Case No: 1998 A458

IN THE HIGH COURT OF JUSTICE
QUEENS BENCH DIVISION

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: Monday 26 March 2001

Before:

THE HONOURABLE MR JUSTICE BURTON

A AND OTHERS	**Claimant**
- and -	
THE NATIONAL BLOOD AUTHORITY AND OTHERS	**Defendant**

Michael Brooke QC, Stuart Brown QC, Ian Forrester QC (Scotland) and Jalil Asif (instructed by **Deas Mallen** for the Claimants on generic issues, and instructed by **Deas Mallen, DMH, Evill & Coleman, Freeth Cartwright,** and **Howard Cohen & Co** on lead cases)
Nicholas Underhill QC, Philip Brook Smith and Louise Merrett (instructed by **Davies Arnold Cooper** for the Defendants)

JUDGMENT: APPROVED BY THE COURT FOR HANDING DOWN (SUBJECT TO EDITORIAL CORRECTIONS)

Mr Justice Burton:

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 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, being a Council Directive of 25 July 1985 ('the Directive'). 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 European Court 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 European Court dismissed that application, it is apparent from the judgment of the European Court, reported as European Commission v United Kingdom ('Commission v UK') [1997] AER (EC) 481, that, there not at that stage having been any decisions of the English courts, nor indeed any facts before the European Court, the European Court 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 Section 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, insofar 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 Article 6 of the Directive (the equivalent being Section 3 of the CPA) and Article 7(e) (the equivalent being Section 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 fourteen 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 No. 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 No. 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, i.e., 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 Section 3 (Article 6) and not exonerated within Section 4(1)(e) (Article 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, insofar 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 nineteen 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 fourteen 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 paragraph 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 Corporation ('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. Insofar 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 life-style 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 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, e.g., 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 UK 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 UK Advisory Committee on Virological Safety of Blood ('ACVSB'), and the UK 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 UK 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.

iii) it is not sought to be alleged (at least not in this trial) that the UK 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.

iv) that it left an escape clause [in those Community jurisdictions, like the UK, 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 preparatoires,*' 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 nineteen 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 product 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; insofar 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 preparatoires* 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:

> *"1. The producer shall be liable for damage caused by a defect in his product.*
>
> *4. The injured person shall be required to prove the damage, the defect and the causal relationship between defect and damage.*
>
> *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.*
>
> *6.2 A product shall not be considered defective for the sole reason that a better product is subsequently put into circulation.*
>
> *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; ...

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.

8.2 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 him the injured person is responsible.

9. For the purpose of Article 1, 'damage' means:

(a) damage caused by death or by personal injury ...

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

15.1 Each Member State may ...

(b) by way of derogation from Article 7(e) maintain or ... provide in its legislation that the producer shall be liable even if he proves that the state of scientific or 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, Iman Abouzaid v Mothercare (UK) Ltd 21 December 2000 ['the Cosytoes case'] and one a decision of Ian Kennedy J, which has been reported (Richardson v LRC Products Ltd [2000] Lloyds (Med) 280 ['Richardson']: 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 Articles 6 and 7(e) of the Directive (respectively sections 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 European Court. 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* edited by Professor Howells ['Butterworths *Product Liability*'].

18. The most authoritative consideration of the CPA has of course been in the case of Commission v UK, to which I have referred in paragraph 2 above, and that was consideration in principle, not by reference to the facts of any case, and directed specifically to Article 7(e) (and Section 4(1)(e)). As I have set out in paragraph 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's 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 paragraph 16 above. Section 4(e) of the CPA as enacted is as follows (I underline 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 European Court that the UK Government had not done so. The European Court 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. At 490h, paragraph 25, the Advocate General (Tesauro) stated in his Opinion:

> *"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 Section 4(1)(e) of the [CPA] contains an element of potential ambiguity: insofar 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."*

20. After its own analysis of Article 7(e), the European Court concluded, at 495g - 496d, paragraphs 32-39:

> *"32. The Commission takes the view that inasmuch as s4(1)(e) of the [CPA] refers to what may be expected of a producer of products of the same description as the product in question, its wording clearly conflicts with Article 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 insofar as it selectively stresses particular terms used in s4(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 Article 7(e) of the Directive would clearly not be achieved in the domestic legal order.*
>
> *34. First s4(1)(e) ... places the burden of proof on the producer wishing to rely on the defence, as Article 7 of the Directive requires.*
>
> *35. Second s4(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.*
>
> *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 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 the United Kingdom, if called upon to interpret s4(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 Article 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, that, having regard to its general legal context and especially s1(1) of the Act, s4(1)(e) clearly conflicts with Article 7(e) of the Directive. As a result the application must be dismissed."*

21. Although the UK Government has not amended Section 4(1)(e) of the CPA so as to bring it in line with the wording of the Directive, there is thus binding authority of the European Court 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 Article 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 Section 3 of the CPA which implements Article 6, although it may be worth pointing out that the words in Article 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"* (s3(2)(a); and that the words with which s3(2) ends are perhaps a cogent way of expressing Article 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 Sections 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 Article 6 and the Defendants have no escape within Article 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 Article 6. I shall also make sufficient findings to resolve any factual issues under Article 7(e), as to which see paragraph 28 below.

27. I must then resolve the issue of the nature and measure of damages under Article 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]

    ii) on the basis of my conclusions on Issue II [Issue IIIb]

28. I must decide whether the Defendants escape any such liability under Article 7(e):

i) in the light of my conclusions on the construction of Article 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, i.e., 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)

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 Section 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 Article 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', i.e., 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 [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 Cambridge Law Journal [1988] CLJ 47(3) at 455 where, before going on to deal with Article 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 sub-paragraph, he no longer actively pursued that contention. The common ground is that the question is what the legitimate expectation is of persons generally, i.e., 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* described the Judge (as translated from the German) as '*an informed representative of the public at large*'. Mr Brown QC 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 Butterworths *Product Liability* at 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 – e.g., 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, i.e., 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 paragraph 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 Article 6, and to the public's expectation, and legitimate expectation, and on the other rules out the producers from the protection of Article 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 Article 6, and, because they were unavoidable, qualify them, if necessary, for Article 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 Article 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: 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 Article 6. Insofar 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 Article 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. Insofar 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 Article 6, then it is all the more necessary to construe Article 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 Article 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 Article 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, Article 6 provides that the Court (on behalf of the public at large) takes into account *all circumstances,* including:

i) *Presentation*, i.e., the way in which the product is presented, e.g., warnings and price. As set out above, the expanded wording of s3(2)(a) of the CPA is helpful.

ii) The *use* to which the product could reasonably be expected to be put, e.g.:

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, e.g., 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.

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 Article 6. Are they exclusive? Neither side, rightly, now suggests that they are. Indeed Mr Forrester QC, 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 *eiusdem generis*. This is asserted by Professor Taschner, the leading European expert on the Directive, in his 1990 book *Produkthaftungsgesetz und EG-Produkthaftungsrichtlinie,* at page 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 Article 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 QC, I think, did not so contend, but accepted that the *circumstances* would have to be 'relevant' circumstances. Mr Forrester QC 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* at 131 cites Professor Taschner in concluding (translated from the German) that, in relation to the Article 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 paragraph 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 Commission v UK at 488b para 17 records that the Commission's original proposal in 1976 drew its inspiration from the US model, it is clear from the *travaux preparatoires* 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. GRO-A v Overlook Hospital 317 A 2d 392 (1974) [subsequently affirmed by the Supreme Court of New Jersey]), 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 (GRO-A v McNeal Memorial Hospital 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 enquiry, 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 Article 6.2, to assert that the greater safety offered by a subsequent model was not to be held against him, pursuant to Article 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 QC'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, i.e., that such will automatically be defective within Article 6: Italy and Spain have done so by express legislation, and Dr Weber, in *Produkthaftung im Belgischen Recht* 1988 at 219-20, 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 1 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 (section 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) at page 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 at 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 (loc. cit. at 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 preparatoires*, 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 QC 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.

iii) Consequently, whatever may be the position in US jurisprudence, Article 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 one hundred 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 UK courts have responded stringently to manufacturing errors: this appears clearly from the House of Lords decision in Smedleys Ltd v Breed [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 Article 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 [the 'Danish Kidney Case'] Case C-203/99 at para 27, which has not yet been considered by the European Court). There is of course no 'blood-shield' statute in the UK.

Travaux Preparatoires

43. There is nothing much to assist in the *travaux preparatoires*, save for:

    i) The rejection of the express US approach and *risk-utility* analysis (see paragraph 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 Article 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 Article 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 Article 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 precautions by a producer is relevant, or a *circumstance*, in the context of Article 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 ten to fifteen 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 European Court 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 paragraph 30.)

i) UK. On the Article 6 issues which I have to decide, Richardson 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 (Article 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 Article 6, the claim succeeded. Chadwick LJ at paragraph 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 paragraph 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' 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 Article 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 Article 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 Article 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 GRO-A v The Foundation Sanquin of Blood Supply. 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 (paragraph 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 Article 6 (or the Dutch implementing equivalent), as follows:

> *"The Court agreed with* GRO-A *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 Article 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 the Columbia Law Review (1973) Vol 73 at 1531ff, 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 question as to whether safety standards arise for consideration within Article 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 Article 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 Article 7(e) if he had already succeeded on Article 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 47 (31) 455); in the former at 296-7 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 paragraph 31 above.

iv) Professor Stoppa of Rome University appears to do so also, in an article on the CPA in Legal Studies 1992 Vol 12 page 210, where he states at 212 (following Professor Alistair Clark of Strathclyde University, at page 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 213-217). 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 similar 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."*

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 3.019 he states: "*Strict liability is likely to have a significant impact on design defect claims. 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 paragraph at 3.023 appears not to contradict this, but simply to amount to 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 236: "*Despite the 'strict liability' rhetoric in its Preamble the Directive rarely 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 271-272. At the passage at page 236, she refers to the view of the then 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 UK by the CPA, in an article in the Tulane Law Review, Vol 62 at 353ff. The latter there opine (at 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 (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 exercise of an analogous kind"*. Professor Stapleton simply concludes at 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 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 Bielefeld University, *Produkthaftungshandbuch* (1990) at paragraphs 23-24 states as follows, in relation to the German implementation of Article 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 QC 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 Article 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 twenty 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 paragraph 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 Article 6 is on the Claimants. The Defendants submit that if the Claimants were right about Article 6, because '*unavoidability*' would not then assist them to avoid liability, Article 7(e) should certainly then be so construed as to exclude them from liability: and conversely if Article 7(e) is too limited to enable them to be exonerated, all the more should Article 6 be construed in their favour. I turn therefore to consider Article 7(e) before I reach my conclusions.

ARTICLE 7(e)

47. I repeat, for the sake of convenience at this stage, Article 7(e):

> *"The producer shall not be liable as a result of this Directive 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 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 preparatoires*; 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 'Article 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 European Court (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 any one, 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 Commission v UK at paragraphs 22-24, which, although not expressly approved in the judgment of the European Court, 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 journal and, to take an example given by the Commission, similar research carried out by an academic in Manchuria published in the local scientific journal in Chinese which does not go outside the boundaries of the region.*
>
> 24. *In such a situation, it would be unrealistic, 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 paragraph 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 was put into circulation, was not such as to enable the existence of a defect to be discovered."*

It is clear from the passage which I have already quoted, in paragraph 20 above, in paragraph 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 Article 6 should be defined as '*unscreenedness*' as discussed in paragraph 46(i) above, there is no dispute that the defect for the purposes of Article 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 Article 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, i.e., in the population of products? If it be the latter, it is common ground here that the existence of the defect in blood generally, i.e., 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 Article 7(e). It may qualify for Article 6, not because it was unavoidable (see their contentions set out in paragraph 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 Article 7(e). Hence an Article 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 Article 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 Article 7(e). As it is common ground in this case that there was such knowledge, the Defendants cannot avail themselves of Article 7(e).

ii) The Defendants say that if a risk is unavoidable, it falls within Article 6 (see their contentions in paragraph 35 above) but, if not, then it can still qualify for protection under Article 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' – i.e. 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 Article 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 Article 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 Commission v UK (to which I shall refer further below) that Article 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 Article 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 Article 7(e).

v) The knowledge in Article 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 Preparatoires

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 Article 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 paragraph

43 above, the introduction of what eventually became Article 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 Article 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 European Court of Commission v UK, although, as discussed above, it was not in terms addressing the particular issue here:

i) Commission v UK. While clarifying that the knowledge to be imputed to a producer must be accessible, i.e., not restricted within Manchuria, the European Court nonetheless 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 paragraph 20, the material part of which reads as follows:

> "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 UK Government in implementing Article 7(e), i.e., Section 4(1)(e) of the CPA, seemed clearly to suggest a much more subjective and more negligence-orientated defence than was provided for in Article 7(e); and the Advocate General, and in due course the Court, while content to give the UK 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 paragraph 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 paragraph 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, i.e., 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 QC 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 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 underlining]. 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 paragraph 20 of the Opinion is referred to, there is not specific approval by the Court of the whole of it (nor any mention of paragraph 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 UK. In Richardson, Ian Kennedy J, albeit having dismissed the claimants' claim, continued (*obiter*) to consider the Article 7(e) defence and would have rejected it. He states (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 page 23 as having concluded) that Article 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 paragraph 18 above). But, as made clear at paragraphs 39 to 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 paragraph 44(ii) above, that, in relation to the claim in respect of the exploding mineral water bottle, the Court rejected the defence under Article 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* [my underlining]. *The purpose of the* [Directive] *is merely to exclude liability for so called development risks."* 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 Article 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 GRO-A after resolving the Article 6 defence in favour of the Claimant, the County Court of Amsterdam reached a conclusion supportive of the Defendants on Article 7(e). The Court's conclusion on Article 7(e) at pages 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 Article 6, do not agree with its decision on Article 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 Article 6, which had been resolved in favour of the claimant:

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 Section 75AK(1)(c) of the Trade Practices Act 1974, which is to the same effect as Article 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'*, i.e. 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 (Lee, Lindgren, Kiefel JJ) of 9 August 2000, which was referred to by Mr Underhill QC. 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, insofar 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 the 1988 CLJ was written before the rejection by the European Court in Commission v UK of the UK 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 at 166-8 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 at 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 (loc. cit.) at 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 at 257:

> *"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."*

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) Article 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 Chapter 10 of her 1993 book, at 237. She there states, as part of her proposition, that the Directive *"rarely imposes more than a negligence regime on manufacturers"* (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 Article 6, and Article 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"* (238) and that *"the Article 7(e) defence only requires a defect to be discoverable by someone"* (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 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/Riesch *Produkthaftungsgesetz und EG Produkthaftungsrichtlinie* [(2nd Ed.) at 291] and von Westphalen loc. cit. 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 i.e., "*... 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 (loc. cit.) at 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 Article 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 paragraph 16 of the Advocate

General's Opinion in Commission v UK 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 European Court in its judgment perhaps refers implicitly to this when it states at paragraph 24:

> *"In order for a producer to incur liability for defective products under Article 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 QC 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 QC 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 QC'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'). 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 QC accepts is impermissible and what he is inviting the Court to do. As Mr Brown QC pointed out, certain of Mr Underhill QC'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] 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 twenty 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 QC would perfectly understandably submit (Day 7, page 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 twenty 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 QC 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 QC 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 Article 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 Article 7(e) in the context of consideration of Article 6. Article 7(e) provides a very restricted escape route, and producers are, as emphasised in 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 Article 6, as construed by Mr Underhill QC, 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 paragraphs 26, 36 and 38 of the European Court's judgment). This must suggest a similarly restricted view of Article 6, indeed one that is even more restricted, given the availability of the (restricted) Article 7(e) escape route. If that were not the case, then if the Article 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 Article 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 Article 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 QC 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 one hundredth.

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 QC 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 QC 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 Article 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 Article 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 Article 6 question, and the facts may be sufficiently clear. But an expert may be needed (and they were instructed in Richardson, Cosytoes and the German Bottle Case). For Article 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 Article 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 Article 7 or in respect of misuse or contributory negligence (Article 8, set out in paragraph 16 above).

67. The first step must be to identify the harmful characteristic which caused the injury (Article 4). In order to establish that there is a defect in Article 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 Article 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 Article 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 – i.e., 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 – i. e. impossibility or unavoidability in relation to precautionary measures.

ii) The impracticality, cost or difficulty of taking such measures.

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 (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 Article 7(e)) it would not only be toothless but pointless.

70. The submissions of Mr Underhill QC 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 QC 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 Article 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:

    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 Article 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 Article 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 Article 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 Article 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 Article 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 Article 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 Article 7(e), and indeed I am firmly of the view that such is not the case in Article 7(e).

ii) The analysis of Article 7(e), with the guidance of Commission v UK, seems to me to be entirely clear. If there is a known risk, i.e., 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.

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 Article 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 Article 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 Article 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 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 Section 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 Article 7(e). Non-standard products may qualify once – i.e. 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 Article 7(e).

THE RESULT IN LAW ON ISSUE I

78. Unknown risks are unlikely to qualify by way of defence within Article 6. They may however qualify for Article 7(e). Known risks do not qualify within Article 7(e), even if unavoidable in the particular product. They may qualify within Article 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 Article 4, the blood bags being concluded to be defective within Article 6, and Article 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.

ii) surrogate tests would be introduced in the UK by March 1988 and would continue until at least April 1991: continuing alongside the assay if and insofar as the assay were itself introduced prior to that date.

84. In the light of my construction of Article 7(e), and the conclusion that the risk of Hepatitis C infection was known, the Article 7(e) defence does not arise. However I must on a similar basis also nevertheless address Article 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, i.e. 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 seventy 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 thirty 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 eighteen textbooks and over one thousand 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: i.e. 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 two hundred 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 & Drug Administration ('FDA') insofar 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 thirty 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 paragraph 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 UK, 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 QC 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 QC, 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 UK 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 ("the Department") 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 UK 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, insofar 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-paragraph (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?

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 QC has laid out for me is not easy. Subject to that, a number of tests have been suggested, largely by Mr Underhill QC, 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 QC 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 QC 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 paragraph 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 3 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 QC 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 QC'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 QC was firm in his assertion of the inappropriateness of the test in Bolam v Friern Hospital Management Committee [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 which would take a contrary view'* (per McNair J at 587-588) [the 'Bolam Test']; and Mr Underhill QC 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 QC 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 QC 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 QC 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 QC, with an eye on the 1989 Guidance, and the evidence to which I have referred in paragraph 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 QC's formulations, which I have recited at (i) above.

106. The broad-brush 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 Article 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 QC's formulations, I would declare myself as prepared, while walking Mr Underhill QC'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 paragraph 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 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 UK, 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 UK, 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 1988/89 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 UK as an individual country ought to have introduced the surrogate tests that is before me. As for other international or trans-national bodies, introduction of the test was, Professor Zuckerman told the Court, never recommended by the WHO, nor was it recommended, as Professor Högman explained, by the Council of Nordic Transfusion Services.

The Literature

109. Before considering the actual pros and cons, I must summarise the literature on the topic and its effect. It is important to weigh up the opinions set out in that literature, but it is equally important not to over-emphasise it for the following reasons:

i) Not all of it carries equal weight. Some are short letters, albeit from influential and distinguished writers; some are fully researched and detailed surveys or reviews; some articles falling somewhere between the two. Some of the research cannot be assessed or examined on the basis of what has been published in the articles, others are not only fully researched but their workings fully disclosed to view. Some of them are highly respected and have never been questioned; others have been subjected to criticism.

ii) Inevitably the literature I have is selected or culled from a very much larger corpus. Plainly it contains all which either side considers to be relevant, and indeed has, most of it, been combed through during the course of this trial and all material passages identified. Nonetheless, it cannot necessarily be concluded to be a complete picture: it is also drawn from a number of different countries, not all of which will necessarily be relevant to my decision as to the United Kingdom.

iii) Many of those who wrote had, often very well known, preconceived positions or were 'arguing a corner', which they were perfectly entitled to do.

iv) At the end of the day, and most importantly, I am not deciding this case on the number of experts ranged on either side, but by reference to the arguments that can in fact be drawn from the literature: and in particular I am not, as I have concluded, deciding this case by reference to whether it was reasonable for the Defendants to rely on one expert view or another, but making up my own mind, informed and enlightened by the evidence and the arguments.

The United States

110. Consideration of surrogate tests in the literature must inevitably commence from the United States, and in particular the starting point of the studies by the NIH, and the TTVS. The TTVS published its report in April 1981, the first named author being Dr Aach, and the NIH published in August 1981, led by Dr Harvey Alter. The two studies, both of them highly researched and very well respected, came to much the same conclusion as to ALT tests, namely that they were worthwhile considering in the context of reducing Hepatitis C and were capable of detecting and avoiding some 30% of Hepatitis C infected blood, at a loss of what was estimated to be 1.6% of donor units; i.e., 1.6% of donations would have to be thrown away as a result of the test, but the effect was predicted to be the reduction of transfusion associated hepatitis by some 30%. These studies were both what are called 'predictive' studies rather than 'prospective' studies, i.e., they looked back, e.g., by reference to identifying recipients with raised ALT elevations in their blood, to see who their donors were, and then identified whether those donors had raised ALT elevation, and so could have been excluded had there been an ALT test in place: prospective tests would involve running partial ALT testing, and then following up the consequences for those who had received ALT tested blood as opposed to those who did not. The USA did not immediately react by introducing ALT testing. A special report by an Ad hoc Committee on ALT testing (containing, among others, Dr Harvey Alter's co-author at the NIH Dr Holland) concluded in 1982 that "*widespread ALT testing [is not to] be recommended at present. Many important questions have been raised and some appropriate studies are under way. Until more data are available, we believe that the best interests of the many patients who depend on a reliable supply of blood are best served by continued investigation rather than a change in donor eligibility standards*". The factors that they set out will, with one exception, feature in my assessment of the pros and cons below:

i) ALT was not a specific, or direct, test for Hepatitis C.

ii) There had been no prospective studies.

iii) The long term significance of Hepatitis C was unknown, and the associated liver pathology was considered to be mild.

iv) There was uncertainty about the cut-off level.

v) The methods for ALT testing needed to be evaluated [this is the aspect which does not further feature].

vi) The effect on the donor base was unknown and potentially detrimental.

111. Nevertheless the debate continued, and an important series of contributions by many of the most well known international figures in the field appeared in the journal *Vox Sanguinis* in 1983. Dr Aach was cautiously in favour of introduction of ALT testing:

> "*A decision must soon be made regarding donor ALT screening. Either the issue is not resolved, and requires a properly designated randomised study which should be initiated now, or a target date for routine ALT testing should be set for those donor populations in which an association with NANBPTH has*

> *been identified. It is unfair to postpone the decision, possibly indefinitely, because of the expectation that a specific and sensitive NANB test will soon come along to lead us out of the wilderness."*

He had some support from the French contributors, led by Dr Chataing. The German view, firmly given by Dr Müller, was in favour of the introduction of ALT testing. The other contributors, including Drs Bayer, Holland and Reesink, and, from the UK, Drs McClelland and Mitchell, were against. In 1984, the TTVS, led by Dr Stevens and Dr Aach, published its research in relation to possible introduction of the anti-HBc test. The report concluded that the introduction of such a test might reduce Hepatitis C by about one third, but at a heavier loss of the blood supply than the introduction of ALT testing, which the TTVS considered to be of greater efficacy than anti-HBc; and the consensus of the group was to favour ALT screening over anti-HBc screening. Later in 1984 Dr Harvey Alter and Dr Holland reviewed the recent TTVS study, noted what they considered to be the *"disturbing dichotomy"* that the two tests had identified different donors, and recommended the rapid institution of a randomised controlled study, relating to the possible introduction of both surrogate tests. Meanwhile, as Dr Harvey Alter published in early 1985, he had himself introduced some partial routine ALT testing, which to his surprise, failed to demonstrate any impact on reduction of PTH; and he once again recommended a controlled study. In 1986 there was another article published in the United States, by Drs Hanson and Polesky, which did not favour introduction of an anti-HBc test, but in the same year the NIH published what seems clearly to have been an influential article, led by Ms Koziol. The conclusion was to recommend introduction of both surrogate tests, even without such controlled studies:

> *"Prospective studies indicate that at least 5% of transfusion recipients develop bio-chemical or clinical evidence of NANBH. For an estimated 3 million blood recipients, this percentage represents 150,000 cases of transfusion-associated NANBH in the United States annually. If half these patients have chronic ALT elevation and 10% of these develop cirrhosis, then up to 7,500 cases of non-A non-B –related cirrhosis might be induced annually as a result of blood transfusions. If, as predicted, surrogate screening of blood donors could prevent approximately one third of these cases, then this could represent an annual reduction of 50,000 cases of Hepatitis and 2500 cases of cirrhosis. The potential to achieve this degree of disease prevention now appears to outweigh the disadvantages inherent in the adoption of surrogate tests for the non-A, non-B virus carrier state."*

In an article in 1986 which he co-authored with Dr Dienstag, Dr Harvey Alter wrote as follows:

> *"Because of the cost and significant donor loss engendered, and because of recent introduction of mandatory screening of all donor blood for antibody to [HIV], adoption of yet another one or two donor-blood screening tests represents a very complex and difficult decision. Nonetheless, increasing documentation*

> *of the chronic sequelae of NANBH and the continued high incidence of this disease after transfusion has tipped the balance in favour of adopting indirect assays for NANBH carrier detection.*"

The United States' introduction followed, later that year, of both surrogate tests. In the absence still of a specific assay, and in the light of the introduction in the United States of the two surrogate tests, Dr Harvey Alter published his review in 1988 entitled '*Transfusion-Associated Non-A Non-B Hepatitis: the First Decade*'. He referred to the TTVS and NIH studies, and in particular to the findings on their behalf more recently, by, severally, Koziol and Stevens, of some efficacy for anti-HBc, and he also referred to a recent study by Dr Sugg in Germany, whereby anti-HBc testing offered an additional 42% predicted efficacy to prevent NANBH infection. He concluded:

> "*The predicted efficacy for [anti-HBc] testing was 28%, diminished by the lower efficacy in the large TTV Study. Based on these three studies, on prior data relating to ALT, and on the evidence for significant chronic liver disease following NANBH, the major blood organisations in the United States have elected to adopt both the ALT test and the [anti-HBc] test as routine screening measures for all blood donations. Although I am in agreement with this decision, I wish to stress again that these are predicted efficacies, not proven efficacies, and that, in countries that can do so, an effort should continue to be made to perform a controlled, prospective study to demonstrate whether such costly measures are truly indicated.*"

112. This was, subject to the European studies to which I shall refer, the state of play at the time when it is suggested by the Claimants that the Defendants should have introduced surrogate testing. It is right to say that Dr Harvey Alter ten years later (his proficiency and his interest in the subject manifestly undiminished) has written, in retrospect, in a 1998 joint publication with Dr Seeff, as follows:

> "*The TTVS and NIH Studies predicted that the combined use of ALT and anti-HBc testing would prevent 40% to 50% of transfusion-associated hepatitis. There is now some indirect corroboration of this prediction ... Although other changes were occurring in the donor population simultaneously with the introduction of the surrogate tests, it seems from both these analyses that surrogate marker testing did accomplish its goal of recognising a significant number of HCV carriers, and hence has prevented as much as 50% of transfusion-associated hepatitis.*"

113. This of course is inadmissible with regard to the question which I am presently deciding, although it has some influence on the question I must decide later in this judgment as to the actual efficacy at the time of surrogate testing if it had been introduced; because I must ignore what came after in deciding what ought to have occurred in Spring/Summer 1988. For similar reasons therefore, I must for this purpose ignore also the following:

i) subsequent lookbacks or articles viewing ALT and/or anti-HBc retrospectively with enthusiasm: by Drs Morgan and Young (Queensland) (ALT): Dr Donahue (USA) (both): Dr Jullien (France) (both): Dr McOmish (with Dr Simmonds *et al*) (UK) (both) and Dr Blajchman (Canada), who started, but did not complete, because of the introduction of the assay, the controlled study in Canada which Dr Harvey Alter had wished someone could do (both).

ii) reports which were unenthusiastic or unfavourable: by Dr Garson (UK) in 1990 (ALT): Dr Esteban (Spain) in 1990 (ALT).

iii) four further reports which, albeit nearer the time, appear too late for consideration. Three of them were favourable to ALT, namely by Dr Van der Poel, with Dr Reesink, (Netherlands) in August 1989, by Dr Janot (France) in September 1989 (relatively supportive of ALT though overtaken by the assay) and by Dr Young (Queensland), submitted in April 1989 but published in 1990: and one unfavourable, namely the report of findings as to ALT efficacy presented at the Ortho meeting in Rome in September 1989.

114. I turn therefore briefly to summarise the relevant contemporaneous literature other than from the United States:

i) Supporting or favourable to ALT. Dr Richard (France), who published in 1987 a review paper, which in fact supported introduction of both surrogate tests: Dr Reesink (Netherlands), who supported it in 1988 [although in June 1989 – just prior to publication of the Van der Poel/Reesink paper, which was further supportive of ALT, as referred to above – the Dutch Health Council decided not to recommend introduction of the test *"at present"* – albeit expressly with an eye on the recently publicised assay]: and Dr Widell (Sweden) in 1988.

ii) Against ALT: Dr Katchaki (Netherlands) in 1981: Dr Steinbrecher (Canada) in 1983: Dr Woodfield (New Zealand) in 1988 and Dr Gillon (UK), (based in Scotland) in 1988. Dr Gillon and his Scottish colleagues stated:

> *"The Americans have concluded that a prospective randomised trial to test these hypotheses will never be carried out, for logistical and ethical reasons ... We conclude that the introduction of these screening tests cannot at present be justified. Further studies of recipient NANBH and the natural history of the disease are necessary, and a properly conducted prospective trial of screening for surrogate markers is essential. More extensive studies of the donor population would be valuable, with a particular need for elucidation of the apparent relationship between body weight and ALT level. Such studies would prove useful in the management of donors, should the case for screening ever be well enough established for its introduction to be considered necessary."*

iii) In favour of anti-HBc Testing: Dr Cossart (Australia) in 1982: Dr Sugg (Germany) in 1988.

iv) Unfavourable to anti-HBc: Dr Hoyos (Spain) 1982: Dr Aymard (France) in 1986 (though France introduced it two years later): Dr Reesink (Netherlands) in 1988: and finally in an article in 1988, Dr Kitchen of the UK, together with other English colleagues, including Professor Zuckerman. They concluded:

> *"The apparent lower incidence of reported cases of PTH in the United Kingdom is demonstrated by the fact that during the last twelve months, in the area served by the North Thames RTC, approximately 120,000 units of blood were transfused and only three cases of PTH were reported for follow up of the implicated donors. In the light of the findings of this study, and the very small number of cases of PTH reported in the United Kingdom, we believe ... that at the present time there is likely to be very little benefit in the introduction of anti-HBc screening of blood donors. The loss of approximately 2% of available donors because of deferment would cause problems for those transfusion centres facing shortages of donors, especially those serving the Greater London Area. The cost of testing donations for the presence of anti-HBc is high and in the current financial climate would be hard to justify. A further consideration is the need to counsel those donors found to be anti-HBc positive. Although the introduction of surrogate testing may eventually be unavoidable, we believe that only a controlled prospective study would provide the necessary information to determine the significance of donor anti-HBc levels in relation to PTH, especially NANB, in the United Kingdom."*

Professor Zuckerman was thus opposed to the introduction of anti-HBc, but seemingly largely on grounds of a conclusion of a relative lack of seriousness of the impact of Hepatitis C in the UK, together of course with the other factors there set out. This must be seen together with the paper that he gave in Taipei in December 1988, which he supplied to the ACVSB before its meeting in May 1989. He there concluded that ALT was a better prospect than anti-HBc *"since the corrected efficacy of anti-HBc as a screening test was slightly less than that of ALT and the number of blood units lost would be twice those which would be if ALT were used"*. However he concluded that *"despite the high specificity, the predictive value is only 42%. Thus almost two out of three units with an elevated ALT level will not transmit NANB. ALT levels vary with age, sex, alcohol and geographical region and therefore would not be useful as surrogate marker of NANBHI"*.

115. This brings me to a brief consideration of the evidence given orally by the expert witnesses, although I shall deal more fully with this when I come to set out the pros and cons which became clear on the totality of the evidence. Professor Zuckerman had been cautious about ALT as early as 1982, but never, it seems, totally hostile; he then wrote *"the benefits of ALT screening, which is a non-specific test and which carries several problems ... must be carefully weighed against the number of potential donors*

who would be excluded, the overall incidence of hepatitis in recipients and the severity of the disease". He repeated in evidence his lack of support, apparent from the other quotations I have given above, for the introduction of surrogate testing, for the reasons set out further below. In his important letter to Dr Rejman, the Senior Medical Officer at the Department, of 19 December 1989 (admittedly after the ACVSB had already, at its 6 November 1989 meeting, concluded that its feeling was that there was no case for using surrogate tests (while supporting, on terms that will appear later, the introduction of the assay)) he had however simply said as follows:

> *"A case can be made for the introduction of routine surrogate testing, particularly for ALT elevations, for detection of early infection of Hepatitis C virus ... However this aspect of screening is also subject to debate in view of the non-specificity of the test."*

116. Dr Barbara is, and has always been, opposed to the introduction of surrogate tests, although, as set out in paragraph 108(iii) above, he confirmed that *"the predictive value of surrogates increases if both the surrogate markers are positive"*. In his 1983 textbook *Microbiology in Blood Transfusion* Dr Barbara described the ALT test as *"the most promising (though not without difficulties) of the non-specific markers"*. By April 1987 however, he had joined in a letter to the Lancet with Dr Contreras and others concluding:

> *"Before we are forced to accept two screening tests of unproven benefit, which have high revenue implications, we need a national study to assess the incidence of raised ALT and anti-HBc in donors in different parts of the country. Also, and perhaps more importantly, a study is needed to assess the incidence of acute post-transfusion NANBH, and to assess how many of those affected develop evidence of chronicity and serious clinical sequelae. If the true incidence of post-transfusion NANBH and its serious clinical sequelae are at a much lower level than reported from the USA, then screening of donations to reduce the incidence of NANBH may not be cost-effective in the UK."*

117. This letter (upon which he and his co-authors expanded, in a published article in the June) was part of a run of correspondence to the Lancet in 1987 relating to possible introduction of the surrogate tests. Letters to similar effect were sent by other blood transfusionists. A second letter, from Dr Dow and others, urged that because *"99% of hepatitis cases are never brought to the attention of transfusion centres, or are not considered to be hepatitis by clinicians, or are not even thought to be serious enough for the patient themselves to seek medical attention ... it would be prudent to do a UK study to assess the real incidence of acute post-transfusion NANBH and to assess the proportion of those chronically affected, before considering following American surrogate testing policy"*. A third from Dr Gillon and others, concluded that *"the introduction of ALT/anti-HBc screening tests as an indicator of NANBH carrier status in blood donors cannot at present be justified"*. A fourth letter disagreed with these other three, and it was headed *Testing Blood Donors For NANBH Irrational, Perhaps,*

But Inescapable. It was written by a number of senior Scottish transfusionists, including two, Dr McClelland and Dr Mitchell, who had been participants in the *Vox Sanguinis* debate four years before to different effect, as set out above (Dr Mitchell was also, strangely, seemingly a signatory of Dr Dow's letter with which this letter was taking issue!) and Dr Cash, National Medical Director of the Scottish NBTS, and others. As is plain from the title of the letter, the signatories recognised that there were disadvantages in the proposed tests, but recommended their introduction. They considered that the time for any prospective controlled studies had long passed, and concluded:

> *"Looking at the three factors – producer's liability* [by reference to the Directive] *competition, and value for money* [being the cost of avoiding disease] – *we suggest that the decision that has to be made is when rather than whether UK transfusion services follow the lead of the United States and other European countries in donor screening."*

118. This then, and in particular the 1986 introduction of surrogate tests by the United States, Dr Gunson's paper at the Council of Europe, Professor Zuckerman's paper and article and the controversial correspondence in the Lancet, was the main background behind any consideration in later 1987 or early 1988 of the introduction of surrogate tests.

THE PROS AND CONS OF SURROGATE TESTING

119. I turn to consider the advantages and disadvantages of surrogate testing, or points in favour and points against, as disclosed to me on the evidence.

The Points In Favour

120. First. Whatever may have been said in some of the articles and letters to which I have referred, it is common ground, on the evidence before me, that the tests were relatively inexpensive. There was an express conclusion by the Defendants in November 1987 that reproducibly accurate ALT results could be produced *"at low test costs with a minimum of technical expertise and operator interactivity"*, and it was not suggested the position was any different in relation to anti-HBc: indeed Mr Underhill QC conceded that cost was not a factor.

121. Second. As to the reliability of the ALT test, no criticism is made. With regard to the anti-HBc test, Dr Caspari (with others) in a 1989 article criticised its consistency and specificity, which criticism he confirmed in evidence; but so far as the United Kingdom is concerned, in the Multi-Centre Study of 1988/89 this view was not shared; indeed, although recommending against its introduction, in the light of the imminent assay, the report was not uncomplimentary to the reliability of the test.

122. Third. No substitutes were available. By March 1988 there was no sign nor news of the assay, although no doubt everyone was hoping that something would turn up. In the light of the priority which had been given to hepatitis, as set out above, as long before as 1979, it is not surprising that Dr Gunson was *"sufficiently troubled"* to reconvene his WPTAH (which had petered to an end in 1983 when no grant was obtained for the studies into surrogate testing that they wanted to implement) at the

end of 1986; and yet, as he accepted in cross-examination, *"between the Autumn of 1986 and the autumn of 1988, apart from* [his] *own group looking at matters informally, nothing was happening"*, so far as he knew.

123. Fourth. Prevalence in the United Kingdom was not known, but, as set out in paragraph 99(iv) above, Dr Gunson, on behalf of the Defendants, was operating on the basis that it was in the region of 3%.

