACVSB in November 1989 to defer any further consideration of surrogate tests, while concentration was dedicated towards implementing routine screening, which did not in fact take place for another 22 months, routine screening ought to have been introduced at the earliest practicable time, which I have concluded to be 1 March 1990.

DEFECTIVE WITHIN ARTICLE 6

[173] In the light of these findings of fact, I can now decide whether the blood infected with Hepatitis C was defective, on the 'Brown case'. I take into account all the *circumstances* in the basket. (i) Those set out in [100] in sub-paras (i) to (vi): as to sub-para (vii), I take into account the claimants' pleading, by a late re-amendment to their reply, for which I gave leave during the hearing without opposition from the defendants, being para 4(h)(i), of the specific *circumstance* that 'past intravenous drug users were continuing to donate blood, which was being processed and supplied to patients'. (ii) The fact that the precautions of the introduction of surrogate testing and earlier introduction of routine screening were not taken. I conclude that, taking into account *all circumstances*, such blood so infected on and after 1 March 1988 did not provide the safety which persons generally are entitled to expect.

NATURE AND MEASURE OF DAMAGES

[174] Now that I have found the defendants to be liable, I must address the basis upon which damages are recoverable under art 4 (and s 2 of the CPA). I deal first with two short points. (i) *Time scale*. I have found the defendants liable (generically) for supplying defective blood on the basis of the proper construction of the directive: alternatively, on the broader consideration of *circumstances*, I have in any event found the defendants liable in respect of the period from 1 March 1988 (surrogate testing and subsequently also routine screening). No question therefore arises as to differentiation between the claimants by reference to their date of infection. (ii) *What is the defect?* Although Mr Underhill pursued his submission, referred to in [46](i), that the defect in the blood was *unscreenedness*: (a) he conceded that he could not make such a submission if the claimants succeeded on the 'Forrester case', which would not depend upon whether there was or was not screening or testing. This has, of course, arisen; (b) with regard to the pursuit of his contention even with respect to the 'Brown case', he quickly recognised the difficulties pointed out both by the claimants and, indeed, in the course of argument, by me. *First*, if he be right, then the definition of 'defect' for the purposes of art 6 must be different from its definition for the purposes of art 7(e). In the latter article, *defect* plainly applies to the impugned condition—infection by Hepatitis C in this case—which either is, or is not, known or is, or is not, capable of discovery. It is not the 'existence of the unscreenedness' which is, or is not, to be discovered. Whereas it is always possible to argue that a word or words may have different meanings in different sections or sub-sections of the same statute or directive (and that may arise in relation to words in art 7(b) as discussed in a different context in [51](iv) and [74](i) above) that cannot in my judgment possibly arise in relation to words central to the directive. *Defect* is referred to in the operative arts 1 and 4, and defined in art 6, with relevant escape clauses in art 7, and must be consistent in its meaning. *Secondly*, as Mr Brown

pointed out, if *unscreenedness* be the defect, then *all* blood bags must be defective, when none is screened: only one in 100 blood bags would be defective *and* harmful. This creates a quite unnecessary additional tier of argument and proof. The only purpose for Mr Underhill to put forward the proposition of 'unscreenedness' was to assist him in the argument and presentation of his case that the defendants could not be liable for all the damage otherwise flowing from the infection (a contention to which I shall now come), by reference to a case that the claimants should only be entitled to recover damages insofar as they flow from the *unscreenedness* and not from the infection. The peg of *unscreenedness*, however, is too fragile to withstand the weight of such argument, and the argument must stand on its own or not at all. I am afraid that *unscreenedness* suffers from the defect of unpersuasiveness.

ISSUE IIIa

[175] In the light of my conclusions on Issue I, the blood was defective by virtue of its infection with Hepatitis C, notwithstanding and in the light of all relevant *circumstances*. As Mr Brooke succinctly put it in argument, the *defect* was the virus in the blood and the *damage* was the virus in the patient. Mr Underhill does not contend, having lost on the 'Forrester case', for any other result, nor that his 'loss of a chance' case applies in this regard.

ISSUE IIIb: LOSS OF A CHANCE

[176] If I were wrong in my conclusions on Issue I, then the claimants have only succeeded on the 'Brown case', and Mr Underhill contends, as summarised above, that the defendants are not liable for all the consequences of the infection, but only for that damage which results from the failure to introduce surrogate testing and/or to implement routine screening earlier. Thus he asserts that it would be necessary to arrive at the percentage chance by reference to the findings of fact I have made, that the claimants would not have been infected by the virus if the defendants had taken further or different steps.

[177] He puts his case as follows. (i) He prays in aid the speech of Lord Hoffmann in *South Australia Asset Management Corp v York Montague Ltd, United Bank of Kuwait plc v Prudential Property Services Ltd, Nykredit Mortgage Bank plc v Edward Erdman Group Ltd* [1996] 3 All ER 365, [1997] AC 191 (BBL). He refers to the following passages in particular:

> 'A plaintiff who sues for breach of a duty imposed by the law (whether in contract or tort or under statute) must do more than prove that the defendant has failed to comply. He must show that the duty was owed to him and that it was a duty in respect of the kind of loss which he has suffered ... How is the scope of the duty determined? In the case of a statutory duty, the question is answered by deducing the purpose of the duty from the language and context of the statute ... There is no reason in principle why the law should not penalise wrongful conduct by shifting on to the wrongdoer the whole risk of consequences which would not have happened but for the wrongful act ... But that is not the normal rule ... Normally the law limits liability to those consequences which are attributable to that which made the act wrongful.' (See [1996] 3 All ER 365 at 370–371, [1997] AC 191 at 211–213.)

As the claimants here are only entitled to the loss which resulted from the failure to screen, and as they would or might have suffered from Hepatitis C in any event, their damages must be reduced accordingly. (ii) The proposition is by reference to, and in accord with, the speech of Lord Diplock in *Mallett v McMonagle* [1969] 2 All ER 178 at 191, [1970] AC 166 at 176:

> '... in assessing damages which depend on its view as to what ... would have happened in the future if something had not happened in the past, the court must make an estimate as to what are the chances that a particular thing will or would have happened and reflect those chances, whether they are more or less than even, in the amount of damages which it awards.'

(iii) If on no other basis than justice or fairness, the defendants ought not to be liable for, and the claimants not entitled to recover, loss, which they would or might have suffered in any event. The example that was given by Mr Underhill was of a product, which was dangerous, but would not have been found to be defective within art 6 if a clear warning had been given by way of a label: and where the claimant, who is blind or illiterate, would not in any event have been able to read the label and thus would have suffered the same damage. It would, submits Mr Underhill, be wrong for such a claimant to recover for loss which would still have been suffered, even had the product carried the label, and would thus have been found, on the hypothesis postulated, not to be defective. (iv) So far as comparison is drawn with contract, the analogy is not with a product which is found to be not fit for its purpose, or not of merchantable quality, but one in relation to which there has been found to be a breach of a warranty that it had been screened.

[178] I prefer the submissions of the claimants, which I summarise and adapt below. (i) BBL is wholly inapt. This is not a case of breach of duty, but a claim for compensation in the context of strict liability for the supply of a defective product. Even if (for the purpose of the argument) *avoidability* and hence conduct is an issue, such conduct was not (on Mr Brown's case nor, on the basis of his disavowal of investigation of fault, Mr Underhill's) *wrongful*. (ii) The claim is based simply upon the product being defective. The conclusion is that it is defective. What made it defective is not in the end of relevance: it is simply that it does not *provide the safety which a person is entitled to expect*, just as if it were not of merchantable quality or were unfit for its purpose. (iii) The issue of conduct and *avoidability*, even if admissible (with the careful avoidance of such epithets as wrongful, negligent or faulty), is only part of what has to be included in the basket or weighed in the balance. In the hypothetical case of the blind or illiterate claimant, suggested by Mr Underhill, it was postulated that one factor, lack of warning, was or would have been determinative. That may or may not have been the case (warnings in the context of arts 6 and 12 will not be a straightforward matter), but the conclusion would nevertheless be that the product was defective. In any event, in this case, it is not the case that screening/testing was the only factor in this case, as is clear from [173] above—indeed it was not even the only area of contested fact, for questions of seriousness, incidence, efficacy and the nature of donors have had to be considered. (iv) The structure of the directive and of the CPA is supportive of the claimants' case, and of Mr Brooke's aphorism set out in [175] above. As far as the directive is concerned, art 1 enunciates liability for damage caused by a defect; art 6 defines when the product is defective; art 4 requires 'the injured person ... to prove the damage, the defect and the causal

relationship between defect and damage'. The structure seems to me to admirably simple and not to encourage complicated compartmentalisation of the damage. So far as concerns the CPA, I indicated, in [23] above, that I would set out the two relevant sections:

> '2.—(1) Subject to the following provisions of this Part, where any damage is caused wholly or partly by a defect in a product, every person to whom subsection (2) below applies shall be liable for the damage ...
>
> 5.—(1) Subject to the following provisions of this section ... "damage" means death or personal injury or any loss or damage to any property (including land).'

The damage to be compensated to the claimant is the damage caused by a defect in a product, and not by any conduct, wrongful or otherwise, or breach of duty. (v) No issues of fairness or justice such as are contended for by Mr Underhill, for the purpose of his loss of chance argument, can be supported within the context of a directive such as this, at least without consideration of the objectives of the directive. If such are to be examined, it might be more appropriate to consider: (a) that the directive was intended to increase or improve the recovery of compensation for consumers; (b) that it was intended to remove rather than increase any onus of adducing evidence to prove fault on the part of the producer, which would not encourage a court to investigate yet more evidential questions relating to the conduct of the producer, such as what precise loss flowed from what aspect of such conduct and what did not; and (c) that fairness to the producer may be considered to be sufficiently provided for by the express exonerating circumstances of art 7, and the contributory negligence aspect of art 8.

[179] These persuasive arguments are, in my judgment, sufficient to outweigh and answer the submissions of the defendants. The claimants had two further contentions, with which I do not feel it necessary to deal, in the light of my conclusion that the loss of a chance argument does not arise. (i) The claimants contend, in the light of s 5(1) of the CPA, which I have just set out, and in any event, that there can be no recovery under the directive for economic loss, except in so far as it is consequential to, or parasitic upon, damages for personal injury, and that a claim for loss of a chance is a claim for economic loss. (ii) They further submit that, where the claim is for personal injury, and by analogy with such claims as medical negligence, the issue of loss of a chance is not, in any event, available; but the issue must be one of causation, and thus either total success or total failure: they refer to *Hotson v East Berkshire Area Health Authority* [1987] 1 All ER 210 at 223, [1987] 2 All ER 909 at 913, 916, [1987] AC 750 esp at 769, 782, 785–786 per Croom-Johnson LJ, Lord Bridge and Lord Mackay respectively, and to *Judge v Huntingdon Health Authority* (1994) 27 BMLR 107.

[180] I accordingly resolve Issues IIIa and IIIb in favour of the claimants: no reduction to their damages is to be made by reference to any loss of chance argument.

ISSUE IV: AVAILABILITY OF ARTICLE 7(e)

[181] I have already made clear, in [74]–[77] and [82] above, that in the light of my conclusions on the construction of art 7(e), the defence is not available to the defendants (Issue IVa). However, I must turn, as foreshadowed in [84] above, to decide the issue of the availability to the defendants of the art 7(e) defence on the

assumption that, contrary to my conclusions in law, the defendants' construction of art 7(e) prevails: namely as to whether, on the basis of my findings on Issue II, the *state of scientific and technical knowledge at the time when* (the defendants) *put the product into circulation was not such as to enable the existence of the* (infection in the particular bag of blood) *to be discovered* (Issue IVb).

[182] The first question is what is meant by 'such as to enable the existence of the defect to be discovered' in the particular product, in the context of my findings as to surrogate testing and earlier screening. (i) As for routine screening, this was of course, as explained in [11] above, not a test which discovered the virus or antigen itself (this came only later with the expansion of the limited early technology of PCR testing, and the development of NAT), but identified the antibody to Hepatitis C. Unlike with Hepatitis B, where an antibody can continue in the blood long after the virus has disappeared, it is, or at any rate, was, before treatments were developed, not usual for Hepatitis C virus to clear from the blood or in any event from the body, so that the presence of Hepatitis C antibody is likely to carry with it a high degree of certainty of the presence of Hepatitis C virus. That may be his reason, but in any event Mr Underhill does not seek to take the point that to screen for and discover the antibody is not to discover the virus. (ii) So far as surrogate testing is concerned, he does however pursue what has been called a 'technical defence'. As is apparent from the detailed consideration in this judgment, neither the ALT test nor the anti-HBc test, being 'indirect', were intended to identify the Hepatitis C virus. They were used so as to identify blood which might be infected by the Hepatitis C virus, and which would, in any event, if it failed either of the two tests, be discarded and not supplied to recipients; whereby the risk of transmission of infection by Hepatitis C was reduced. Mr Underhill submits therefore that, assuming, as I have found, that surrogate tests should have been introduced, they were not such as to 'enable the existence of the defect to be discovered'.

[183] I conclude as to the 'technical' argument as follows. (i) The purpose of the art 7(e) defence, as interpreted by both sides, is to see whether the defect could be, as it was put by the Advocate General in *European Commission v UK* Case C–300/95 [1997] All ER (EC) 481 at 489 (para 20) *eliminated* or *prevented from arising*. Certainly it is fundamental to Mr Underhill's submission (which for this purpose must be deemed to have succeeded) that it is the lack of opportunity to discover the defect in the particular product which is essential to art 7(e), so that diligent producers can be excused and encouraged. I conclude that the article should be construed purposively, that is in order to assist the purpose of the directive (and further that the ambit of the art 7(e) escape route or exception should be construed restrictively), such that the existence of the defect is *discovered* in the actual product if it is eliminated or removed or prevented from arising. Even if the nature of the defect is not specifically identified, the defect to my mind would be discovered if the precaution was taken which in fact eliminated the defect. (ii) Further, as set out in [51](v) above, it is to be recalled that *enable* is conveyed in other languages of the directive by words equivalent to *permit*. It seems to me that it can be said that surrogate testing would *permit* or *enable* the discovery of the defect, either because there is simply the assumption that blood is or may be infected by Hepatitis C as a result of a positive test, so that there is for these purposes a 'provisional' discovery of the defect, or that, more indirectly, it would *enable* or *permit* subsequent discovery of the virus if the blood

were retained (as will very regularly have been the case) for subsequent research and later, perhaps more direct, testing. Accordingly I reject the 'technical' defence.

[184] The next question is to determine the time when the *accessibility* of *the state of scientific and technical knowledge* must be tested. (i) Surrogate testing was available prior to March 1988, and because that date is the first date for claims under the CPA, there is no need to look at any other date, and the information was plainly *accessible* as from that date. (ii) Screening. I have concluded that routine screening ought to been introduced within the United Kingdom as from 1 March 1990. Information about such tests can however be said to have been *accessible*, on a non-Manchurian basis, since April 1989, when there was the publication referred to in [158](ii) above, or from the Paris or Rome symposia, or from the first introduction of such a test, namely in Japan in November 1989. I find it a difficult question as to which date to take. My conclusion has been that on a proper construction of art 7(e) it is *not* the precautions, which could have been taken to discover the defect in the particular product, which are relevant. I am satisfied that it is the *knowledge*, which thereafter puts the producer at risk if he then supplies. The fact that he only acquires, or could have acquired, the *knowledge* shortly before the supply of the product would not absolve him from liability, provided that the knowledge was accessible. If, on the other hand, the issue is the accessibility of *precautions* which might have discovered the existence of the defect in the particular product, which precautions were available in Japan or the United States, but which would inevitably take some time for him to implement, then it makes less sense for him to be immediately imputed with the knowledge of precautions about which he can then do nothing, and more sense to suggest that there must be some period of time for him to implement the precautions. It is clearly against that background that Mr Underhill made the submission that 'the virus only became discoverable as from the date at which it became reasonably practicable to introduce a routine screening test in the UK'. If I am compelled to accept the Underhill case, for the purposes of determination of Issue IV(b), then: (a) it makes much more sense to have an identical date in both art 6 and art 7(e), the date by which the defendants *should* have implemented the precaution; but (b) that means to my mind a clear undermining of the stringent approach to accessibility emphasised in *European Commission v UK*. Mr Underhill pointed to para 24 of the Advocate General's opinion ([1997] All ER (EC) 481 at 490), as if it supported the proposition that some time was to be allowed after acquisition of the knowledge—

> 'more generally, the "state of knowledge" must be construed so as to include all data in the information circuit of the scientific community as a whole, bearing in mind, however, on the basis of a reasonableness test, the actual opportunities for the information to circulate.'

but I am quite satisfied that that is referring to the *opportunities to circulate* in the sense that if the information is locked within Manchuria it has no such opportunities: and not to some implication of a reasonable period of time for dissemination of the information. I am quite clear that this very discussion emphasises why the claimants' construction of art 7(e), which I have accepted, is the right one. If, however, I must adopt the defendants' construction for the purposes of Issue IVb, then, with some misgiving, alleviated by the fact that if my first conclusion is right then no harm is done, I will adopt the same date for

art 7(e) as for art 6, namely 1 March 1990, as the date of what Mr Underhill calls *discoverability* with regard to the introduction of screening.

[185] I turn then to the central question, namely whether the defendants can show (the onus of proof being upon them) that *the state of scientific and technical knowledge at the time was not such as to enable the existence of the defect to be discovered* in the particular product.

[186] I deal first with the period from 1 March 1988 to 1 March 1990. (i) If the surrogate tests had been in operation, what would the consequence have been? I have already concluded that at the material time the contemporaneous research showed an adjusted efficacy of 40% for both tests. If they had been introduced, what effect would they actually have had? I refer to [112] and [113], and to the favourable 'look-back' research that was carried out. Can I now conclude that the efficacy was in fact higher than 40%? I just do not feel that, on the basis of the selective academic literature I have seen, and particularly without the benefit of any further evidence from Mr Charlett (who of course in any event, was the *defendants'* witness), that I can be sure, on the balance of probabilities, that the adjusted efficacy of both surrogate tests together was higher than 40% during the material period, namely from 1 March 1988 until the notional commencement of routine testing by 1 March 1990. Mr Underhill's case on that basis is that he can satisfy the onus of showing that, even with the implementation of the then most up-to-date precautions available, namely both surrogate tests, since only 40% of blood infected with Hepatitis C would then have been caught, on the balance of probabilities infection in the blood supplied to the claimants would not have been detected. (ii) Mr Brown submits that I should not be restricted to the 40% who would have been picked up by the surrogate tests, but that I should add a further factor for unwanted donors who were giving blood (see [100](vii) above). However, whereas I can entirely see the relevance of this to the question as to whether the blood was defective within art 6 (see [173] above), I do not accept its relevance to this aspect of the case. Although of course the onus is on the defendants, not only was there no case pleaded by the claimants, but no case ever adequately or at all explored with the relevant witnesses, that there was any other step that the defendants could or should have taken in relation to the elimination of such donors, in addition to the implementation of the missing tests, and in the absence of any such suggestion, together with an assessment or estimate of what further proportion of infected blood might thus have been removed, I cannot simply add a notional figure to the 40%. (iii) Mr Brooke submits as a matter of law that I cannot accept the proposition that, because the predicted efficacy of the tests was only 40%, therefore the claimants' defective blood would not, on the balance of probabilities, have been discovered, but that the defendants must show, by reference to each bag of blood and each claimant, that in fact a test would not have detected the virus in their blood. He refers again to *Hotson v East Berkshire Area Health Authority* [1987] 1 All ER 210 at 223, [1987] AC 750 at 769 per Croom-Johnson LJ:

> 'In his closing speech, the plaintiff's counsel said: "It is our submission ... that the loss of a chance, even a less than 50% chance, is enough to found a claim for damages in tort ... damage is proved by proving on the balance of probabilities the loss of a 25% chance." Put simply that way, the proposition is unsustainable. If it is proved statistically that 25% of the population have a chance of recovery from a certain injury and 75% do not, it does not mean

that someone who suffers that injury and who does not recover from it has lost a 25% chance. He may have lost nothing at all. What he has to do is prove that he was one of the 25% and that his loss was caused by the defendant's negligence. To be a figure in a statistic does not by itself give him a cause of action.'

It is my conclusion, however, that that logic, apply as it may do in the case of whether a claimant can establish a cause of action for loss of a chance (I have left that matter over for reasons appearing in [179] above), does not apply in a case such as this. In this case the defendants have to prove an escape route on the balance of probabilities. There does not seem to me to be a fundamental issue of jurisprudence at stake, but more a question of evidence. Am I satisfied that, in the absence of specific evidence about what in fact happened to the particular claimant's blood donor or donation, the defendants can still prove on the balance of probabilities that a test would have done no good, if, in fact, such tests do, more often than not, do no good? That is the conclusion I reach here (although, unless my earlier conclusions are wrong, the decision is of academic interest only); namely that the defendants would, on their construction of art 7(e), establish that in respect of the period between 1 March 1988 and 1 March 1990, the introduction in the United Kingdom of surrogate testing would not have led, on the balance of probabilities, to the discovery of infection in a particular donation, such that they would be entitled during that period to the protection of art 7(e).

[187] I now apply the same approach to the period from 1 March 1990 onwards. (i) On the basis set out above, routine screening was accessible/discoverable from 1 March 1990. I am satisfied that, on the balance of probabilities, blood infected by genotype 1 would have been discovered by the first generation tests, because it is common ground that the efficacy of such tests in relation to genotype 1 was 90%. Thus on the balance of probabilities, the defendants' case under art 7(e) fails in regard to those infected by the genotype 1 virus, even on their own construction. (ii) With regard to genotypes 2 to 4, the screening on its own would only have had an efficacy of 32%, according to the unchallenged evidence from Dr Simmonds and from the research of Dr McOmish and himself. However, I have concluded that surrogate testing should have been implemented and would have continued alongside routine screening at least until 1 April 1991, now the relevant date. Again on the basis of the unchallenged evidence from the genotype experts, it is clear that the combined efficacy of screening and surrogate testing would be well over 50%. The figures from Dr McOmish appear to be 95% for genotype 1, 70% for genotype 2 and 86% for genotype 3, the other genotypes being more or less identical. In these circumstances in respect of the period from 1 March 1990 onwards, the defendants' case under art 7(e) would in any event fail.

ISSUE V: GENERIC ISSUES OF QUANTUM ARISING OUT OF THE LEAD CASES

[188] I turn to the six lead cases. I deal first with general questions of quantum which are raised by them and which will also be relevant to the claims made under the CPA by other claimants within the group action.

Evidence

[189] The evidence given in respect of Issues I to IV was of course to a certain extent relevant to Issues V and VI, and in particular there was specific reference

back to the evidence given by Professor Dusheiko, which specifically straddled what might in general terms be called liability and quantum. In addition, however, there were of course particular witnesses dedicated to the six lead cases and to the general issues of quantum. (i) *Factual witnesses*. The six claimants in the lead cases each gave evidence, together with relevant members of their families. The defendants called no factual witnesses. So far as care was concerned, which related to the circumstances of Mr W and Mrs X, although detailed assistance was provided from Mrs Maggie Sargent RGN for the claimants and Richard Ryland of Care Providers Ltd for the defendants, in the event their evidence was co-ordinated and agreed, so that neither of them had to be called. Accountancy evidence in the case of Mrs X was provided by the late Alan Bragg FCA, whose evidence was read. (ii) *Medical expert witnesses*. As in relation to the evidence given on the liability issues, all the witnesses were extremely distinguished and experienced. For the claimants, in addition to Professor Dusheiko's evidence, there was evidence, both generically and in respect of the particular circumstances of the six claimants, from Dr Ryder, consultant physician in hepatology and gastro-enterology at the Queen's Medical Centre, University Hospital, Nottingham, with very considerable clinical experience, and more than twenty publications in the relevant area. Dr Dinshaw Master was called in relation to the psychiatric issues raised, to which I refer below. He is a consultant psychiatrist at Guy's Hospital, and senior lecturer at Guy's, King's and St Thomas' Schools of Medicine and Dentistry, and he too has published widely. Evidence of Professor Day, of the Freeman Hospital, Newcastle, which would have been called as to the cost of treatment, was agreed. His agreed evidence related to the cost of either six months (24 weeks) or 12 months (48 weeks) of treatment for Hepatitis C. As will appear below, the present recommended and most successful treatment is what is called 'combination therapy'. Originally there was 'monotherapy', by the use of Interferon alfa alone. This is an artificially-made clone of natural interferon, to fight viral infection, taken by self-injection. Combined with this, unless its use is contra-indicated in respect of a particular patient, has been for some time a viral inhibitor, taken by tablet, called Ribavirin, and the two together are called 'combination therapy'. Recently there has been a sophistication of the Interferon, by virtue of the use of what has been called 'pegylated Interferon', which involves a module made artificially more massive by the addition of polyethylene glycol molecules. Its effect is to slow down the rate at which interferon is filtered out of the body: there is one weekly self-injection instead of three. The cost of standard combination therapy was agreed, in accordance with Professor Day's evidence, at £6,006·10 for six months, and £11,458·20 for 12 months: and of pegylated combination therapy as, respectively, £6,631·10 and £12,708·20. Additionally Mr Terrence Hope, Consultant Neurosurgeon at University Hospital, Nottingham, was called to give evidence in the field of cerebro-vascular disease, which is his speciality, with regard to the specific circumstances of Mr W. For the defendants I heard the impressive evidence of Dr Alexander, who is lecturer in medicine at the University of Cambridge School of Clinical Medicine (Addenbrooke's NHS Trust), where he is honorary consultant physician/hepatologist, again with very considerable clinical experience: and he has more than 200 publications in the field between 1980 and 2000. Evidence of Dr Kelly, a consultant paediatric hepatologist from Birmingham Children's Hospital, was read. Lastly there was called by the defendants, on the psychiatric and related issues, Professor Simon Wessely,