124. Fifth. The seriousness of the consequences to recipients who were infected by Hepatitis C was not fully appreciated. However, as set out in paragraph 99(ii) above, Professor Zuckerman confirmed that the belief at the time was in fact that no one ever recovered from it, and that they knew it was an important problem. There was a lack of understanding in the United Kingdom about the sequelae; but Dr Barbara confirmed that he knew at the time that there was underreporting. Dr Alter, in his 1985 article, had set out, in detail, his appreciation of the sequelae, including his view that *"an astounding number of acute NANBPTH cases progressed to chronic hepatitis, at least as judged by persistent ... ALT elevations"* and *"there is accumulating evidence that some cases progress to severe chronic liver disease ... If we assume that 7% of transfusion recipients develop biochemical evidence of hepatitis, that 50% of these manifest chronic ALT elevations and that 10% of the latter develop cirrhosis, then cirrhosis will eventually develop in 3-4 of every 1000 patients transfused ... This would represent 9,000-12,000 cases annually among the estimated 3m transfusion recipients in the United States"*. Professor Dusheiko accepted that clinicians were blind until the late eighties, and it was only the discovery of the Hepatitis C virus that enabled a grip to be got on the size of the problem. However, he confirmed that the chronicity and the potential for severe disease were appreciated. The article by Dr Kitchen and Professor Zuckerman from which I have quoted in paragraph 114(iv) above in 1988 referred, as there appears, to *"apparent low incidence of reporting cases of PTH ... very small number of cases of PTH reported in the United Kingdom"* [my underlining], and yet, as I have set out above, Dr Barbara accepted that it was known that there was underreporting.

125. Sixth. The United States had introduced the surrogate tests. No actual study of the effects of such introduction in that country could sensibly have been made at that stage, because of the fact that it followed so shortly on the heels of the abolition of paid donors, the introduction of HIV screening and increased self-exclusion, all of which would in any event have led to an improvement in the donor panel and a decline in incidence. But there is no evidence of any problem either with shortage of supply in the blood pool or with the donors, notwithstanding the considerable anxieties in those regards, and others, that were expressed prior to the introduction of screening. It is not simply the fact that no evidence has been put before me that there were any such problems, but that, given that the worries which had been expressed prior to introduction in the United States appeared to be the same worries that were now being expressed in the United Kingdom, it is itself perhaps a matter of significance that no attempt was made to explore the position in the United States (or indeed in Germany, where again there is no evidence of there having been any problem) before the repetition of the same anxieties was allowed to prevail in the United Kingdom.

126. Seventh. The studies in the United States had been only predictive. Although there was discussion of the possibility of prospective studies, in fact it was soon clear, at

least in the United States (see Dr Alter's article referred to in paragraph 111 above) that this was not going to be possible. In any event, as the witnesses have recognised, it would not have been possible to do so in the United Kingdom. Dr Gunson had applied for a grant to carry out such a study in relation to surrogate testing, in 1982, which had been refused, and when he made a further application in 1987, which was granted in 1988, it had to be limited to looking at donors, and became the Multi-Centre Study. The main reasons were two-fold: first there was or might have been, it was concluded, an ethical problem by that stage in giving some patients tested blood and others untested (plainly if there had been no question of any efficacy of the surrogate test such ethical problem would not have arisen). Secondly, the very real problem with prospective tests in relation to an infection with low incidence, such as 3% or less, was the very large number of prospective patients who would have to be studied, rendering it impracticable. It is in those circumstances that Dr McClelland and his Scottish colleagues wrote their '*Irrational .. but Inescapable*' letter. Dr Gunson considered that what influenced the Americans in introducing the tests was that Dr Aach had said in his statement in the *Vox Sanguinis* debate "*we really have to make up our minds; if we do not do a detailed survey then we should start testing*", and that, in the absence of such a detailed survey, that is what had occurred in the United States.

127. Eighth. As for the efficacy of the surrogate tests, it was known at the time that the incidence of NANBH in the UK (as in the rest of Europe) was less than the United States, and efficacy in preventing it was likely therefore to be less also. The evidence of efficacy really came substantially through the assistance of Mr Charlett, who addressed most of the published research in the trial papers for the purpose of assessing adjusted efficacy of the two tests so far as he could. So far as the United States is concerned, Dr Stevens in 1984, by reference to the two tests separately and together, had predicted 33% adjusted efficacy for anti-HBc, 47.5% for ALT and 61.2% for both together. Mr Charlett has recalculated those at, respectively, 21%, 30% and 39%. As for Ms Koziol in her 1986 article, Mr Charlett calculates adjusted efficacy for anti-HBc, in relation to the two panels appearing in the article, at 42.7% and 48.9%, and for ALT at 22%, and both together at 57%. Mr Charlett's calculations for adjusted efficacy appearing from the European ALT studies is summarised by Mr Brook Smith, on the Defendants' behalf, in a Schedule attached to the Defendants' Closing Submissions; and I have carefully considered not only his calculations, but also the caveats Mr Charlett makes in the course of his evidence. I conclude, taking both the American evidence, as discounted, and the contemporaneous European evidence into account, that the likely adjusted efficacy of ALT at the material time on the balance of probabilities was 20-25%. So far as the anti-HBc test is concerned, the figures are sparser, but, as can be seen from the two main American studies, and in particular Koziol's, they had a reasonably optimistic view of its efficacy, even though others have thought, as set out in detail in the articles to which I have referred above, that, at any rate in Europe, it was ALT which had the greater predicted efficacy. On the other hand there are two particular surveys which Mr Charlett studied, and where he calculated an adjusted efficacy for non-American research into anti-HBc; in respect of the Cossart research in 1982 in Australia, Mr Charlett calculated the adjusted efficacy as 48.5%, while in respect of the Sugg research in Germany in 1988, he calculated it at 42%. The Claimants do not suggest that anti-HBc alone should have been introduced as a surrogate test. Their main case is for the introduction of ALT tests, which had the well-respected pedigree, albeit with a higher cut-off, in Germany, and for which there is reasonably substantial support among the articles to which I

have referred; while they accept that, not least because their own expert witness, Dr Caspari, is not a supporter of anti-HBc, their case for that test is much weaker. They contend however not simply – though primarily - for the introduction of ALT, but for its introduction together with anti-HBc, namely for the same reason as the United States, because it covers an additional donor population and it increases efficacy. I do not therefore need to reach a conclusion as to what adjusted efficacy anti-HBc would have had on its own. I am however satisfied that, if the two tests together had been introduced, the adjusted efficacy of the two combined would have been 40%.

128. So far as efficacy is concerned, the Claimants drew attention to Dr Alter in an article in the Lancet in 1970, when he supported the introduction of Hepatitis B screening, where he said that "*granted that ... the exclusion ... would prevent no more than 25% of these cases, this still represents a highly significant decrease in hepatitis-related morbidity and mortality*". Professor Zuckerman accepted the evidence with a "*lot of ifs and buts*" that a 20% reduction through the adoption of ALT screening would have been a worthwhile thing to do.

129. Ninth. Finally I turn to the two tests themselves:

i) There was some advantage in introducing anti-HBc in being a supplementary back-up for anyone who might escape the net of Hepatitis B screening (HBsAg): this is clearly at best marginal.

ii) It is important to recall that the way in which NANBH was diagnosed, in the days before the identification of the Hepatitis C virus, was through raised ALT in the recipient, so that it appears logical to identify raised ALT in a donor as a potential risk.

iii) In the light of what I have set out in paragraph 100(vii) above as to 10% or so of drug users, or other unwanted donors, who slipped through the net, anti-HBc would have been an additional method of identifying – by reference to life-style, as set out in paragraph 9(ii) above – those who might fall within that category. This was, as set out above, a problem of which the Defendants were aware at the time. It is plainly an advantage to exclude, so far as possible, such drug users, and to endeavour to identify them by reference to those who had previously had Hepatitis B and thus retained the antibodies, just as it was accepted practice to exclude known drug users, those with jaundice or with HIV etc.

The Points Against

130. The first is the loss to the blood supply. If ALT testing had been introduced, at least 2.5% of donations would have been lost. As for anti-HBc, notwithstanding what was written in some of the literature to which I have referred, it was common ground that the loss resulting from that test would have been less. A total loss in respect of the two tests of 4% was accepted, indeed propounded, by Dr Gunson in his evidence and accepted by the Defendants in the course of their submissions. 4% of 2.5 million donations is approximately a loss, averaged over the year, of 8,000 per month. It is apparent from the figures for blood stocks which were disclosed by the Defendants during the hearing that this could on occasion have meant running the blood stocks very low. The monthly records produced for 1990 and 1991 showed that reserves in fact fell in January 1990 to below 18,000, and between May and June 1990 to below

20,000, and again fell below 18,000 in January 1991: and the Defendants point to a passage in Dr Gunson's own co-authored *Fifty Years of Blood Transfusion* where he states as follows:

> *"The difference in quantities between a satisfactory supply and a shortage was small. Whilst total daily red cell stocks were in the order of 25,000, approximately 2½ days' supply, there was rarely a need to transfer blood between RTCs. Below this level there were shortages at one or more RTCs; above it there was a surplus. The advantage of having a national dimension for the blood stocks was that when the trend was downwards it was possible to initiate local, or if necessary national, publicity to increase the blood supply before a major shortage occurred."*

The Defendants referred to this in their submissions as indicating what they described as a *"danger level"*, but I do not consider that that is what that passage says, and the words certainly do not appear in it. But Mr Garwood was concerned about the adequacy of the blood supply in such circumstances, and said that it could take up to two years to recover the loss. Dr Caspari in an article in 1975 described donations lost as a result of ALT tests as a *"sacrifice"*, which it obviously was. It was only Dr Gunson's hard work, it is apparent, and his constant attention, which achieved the security of supply meeting demand throughout the country, including transfer if necessary of a blood surplus in one centre to another centre which was short; and it is plain from the conclusions of the Council of Europe Working Group, which I have quoted in paragraph 108(vi) above, that it was foreseen that *"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 which must be taken into account"*.

131. However:

i) As I have indicated in paragraph 125 above, there is no evidence that the United States, with a higher incidence of NANBH, suffered problems in blood supply after the introduction of the tests, notwithstanding the expressed concerns prior to their doing so.

ii) It is apparent that the pool could be increased by additional efforts – such as for the purpose of the Gulf War (again made clear by Dr Gunson in a lecture note disclosed in the papers in which he indicates that *"we were successful in increasing the blood supply. The normal collection level in England and Wales is approximately 9,000 donations per day. On 18 January this rose to 30,000 ... This experience shows ... that motivation will encourage voluntary, unpaid donors to come forward to help others"*) and it is certainly the case that the blood stock figures show such an increase during that period. If there had been an emergency shortage of blood it would seem possible that the missing 8,000 donations per month might thus have been found.

iii) But the most significant factor in the evidence was that the man in charge himself, Dr Gunson, was, although concerned, not saying that he could not cope with a 4% loss to the blood supply. In re-examination, he said as follows, in answer to Mr Underhill QC:

> *"Q. What was the prediction for the loss that would have been caused by the introduction of both forms of surrogate testing?*
>
> *A. Both forms, something in the order of 4%...*
>
> *Q. What impact would that degree of loss have had on the blood supply in the period between 1988 and 1991?*
>
> *A. That I consider to be a significant loss because it is added to... the [12% to 15%] annual loss of donors... and this would have meant that we would have been losing probably in the order of one-fifth of our blood supply each year and this would have to be replaced by recruiting new donors...*
>
> *Q. I think it may be suggested, as seems to be the thrust of the questioning, that the improvements which you undoubtedly made... would have meant that the loss of this degree of donors would not have been a problem. What would you comment on that?*
>
> *A. Well I find it difficult to decide whether it would have been a problem or not, because it is purely speculative, but it would probably have been lessened by the movement of blood throughout the country.*
>
> *Q.... Would it have been a source of concern to you at the time if you had been told that this testing would be introduced and you would therefore lose about 4% of your donors?*
>
> *A. Well, yes, until I had been able to analyse the effect of the testing.*
>
> *Q. You would have had to see how it worked out?*
>
> *A. Yes, indeed."*

In my judgment, that indicates plainly a source of concern, but manageable.

132. The second point was the welfare of donors. The importance of not doing anything to the detriment of donors is manifest and has been emphasised in paragraph 100(ii) above. There was some implicit suggestion in argument of a dichotomy between a 'pro-donor' attitude, on the one hand, of the NBTS, intent largely on safeguarding their donors and their blood supply, and a 'pro-recipient' attitude, on the other, of clinicians interested in the patients. But I do not consider that to have been the case, and indeed it is entirely clear to me that Dr Gunson did, as he said, put the recipients at the top of his priority list. There is, in any event, not, it seems to me, a tension, but rather a balance: both of them have to be considered and provided for. Care manifestly would have to have been taken, in the event of the introduction of surrogate tests, not to create what was sometimes referred to as a new class of unhappy, excluded donors,

even *'lepers'*: indeed, there was some talk even of possible litigation by stigmatised, rejected donors. It is absolutely clear that proper consideration needed to be given to having proper procedures for counselling in place, prior to any tests being implemented, just as in the event took place in respect of the assay, and as indeed was once again foreseen by the Council of Europe Working Group: "*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*". Again there does not seem to have been any evidence of any problem in the United States after the introduction, notwithstanding prior expressed concerns. Dr Caspari described the system adopted in relation to ALT testing, established for many years, in Lower Saxony, where they only notified patients whose ALT is elevated to 100 iu/l (which in fact as I understand it would be four times the US cut-off) while in the case of those who were elevated above the 45 iu/l cut-off, but not to that extent, they would, at least in the first instance, simply reject the blood, while not notifying or counselling the donors. This was a process which was not satisfactory to the British transfusionists and hepatologists who gave evidence (nor to Dr Högman, the Swedish expert) who would certainly have wished to ensure that all those with elevated ALT were notified, rather than simply having their blood rejected, as a matter of what they firmly considered to be medical ethics, which I of course accept; although I do note Dr Gunson's account of United States practice, in paragraph 49 of his statement (as to which he was not cross-examined), whereby, albeit at a lower cut-off rate, a somewhat similar system of levels for discarding and notifying, and for discarding but not notifying, was adopted.