professor of epidemiological and liaison psychiatry at Guy's, King's, St Thomas' School of Medicine and Institute of Psychiatry, honorary consultant psychiatrist at Kings College and Maudsley Hospitals and director of the Chronic Fatigue Syndrome Research Unit: he has a veritable library of more than 300 publications to his name. (iii) *Other experts*. The claimants adduced the evidence of an employment expert, Clive Langman of Langman Human Resource Development Ltd, who prepared his evidence by reference to questionnaires sent to a large number of the claimants and to his own experience, whose statement was, in the event, read. Three witnesses were called in relation to insurance and financial services; two for the claimants, Miss Susan Daniels, of JTA Financial Services, an Independent Financial Adviser (IFA), specialising in obtaining insurance and other financial products particularly for those with medical problems, and Mr Eric Purdy, chief underwriter and underwriting manager at the M & G Group; and one for the defendants, Mr Roy Brimblecombe, of Aon Consulting Ltd, formerly executive director and chief actuary of the Eagle Star Insurance Group, and a former chairman of the Life Insurance Council of the Association of British Insurers and member of the board of the Life Assurance and Unit Trust Regulatory Organisation (LAUTRO) and chairman of its monitoring committee. During the course of the hearing, and again by dint of a good deal of work behind the scenes, the three co-operated in an extremely clear and lucid joint report, cross-referring to the original reports of all three of them and reaching joint conclusions: in the circumstances Mr Purdy did not need to give any evidence, but supplementary evidence was orally given by Miss Daniels and Mr Brimblecombe. (iv) *Literature*. Apart from publications and studies by the witnesses who were called, there was reference both to the four core files of medical literature used for the liability part of the hearing and to a fifth produced specifically for Issues V and VI. The most central publications were: (a) the NICE guidance referred to in [90] above; (b) the consensus statement of the EASL (European Association for the Study of the Liver) International Consensus Conference on Hepatitis C (Paris, 26–28 February 1999) (the 'International Consensus Statement') in which, together with others, such as Drs Alter, Miriam Alter and Esteban, Professor Dusheiko participated; (c) articles, published in 1997 (described as 'landmark' by Dr Alexander), 1998 and 2000, by Dr Poynard and others; and (d) articles by Drs Fraser and others (Israel 1996), Hoofnagle of the NIH (1997), Fattovich and others (1997), Gane (Auckland Hospital, New Zealand 1998), Foster (St Mary's, London, 1999), Rodger and others (Australia 1999), Goh and others (Ireland 1999), Caronia and others (1999, including Dr Alexander), Mason and others (1999, also including Dr Alexander) and Knobler and others (Israel 2000). I have drawn on all this literature, and on the evidence given by the witnesses to whom I have referred, and their publications, in my attempt to summarise and make findings about the relevant scientific, epidemiological and medical background of Hepatitis C, as set out below.

HEPATITIS C: THE DISEASE AND ITS TREATMENT

[190] The key word which Mr Brooke continually dinned into my ears throughout the course of this hearing—and it is fully supported by all of the evidence—is uncertainty. The medical profession is still learning about Hepatitis C, and we have had the benefit of evidence and input from some of the leading protagonists. Dr Dusheiko said as follows:

'I think it is most important that we have a balanced view of the natural history of Hepatitis C, [not least] from the point of view of deciding which patients need therapy in acquiring resources for treatment. If one is to understate the disease, that may be detrimental from terms of public health, and the management of the disease. If we are to overstate the disease, that would again also be detrimental.'

It may be that even this very case has contributed to the learning about Hepatitis C, both by virtue of the detailed consideration of the circumstances of the more than 100 claimants within the group, and by the examination of the full picture for the purposes of this hearing. The outlook is far less gloomy than it was in 1988–1989, as was made clear by Dr Alexander. Of course Hepatitis C was only identified in 1988, and the earliest date of infection of these claimants was 1 March 1988, by virtue of the fact that they are making claims under the CPA; and so the longest period of time for which any of them has been infected by Hepatitis C is 13 years, and it is, as will be seen, a disease with a potential duration of 50 years or more. Out of the cohort of claimants, I am informed that six have died of Hepatitis C-related liver disease and one, as it happens one of the six lead claimants, Mrs X, has had a life-saving liver transplant.

Clearance of the virus

[191] Hepatitis C can spontaneously clear, and does so in relation to 20% of those who are infected by it. Why that is so is unclear—it was suggested by Professor Dusheiko that there may be a genetic cause. In answer to questions from me he said as follows:

'Q. Is there any indication of what gives you a better chance of being in the 20% than in the 80%? *A.* There is some evidence that there is a genetic basis for this. Certain individuals with particular HLA types, determining their genetic type, seem much more likely to clear the virus. It clearly depends upon an appropriate cellular and human immune response, and we are just beginning to gain an understanding, but those individuals who are infected with Hepatitis C and mount a vigorous immune response ... do seem to be able to clear the virus. *Q.* Presumably ... it might be that the secret of why these 20% clear the virus might unlock a cure? *A.* It is a study—a very active area of research at the moment.'

[192] The way in which such 'clearance' of the virus can be identified is by the use of a PCR, that is the form of blood test, now much more fully available than it was in the 1980s, which can test for the virus (not the antibody) in the blood. Indeed there is now a 'qualitative PCR', which identifies whether there is virus in the blood (PCR positive) and, if there is, there can then be, if required, a 'quantitative PCR', which can calculate the amount of virus in the blood, that is the quantum of viraemia or 'viral load', which has a relevance to prognosis and to treatment. Apart from such spontaneous clearance, the aim of the treatment to which I have referred above, monotherapy or combination therapy, whether pegylated or otherwise, is of course to achieve such clearance. On occasion blood can test PCR negative during or after such treatment, but nevertheless revert to PCR positive (this disappointment occurred for Miss T). However, if it remains PCR negative for six months or more after treatment, it is regarded as clear, and, as will be seen below, reversion to positivity thereafter is very rare

indeed. The virus may still remain in the blood, but at such a low level that it cannot be measured by PCR, or it may be entirely absent from the blood but still remaining in tissue, be it liver or pancreas: but if treatment has been successful, the patient is clear and the prognosis is excellent. As I understand it, whereas there is no evidence of a case in which spontaneous clearance has ever subsequently reverted, so far as those whose blood is cleared of the virus as the result of treatment, late reversion has, rarely, been experienced; but although strictly it is a matter not of *clearance* but of 'control' of the virus, they too, subject to the possible need, hopefully decreasing, for the occasional check-up or blood test, can be regarded as cured. (I refer to this further below, when dealing with the question of provisional damages.)

The course of the disease

[193] Approximately 20 to 25% of those who are infected by the Hepatitis C virus have, during the period of acute infection, jaundice, the specific and obvious symptom; the others being 'anicteric' (without jaundice). The jaundice clears fairly quickly: there may be some interrelation between those who have jaundice and those referred to above who spontaneously clear (research is continuing). In any event, the main issue is not acute hepatitis but chronic hepatitis. As set out in [191] above, 20% of those infected do not proceed to chronic infection, but spontaneously clear. But, subject to the development of combination therapy, and some considerable ongoing research and study into other treatments, it is the balance of 80% who suffer, in varying degrees, from Hepatitis C for the rest of their lives. The prognosis is very variable. (i) Approximately one third of those with chronic Hepatitis C (Category A) will be largely asymptomatic during their lifetime. They may have relatively minor symptoms, such as will be discussed below, affecting their quality of life, but they will not suffer from any, or any material, liver disease. Any lesions to their liver will be benign and of no materiality. (ii) Approximately a further one third (Category B) will suffer from mild to moderate liver disease, with necro-inflammatory lesions and mild fibrosis, progressing slowly, if at all, to serious liver disease. Fibrosis is measured by a number of different systems, each with a level, either from one to five or one to six, but, on all such systems, levels one and two, and often three, are regarded as benign, and such fibrosis will have no deleterious effect on liver function. Professor Dusheiko described fibrosis as follows:

> 'For reasons that are not clear, because we do not understand the pathogenesis of the disease, it is a disease characterised by a sort of creeping fibrosis of the liver, where scar tissue, known as fibrosis, is laid down in a particular architectural distribution, starting with a small amount of fibrosis, if present at all, with the portal tracts: gradually then extending from portal tract to portal tract in the liver, linking [them], which is known as linking or bridging fibrosis, gradually then encircling the nodules of the liver.'

At present the only effective way in which to estimate the extent and development of the fibrosis is by a biopsy. (iii) One third (Category C) will suffer from more serious liver disease—chronic liver disease (CLD). Some progress slowly and some more quickly, as the fibrosis increases, if it does, and, in doing so, it gradually encircles the nodules of the liver, as discussed above. Cirrhosis is simply extensive fibrosis, leading to a nodular change in the liver, with gross nodules visible to the naked eye and a gradual abnormality of the texture of the

entire liver. In the Poynard studies, to which I have referred in [189](iv)(c), the median estimated duration of infection through to cirrhosis was 30 years. It is now estimated that, of those with chronic Hepatitis C, 20% (ie about two-thirds of Category C) will develop cirrhosis in 20 years, and another 10% in 30 to 50 years. Cirrhosis itself can be asymptomatic for some time so far as its effect on liver function is concerned: it is gradual and can reach a plateau. There is a period during which the liver can cope, which is called 'compensated' cirrhosis. The later stage is called 'decompensated' cirrhosis; Professor Dusheiko describes it as follows:

> 'Compensated cirrhosis means the presence of cirrhosis histologically, proven by a liver biopsy, but where the patient has not suffered any gross sequelae of cirrhosis. So the patient is never presented with a variceal bleed, never presented with ascites, accumulation of fluid [in the peritoneal space within the abdomen], never presented with encephalopathy, the coma states that accompany it, never presented with any oedema or swelling in the legs. Decompensated cirrhosis is where patients begin to be hospitalised for complications such as those I have mentioned ... you could also use a biochemical test of liver function to start to recognise decompensation.'

Those in Category C are also at a small risk of liver cancer (hepatocellular carcinoma).

[194] There can, very exceptionally indeed, be extra-hepatic complications, such as porphyria, cryoglobulinaemia, glomerulonephritis and diabetes mellitus.

[195] For those with serious decompensated cirrhosis or liver disease, a liver transplant may be considered and carried out, as with Mrs X. Although there can be a risk of immediate rejection, and a very small risk of what is called late acute rejection, there is no reason why such transplants should not be successful, and indeed in the case of Mrs X it has been so. However, a liver transplant simply replaces the diseased liver, but it does not eradicate the virus. There is an inevitability of re-infection of the new liver while the virus remains in the blood, and the present figures are of a 10% risk of cirrhosis within five years of the transplant, with a 60% survival rate for ten years from transplant.

Prevalence of Hepatitis C

[196] The global prevalence of chronic Hepatitis C was estimated in the International Consensus Statement in 1999 as 150m (I note that Dr Gane had earlier given an estimate of 300m infected) and as 5m in Western Europe. The NICE guidance estimates 200,000 to 400,000 in England and Wales. Hepatitis C accounts for some 20% of acute hepatitis worldwide and 70% of those with chronic hepatitis (no doubt because of the relative absence of treatment or cure for Hepatitis C), for 40% of those with decompensated cirrhosis and for 30% of all liver transplants. Up to 50% of intravenous drug users suffer from Hepatitis C.

Transmission of Hepatitis C

[197] The main method of transmission of Hepatitis C is through intravenous drug use. According to the International Consensus Statement, its transmission by blood products has been reduced worldwide to near zero. Apart from drug use, there are other methods of 'horizontal' transmission of Hepatitis C. There is a small risk through tattooing, body piercing, electrolysis, and acupuncture.

[198] It is common ground between the experts that the risk through sexual transmission is very small indeed. Dr Ryder stated that—

> 'sexual transmission can occur, but it is very uncommon: the evidence is that sexual transmission is most likely to occur in individuals with multiple partners and high risk sexual practices, and the transmission in a stable monogamous relationship is very uncommon, and there is a fair amount of data from both the haemophilia cohorts and also the immunoglobulin D-spread cohorts that sexual transmission is uncommon in that setting.'

In a group that he has studied, he could only identify sexual transmission as the sole probable mode of transmission in 1·3% of the cohort. Dr Alexander considered that there was a very rare risk of transmission if a patient had a very severe venereal infection, in which case the number of leucocytes in semen or vaginal fluid would increase; such that there might be a small risk if there was a high leucocyte count, and significant abrasions to the vagina or penis. But in other circumstances his view was that sexual transmission did not occur at all, and his experience in Cambridge was that they had screened many, many people, and never found it. His conclusion was that, excluding those involved with drug use, there was no risk of sexual transmission at all, and that the very small percentage risk, below 5%, mentioned in literature, could all be accounted for by the factors of drug use or venereal disease.

[199] As for vertical transmission, that is infection passed from mother to baby through pregnancy (there is no association at all from breastfeeding), it was common ground that there is a very low risk indeed. Dr Ryder put it at less than 5%: his, very wide, experience was certainly of substantially less than the 5–6% risk quoted in literature, and in his cohort of 30 children born to Hepatitis C positive mothers, he and his colleagues had not seen a single infected child. Dr Alexander adds further, while agreeing about the smallness of the risk, that children have a low risk of liver disease relating to Hepatitis C, certainly through the early years of childhood, so that the risk of any liver damage would be small, and further, that a baby or child infected would be the most likely to respond successfully to therapy.

Prognosis

[200] As set out above, the condition can be all but asymptomatic for many years, and the most likely outcome is no serious liver disease. Cirrhosis may take between 20 to 50 years to develop, if it develops at all, although, it can, as in the case of Mrs X, who was 45 at the date of her infection, occur much more quickly. As for progress to fibrosis and cirrhosis, Dr Poynard predicted that this was linear. It seems now that there is considerable doubt about that. Though slow to start, it may speed up: it may speed up with the onset of age, it may be quicker if (as in the case of Mrs X) the patient is older when infected. There are five predictive factors, which have developed and been generally accepted as the clearest indicators of the likelihood of worsening progression of liver disease and hence prognosis. (i) Age at time of infection: those who are young have a better prognosis and a slower rate of infection; over 40 is the yardstick. (ii) Degree of inflammation (and/or ALT score) on the first—or 'index'—biopsy (normally now taken about one year after infection); Dr Alexander explained that there is an 85% chance on index biopsy of accurately forecasting the development of the liver over the next five years. (iii) Male gender: a much greater risk than female.

(iv) Alcohol intake: worse with intake of more than five units per week; Dr Alexander in particular would encourage less. (v) Co-infection with Hepatitis B or HIV: and possibly the degree of steatosis (fatty liver). This is a very helpful guide indeed for those estimating prognosis within the rest of the group actions, and is well exemplified in the lead cases by reference to Miss T and Ms V.

Treatments

[201] As set out in [193](ii) above, biopsies at present are an essential tool for diagnostic and predictive purposes. Index biopsies are normally after one year, and then there is normally a need for follow-up biopsies, although hopefully the less regularly as time goes by (to which point I return below), because of their invasiveness and discomfort. They are certainly needed on a fairly regular basis after any transplant, and there would need to be a biopsy before the onset of any treatment or therapy. It is very much hoped and believed by Dr Ryder, Professor Dusheiko and Dr Alexander that there will soon be successful development of non-invasive methods as a substitute for a biopsy. Dr Ryder estimated that the existing research may well produce such methods over the next five to ten years. Dr Alexander considered that, although he did not think that within five years there would necessarily be a substitute for the index biopsy, follow-up biopsies might certainly be substituted by blood tests during that period; and he did not think it was optimistic, but reasonable, to expect that a significant proportion of his patients would be taken out of the schedule for follow-up biopsies on that basis. As for treatment by Interferon, combination therapy (or monotherapy in the event of contra-indication, or intolerance, of Ribavirin) has been given specific approval in the NICE guidance, which licenses the use by health authorities of such products, with the exceptions and expansions there set out. In particular:

> '1.1 Interferon [alfa] and ribavirin as combination therapy is recommended for the treatment of moderate to severe Hepatitis C (defined as histological evidence of significant scarring (fibrosis) and/or significant necrotic inflammation) at standard doses for patients over the age of 18 years as follows:
>
> 1.1.1: All treatment naive patients (that is, those who have not previously had Interferon [alfa] monotherapy or combination therapy) and all patients who have been treated with Interferon [alfa] monotherapy, and have had some response but have since relapsed. Such treatment should be continued for six months for all patients.
>
> 1.1.2: A further six months combination therapy is recommended only for patients infected with Hepatitis C virus of genotype 1, who respond to therapy by becoming clear of circulating viral RNA as detected by ... PCR in the first six months.
>
> 1.1.3: Those in whom liver biopsy poses a substantially increased risk (such as patients with haemophilia) may be treated on clinical grounds without histology.
>
> 1.5: ... The recently licensed pegylated Interferon monotherapy has not been considered in this Guidance.'

[202] It is anticipated that pegylated combination therapy will replace standard combination therapy in what Professor Dusheiko called the 'not too distant future'. Dr Ryder considered that it would be licensed for use as an NHS

product by summer of this year, although it will not necessarily be an immediate part of the NICE guidance, with the result that not every authority will be able or prepared to fund its use, as would be the case if it were incorporated expressly into the NICE guidance. Dr Ryder himself had not had a problem in funding *standard* combination therapy prior to NICE, but he accepted that that would not have applied to all authorities.

[203] Other treatments are being urgently researched, priority already having been given over the last few years by drug companies. Dr Ryder foresaw at least ten years before there would be effective alternative treatments, but Dr Alexander, who is actively involved in their research, looked, although without certainty, to an availability within four or five years.

[204] As for the present combination therapy, there are once again predictive factors, first advanced by Poynard and now generally accepted, for the likely success of such treatment. (i) *Genotype*. There is a very marked greater likelihood of success of the treatment for those with genotypes 2 and 3: genotype 4 less successful, and genotype 1, as is apparent from the provision in the NICE guidance for a 12-month rather than six-month treatment, much less likelihood of success. (ii) *Age at time of treatment*: again those under 40 have the better chance. (iii) Those with a *lower viral load* at time of treatment: certainly those with less than 2,000,000 copies per millilitre of virus in the blood have a better chance. (iv) Once again *male gender* is a worse indicator than female. (v) *Degree of existing fibrosis*. This guide is also vital, for consideration of whether to carry out the existing therapy.

[205] Not all patients are suitable for the treatment, and of course the indicators above will be a factor for consideration, as will be the NICE guidance, particularly so far as funding is concerned. The Interferon treatment itself is not pleasant. It requires self-injection (three times per week for standard or once per week for pegylated), monitoring and blood tests, and it has, in most cases, side-effects: most frequently complained of are flu-like symptoms, headaches, fatigue, dizzy spells or nausea, nosebleeds, appetite loss. In addition there is the risk of hypo- or hyper-thyroidism (from which Miss T temporarily suffered), and a 15% risk of clinical depression (from which fortunately none of the lead claimants suffered). According to the NICE guidance there is a 10–20% discontinuance of the treatment. However, its success level, particularly for those of genotypes 2 and 3, is very promising, and indeed improving. So far as non-pegylated standard combination therapy is concerned, the figures for genotypes 2 and 3 appear to be around 60% success, and for all genotypes between 35% and 47%. Dr Alexander has a rigorous system of supervision, because he believes that much of the failure rate results from non-compliance by patients, and his overall success rate (the majority of his patients being genotype 1) is 55%. As for pegylated combination therapy, results of recent trials for genotype 1 appear to be improving from 30% up towards 40%, and for all genotypes to 53%: the common ground as to the success rate for genotypes 2 and 3 appears to be 80–85%. Indeed Dr Ryder referred to infection with genotypes 2 and 3 as 'in general now ... almost a curable disease'.

The effect of Hepatitis C

[206] *Quality of life*. The effect of Hepatitis C, apart from the possible development of serious liver disease, may be, or include, irritability, nausea and headaches. It may include fatigue and lethargy (to which I refer below). There

may be worry and stress about the future and prognosis, at least unless and until there is a more certain prediction derived from *clearance* of the blood or from a favourable biopsy or otherwise (what has been called the 'Sword of Damocles' factor). There is the need for fairly regular medical supervision—perhaps six-monthly blood tests, perhaps biopsies every three to five years, more often if there is evidence of some deterioration, or if treatment is being considered. There is the possibility of social 'stigma', to which I refer again below. There may be worry about sexual transmission, although the risk, as set out in [198] above, is agreed by the experts to be extremely small, and the firm and unanimous advice of the experts is that no extra or different precautions are necessary—for stable relationships no precautions that would not otherwise be taken are needed, while in the case of multiple relationships, the use of precautions would be recommended in any event, even apart from Hepatitis C. There may be worry about vertical transmission, again notwithstanding the very small risk. There is an effect, which Dr Foster has sought to identify and estimate in his published study, using approved questionnaires, on the 'Quality of Life'. Of course if and when CLD were to ensue, then there would be other and specific symptoms.

[207] *Fatigue.* Plainly fatigue is one of the possible, and indeed very common, complaints of those suffering from Hepatitis C, as is confirmed by the clinicians, who have seen so many. Fatigue is, however, as Dr Alexander pointed out, common among patients of all kinds, and certainly so among liver patients (though, according to Dr Ryder, not normally with those suffering from Hepatitis B). The question which was proposed by Professor Wessely, which it is necessary for me to resolve, is whether fatigue is an automatic concomitant of Hepatitis C. The report he prepared was accepted by all his fellow experts to be extremely learned and persuasive. He agreed that there was a clear aetiology for fatigue, which would lead to its being a regular feature among Hepatitis C sufferers. (i) Fatigue is common in any event (although he referred to the NIH study by Dr Hoofnagle, which showed that there was apparently a higher indication of fatigue among his cohort of healthy blood donors than amongst those infected by Hepatitis C). (ii) Fatigue is a very likely consequence of stress and worry, such as would be inevitable from learning and awareness of Hepatitis C infection: a number of studies indicate a tie-up between knowledge of Hepatitis C and fatigue. (iii) Fatigue will be a symptom of deteriorating CLD (characterised by Dr Alexander as 'exhaustion'). (iv) Fatigue will, or may, accompany depression or psychiatric disorder.

[208] However, Professor Wessely did not consider—and I accept his persuasive evidence—that fatigue was an automatic concomitant and a necessary symptom of the Hepatitis C condition. Of course, if a Hepatitis C patient is found to be suffering from fatigue, then that will be so, in his or her case. But it is not to be presumed or assumed as automatic. The consequence, as Mr Underhill has submitted, is that not only will it be necessary to establish, and prove, a period or periods of fatigue or indeed a continuity of fatigue, if such be the case, in the case of any particular claimant, rather than simply assuming it, but also: (a) if fatigue be proved, it may well be more likely to have occurred only after knowledge, and to improve if and as the stress and anxiety caused by such knowledge ameliorates, either by habituation to the condition or as a result of the advice of a favourable prognosis; (b) if it is a concomitant to depression, then it may ameliorate as the depression improves or is recovered from; and (c) if it is a symptom of the liver disease then it may, for example, improve upon treatment or even disappear after

a transplant. This assessment, and in particular the linking of fatigue either to the date of knowledge of infection or to the onset of CLD, was fully exemplified, in my judgment, in the facts of the lead cases. Fatigue in the case of Mrs X was, in my judgment, plainly associated with the early onset of CLD (and there has been a dramatic improvement since her transplant). In the case of those who had interferon treatment (T, U, V, W), or an adjustment disorder, it was a likely b concomitant or side-effect. But otherwise it improved or evaporated once stress and anxiety were alleviated by a successful treatment and/or a favourable prognosis.