133. However, even assuming adoption of the tests on the basis of full notification of anyone whose test, be it ALT or anti-HBc, was positive, I see no reason whatever why, given the necessary introduction and implementation of procedures, this should not have been manageable. There would be approximately 2.5% of donors with elevated ALT and approximately 1.5% with anti-HBc. I am entirely satisfied that this could have been sensibly dealt with:

i) As to those positive for anti-HBc, all that needed to have been said was (as was the case) that they had antibodies to Hepatitis B, i.e., they had previously had Hepatitis B. What would have then needed to have been said (and no doubt previously recorded in literature) was that, like those with jaundice etc., those who had in the past had Hepatitis B could not give blood. This would not seem to me likely to have caused either confusion or distress, nor probably to have given any information that the donor did not already have, albeit he might have forgotten about it, and would certainly not result in any stigma.

ii) As to ALT, there would be no question of any diagnosis of any condition: the test was not, and would not have been represented as being, a Hepatitis C test: nor could it have been represented as being a test for HIV, for which donors would in any event have been separately tested. Thus there need have been no question of their being *'lepers'* or stigmatised by unknown infection. They would simply have been told that they had elevated ALT, which might indicate some liver condition or simply obesity or excess alcohol, but that anyone with elevated ALT was again one of those who were excluded from donating blood. Professor Dusheiko at any rate (though Professor Zuckerman was less

sanguine) did not consider that any resulting referrals would not have been coped with.

iii) One of the advantages if the two tests had been combined, would have been that different consideration could be given to counselling of those, if any, who showed positive on both tests, as they would (as Dr Barbara made clear) be more likely in fact to be suffering from Hepatitis C.

134. The third point is the case that neither anti-HBc nor ALT are 'specific' tests, that is they do not test for NANBH (I would prefer, because of the multiple meanings of the words 'specific' or 'specificity', to recategorise the criticism as 'indirect', as opposed to 'direct'). I have already quoted in paragraph 114(iv) above from Professor Zuckerman's paper at the second International Symposium on Viral Hepatitis at Taipei in December 1988, and he repeated his view in evidence that there was no sufficient connection between either test and diagnosis of NANBH. Further criticisms were that the ALT test had a variable cut-off, as discussed above. Dr Caspari's support for ALT should be discounted because (a) Germany has a higher cut-off (b) Germany, having introduced the test in 1965, never addressed any of the questions, considered in the 1980s, as to whether the test could or should have been introduced specifically with a view to filling the gap in the absence of a specific test for NANBH, but was simply keeping in place an already existing test. As to anti-HBc this test was, as set out above, not supported by Dr Caspari, although, at least as to its reliability, there is no evidence that there was publication in regard to this at the time, and, as appears in paragraph 121 above, when the Multi-Centre Study did look at it, it does not seem to have reached the same conclusions as Dr Caspari.

135. The 'indirectness' of both tests is plainly of concern. However:

i) The very availability of a variable cut-off meant that, if the test had been introduced, it could have been adjusted if it turned out there was an unacceptable loss to the blood supply.

ii) There would on any basis have been an increase in prevention of NANBH if one or both tests had been adopted, due to what was, as appears in paragraph 127 above, adjusted efficacy in respect of NANBH infection of between 20% and 40%.

iii) Past drug users, who would otherwise have donated, would be more likely to be eliminated from the pool.

iv) Dr Caspari's lack of support for anti-HBc might be explained by the fact that, as he accepted, the donor population of his area was *"rural, which contains almost no risk groups, that is drug addicts for example or other people who have a high likelihood of having Hepatitis B and C from the same source"*. In answer to Mr Brown QC he agreed that his conclusion might have been different if he had been doing work in a German urban centre as opposed to a Red Cross rural population.

136. The fourth point is the case that the US studies which had led to the introduction of the tests in the United States were predictive studies, and were therefore not as reliable as prospective studies (although Professor MacRae gave evidence that predictive studies were nevertheless valuable). The United States had introduced the tests under

what was described as political pressure, which Dr Caspari and Dr Barbara both believed related to public fears about AIDS, and which was described as follows in the June 1989 decision by the Dutch Health Council, to which I have referred in paragraph 114(i) above, namely that "[the American Blood Bank Organisations] *changed their mind, which was partly due to pressure from the public and the risk from damage claims as a consequence of liability*". The crux of the argument is that the simple fact that the United States had introduced these tests should not mean that the United Kingdom should follow. The view of the first reconvened meeting of Dr Gunson's WPTAH on 24 November 1986, quite clearly adopting or favouring the view of Professor Zuckerman, was that *"the USA experience did not relate to the UK. The* [Hepatitis B] *rates in the USA were higher, and any NANB viruses prevalent in one country were not necessarily going to be equally prevalent in the other ... limited UK data did not of itself warrant introduction of anti-HBc/ALT screening at this time*". This was a view similar to that which had been consistently held by Professor Zuckerman, and indeed stated by him in a 1982 publication shortly after the original TTVS and NIH studies, namely that *"it is difficult to extrapolate these observations to other countries and to countries with different blood transfusion practices*". Again, the final conclusion in the seminal report of the Council of Europe Working Group, itself post-dating the United States introduction was that: *"individual countries will have to assess the situation locally and decide on the appropriate action to take*".

137. However:

i) Even if it was 'political pressure' in the United States which caused the introduction of the surrogate tests – or even fear of litigation – that does not seem to me necessarily to be outside the sphere, but possibly even to be the result, of legitimate expectation of the consumer. However it is far from clear that that was the case: there appear, as set out above, in fact to be two more substantial reasons:

a) Pursuant to Dr Aach's position in the *Vox Sanguinis* debate, as postulated in evidence by Dr Gunson, since a proper prospective study could not now be carried out, therefore the United States had had to proceed to testing on the basis of what they had, namely the predictive studies. It is clear that the United Kingdom had reached a similar position, so far as any detailed prospective studies are concerned, from the very same meeting of the WPTAH on 24 November 1986 to which I have just referred, for it was there *"agreed that a full prospective study of a group of recipients of all transfused blood ... along the lines of the USA TTV study would be too expensive and inappropriate in the UK*". The logistical and likely ethical problems have been referred to in paragraph 126 above.

b) Dr Alter's stance on the introduction of the surrogate tests in the United States seems to be that recorded in his jointly authored 1986 article, to which I have referred in paragraph 111 above, namely that the *"chronic sequelae of NANBH and the continued high incidence of this disease after transfusion have tipped the balance in favour of adopting indirect assays for NANB carrier detection*". A similar view was expressed by Drs Dienstag and Seeff in a 1988 editorial, when the authors wrote as follows:

> *"This decision* [to introduce surrogate testing in the US] *was based in part on new data about the value of anti-HBc as a surrogate test;* [viz. Koziol]; h*owever these data were also retrospectively derived and not substantially different from those in earlier reports, which they confirmed. Undoubtedly the decision was also rooted in mounting concern over the recognition that serious chronic liver disease could follow transfusion-associated NANBH."*

This was plainly the case in the United Kingdom also, through the eighties.

ii) In fact it is not necessarily the case by 1987 or 1988 that the postulated incidence in the United Kingdom of 3% was much if at all less than that of the United States, which had fallen during the 1980s for the reasons discussed in paragraph 125 above. In 1987 Dr Richard of the National Blood Transfusion Centre in Paris wrote that the actual relative risks *"are obviously different from one country to another, but for most developed countries the available data suggests that fundamental differences do not exist".* Dr Gunson confirmed in evidence that *"by the end of the 1980s the prevalence of* [Hepatitis C] *in the donor population in the United States* [was] *very broadly the same as the believed prevalence in the United Kingdom".*

138. The fifth point is simply the case that more tests should be carried out first, and/or that it was right to wait for a specific assay to be developed, which, it was believed, had to happen soon. The question of what further tests could be carried out has been canvassed above. The only work that was done in the United Kingdom after the autumn of 1986 was the Scottish work by Dr Gillon, referred to in paragraph 114(ii) above, and the Multi-Centre Study, which itself was not able to start until mid-1988, reporting in draft in October 1989. Neither of these recipient-based studies was likely to reach any fresh conclusions. There could be no direct tests until the NANB virus itself could be identified, which had still not yet occurred. Set against that is the priority set for NANBH, and the adjusted efficacy, based on the predictive studies, of the surrogate tests.

139. The sixth point was the burden on centres of two new tests. This was canvassed in closing submissions by Mr Underhill QC, but I saw no evidence to support it. In any event, logistics would be a factor to be taken into account, and no particular difficulties have been identified.

140. The seventh point is that so few other countries adopted it. The countries that did have been set out. This is obviously a relevant matter, not least if it were the case that the tests being canvassed were so outrés that the United Kingdom would be out on a limb if they had introduced them. It seems to me that it is no answer, however, if the United Kingdom public can otherwise legitimately expect the tests to have been adopted. The re-establishment of Dr Gunson's WPTAH in autumn 1986, followed by the vivid correspondence in the Lancet, might well have been expected to lead to implementation in 1988, in the United Kingdom, just as did a similar process in the United States. The Council of Europe left the decision to individual countries to make.

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 Article 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 paragraph 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 paragraph 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)
1990/91	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 QC 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 QC did indulge occasionally in what he called 'poison and prejudice', he recognised the limits of the ambit which Mr Underhill QC 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 paragraph 102 above, this would not involve, as would what Mr Underhill QC would call a negligence inquiry, or Mr Brown QC 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, i.e. 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.

The Chronology of the Introduction of the Assay in the UK

147. At a meeting in August 1988 in Manchester, Drs Gunson, Barbara and Contreras (among others) discussed what was then called the 'Chiron test' and hoped to carry out some trials. In a December 1988 Newsletter, Dr Barbara discussed the position as follows:

> "*Scientists at* [Chiron] *have recently announced that* ...[researches] *appear to have borne fruit in the shape of an ELISA for antibody to NANBH: this test will be marketed by* [Ortho]. *Although not yet the subject of a formal report in a scientific journal, many NANBH researchers (such as Dr Harvey Alter,* ... [etc]*) seem confident that we are dealing with the first specific assay for antibody to the major post-transfusion NANBH agent ... Dr Alter reports complete consistency of the test ... Samples for two donors at the North London* [RTC] *were sent to the USA ... found to be* [anti-Hep C] *positive when tested blind ... Even if, as seems likely, this assay proves to be specific (and sensitive) for* [anti-Hep C], *there will still be 'gaps' in our ability to detect NANBH ...*"

At a meeting on 29 March 1989, Drs Gunson, Contreras, Barbara and others discussed how trials were to take place of the then newly developed Ortho assay; Dr Barbara met a representative of Ortho on 13 April 1989, and on 19 May, he reported to the second meeting of the recently established ACTTD as to the progress of testing the Ortho assay. Dr Gunson reported to the second meeting of the also recently established ACVSB on 22 May 1989 that the assay "*may ... make surrogate testing obsolete, provided that the* [NBTS's] *and other studies confirm the promising results so far reported, and assuming that the cost/benefit analysis is satisfactory*": and the members of the ACVSB "*regarded the matter to be a priority*". On 30 June there was a symposium in Paris, organised by Ortho, from which Dr Barbara returned with a positive reaction. He was concerned about the absence of confirmation, i.e. of a confirmatory or supplementary assay, and by the inconvenience that would be caused if the duration of the tests was, as it then appeared, some three hours, but had otherwise concluded, and reported, that the test seems "*reproducible, robust and meaningful*", which he explained in evidence as meaning of good specificity, reliable in operation and clear, rather than indeterminate, in its results. The report was given to the third meeting of the ACVSB on 3 July 1989, by Dr Mortimer, who had also attended Paris, that "*he considered the findings represented a persuasive case that the Chiron test results were reliable*'.

148. The limited evaluation that was then being carried out of the assay appears to have been co-ordinated by Dr Contreras and Dr Barbara (although in addition the already

commenced Multi-Centre Study, set up to examine ALT testing, was now also looking at the assay), and they wrote together to the Lancet in August 1989. The letter made a number of points. It began by agreeing that the assay was specific (i.e. 'direct') for NANBH, and thus "*clearly superior to all previous attempts at an assay for NANB virus and* [it] *provides a welcome advance over surrogate markers for infection with this virus*". However the writers advised that "*in the context of donor screening, precipitate action should be avoided*". They pointed out that (even in the absence of a confirmatory or supplementary test) they had evaluated that 0.5 to 1% of blood donations had been found to be repeat-reactive and "*excluding such blood donors might not seem to be a problem*". However they pointed out that contacting and counselling 12,500 to 25,000 donors would "*be an enormous and costly undertaking, especially when the significance of a positive test in a healthy person is as yet unknown*". Meanwhile Dr Lloyd, Director of the Newcastle RTC wrote to his Regional Health Authority on 20 July, and Dr Cash, National Medical Director of the Scottish NBTS (who had reached a similar conclusion to Drs Barbara and Contreras about 0.5 to 1% repeat-reactives) wrote to a number of his colleagues, including Dr Gunson, on 3 August 1989, urging planning for implementation, and particularly plans for counselling, although, as will be seen, none then materialised.