[209] *Vulnerability to depression.* Three of the lead claimants, and no doubt others of those within the group action, have suffered a period of depressive disorder, and that is a matter for specific consideration. However, an issue has c been raised by Dr Master with which his colleague Professor Wessely specifically disagreed and I must resolve it. Dr Master expressed the opinion that once a person has been infected by Hepatitis C, which is a 'life event', then, irrespective of whether such person recovers from any psychiatric disorder that may result from that life event, or indeed puts it entirely from his mind, he has an objective d vulnerability to further life events, of whatever kind, so as to be the more liable to suffer psychiatrically in future. He put it in this way in answer to Mr Brooke:

> 'A. We probably all have a threshold for developing mental illness. It depends on the product, in rough terms, of the vulnerability, and the significance and impact of any given life event. So my postulation is that, e having suffered from Hepatitis C infection, the vulnerability factor is increased. Q. [by me]: Are we talking about a vulnerability to the onset of Hepatitis C, then knocking him down yet further ten years later, or are we talking about a greater vulnerability generally, so that if his grandmother dies, he is then knocked down; which is it? A. It is the latter. I think there is a general increased vulnerability to develop further episodes of mental f illness.'

Then further in cross-examination by Mr Underhill:

> 'Q. One of the things you were saying, the most general thing you were saying, is that the impact of adverse life events, as regards their liability to g lead to psychiatric illness is cumulative. That is, the more adverse life events you suffer, the more likely you are to develop a psychiatric illness next time one comes along ... A. As a general proposition, I would say that ... Q. At one point, I thought you were qualifying it by saying that you are only really concerned with continuing life events ... That would ... deal with those h people who treated the knowledge of their Hepatitis C infection as a continuing problem for them, but it would not explain those people, who had as far as one could tell, entirely put it behind them. By the end of your evidence it was clear you were saying that even for the latter group, there was an increased vulnerability? A. Yes, I am ... Q. The consequence is ... that every one of these claimants would be entitled to have some element of j their damages to reflect an increased risk of developing psychiatric illness compared with if they had never been infected? A. Yes.'

[210] Professor Wessely accepts, as of course Dr Master confirms, that there may have been people who would not have been able fully to recover from the effect of the first life event—ie a continuing 'Sword of Damocles' effect—but he

does not accept that there is any such objective vulnerability as Dr Master postulates. A person is dealt what he called a 'hand of cards', derived genetically, or from his or her early development (he draws this from his own published studies and also from the seminal work of Brown and Harris *Social Origins of Depression* (1978)). A person who suffers from a life event *may* be rendered vulnerable by that circumstance to succumb to another life event, to which he might not otherwise have succumbed. On the other hand, it is equally if not more frequent that a person is rendered more *resilient* by suffering, so that, having succumbed on the first occasion, he is the less likely to do so on the second and future occasions. It all depends. If Dr Master were right as a matter of course, then, as it is commonplace for everybody to suffer more than one life event, if only by losing more than one parent, there would be what Professor Wessely described as 'an ever accelerating spiral' or 'an accelerating cascade of psychiatric disorder, because after each life event, you will be continually upping the stakes, as it were, until finally ... everybody would break down, because we all encounter adversity. So I do not accept that life events themselves feed onto the risk for the next life event'. This tournament between Master and Wessely, if I may allude to the similarity of the latter's appearance to that of a well-known irascible tennis player, was, in my judgment, won, game, set and match by Professor Wessely. If a claimant has suffered prior to trial from a psychiatric disorder then he is entitled to be compensated for it, and if (which has not been the case for any of the lead claimants) it be a continuing disorder, then on that basis. My judgment is, however, that there is no automatic continuing vulnerability in the absence of specific evidence in that regard. If in the future a claimant were to suffer from psychiatric disorder which he could bring within the agreed provisional damage 'triggers', to which I shall refer below, so as to be able to claim additional damages, then those damages will arise out of such fresh disorder.

ISSUES OF DAMAGES

Provisional damages

[211] Mr W, who is nearly 72, does not seek provisional damages. In the light of the uncertainties, to which I have referred above, all the other lead claimants, and, I anticipate, most if not all of the other claimants, will seek to take advantage of the sensible and flexible provisions of s32A of the Supreme Court Act 1981, which—

> 'applies to an action for damages for personal injuries in which there is proved or admitted to be a chance that at some definite or indefinite time in the future the injured person will, as a result of the act or omission which gave rise to the cause of action, develop some serious disease or suffer some serious deterioration in his physical or mental condition.'

Pursuant to CPR 41.2, I can only make an order for an award of provisional damages if I am satisfied that the section applies, and if the particulars of claim included a claim for provisional damages (which they did). If I make such an order, I must specify the disease or type of deterioration in respect of which an application may be made at a future date, and specify the period within such application be made, although such period may be the duration of the life of the claimant. My attention has been drawn to two relevant authorities, *Willson v*

Ministry of Defence [1991] 1 All ER 638, and *Thurman v Wiltshire and Bath Health Authority* [1997] PIQR Q115. The defendants did not oppose in principle the making of an order for provisional damages, although there was a good deal of disagreement between the parties as to the trigger or triggers for any such future damages. This led to a considerable amount of submission and exchange, and various and continuing amendments to the proposed triggers, but resulted in five triggers which satisfied, as I understood it, all the objectives and objections of both sides. I am entirely satisfied, as I must be, that this is a suitable case for provisional damages. I am also satisfied that the five triggers eventually resolved upon are sensible and necessary. I shall set them out below, together with a short explanation of each. I was satisfied that each trigger could only be used once (by each claimant) and therefore it was not possible to have one trigger containing more than one possible event (unless they were alternatives); and hence that all five triggers, none of which of course may be necessary in the case of any one claimant, are required in case there is one claimant, who, during a lengthy lifetime, might qualify under more than one trigger as time goes past. I am satisfied that the duration referred to in CPR 41.2 should indeed be the duration of the life of each claimant.

Trigger 1: 'Testing Hepatitis C RNA Positive in blood, having always tested RNA negative in blood in the past or having tested RNA negative in blood for at least twelve months following anti-viral treatment, leading to a prognosis materially worse than at the date of assessment of damages.'

As discussed in [192] above, there is a risk, presently considered to be very small, that one who has tested negative for such a period that it can be assumed that there has been clearance of the blood may subsequently revert to testing positive. This might simply occur because of the development of some even more sensitive test, so that it could be concluded that, although there has been a positive test, it does not in the circumstances lead to a materially worse prognosis. But, such unlikely circumstance apart, on the assumption that on any reasonable basis the particular claimant is now to be regarded as positive rather than, as before, negative, then that will, if not falsify, certainly change the basis upon which damages will have been assessed: eg PCR negative, never likely to deteriorate or suffer material liver disease, no further treatment, no or no further social, employment or insurance handicap (so far as that may be relevant, as I discuss further below), no further biopsies or follow-ups etc. Notwithstanding the smallness of the risk—seen by all the experts as perhaps between 1 and 2%—I am satisfied that this is an appropriate trigger, and enables me to assess damages for those, like Mr S and Mr U, who have cleared the virus, on that positive (or rather negative!) basis.

Trigger 2: 'Developing decompensated cirrhosis and/or liver cancer and/or serious extra-hepatic complications resulting from Hepatitis C.'

This speaks for itself. I am therefore able to assume that all those claimants who have not done so already will never deteriorate to decompensated cirrhosis. There is, as I have indicated, a small risk of liver cancer, and a very small risk of the extra-hepatic complications which I have set out in [194] above, and again notwithstanding the smallness in particular of the last-named risk, I have been satisfied that it is appropriate to have a trigger making specific reference to them.

Trigger 3: 'Developing decompensated liver disease and/or cancer and/or serious extra-hepatic complications resulting from Hepatitis C after transplant.'

The need for this separate and otherwise repetitive trigger results from the factor, referred to above, that each trigger can, it seems, only be used once.

Trigger 4: 'Onset of late rejection of a liver transplant.'

Once again this was a very small risk, as seen by all the experts, perhaps 1% to 2%, but needs to be provided for, in my judgment, so that it would be possible, for example in the case of Mrs X, to assess her claim on the basis that there will be no, very exceptional, late rejection of her liver transplant.

Trigger 5: 'Recurrence of, or onset of a fresh, serious psychiatric condition as a result, whether direct or indirect, of the claimant's Hepatitis C condition.'

The reason for this is really fully apparent from my discussion of the evidence of Professor Wessely. It is to be noted that, in order to comply with the statute, the condition, if it were to arise, would have to be a 'serious' one.

Heads of damage

[212] Mr Brooke has submitted that general damages for pain, suffering and loss of amenity (PSLA) should in this case be split out into sub-categories. This is, he says, a modern trend, but in any event is desirable in this case because of the fact that there are here lead cases and lead claimants, and assistance may be drawn from findings and separate assessments of sub-categories when coming to consider the cases of other claimants. The defendants have not opposed this as a matter of principle, and I am prepared to follow this course, subject to some slight emendation, as will appear below. But it is important, as the defendants have submitted, and I accept, to appreciate that it may be that once each such sub-category of damage is added up, the total of general damages for PSLA will not be simply the aggregate of them. It is essential, as has been pointed out on numerous occasions by higher authority, that general damages be looked at in the round and that, in particular if there be sub-categories, there should not be in the end any overlap or duplication: one example of reference to such overlap by the Court of Appeal is contained in an authority relied upon in one of the lead cases, *Curi v Colina* [1998] CA Transcript 1300 (Kemp and Kemp, *The Quantum of Damages* B2-008/1.)

PSLA

[213] *Infection simpliciter.* It is obviously necessary in assessing such damages first to identify the condition, to conclude whether there has been *clearance* of the virus and if so at what stage, and to decide whether the assessment is to be on the basis of provisional damages: then to assess the prognosis, treatability and treatment, the symptoms identified so far and continuing, and the state of mind, whether optimistic, resilient, pessimistic, anxious or fearful, and the circumstances of the claimant. Mr Brooke speaks of 'infection *simpliciter*'. But the meaning of this is not entirely clear. I take it to mean that it excludes any specifically liver disease-associated symptoms, or any identifiable psychiatric disorder. But he also seeks to extract, as a separate head, fatigue. That seems to me to have been put forward on the basis, which I have not accepted, that there

will almost automatically be fatigue as a concomitant to Hepatitis C, such that in a particular case there might be specific evidence of fatigue for separate identification. I conclude, in the light of my decision on the question in [207] and [208] above, that fatigue, if it is shown to exist for any period in relation to a particular claimant, ought to be included as part of 'infection simpliciter'. It seems to me very difficult indeed to sever off questions of fatigue from those of stress or anxiety or irritability or from any other factors counting by way of diminution of the quality of life. Subject to this adjustment, I accept Mr Brooke's invitation to sub-categorise by reference to 'infection simpliciter'. The assessment of it, taking into account questions such as the general need for monitoring and any specific concerns or worries of the individual claimant, will be carried out on the basis, discussed above, of the likely prognosis of that claimant, but upon the assumption that he or she will not reach the next relevant trigger: eg that Mr S and Mr U will remain PCR negative etc. I shall assess the sums for each claimant in such a way I hope, that, particularly as the lead claimants have been so well chosen, there will be assistance in quantifying the claims of others. However, I do not consider it helpful or appropriate to give a bracket of damages, as was at one stage canvassed, but not, I think in the end vigorously insisted upon by Mr Brooke.