149. As referred to in paragraph 11 above, the Rome symposium took place on 14/15 September 1989. Dr Barbara joined with Dr Alter and others in reporting after the Rome symposium that "*results obtained using this assay indicate that it is a specific and sensitive test ... and ... represents a valuable screening test for blood donations that would otherwise transmit NANBH following transfusion*". Just prior to the third meeting of the ACTTD on 9 October 1989, Professor Zuckerman wrote in the British Medical Journal that "*the most recent published seroprevalence studies of* [anti-Hep C] *antibodies using the assays developed by the Chiron Laboratories confirm the apparent specificity and (relative) sensitivity of the assays ... The ability to detect* [anti-Hep C] *antibodies, generally only several months after acute infection, is an important advance that is expected to provide not only a clinical diagnostic test but also a screening procedure for blood donations ... Preliminary serological surveys of healthy blood donors indicate average rates of* [anti-Hep C] *antibodies in 0.5 to 1% in the* [NBTS] *of Britain, with a similar rate in several other industrial countries that use a voluntary blood donation system. Nevertheless, important problems remain. Many of these serological findings should be interpreted with some caution in the absence of a confirmatory test ... The urgent and important problem is the lack of confirmatory assays*".

150. The Scottish evaluation of the Ortho assay, completed by a report on 5 October 1989 by Drs Dow, Barr and Mitchell, reaching a similar conclusion as to reliability ("*the test itself was 'user friendly'*") and as to the percentage of repeat-reactives, was reported to the third meeting of the ACTTD, at which a draft paper from Dr Gunson reporting on the Rome meeting was, after a number of changes, approved for submission to the ACVSB. Mr Brown QC made considerable play with the changes in this document, from the draft which Dr Gunson originally presented through to that which was presented to the ACVSB at its fourth meeting on 6 November 1989. What is clear is that Dr Gunson's own greater enthusiasm for the new assay was toned down in the final draft, as a result of Committee discussion. In some respects it was more favourable, in that the reference to the three-hour duration of the test was excised. However it is certainly true to say that Dr Gunson's originally expressed view that "*it will be difficult not to introduce routine screening of blood donations for* [anti-Hep C]

since there is, even from the earliest studies, the possibility that the incidence of transfusion-transmitted NANBH will be significantly reduced. Although this disease is usually mild with recovery, some patients may develop cirrhosis of the liver" was replaced by *"routine screening of blood donations ... should be introduced when practical, since there is, even from the early international studies, the probability that the incidence of transfusion-transmitted NANBH will be reduced"*. Nevertheless the primary conclusion remains the same, namely that the ACVSB was *"asked to approve the routine testing of blood donations for* [anti-Hep C] *in principle, and request the National Directors in England and Scotland to arrange for the simultaneous introduction of the tests at an appropriate time when a policy for counselling and management of the sero-positive donors, has been defined"*. The conclusion of the ACVSB meeting on 6 November 1989 was summarised in paragraph 28 of the Minutes as follows:

> *"The feeling of the Committee, as summed up by the Chairman* [Dr Metters of the Department] *was that the test represented a major step forward, but that the Committee need to know a great deal more about it, and acknowledged the need for a confirmatory test. It was agreed that while the UK would not want to go on in advance of an FDA decision, it could prove difficult if the FDA does not decide in favour of the test. Nevertheless, it was felt that if the UK do put the test into general use, RTCs will need to have had experience with it, and therefore pilot studies should go on in Birmingham, Sheffield and Brentwood, to show the feasibility of adding this test to routine practice."*

At the next meeting of the ACTTD on 22 November, chaired by Dr Gunson, the result of its report to the ACVSB was reported back as follows:

> *"It was agreed that the* [anti-Hep C] *test was a major step forward in identifying those who could potentially transmit* [Hep C]. *The ACVSB had noted the need for a confirmatory test either before or shortly after any routine testing of donations. They also agreed that routine screening should not commence until the FDA had granted a licence, which may be June/July 1990."*

151. The pilot study at the three Centres took place and was completed by 18 December. Dr Gunson reported on it to the fifth meeting of the ACVSB on 17 January 1990: repeat-reactives varied from 0.18% in Sheffield up to 0.61% at Brentwood and *"all commented that the test was straightforward and easy to perform"*. Meanwhile, although this was not reported to the ACVSB meeting, on a date which Dr Gunson said in evidence he believed was 23 November, and as he was notified by Ortho on 27 November, the FDA approved an Export Permit for the Ortho assay, which meant, as explained by Mr Hardiman's evidence, that Ortho was then and thereafter free to make the assay available for routine blood donor screening in the United Kingdom; the United Kingdom being one of the twenty one countries identified in US legislation as being permitted recipients, once an export licence was granted, of a drug or biological product in advance of a grant by the FDA of a full product licence for its use within the United States. The ACVSB meeting received Dr Gunson's paper on the

results of the pilot studies, and a costing paper estimating the cost of introduction of routine screening at between £5m and £7m per annum. They also received a copy of what I have referred to, in paragraph 115 above, as Professor Zuckerman's important letter of 19 December 1989, to which I shall return below: in the course of discussion of which it appears that Professor Zuckerman indicated that *"he felt that it was unlikely that the FDA would licence the Ortho test in the absence of a confirmatory test, and it would be difficult for* [the UK] *to approve a test which was not approved in its country of origin"*. The general consensus of the meeting was again summed up by Dr Metters, and included the statement that routine testing should not be introduced in advance of the FDA decision.

152. In February 1990 a supplementary test, which had been pioneered for the purpose of providing some confirmation of the assay ("RIBA 1") was sent by Ortho to Drs Barbara, Mortimer and Follett, for evaluation by them. Although at the next meeting of the ACTTD on 16 March 1990 [as it turns out, the last such meeting until 8 January 1991], when the ACVSB decision to defer introduction of routine screening at their last meeting was reported, Dr Follett was present and Dr Mortimer, although absent, represented by a Dr Parry, there was no mention of RIBA 1 at the meeting. Dr Barbara was asked in evidence about what work was done by him or by Dr Follett in relation to evaluation of the RIBA 1 at that stage, and he could not remember what was done, but he certainly confirmed that nothing was published by him or, so far as he knew, by Dr Follett, at least until many years later. There was no reference in evidence to any report presented to the ACVSB or otherwise of any evaluation of the new supplementary test, whose absence had formed such an important part of the critique of the assay by Dr Barbara and others, as set out above. Had the evaluation been carried out and/or published or reported on, I have no reason to doubt that it would have been favourable. First of all and most significantly, Mr Underhill QC concedes that, although it was to be substantially improved once a second generation RIBA materialised in 1991, it is not his case that it was necessary to wait for RIBA 2, or that RIBA 1 was not a sufficient answer at least at that stage, to the need for a supplementary test. Secondly Dr Ebeling in Finland did in fact carry out, with others including Dr Leikola, an evaluation of the RIBA which satisfied her, as she reported in the Lancet in a letter published on 21 April 1990.

153. On 24 April 1990, there was the sixth meeting of the ACVSB. Dr Mortimer and Professor Zuckerman reported on an Ortho symposium that they had attended in London. Dr Mitchell reported on a symposium held by Abbott, who had not yet marketed their own assay, at Chicago, and Professor Zuckerman reported on a Hepatitis Conference in Houston. He reported that RIBA had been assessed. He *"remarked that RIBA was not good enough to use routinely as a confirmatory test"*: he made clear however in evidence that his objection to RIBA was not its unreliability *per se*, but to the fact that it was not a genuinely confirmatory test, as it also tested for the antibody. It was reported to the meeting by Dr Metters that France, Belgium and Luxemburg had introduced routine screening. There was concern about the specificity of the test (to which I shall refer further below) and that there were reports of 'false positives'. Both Dr Gunson and Dr Mortimer wanted to have trials of both the Ortho assay and the anticipated Abbott assay, and there were plans for a prospective study involving 25-50,000 donors. Dr Metters' summing up of the discussion was, by reference to there being inadequate scientific data to support the introduction of the test, the lack of a confirmatory test, and the fact that the FDA had not yet approved the assay (although the American Blood Banks' Guidance for Planning the

Implementation of the assay was before them) effectively of a decision to take no action to implement the assay. However a sub-group was to be set up to prepare a protocol for a substantial pilot study.

154. On 2 May, the FDA granted a full product licence. On 11 May the RIBA test was available, as Ortho informed Dr Gunson by letter of that date. So far as there had been three conditions or concerns expressed at the ACVSB meeting of 6 November 1989, they had all now been satisfied, successful pilot trials in December, FDA full Product Licence and now (although not strictly a confirmatory test but only a supplementary one) the existence of the RIBA. The seventh meeting of the ACVSB (brought forward from the end of July) took place on 2 July. The Department were and remained very concerned about the cost implications of routine screening. A memorandum from Mr Canavan of the Department dated 14 June 1990 records:

> *"I am returning to the cost/benefit question as it seems likely the ACVSB will recommend* [anti-Hep C] *screening at is specially convened meeting of 2 July. You will see from the draft minutes of the last meeting that a pilot study was the preferred next step at that time. However our experts now seem to think advances in knowledge about the* [anti-Hep C test] *and the means of confirming the result make it very difficult to resist the introduction of screening. A number of countries have already done so."*

In fact the 2 July meeting did not recommend immediate introduction of screening, notwithstanding the fulfilment of the previous conditions. Dr Metters summed up the decision as being that the UK should introduce Hepatitis C testing, but the decision as to which Hepatitis C test to use would be made after the results of a pilot scheme to compare the Ortho test and the Abbott test (which was about to become publicly available) to see which was the better test for the RTCs: it was estimated that the overall time scale for the study would be approximately four months, after finance had been agreed. These tests, in Glasgow, North London and Manchester, were carried out, once funding became available in September, in the months of October and November, and, because they were expanded to include a trial and assessment of the RIBA confirmatory test, continued through into December.

155. On 21 November 1990 the ACVSB held its eighth meeting. There was a report on the, not quite completed, pilot scheme, and a paper from Dr Gunson indicating the need for a UK wide consensus to be sought on a policy of counselling of donors, once the tests were implemented. The decision was made to recommend introduction of routine screening as soon as practicable (and the RTCs would decide individually whether to use the Ortho or Abbott test). Recommendation was to be sent to Ministers for their approval, which was eventually given on 21 January 1991. Meanwhile there had been a sixth meeting of the ACTTD, the body primarily concerned with implementation, the first, as I have set out in paragraph 152 above, since March 1990. Plans and arrangements were now made in respect of implementation, and on 22 January 1991 Dr Gunson wrote to all RTCs, the decision having been made for uniform introduction throughout the country, seeking from them their earliest start dates. In the light of the information received, Dr Gunson settled on a start date of 1 July 1991.

156. On 25 February 1991, at the ninth meeting of the ACVSB, the fact that there were now about to be available second generation Ortho and Abbott assays, obviously improvements on the first generation assays, was considered, and, at the 25 March 1991 meeting of the ACTTD, a decision was made to postpone introduction of routine screening until after an opportunity had been provided to evaluate the new second generation assays. Hence the RTCs were informed on 3 April 1991 of the revised start date of 1 September 1991, to allow such evaluation. Dr Lloyd of Newcastle, impatient to start, in fact started up routine screening at his RTC in advance of the rest of the country, somewhat to the disapproval of his co-Directors, using the second generation assay, and his screening, together with tests at Leeds, Liverpool, Sheffield, Bristol and Glasgow, was used for the purpose of the evaluation of the second generation assays referred to above.

157. Routine screening was introduced throughout the country on 1 September 1991. I have already indicated that, in the light of the 90% settlement agreement, so far as what actually happened within the United Kingdom is relevant at all (and, as discussed, it is only so because of the need for consideration as to what legitimately expectable steps had to be taken and how long it was legitimately expectable they should take) I am not invited to consider the period after 1 April 1991.