[214] *Biopsies etc.* (i) Mr Brooke invites me, and the defendants do not oppose this in principle, as I have indicated, to put a separate figure on past and future biopsies. This is not an easy task, as neither side has been able to find any relevant authorities. Mr Brooke has taken me to examples in *Kemp and Kemp* of minor injuries, but I accept Mr Underhill's submission that, where there has been some minor accident or assault leading to minor injuries, and requiring compensation, that cannot, being the totality of the claim in the particular case, be of much help in relation to a case where there is a much larger claim, one of the incidents of which is the need for occasional hospitalisation. Given the relative rarity of the compartmentalisation of damages for which Mr Brooke contends, it is perhaps not surprising that there are no precedents that either side can find. A hospital visit is planned and expected and, in the case of biopsy, is short or relatively short, and does not carry with it the trauma, minor though it may be, of an accident or assault. The figures which he showed from *Kemp and Kemp* were for minor injuries, resulting in cuts, bruises, discomfort or nervous reaction for up to a week or so, for which in the region of £500 or so has been awarded for the totality of the incident: the valuation of the biopsy is, however, collateral. In valuing the biopsies, obviously it is necessary to bear in mind the particular circumstance relating to the individual claimant: whether it was a short visit, whether the claimant remained overnight, whether there was or was not general anaesthetic and whether there was more than usual pain or discomfort. As for future biopsies, an assessment must be made whether the particular claimant will require any, and if so how regularly. (ii) Evidence was given both about further biopsies, and indeed about follow-up treatment generally, which it seems appropriate to deal with now, as a matter of general application. (a) With regard to follow-up, evidence was given by Dr Ryder, in cross-examination by Mr Brook Smith, by reference to the circumstances of Mr S, one of the lead claimants who has *cleared* the virus, as follows:

> 'Q. [Mr S] is currently on annual tests. He has cleared the virus completely. Can you contemplate a time when, if his tests remain as well as

> they currently are ... there will no longer be a need even for annual tests, that he could come back for three-yearly tests or even five-yearly tests? *A.* At the moment, it is very difficult to give a definite answer to that, as our knowledge accumulates. One could say that it could be that we would be more reassured as time goes on, and therefore what you suggest is perfectly reasonable, but equally if more data becomes available such as that from the Edinburgh Group about the significance of intra-hepatic Hepatitis C, one may have to do more. I am afraid I can't really speculate on what we may do in the future. I think it is safe to say that over the next five to ten years a yearly check is likely to be required.'

Dr Ryder, however, also agreed, when cross-examined by Mr Underhill, that after another five years had gone by he might well think in terms of either discharging those who had successfully responded to treatment altogether, or at any rate making the follow-up much less frequent than annual. Dr Alexander said, in chief, when questioned by Mr Underhill about his anticipation for the follow-up regime for the next few years for those lead claimants, Mr S and Mr U, who had *cleared* the virus, as follows:

> 'I think on the current levels of evidence I would want to see those patients on an annual basis. There are several reasons: one can be checking to see if they remain PCR negative; one might also want to update them on any new information that has come around. I cannot foresee us doing that in the long term, because I do not think the majority of patients would need to be followed up in the very long term. I think what we are waiting for is strong evidence that we can allow some of these patients to be discharged from our clinic, and I think as soon as we have that we would be happy to do that ... I think we need someone to prove conclusively that a large number of patients who are PCR negative for five years never get liver disease. I suspect that evidence will come quite soon, and then we will have the confidence to do it ... I would imagine in five years we would be able to make those comments ... I think if we have a patient who is consistently negative in blood ... four or five years from now I am sure we would be able to discharge those patients, particularly when they have had liver biopsies showing no significant liver damage.'

I conclude, preferring, in so far as there is a marginal difference, the evidence of Dr Alexander, that it is highly likely that, after five years, the regularity of such check-ups of those who have been PCR negative in blood for five years will substantially reduce, such that in the calculation of any damages relating to such ongoing follow-ups in the future there must be a discount. The letter received by Mr S, who has been PCR positive for five years, discharging him from further review, quoted below, appears to support this. (b) As for biopsies, I am satisfied that they are only relevant to those who remain at present PCR positive. Dr Ryder gave clear evidence in respect of those, such as Miss T and Ms V, who suffer from mild, if any, liver condition and may hereafter have further therapy. His evidence was that if such treatment was *successful*, and the patient became and remained PCR negative after six months, then they would be treated as having *cleared* the virus and thus require no further biopsy (and Dr Alexander agreed in terms): if the treatment was *unsuccessful*, then monitoring would continue, just as if they had not had the therapy, but such patients would also

never again have to have a routine biopsy. This too therefore will be relevant in the assessment of damage for those such as Miss T and Ms V, for whom, on the assumption that they will not deteriorate to cirrhosis (covered by a trigger), there need be no provision for any further routine biopsy, if I am persuaded to decide that they will have further therapy. There may further need to be consideration of, and discount for, the availability of non-invasive alternatives to, or substitutes for, biopsies within five years or so, as set out in [201] above.

[215] *Interferon treatment.* Again I am invited separately within PSLA to assess damages for those claimants who have gone through past therapy, and also for those claimants with regard to whom I conclude there will be future therapy. As set out in [205] above, Interferon is not pleasant. It requires self-injection, and carries with it the risk, if not the certainty, of the side-effects there set out. As it happens, none of the claimants in this case has suffered from any Interferon-related depression, which I do not need separately to assess, as I would otherwise have done. However, the circumstances of each claimant need to be looked at: for what period of time they had the treatment, what side-effects they suffered, how badly affected by them they were. Mr Brooke invites me to assess a different figure in relation to therapy which has been unsuccessful as compared with that which was successful. I do not accept the logic of this. If the treatment was, and remained, successful, then of course the damages of that claimant would otherwise reduce, by virtue of the more favourable prognosis. If it was, or soon afterwards was seen to have been, unsuccessful, then the damages for that claimant will increase, because of the more unfavourable prognosis. But each of them will have gone through the same discomfort, if discomfort it was, with regard to the therapy at the time. I can see that if there is some particularly identifiable trauma arising in respect of the disappointment of a particular claimant as a result of failed treatment, then that might be separately compensable.

[216] *Future treatment.* This is relevant under two heads. The first is in respect of PSLA. If in fact there is the chance of future treatment, then that may impact upon the general damages. (i) The prognosis of the individual claimant may take into account the chance of success of such treatment (although given the existing good prognosis for the only relevant lead claimants, Miss T and Ms V, this will not be a substantial factor in these cases) eg: (a) the prognosis may improve; (b) any continuing stress or worry may be capable of being alleviated; (c) the duration of any existing anxiety state or of fatigue, or of social 'stigma' (if applicable) etc may be shortened. Assessment of general, and indeed of any special, damages may well be affected if a shorter period than the whole of life is being looked at. I refer again to Dr Ryder's reference set out in [205] to infection with genotypes 2 and 3 almost being a curable disease. The question not only of the availability of existing or imminent therapy, but of possible improved treatments may be filtered into consideration. (ii) On the other hand there will be future discomfort from any such treatment to be allowed for, as mentioned in [215] above.

[217] There is then the fact that there is a separate head of damage sought by the relevant claimants in respect of the cost of future treatment. What is said by the relevant claimants is that, insofar as they have not yet for any reason attempted, or have previously attempted but failed, combination therapy or in particular pegylated combination therapy, they should be compensated by the defendants in respect of the cost of such therapy, as and when appropriate in the future. There are three issues. (i) Is it reasonable for such treatment to be

provided for in respect of a claimant? That would be a question of assessment of the medical evidence. It would seem to me not to be reasonable if medically contra-indicated, as it is suggested to be for example in the case of Mr W, or if it were pointless (or a combination of the two). (ii) It will not be recoverable unless the court is satisfied that in fact the treatment will be taken by the claimant. That may to an extent be only a refinement of (i), for if it were contra-indicated medically, it would be unlikely that it would be taken by a claimant: and certainly in the case of unpleasant treatment, such as Interferon, it might be unlikely that it would be attempted if it were clearly pointless. (iii) The third question is whether such treatment, if to be attempted by a claimant, will be provided and accepted on the NHS, and therefore not be required to be paid for by the claimant (and hence not claimable from the defendants). There is in the event no issue between the parties as to the law in this regard, although Mr Brooke did make reference in opening to the Law Reform (Personal Injuries) Act 1948, s 2(4) (as amended), whereby 'In an action for damages for personal injuries ... there shall be disregarded, in determining the reasonableness of any expenses, the possibility of avoiding those expenses or part of them by taking advantage of facilities available under the National Health Service Act 1977'. The relevant question is, as both parties have accepted, more by reference to *Harris v Brights Asphalt Contractors Ltd* [1953] 1 QB 617 at 635 per Slade J 'I do not understand section 2(4) to enact that a plaintiff shall be deemed to be entitled to recovery of expenses which in fact he will never incur' and *Cunningham v Harrison* [1973] 3 All ER 463 at 474, [1973] QB 942 at 957 per Lawton LJ 'the defendant cannot say that he could avoid that expense by falling back on the National Health Service ... What she can, however, submit is that he will probably not incur such expenses'. I accept Mr Underhill's submission that, if in fact the pegylated therapy is available on the National Health Service at the time when the relevant claimant seeks to take advantage of that treatment, and it is available to him within the NICE guidance, then it is likely that he will indeed accept that treatment on the National Health Service rather than seeking to pay for it himself, which would, whatever might be the case in other circumstances, gain him nothing in this case, as confirmed on the evidence.

[218] But the issue is rather whether, at the material time, pegylated combination therapy will indeed be so available, given that, at this stage, even pegylated monotherapy is not yet available within the NICE guidance. It will be a matter for consideration in each case whether I conclude, given the relevant time scale, that pegylated combination therapy will be so available within the NICE guidance. My conclusion is that it is likely within two to three years to be so available. However, it is quite a different and additional question as to whether a particular claimant is likely to qualify within the NICE guidance for such treatment. For example, it would seem to be common ground that, for differing reasons, none of the lead claimants, as things stand at present, would qualify within the existing guidance. That will have to be looked at in relation to each claimant: and of course there is the further element, which again will have to be considered in relation to each claimant, as submitted by Mr Underhill, namely that it may be that in relation to some, or even all such claimants, the only circumstance in which they will seek combination therapy, given its unpleasantness, will be if an existing acceptable condition and prognosis were to deteriorate, rendering it advisable or desired to have such therapy. In that case such claimant would then be likely to qualify within the guidance. However,

Mr Brooke's case in relation to the existing lead claimants is that the desire of those such as Ms V to have such therapy in the future is not conditional upon any change in their condition, but simply because, in her case for example, she has not until now felt able to take on the treatment, given her other family responsibilities, but believes that she will in the future wish to do so.

'Stigma' or handicap

[219] Use has been made in the course of opening and closing submissions of the word 'stigma'. It falls into three areas: 'social stigma', 'employment stigma' or 'insurance stigma'. I do not see them as similar, and the word itself seems to have crept into play by analogy to 'stigma damages' as coined in respect of the entirely different case of *Malik v Bank of Credit and Commerce International SA (in liq), Mahmud v Bank of Credit and Commerce International SA (in liq)* [1997] 3 All ER 1, [1998] AC 20. As for 'social stigma', what this is said to relate to is to possible prejudice suffered at the hands of others—and there is some evidence in relation to the lead claimants in relation to the experience of some of them with boy- or girlfriends or their families or with dentists—as a result of their Hepatitis C condition. There is of course no need or justification whatever for such 'stigma' or prejudicial treatment as: (i) there is a distinct and sad interconnection between Hepatitis C and drug use, but none of the claimants, all of whom are the innocent victims of blood transfusions, can or should in any way be associated in that regard; and (ii) the reality, I suspect, is that the prejudice towards, and such treatment of, the claimants insofar as it occurs, results not from any disapproval, justified or otherwise, but from fear. The sooner that there is education about, and familiarity as to, the condition of the 200,000 to 400,000 Hepatitis C sufferers in this country, and it is understood that in fact there is almost no risk of horizontal transmission from them, and that they are likely to be around, unchanged and almost completely non-infective for another 50 or so years, the better.

[220] If, however, unless and until there be such education and familiarity, any claimants can establish the suffering, past or future, of some slight or prejudice arising out of their Hepatitis C condition, then that can and must form part of their PSLA 'infection simpliciter' damages. In any event I would prefer to call it 'social handicap' than 'social stigma'. 'Employment stigma' is, however, completely different. Although it was submitted by Mr Brooke, in his opening, that this amounted to a different head or type of damage from *'Smith v Manchester'* damages, in the event he accepted—and Mr Underhill did not contest otherwise—that it was simply an exemplification of that head of damage. If it can be established, in a particular case, that a claimant is less likely to obtain, or more likely to lose, employment because of his or her Hepatitis C condition, then that is not 'employment stigma' or, at any rate, is better described as 'employment handicap' or 'loss of earning capacity'. Finally 'insurance stigma'. This is even less a question in my judgment of 'stigma', as the loss, if it can be shown, does not seem to arise out of some act of personal prejudice, but arises, if it does arise, out of underwriting judgments, which may be misguided (and, if so, it is to be hoped that this case may further educate them) or may be inevitable, for actuarial or other reasons. Thus 'insurance stigma' is plainly not so, but also should rather be described as 'insurance handicap' or 'loss of insuring capacity'.

Employment handicap

[221] In my judgment it is clear that the case that is put forward is not different from a *Smith v Manchester* case, although in relation to some claimants it may not be the normal such case, where a claimant is in employment and is fearful of losing such employment and being left handicapped on the labour market. (i) It is not an essential prerequisite in a *Smith v Manchester* claim that the claimant must, at the date of trial, be in employment. A dictum to that effect by Browne LJ in *Moeliker v A Reyrolle & Co Ltd* [1976] ICR 253 at 261 was corrected by the judge in the reports of that judgment in [1977] 1 All ER 9 at 15, [1977] 1 WLR 132 at 140, and was then recited by him in the subsequent case of *Cook v Consolidated Fisheries Ltd* [1977] ICR 635 at 640, so as to read 'this head of damage generally [corrected from only] arises where a plaintiff is at the time of the trial in employment'. Other cases were cited by Mr Brooke in which the claimant was not in employment at the time of trial, including *Mitchell v Liverpool AHA* (1985) Times, 17 June, [1985] CA Transcript 228 (*Kemp and Kemp* 6-611) and *Goldborough v Thompson and Crowther* [1996] PIQR Q86. (ii) Where the employee is not in employment, there is no need for the two-stage approach to risk of loss, namely the risk of losing the present job followed by subsequent risk on the labour market, but there is simply one test, whether there is a real risk of loss at some stage on the labour market—which need not apply to any particular employment. Of course it will be necessary to show that the difficulty in earning employment relates to an employment which, but for the Hepatitis C, the claimant would have hoped or expected to attain. (iii) As there is no established loss, but simply evidence of a risk of potential loss, the claim cannot be specifically quantified, but is in respect of a loss of earning capacity (see *Foster v Tyne & Wear CC* [1986] 1 All ER 567). Such loss must be calculated 'in the round' (*Smith v Manchester Corp* [1974] 17 KIR 1 at 8) or 'plucked from the air' (*Moeliker v A Reyrolle & Co Ltd* [1977] 1 All ER 9 at 19, [1977] 1 WLR 132 at 144 per Stephenson LJ).

[222] There must be evidence of such handicap or loss of earning capacity from which such rough and ready estimate of the loss can be arrived at. It has to be said that (and this is perhaps fortunate) not much has been found. Mr Langman was very frank:

> 'It is recognised that proving stigma is by no means an easy matter and the existence of stigma in relation to Hepatitis C and its impact on an individual's current and future job prospects must be a matter for the courts to decide on the basis of the available evidence. The results of this research suggests that the majority of [claimants] to date do not appear to have experienced discernible disadvantage in the labour market, and, whilst there may be specific examples amongst the sample of [claimants] who may be adjudged to have been disadvantaged, this could be due to any number of other factors, such as the individual's background and skills, qualifications and experience, the level of competition for the jobs applied for, the individual's age and, in some cases, any previous medical history.'

Any question of prejudice or bias against those with Hepatitis C in the employment field must, of course, be set against the existence of the Disability Discrimination Act 1995. Such prejudice would be irrational (unless grounded on genuine fear as to hygiene or the risk of horizontal transmission, which would appear either to be extremely unlikely or at any rate to be capable of being easily resolved and coped with) and possibly illegal. The area of real concern would

seem not to be in respect of dismissal from existing jobs but the difficulty of obtaining new jobs, and there are said to be some examples of such problems in the cases of Mr S, Miss T and Ms V. Mr Langman, at the end of the day, appeals to what he calls common sense: 'It is also suggested that common sense has regularly prevailed with the courts recognising that if two people go for a job, and are otherwise equal applicants, if one has a possible investigatible blemish in their history, then [he/she is] unlikely to be the selected candidate.' There is some anecdotal evidence given by Mr Langman, drawn from his questionnaires, which is of doubtful admissibility or reliability, although I pay it some regard because it is evidence that could have been called (albeit it would then have been cross-examined), and there is some general opinion about risk, loss or prejudice to those with Hepatitis C drawn by Mr Brooke from Professor Zuckerman and Dr Ryder. Mr Langman also throws out the possibility that those with Hepatitis C may be regarded as less satisfactory employees, either because they may be suffering from fatigue or lethargy or because they may be absent from work due to medical attendance or treatment. At the end of the day—(i) There is no question of any automatic claim to damages for employment handicap or stigma by a claimant affected with Hepatitis C. Evidence either from the claimant or factual witnesses or by way of expert opinion must be called in each case. (ii) The most significant evidence of any risk would be in the event of there being a risk of any 'rational' objection by a potential employer rather than an 'irrational' one: but Mr Langman, though he leaves the door open, and emphasises the need for precautions, states that 'ostensibly there is no reason why an individual with Hepatitis C should not continue working in, or apply for, jobs involving food-handling/catering, hairdressing or teaching'. (iii) The particular circumstances of each claimant must be looked at, relative to the person, his or her age or stage of life, his or her stage and type of employment. Plainly, direct evidence is not necessary, but inferences may be sufficient.

Financial products/insurance handicap

[223] This is an allegation of loss, as discussed in [219] above, of a different kind. (i) It may have already been suffered prior to the hearing—and such a case is made out in respect of Ms V. In so far as not yet suffered, I do not see the difference in principle and do not regard it as in any way a revolutionary new head of loss (although no previous examples have been drawn to my attention). Mr Underhill in any event did not seek to submit that it was objectionable in principle, but simply that, with the exception of Ms V's past loss, no loss was established on the evidence. (ii) It is necessary for the purpose of the claim to identify the specific area of additional expense or loss resulting from the unavailability, or more restricted availability, of financial products. It will be important, for example, not to allow such a claim to be a substitute for, or a duplication of, a lost years claim, by way of an inability to recover life insurance. (iii) There must be evidence of the fact that a product would otherwise have been sought and obtained by a claimant—eg a mortgage would perhaps have been unlikely in the case of one who had no intention to purchase private housing (see the evidence of Mr Brimblecombe that applications for mortgages to buy houses have slowed down since the 1980s) and life assurance would not necessarily be taken out by everybody (again I note Mr Brimblecombe's view that only some 30% of the adult population actively sought to make such arrangements). (iv) There must further be evidence that such products, if sought

by the relevant claimant, would not be available or would be available only at a disadvantage to the claimant. The products which have been canvassed by the experts in this case include life insurance (term or whole of life), critical illness cover, permanent health insurance, private medical insurance, mortgage protection, unemployment insurance, travel insurance, and internal private or public company insurance benefit or pension arrangements. So far as the last is concerned, the issue is particularly speculative, because much may depend upon whether the company in question, or its insurer or pension fund, does, or does not, insist on the filling out of medical information in respect of existing or any employees. Travel insurance is also much more speculative, not least in the light of the fact that a number of the claimants in this case (all those, I think, who have wished it) have been successful in obtaining it, and there is, it seems, a real marketing opportunity for sensible travel insurance companies: like Prudential, which was prepared to offer unconditional travel cover to Mrs X. However, in general in relation to such products, the question will be whether such cover was, or was not, available on the same terms that it would have been if the claimants had not suffered from Hepatitis C, which they would of course be obliged to disclose in any application. The various possible answers would be unchanged cover; no cover; less benefit; higher premiums; special terms; unavailability of automatic increase in benefits or of waiver of premiums. (v) Once again, as with 'employment handicap', this loss, if established in a particular case, is one difficult to quantify and must be seen 'in the round'. Mr Asif, on the claimants' behalf, skilfully drew attention to Mr Purdy's evidence about likely standard premiums, to exemplify what a loaded premium might entail, but this could only be part of a hypothetical exercise.

[224] I have had the benefit of very helpful evidence from the three experts, and particularly the joint report referred to above. I shall have to make my mind up in relation to each specific claimant. However, the following appear to me to be general points to be made. (i) As set out in [220] above, this does not seem to me to be a matter of stigma or irrational prejudice. Underwriters are entitled to make their own judgments. It will be extremely important to make sure that such underwriters are fully educated generally about Hepatitis C, and informed in particular as to the individual circumstances and prognosis of an applicant. (ii) Some insurance and financial service companies are already more aware both of their obligations and their opportunities in this area, as is clear from the evidence by our experts. In particular it would seem that a compassionate and realistic and educated view has been taken by Norwich Union and Sun Life, and to some extent also by Swiss Re, M & G, and Medicals Direct, and, Ms Daniels also told the court, by Allied Dunbar. It is to be hoped that those and other companies, and other underwriters like Mr Brimblecombe and Mr Purdy, are now becoming more educated about Hepatitis C, so that they will be able to take sensible economic judgments and still provide financial products to those with Hepatitis C. Ms Daniels is no doubt not alone in being an IFA who has the specific expertise to help those such as Hepatitis C sufferers to obtain satisfactory insurance. It is plain that with what was called a 'cushioned' approach, ie an approach to a particular and sufficiently senior person at a relevant insurance company or underwriters, with the right amount of information, an application is more likely to succeed. (iii) Though Ms Daniels was less sanguine, Mr Brimblecombe was relatively confident of an improvement in the position:

> 'This is something which is new ... and there is not too much experience of Hepatitis C. Clearly the life assurance industry and underwriters are careful and therefore decisions generally on these issues are taken at a high level. Insurance companies ... once they get a broader experience of Hepatitis C may take a different approach.'

There also seems to me room for a more sophisticated approach from insurance companies, for example by doing what they apparently do not do at present, namely giving cover, for example in respect of critical illness or health, with exclusions in respect of Hepatitis C; this must surely occur, or occur more frequently, once the insurance industry appreciates that, unlike the position in HIV where there are so many interrelated illnesses, with the exception of the very rare extra-hepatic conditions to which I have referred in [194] above, all the complications resulting from Hepatitis C relate to the liver.

[225] Subject to all the above, however, the evidence from the experts was clear. A Hepatitis C sufferer is at present only likely to obtain cover on normal terms if he or she has cleared the virus for at least two to three years. In any other case with chronic infection, even with mild symptoms, cover is only likely to be obtained subject to a substantial loading, with no mortgage protection or critical illness or private health insurance cover.

The provision of gratuitous services

[226] Such a claim arises primarily in the case of Mrs X (though also of Mr S and Mr U), but I consider it at this stage in general terms, since two issues are raised by the parties for decision which will be of general impact. (i) If, as in the case of Mr X, Mrs X's husband, a spouse has given up work, can he claim, in lieu of the commercial cost of care, his loss of earnings, benefits and pensions (in excess of such costs)? (ii) If the appropriate basis of recompense be commercial cost, does there fall, in respect of provision by a loving spouse of household or nursing services, to be a deduction from such commercial cost (in this case not suggested by the defendants to be more than 25%)?

[227] *Housecroft v Burnett*. Although not of course the first decision in this area of recompense for gratuitous services (e g *Cunningham v Harrison*, *Donnelly v Joyce* [1973] 3 All ER 475, [1974] QB 454), the central starting point is of course *Housecroft v Burnett* [1986] 1 All ER 332. The seminal passages are those in the judgment of O'Connor LJ (at 342–343):

> 'Where the needs of an injured plaintiff are and would be supplied by a relative or friend out of love and affection (and, in cases of little children where the provider is a parent, duty) freely and without regard to monetary reward, how should the court assess "the proper and reasonable cost"? There are two extreme solutions: (i) assess the full commercial rate for supplying the needs by employing someone to do what the relative does; (ii) assess the cost at nil, just as it is assessed at nil where the plaintiff is cared for under the national health scheme ... Very often we find rates being agreed and, as is shown by the approach of the judge in the present case, regard is had as to what it would cost to buy the services in the open market, but it is scaled down ... Once it is understood that this is an element in the award to the plaintiff to provide for the reasonable and proper care of the plaintiff and that a capital sum is to be available for that purpose, the court should look at it as a whole and consider whether, on the facts of the case, it

is sufficient to enable the plaintiff, among other things, to make reasonable recompense to the relative. So, in cases where the relative has given up gainful employment to look after the plaintiff, I would regard it as natural that the plaintiff would not wish the relative to be the loser and the court would award sufficient to enable the plaintiff to achieve that result. The ceiling would be the commercial rate. In cases like the present I would look at the award ... and ask: is this sufficient to provide for the plaintiff's needs, including enabling her to make some monetary acknowledgement of her appreciation of all that her mother does for her? I would also ask: is it sufficient for this plaintiff should her mother fall by the wayside and be unable to give as she gives now ... The court is recognising that part of the reasonable and proper costs of providing for the plaintiff's needs is to enable her to make a present, or series of presents, to her mother. Neither of the extreme solutions is right. The assessment will be somewhere in between, depending on the facts of the case.'