The Background Facts

158. The issue in relation to the assay is of course a substantially different one from that relating to surrogate tests, because it is not a question of whether the assay should have been routinely introduced, but of when, i.e., whether it should have been introduced earlier than it was. I set out the following facts or factors which I believe to be either entirely or substantially common ground, but which in any event I find to be the case:

i) The same factors demonstrating priority to be given to steps to prevent or reduce transfusion-associated hepatitis are relevant in relation to the introduction of the assay as in relation to the question of consideration of surrogate testing. Hence I refer to paragraph 100(v) above and the very fact of the existence of, and detailed discussions by, the ACVSB and ACTTD and its members. In addition, however there was the very fact that the discovery of a specific test for NANBH had for so long been looked for – or, as Professor Zuckerman put it in 1985 *"awaited with breathless anticipation"*: Professor Zuckerman confirmed in evidence that such words had *"simply tried to convey... the urgency and the importance"*.

ii) The Ortho assay was published and evaluated internationally as from April 1989. Details of it were published in *Science* in April 1989 under the lead of Dr Kuo and jointly authored by, among others, Drs Alter, Dienstag, Miriam Alter, Stevens and Houghton. Dr Alter published separately in detailed and commendatory terms in the same month in *Transfusion Medicine Reviews*, concluding that *"the discovery of* [Hep C] *is a fundamental breakthrough in virology ... the* [anti-Hep C] *assay is an important adjunct to our anti-viral armamentarium and should be immediately implemented for donor screening when licensure is achieved"*: and Dr Esteban and others from Spain and Drs van der Poel and Reesink and others from the Netherlands both published separate very supportive conclusions in the Lancet in August 1989.

iii) There had, it appears, been at least thought to be 'false dawns' before, but, it seems quite clear, nothing to compare with both the assay itself and the detailed approval now so widely given. I have already referred, in paragraph 147 above, to Dr Barbara's favourable reaction after Paris (*"reproducible, robust and meaningful"*) and to Dr Mortimer's; and Dr Gunson came away from Rome with a *"positive reaction"*, although he was worried about specificity, and thus false positives, in the absence of a confirmatory test. Professor Zuckerman too, in the October 1989 article from which I have quoted in paragraph 149 above, described the test as *"an important advance"*.

iv) France carried out its own evaluation of the Ortho assay very speedily. Dr Gunson told us that France had tested 25,000 donations by the time of the Rome symposium. Hurried on no doubt by the state of public opinion in France, France introduced routine screening, as set out above, on 1 March 1990: unlike the United Kingdom it had already had in place, in the interim, both surrogate tests.

v) There has been no challenge to the sensitivity of the assay.

vi) Although the second generation tests considerably increased the specificity of the tests, substantially reducing the number of false positives, the loss to the blood supply caused by the first generation assay was never regarded as a problem (nor relied upon as such before me). The blood donations that were discarded were those which were repeatedly reactive and the percentage for that appears above, settling down at considerably below 1%. Dr Barbara's concern, which he expressed in evidence, about the 0.7%, which he accepted was known or believed, from a very early stage, to be the likely impact on the blood pool, was not, or at any rate, nothing like to the same extent, shared by Dr Gunson and his colleagues.

vii) As to the efficacy of the first generation assay, I heard considerable evidence about this, but in the end it did not become a central issue as to precisely what percentage this was. The informed view, both at the time and on further exploration in evidence before me, was that the efficacy ranged between 65% and 85%. My conclusion, having heard the evidence of Professor Zuckerman and Dr Caspari, but even the more sceptical evidence of Dr Barbara, and also the considerable assistance, drawn from the literature, of Mr Charlett, would be for a percentage of in the region of 75%. But I do not need to reach such a conclusion. On any basis it was bound to have a substantial effect on the reduction of Hepatitis C. In fact, since the research by Drs Simmonds and McOmish, it is now known that the efficacy of the first generation test was greater with regard to genotype 1, where it picked up 90% of those with the virus, than in respect of genotypes 2, 3, 4 and others, where the success rate was only some 30-32%. This differentiation between genotypes is something that was not known at the time, and only goes to confirm, given the fact that it would appear that at any rate in the United Kingdom, genotype 1 is the most frequent genotype, the overall percentage efficacy for all Hepatitis C virus, as set out above.

viii) Just as there is no case made by the Defendants with regard to loss to the pool, so there is no case made by the Defendants in relation to the cost of introduction of the assay.

ix) I have already set out that the supplementary test, RIBA 1, was available from 11 May 1990. It is common ground that it substantially reduced false positives. There is no suggestion that it was not a good enough supplementary test, and it was expressly conceded by Mr Underhill QC that the Defendants make no case that the United Kingdom should have waited for RIBA2 (although in the event, at least from the end of March 1991, that is indeed what occurred).

What Had to be Allowed For

159. Against the background above, the battleground between the parties has been as to what was legitimately expectable for a blood transfusion authority to allow for, to wait for, or to provide for before the introduction of routine screening, on the one hand, so as to arrive at a legitimately expectable period, and on the other, from the Defendants' point of view, so as to justify the period to 1 April 1991.

Practical Trials

160. The first factor to be allowed for was for appropriate tests to ensure that the assay could be used at the RTCs. There is no issue that these tests took about two weeks in December 1989, and that this was a reasonable time. In fact they were decided on on 6 November 1989, finished by 18 December 1989 and reported on to the ACVSB on 18 January 1990. Whereas of course there must be some allowance for decision-making and indeed reporting back to the appropriate body, the timetable does not seem to me to justify a delay in this regard until the middle of January 1990. There appears to have been no pre-planning, certainly no testing to the extent that there was in France, and very little evaluation of the assay during the period between April, or even, allowing for the Paris meeting, June of 1989 and Rome in September 1989: and there was in itself a delay after Rome. I see no reason whatever why the period of two to four weeks for the carrying out of, and reporting on, practical trials should not have started and completed considerably earlier than it did, not least in the light of the very full publicity and coverage from April 1989 onwards.

The need for Evaluation of the Assay

161. This is the second matter that is put forward by Mr Underhill QC, and it is put forward as an additional point to the carrying out of the practical trials. It seems to cover what was originally run as a separate point, but then became subsumed under the heading of evaluation, namely the need to wait, or at any rate the justification in having waited, for FDA full product approval. The lack of a very persuasive reason for waiting until after FDA approval was perhaps the reason why Mr Underhill QC did not run it as a separate point, but only as part of his case that there needed to be time for evaluation, for the word that featured most often in any explanation was the word '*embarrassment*'. In evidence, Dr Gunson said as follows in answer to a question from me:

> *"Q: Why did you need to wait for the US domestic test, to be done, when it seemed the FDA regarded it as sufficient* [I was referring here to the existence of the November export permit]

> *to allow you to have it on the understanding that you carry out your own tests, which you were perfectly capable of doing?*
>
> *A: The Department ... was anxious to have the FDA approval before we started testing, because it was a test that had been developed in the United States and they considered it would be very embarrassing if we had started testing using this test and the FDA came along and said, 'This test is deficient and you cannot use it in the United States'."*

I have already quoted something to similar effect from Professor Zuckerman in paragraph 151 above. Professor Zuckerman also wrote in his 19 December 1989 letter that *"introduction of the current test for routine blood donor screening in the United Kingdom should await the decision on licensing by the FDA in the USA, due at the end of March 1990* [in fact it was 2 May]".

162. However:

i) In the first draft of Dr Gunson's report on the Rome symposium, prior to its emendation by the ACTTD, he had put it only as low as *"it could be argued that the routine use of the test for blood donations in the UK should not commence before such a licensing procedure is effected"*. It is certainly the fact that the UK did not wait for FDA full product approval previously with regard to the HIV tests, nor, subsequently, prior to the introduction of the second generation anti-Hep C assays.

ii) Professor Zuckerman, it seems, did not know anything about there having been an FDA export licence the previous November, or indeed the nature or relevance of it. Dr Gunson, however, did. I asked him about it:

> *"Q: Just before you* [move on] *I want to be sure about this, and you may say 'I do not know' – please do not let me go forward on a false basis –* [do] *you believe the USA or the FDA do some tests, maybe not as many as they eventually do, before they are prepared to give an export licence to countries which they then expect, because they are what is called 'sophisticated', to do yet further tests of their own?*
>
> *A: Yes, When the test was introduced in the middle of 1988, it was for research purposes only, and all the work that was undertaken had to be reported* [by] *Ortho and they then put in a summary of their preliminary results to the FDA. I think it was November 23 or something like that in 1989, that they said the tests could be exported to other countries."*

Mr Hardiman confirmed that an Export Licence would not have been granted if there had been an objection from the United Kingdom Department of Health. In any event, of course, there had been the published articles, and the Paris and Rome symposia.

iii) If in fact a delay until May 1990 was simply in order to rely on evaluation by the United States, notwithstanding the fact that the Export Licence had been issued on the basis that the United Kingdom would be able to do its own evaluation, then, particularly given the priority to which I have referred, I can see no reason why such evaluation should not have been done; and Dr Gunson confirmed that the Department may well have been satisfied not to wait until FDA licence if suitable testing had been done by the UK. The opportunity was there for such UK tests to be done, by virtue of the early knowledge of the assay referred to in paragraph 147 above, and the limited evaluation that was done by Drs Contreras and Barbara, referred to in paragraph 148 above; and Dr Gunson accepted that some countries did commence testing before FDA approval, having carried out their own trials. The reports from the pilot studies in December 1989 made no mention of the need to wait for FDA approval (the only suggestion of any need for delay being by Mr Fuller of the Procurement Directorate of the Department, namely that in the light of what was suggested to be the impending arrival of the Abbott test (which in fact was seven months later) *"a monopoly-based supply decision would be precipitous at this stage"*. I am satisfied that, had the Defendants carried out their own tests, they would have been happy with the efficacy, would not have been offput (subject to what I say hereafter about counselling) by the percentage of repeat-reactives, and would have been entirely content with the assay's sensitivity, to which no material objection was ever raised. I have already referred to the favourable report by the Finns published on 23 April 1990. Dr Barbara was asked in evidence when he considers that it would have been appropriate to introduce the assay, and he stated that he could not give a date, but his feeling was:

> *"that once we had tests that were reliable, that would be sensitive, and we were able to confirm and we would not be jeopardising the donors, we could then provide the service to the patients without impact on the donors, and that would continue a good donor supply."*

In those circumstances, I am clear that Dr Barbara would have had no objection to going ahead, provided that the impact on donors was minimised, to which I shall turn below.

iv) If the point now being made is that waiting until FDA licence was obtained was in fact waiting for the USA to do the evaluation, and that that is the justification for the passage of time, then concomitant to that would be that the Defendants would have regarded the grant of FDA licence as being equivalent to such evaluation, and would have then proceeded to introduce the assay on that basis. However it is clear that they did not regard the grant of the FDA licence as the green light, or as the effective evaluation of the product, for, as has been seen above, in the ACVSB meeting, held in fact two months after the grant of the licence by the FDA, the decision was made then to go ahead with trials, although by this time it was to be comparative trials as between the Ortho and Abbott assays.

I conclude that, on a legitimate expectation basis, there was no need for the delay until 2 May in respect of evaluation, and certainly none after that. The right course would have been for any trials by way of evaluation, over and

above that which was required for the pilot studies, to have been carried out speedily, and without waiting for the FDA product licence.

The Need for Confirmation

163. The third factor put forward is the need for a confirmatory or supplementary test as an additional cross-check or filter in respect of repeat-reactive donations. The worry was about the counselling that would be required to be given to donors, in the light of the quantity of false positives. Unlike the position which I have set out in paragraph 133 above in respect of what would, or could, have been said to donors whose blood tested positive on either of the two surrogate tests, an apparent positive test on a specific anti-Hep C test would be a different matter, because it might suggest (subject always, of course, to the known substantial number of false positives) that the donor was a carrier of Hepatitis C. Dr Gunson highlighted the problem in his evidence:

> *"A donor whom you did not call for ... his or her usual donation, may phone the centre and would have to be told there was an abnormality in one of the tests and that is why we were not doing it; because you had to be honest with such donors and over the telephone was not the best way of doing it. You were better doing it face to face. Therefore I felt that we must have some positive policy on what we should tell the donors. I agree that the major consideration for the transfusion service is the care of patients, but the care of donors has to be carefully balanced with this, because, if you lose donors unnecessarily, then the care of patients becomes more difficult."*

Mr Underhill QC emphasised the potentially devastating impact of an uncertain diagnosis of Hepatitis C, especially in 1990, when so little was known about it. It was apparent that donor counselling was going to be necessary, and indeed in the report given by the West Midlands RTC in December 1989 of the pilot studies, the authors, while concluding that a 0.38% loss of the panel by virtue of the repeat-reactives would not be difficult to replace, stated that *"donor counselling by BTS consultants and further investigation by local hepatologists will require significant human resources"*. But the issue relating to the confirmatory test, given that repeat-reactives could be coped with so far as the effect on the blood pool was concerned even prior to the introduction of such a test, related to a desire to reduce the number of false positives, in the interests of donors.