The claimants' submissions

[228] Mr Brooke effectively submits as follows. (i) There is no binding rule of law, notwithstanding that passage from O'Connor LJ, that the commercial rate is the ceiling. Stuart-Smith LJ, in *Fish v Wilcox and Gwent AHA* (1993) 13 BMLR 134 at 138, said:

'If the plaintiff had had to give up highly paid work in order to look after her daughter, then no doubt she would have recovered that figure by way of loss of earnings, rather than the figure which the judge in fact assessed, subject, as O'Connor LJ said in the *Housecroft* case, to the ceiling, being the cost of providing professional care. It may that if the plaintiff's earnings had been slightly in excess of the cost of providing professional care, it would nevertheless have been reasonable for her to give up that employment to look after her child ...'

In *Lamey v Wirral Health Authority* (22 September 1993, unreported), a first instance decision of Morland J, reported only in *Kemp and Kemp* (A4-026), Morland J said: 'I do not understand O'Connor LJ as meaning that [sc the ceiling of the commercial rate] is a rule of law but that as a guideline it is an upper limit. It will be particularly an upper limit in cases of routine care of the physically or mentally disabled by a carer with professional qualifications'. (ii) The award must, as Morland J also said in *Lamey*'s case, be assessed 'not only quantitatively but also qualitatively', and care by a loving spouse is just as valuable as that by a commercial carer, but provides additional value by way of love and support. Mr Brooke, referring to the case of Mrs X, submitted in closing as follows:

'What you have is ... Mrs X being looked after by her husband, from clearly a long and strong marriage, who is her best friend, who knows her inside out, who can meet her needs before she actually expresses them, who knows the house backwards, who knows the family; and so the quality of the care she is given by him is clearly far better than the quality of care she would get from a series of day nurses.'

(iii) Where it is in those circumstances reasonable for the loving spouse to have given up work, the recompense is restitution of the loss so caused to the spouse.

In the case of Mr X this is claimed as his loss of earnings, his loss of pension and his loss of a tax-free cash sum to which he would otherwise have been entitled had he remained in employment. (iv) If (contrary to the claimants' submission) it is not appropriate to reimburse the lost earnings and benefits, but to adopt the cost of commercial care, then in the light of the authorities it is neither necessary in law to make any deductions nor, if deductions be made, to deduct 25%. In *Lamey*'s case a sum of apparently more than the commercial rate was awarded to the plaintiff's parents, in *Housecroft*'s case itself the reduction was not expressed in a percentage, but can be calculated out at about 18%, and in *McCamley v Cammell Laird Shipbuilders Ltd* [1990] 1 All ER 854, [1990] 1 WLR 963, a deduction equivalent to 14% was not disturbed by the Court of Appeal. (v) In *Biesheuvel v Birrell* [1999] PIQR Q40 at Q43, Eady J was not satisfied that a distinction could be very readily drawn between 'companionship' and 'care' and, in a case where the claimant himself was contending for a 25% discount and the defendants for a greater one, he took account of the 'level and intensity of the care required' especially by the mother of the plaintiff, who was a tetraplegic, in accepting the 25% discount contended for by the claimant.

The defendants' response

[229] Mr Underhill responds as follows. (i) The logic of *Housecroft*'s case is quite clear, that the 'extreme solutions' (full commercial costs on the one hand and nothing on the other) are normally both inappropriate. (ii) *Fish*'s case makes clear (at Court of Appeal level) that if there is any flexibility in O'Connor LJ's ceiling, it is a minimal one. (iii) The test for recovery of a sum for reimbursement of gratuitous care is of reasonable recompense: thus per Megaw LJ in *Donnelly v Joyce* [1973] 3 All ER 475 at 480, [1974] QB 454 at 461–462 'the proper and reasonable cost of supplying those needs', in *Housecroft v Burnett* [1986] 1 All ER 332 at 343 per O'Connor LJ 'reasonable recompense to the relative' and in *Hunt v Severs* [1994] 2 All ER 385 at 394, [1994] 2 AC 350 at 363 per Lord Bridge 'the reasonable value of gratuitous services rendered to him by way of voluntary care by a member of his family'. (iv) In *Lamey*'s case the care given was recognised as having been extraordinary (per Morland J):

> 'The many many hours of care for her over more than eleven years ... I have no doubt, have caused Mr & Mrs Lamey real and significant distress. Care and supervision have been required day and night. Not surprisingly through broken sleep, worry and anxiety Mr Lamey has been fatigued and unable to concentrate and put as much into his business as he had done before Elizabeth's birth. Mrs Lamey has been depressed and required medication ... Both [experts] found it difficult to suggest what was suitable recompense for Mr & Mrs Lamey's care for Elizabeth at night, which involved putting her back to sleep several times a night, and most nights having to change her bedding when wet ... Miss Smalley's figure of £42,982, did not take into account night care. Both Miss Smalley and Miss Buckle did not regard a paid sleeper's rate, currently £25 per night, as appropriate for parental nightcare. With that view I agree.'

Even in that case Morland J rejected a claim based on alleged loss of profit in Mr Lamey's business as a proper basis for the cost of care; and it was in those circumstances that the sum awarded was slightly over the outsider's rate—but a rate which the judge, and the experts, clearly thought was *not* commercially

appropriate. (v) In *McCamley v Cammell Laird Shipbuilders Ltd* [1990] 1 All ER 854 at 857, [1990] 1 WLR 963 at 966–967, although the Court of Appeal left the judge's award unaltered, O'Connor LJ said as follows: a

> 'The defendants say that the judge has applied the full commercial rate and that we should interfere and reduce it, perhaps by half. The judge has in fact reduced the amount suggested by Mrs Watkins by some £4,000. We confess that we regard the judge's assessment as very high. On the other hand there is no doubt that, certainly in the early stages, a very great burden was put on Mrs McCamley ... The present case is near the bone but the judge has made some reduction and we do not feel it would be right to interfere.' b

(vi) The substantial justification for the deduction from the amount that is actually charged for commercial care, on the evidence of experts, is in respect of tax and national insurance, which is of course not paid to or in respect of a gratuitous carer. This is well established, but is particularly clear from *Fitzgerald v Ford* [1996] PIQR Q72 (a case in which a claim based on loss of earnings was rejected), where Stuart Smith LJ indicated: '... the gross cost of employing a carer. Obviously ... is not the relevant figure. It should be the net cost, which, after a reduction of 25 per cent for tax and national insurance, comes to about £82,000.' c d

[230] I accept the submissions of Mr Underhill, and am satisfied that the following is the position. (i) The appropriate question is reasonable recompense for the carer. The carer is, however, not the victim of the tort, and is not entitled to his or her own claim for reimbursement of loss caused by all and any reasonable steps taken in mitigation or in consequence. The claimant is the victim; and the issue is what is reasonable to pay for his or her care to the gratuitous provider of such services. (ii) It is clear that the care given by a loving spouse may be additionally supportive, and may be preferable from some points of view to outside qualified care: it may also involve considerably more dedication, concentration and effort than would, on the facts of a given case, be given by an outsider. It is plainly right that the services must be valued qualitatively as well as quantitatively. However, the kind of services that are indicated in *Lamey's* case, or indeed in other cases involving care for an extremely physically handicapped or mentally handicapped claimant, fall into such a category. There is no authority relied upon by the claimants which would support the proposition, nor in my judgment is it the case, that simply giving to a claimant the same services, but with greater affection, would justify payment over and above commercial cost. (iii) The justification for the discount is substantially the saving of tax and national insurance (although there may be additional justification for discounts, if, for example, the level of the care is inevitably less than a commercial cost because of the absence of special qualifications possessed by a commercial carer). If such discount is not allowed for, then the recipient is receiving, by way of a gross sum including provision for tax and national insurance for which he or she will not in fact have to account to the Revenue, that amount *more* than the cost of commercial care. (iv) In *Nash v Southmead Health Authority* [1993] PIQR Q156, a deduction of one third of the commercial rate was made by Alliott J in respect of care provided by the plaintiff's parents in respect of dressing, bathing and eating. In *Fairhurst v St Helens and Knowsley Health Authority* [1995] PIQR Q1 at Q4, Judge David Clark QC made a 25% deduction, rather than a one-third deduction, because 'caring for [the e f g h j

plaintiff] undoubtedly involves special skills over and above those normally possessed by Crossroads assistants or nursing auxiliaries'. In *Petrovska v Mullings* (13 August 1999, unreported) I concluded 'that there ought to be a discount of one third, which is or has become the norm for discount from the commercial rate, save where special skills are required (and allowing for the absence of incidence of tax or national insurance)'. On that basis, if a 25% deduction is adopted, which is all that in this case the defendants contend for (the defendants in *Biesheuvel's* case having contended for a greater discount), then there is already a slight uplift to allow, if not for special qualifications, then for extra love and support; although, as pointed out in the course of argument, love and support must be the inevitable basis of the provision of almost any gratuitous services that can be contemplated, so, if material, it would follow that it would be likely to apply in every case.

[231] In the absence of any special evidence of any exceptional circumstances, I conclude that the proper recompense for gratuitous services in these cases will normally be commercial cost, less a deduction to allow at least for tax and national insurance, which in this case is conceded to be no more than 25%; and that it is not appropriate to allow recovery in respect of loss of the gratuitous carer's earnings or benefits of more than that amount.

Discount rate

[232] The final point of general interest raised by the claimants in respect of quantum was Mr Brooke's contention that, notwithstanding, or in the light of, the decision of the House of Lords in *Wells v Wells, Thomas v Brighton Health Authority, Page v Sheerness Steel Co plc* [1998] 3 All ER 481, [1999] 1 AC 345, and notwithstanding the absence of any exercise by the Lord Chancellor of his powers under s 1 of the Damages Act 1996 to set a rate, I should adopt, for the purpose of calculation of the multiplier in respect of future loss, a discount rate of 2%, rather than the 3% adopted by the House of Lords. I dealt at a little length with a similar submission made by counsel for the claimant in *Petrovska's* case, in that case allowing the belated admission of what was, in the event, agreed actuarial evidence in support of such contention, and rejected it. Although my decision in *Petrovska's* case was not appealed, there has subsequently been a binding decision of the Court of Appeal in *Warren v Northern General Hospital NHS Trust (No 2)* [2000] 1 WLR 1404, which firmly concluded that there were no grounds in law, and in any event none in fact, to alter the discount rate of 3% set in *Wells v Wells*. In the event that I had entertained Mr Brooke's submission, Mr Underhill indicated that he would have sought to adduce evidence in opposition to the belated evidence to be adduced by Mr Brooke. I indicated that there was no need for him to do so, as I rejected Mr Brooke's contention. In those circumstances, the position of both sides is preserved so far as concerns any appeal: but I shall continue to adopt the 3% rate, for the reasons given both by me in *Petrovska's* case and more conclusively by the Court of Appeal in *Warren's* case.

ISSUE VI: THE SIX LEAD CASES

[In **[233]**–**[283]** his Lordship considered and resolved the outstanding issues of quantum in the six lead cases. He continued:]

JUDGMENT

[284] I wish to conclude by giving my thanks to solicitors and counsel for their considerable help in relation to the achievement of a full, but also expeditious,

hearing of this action, and for the efficiency and completeness of the evidence adduced and of their submissions; to the expert witnesses for the clarity of their information and exposition; to the transcribers from Livenote, whose dedicated concentration and expertise, in dealing with often complicated legal and technical evidence and submissions, provided 49 superlative daily transcripts, which made my work very much easier; and finally to my clerk for her long hours of enthusiastic and conscientious preparation of the transcript of this judgment. For the reasons set out at length during its course, I give judgment for the claimants on the issues before me. So far as concerns the individual lead claimants, an order will need to be drawn up, in compliance with CPR 41.2(2), and containing the triggers for provisional damages which I have set out in [211]: including, in respect of each lead claimant, the amounts reflecting the conclusions which I have reached, some of which require some arithmetical calculation by counsel, together with the various sums which the parties had agreed in respect of each claimant, and which therefore did not need to form part of my judgment: and with appropriate allowance for the settlement agreement in respect of Mr S and Mr W.

Order accordingly.

Alexander Horne Barrister.