164. The issue therefore, is whether to delay the implementation of screening until a supplementary test, in fact the RIBA test, was available:

i) It is clear that the Defendants knew that the RIBA would soon be available. Ortho wrote to Dr Cash on 27 November 1989 to inform him of the completion of production of prototype RIBA tests, upon which they were seeking *"feedback from several labs throughout the world ... so that we can use this information to introduce our confirmatory tests during the first quarter of next year"*. The minutes of a meeting of the National Management Committee of the NBTS on 4 January 1990, record that *"some progress had been made towards a confirmatory test using the same antigen in block form, and this may be available at the end of January"*. In fact, as set out in paragraph 152 above, it was sent to Drs Barbara, Mortimer and Follett in mid

February 1990, and tests could have been done (as did the Finns), but it seems that, if evaluation there was, it was of no great moment; and I have already there set out my conclusion that, had it been carried out, the United Kingdom opinion would have been as favourable as was that of the Finns. Professor Zuckerman's objection, to which I have referred in paragraph 153 above, was not to RIBA *per se*, but simply to the fact that it was not a true confirmatory test, and his evidence, contained in his witness statement, was that it was a useful test.

ii) The United States did not at any time say that it was going to delay FDA approval (indeed, according to Mr Hardiman, the fact that there were *"only six months"* between the granting of the export licence and the full product licence, indicated rapid movement on the part of the FDA) until the RIBA test was available, although it was in fact available shortly afterwards, and the Defendants submit this was no coincidence. But the Claimants submit that the United Kingdom did not have to wait for the RIBA test actually to be available before introducing routine screening. There was a certain amount of confusion in the evidence between what seem to be two different questions: the question on the one hand of introducing routine screening prior to the RIBA test being actually available, and on the other hand of deferring the informing and counselling of donors. That seems to have risen from a somewhat ambiguous paragraph in Professor Zuckerman's 19 December 1989 letter. The passage read:

> *"The data available to date indicate that the current test will identify a significant number of chronically infected donors. The number of false reactions cannot be determined, but all reactive donors may be deferred temporarily until a confirmatory test, or a test for another marker of Hepatitis C virus becomes available, probably within twelve months."*

Prior to Professor Zuckerman's evidence, it seemed that this was being interpreted literally, indeed by Dr Gunson himself, who, in examination in chief by Mr Underhill QC, said:

> *"Mr Underhill, I was not happy with that suggestion [of deferring telling donors], particularly if it was for a prolonged period. You see, I think in the previous meeting, he [Professor Zuckerman] said even up to twelve months."*

Dr Van der Poel did suggest, in an article in the Lancet in March 1990, that notification of donors could be postponed until after a confirmatory test became available (and it is clear that, at least in that part of Germany in which Dr Caspari has had experience, such deferment was there regarded as legitimate, save where an unconfirmed anti-Hep C test was accompanied by an excessively raised ALT elevation). But Professor Zuckerman, in evidence, firmly explained that (even if that is how the paragraph had read) it was certainly not what he meant, nor would he approve of such lengthy deferment of information to donors. However what Professor Zuckerman did say is that

"if pushed very hard" he would have accepted a few weeks' temporary deferment of information to donors.

165. The reality seems to me to be as follows:

i) Notwithstanding early discussion about the need for counselling procedures to be put in place as early as July and August 1989, as appears in paragraph 148 above, nothing much at all was done in relation to the setting up of such procedures, and in particular Dr Gunson accepted that, in retrospect, the fact that no preplanning was done for a year was obviously not satisfactory. Had there been counselling procedures in place, it appears to me that the system might have been able to cope, albeit with difficulty, as the West Midlands Report had indicated in December 1989, even without the confirmatory test, based on approximately 0.3 to 0.7% of repeat-reactives. There is no evidence of any difficulty in France or any other country which introduced routine screening before the availability of RIBA.

ii) However, whether by virtue of a short deferment of information to donors, or simply by a more adequate and well prepared exercise of introduction of counselling the additional false positive donors, the option of starting screening without RIBA immediately available was open to the Defendants. The evidence was persuasive. Dr Gunson agreed with Mr Brown QC that *"as long as you knew* [the RIBA test] *was coming, you can go ahead without it, provided you knew it was on the way, as everybody* [did ... although] *they were not quite sure when"*. This was consistent with his published position in 1987 in relation to HIV screening. Dr Gunson was reminded of his report to the ACTTD on 22 November 1989, that the ACVSB *"had noted the need for a confirmatory test either before or shortly after any routine testing of donations"*, and of his report to the Special Management Committee of the NBTS on 4 January 1990, to which I have referred above, whereby *"with regard to the absence of a confirmatory test, Dr Gunson advised the Committee that the ACVSB did not see this necessarily as a barrier to the introduction of routine screening, but the ACVSB would insist that any test for routine use must be licensed by the FDA"*. Dr Gunson's evidence was, in summary, that the need was to have a confirmatory or supplementary test available *"within a relatively short time of commencement of routine* [screening]". I am satisfied that it was, in all the circumstances of priority, and in the light of the need to protect recipients, not necessary to wait to implement routine screening until after the RIBA test was actually available.

The Need to Compare Ortho with Abbott

166. The fourth matter that is raised as an essential aspect to be taken into account in the time scale is the question of comparison between the Abbott and Ortho assays. This, as appears in paragraph 162(iii) above, was seemingly in the mind of the Department as early as December 1989, when the Abbott test was very far from being available, and was introduced as a matter of substance, as appears in paragraph 153 above, at the 24 April 1990 meeting of the ACVSB, still two to three months before the Abbott test became available, in July 1990 – more than twelve months after the Paris symposium, when the Ortho test was given its full public airing. Mr Underhill QC emphasises that it must be appropriate for the Defendants to have considered the question of pricing,

of quality and of security of supply, so as to avoid the Defendants being locked into a monopoly situation, and Professor Zuckerman confirmed in evidence that the ACVSB had considered that it was important to test the Abbott and Ortho test against each other, and then have them further tested by RIBA and PCR, before proceeding to the introduction of screening.

167. However:

i) Dr Gunson accepted, with hindsight, that the comparative test could have been done as part of routine screening once implemented:

> *"An alternative would have been to introduce the test using Ortho at some centres and Abbott at other centres, and then combine the results of that screening ... into a formal study. That with hindsight is a possibility that could have been done."*

ii) In fact, it would appear, there would have been no irrevocable act carried out, tying the Defendants in to one supplier rather than another, and thus putting at risk security of supply or encouraging a monopoly situation; since, first of all, the equipment – be it Ortho or in due course Abbott – was in fact, it appears, to be hired rather than purchased, and secondly, negotiations with Ortho sensibly included provision for a 90-day break clause.

I do not consider that, once again considering all the *circumstances*, delay ought to have been incurred, while a three month, or even two month, comparative assessment was first funded, then carried out and thereafter reported on and assessed.

Implementation in the RTCs

168. The fifth matter is the question of implementation. Criticism was made by Mr Brown QC of such matters as inadequate or delayed or infrequent meetings, but, for the reasons set out above, I am not concerned with making findings in that regard. What I have to look for is what in fact was legitimately expectable as a time scale. In order to introduce routine screening, additional equipment would almost certainly be necessary, perhaps additional accommodation, either by way of extensions or possibly new buildings (with no doubt temporary arrangements in the meanwhile); additional staff would need to be recruited and trained. The view of the RTCs, when asked by Dr Gunson in January 1991 as to how long they needed, varied between four and six months (although he said in evidence that he thought six months somewhat long):

i) The first question is whether that amount of time is necessary. It is clearly appropriate that matters should not be unsafely or skimpily rushed, as Mr Garwood warned. Equally in some centres there might have needed to be additional building (there was only evidence of such need in relation to one centre); although, as set out above, there is no reason why temporary space could not have been made available if such building was going to take a considerable period of time. It does not seem to me to be *per se* objectionable to attempt to introduce routine screening simultaneously throughout the United Kingdom: criticism has been made that it appears that the basis of the thinking behind this was to avoid litigation, but the principle does not necessarily seem

to me to be unacceptable, and allows for a co-ordinated national policy. It is obviously important to have a date for commencement, rather than leaving the whole thing flexible, because if staff had to be recruited and trained, it would need to be known by what date this was to be completed, in order to avoid wastage and delay. Mr Garwood estimated four to six months as appropriate. However Dr Barbara, in his explanation of the introduction of new screening tests, did not allow for anything like such a long period. He explained that there would need to be national approval for the equipment (in this case Ortho) and there would then require to be *"local validation, the setting up of information technology systems, production of standard operated procedures, staff training, assessment of staff training and a final process qualification"*. He estimated that those elements would in his opinion *"require one to two months to occur ... especially ... where you had a new marker rather than a replacement test for an existing marker"*. This was in examination in chief: in re-examination he concluded that this *"may be a little optimistic"* and that *"it depends upon the experience within the centre, the staffing that they have in the centre, what structures they have for staffing, what building facilities ... It would vary from centre to centre and some centres would – might have found it quite tight to comply within that time period for that local qualification"*.

ii) Quite apart, however, from how long would be required for such implementation, there would be the question as to from what date such implementation should be started. Apart from the delay which Dr Gunson accepted, in hindsight, had occurred in relation to the devising of policies and procedures in relation to counselling, in the chronology of the United Kingdom's introduction of screening, which, as can be seen, carried through from Rome in September 1989 to September 1991, the implementation period of six months comes at the end, namely in fact from February to August 1991. In Mr Underhill QC's submission there requires to be tagged on, at the conclusion of whatever period should be allowed, a justifiable implementation period of six months. Thus, on his case, based on 1 April 1991 as notional commencement date, such 6 month implementation period would start in November 1990, more or less on the heels of the comparative Ortho/Abbott trials, assuming that those themselves had started a little earlier than they did. But that allows for no preplanning, and for no overlap between implementation and such trials and evaluations as could or should have been carried out. Even leaving aside preplanning, a start after Rome, not to speak of before Rome, like France, upon the evaluations would have led to a much speedier implementation. Mr Underhill QC in re-examination elicited from Dr Gunson the answer that *"the same sort of timetable"* would apply for implementation even had they *"pressed the button immediately after Rome"*. But that in itself, of course, introduces a substantially earlier timescale, and I note the answer that Dr Gunson gave to Mr Brown in cross-examination when asked, if the question of the need for a prior confirmatory assay were left aside, when routine screening could have been introduced, namely that he would not like to be committed on whether the centres could have been ready for the introduction of screening as early as the beginning of 1990, but *"certainly early in 1990"*.

Funding and Decision-Making

169. The sixth and last factor raised by Mr Underhill QC, was what he called funding and decision-making. Clearly there has to be funding, and decisions have to be made. But there is no reason why funding should not be pre-arranged and then provided whilst the process is continuing, rather than holding it up: and there seems to me to be no need in estimating a time-scale for anything other than full allowance that decisions must be taken by those who are fully informed, as opposed to building in positive delays for fixing up of such meetings or the obtaining of ministerial decisions.

Conclusion on Routine Screening

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

> *"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 QC'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 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 QC'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 paragraph 100 in sub-paragraphs (i) to (vi): as to sub-paragraph (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 paragraph 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 Article 4 (and s2 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 QC pursued his submission, referred to in paragraph 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 Article 6 must be different from its definition for the purposes of Article 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 Article 7(b) as discussed in a different context in paragraph 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 Articles 1 and 4, and defined in Article 6, with relevant escape clauses in Article 7, and must be consistent in its meaning.

Secondly, as Mr Brown QC pointed out, if *unscreenedness* be the defect, then all blood bags must be defective, when none is screened: only 1 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 QC 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 QC succinctly put it in argument, the *defect* was the virus in the blood and the *damage* was the virus in the patient. Mr Underhill QC 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 QC 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 Hoffman in Banque Bruxelles Lambert SA v Eagle Star [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* [211g] *... 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.* [212c] *... 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* [212g-213a] *... Normally the law limits liability to those consequences which are attributable to that which made the act wrongful* [213c]."

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 [1970] AC 166 at 176:

> *"In assessing damages which depend upon its views 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 QC, was of a product, which was dangerous, but would not have been found to be defective within Article 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 QC, 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 QC's case nor, on the basis of his disavowal of investigation of fault, Mr Underhill QC'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 QC, 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 Articles 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 paragraph 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 QC's aphorism set out in paragraph 175 above. As far as the Directive is concerned, Article 1 enunciates liability for damage caused by a defect: Article 6 defines when the product is defective: Article 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 paragraph 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 QC, 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:

   c) that fairness to the producer may be considered to be sufficiently provided for by the express exonerating circumstances of Article 7, and the contributory negligence aspect of Article 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 Section 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 insofar 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 Health Authority [1987] AC 750, and especially per Croom-Johnson LJ at 769 (CA) and per Lords Bridge and Mackay at 782d-e, 785-6 (HL), and to Judge v Huntingdon Health Authority [1995] 6 Med LR 223.

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 paragraphs 74-77 and 82 above, that in the light of my conclusions on the construction of Article 7(e), the defence is not available to the Defendants (Issue IVa). However I must turn, as foreshadowed in paragraph 84 above, to decide the issue of the availability to the Defendants of the Article 7(e) defence on the assumption that, contrary to my conclusions in law, the Defendants' construction of Article 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 paragraph 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 QC 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 QC 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 Article 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 Commission v UK *eliminated* or *prevented from arising* (paragraph 20 of his Opinion). Certainly it is fundamental to Mr Underhill QC'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 Article 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 Article 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 paragraph 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 paragraph 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 Article 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 QC 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 Article 6 and Article 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 Commission v UK. Mr Underhill QC pointed to paragraph 24 of the Advocate General's Opinion, 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 reasonable 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 Article 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 Article 7(e) as for Article 6, namely 1 March 1990, as the date of what Mr Underhill QC 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 May 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 paragraphs 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 QC'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 QC 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 paragraph 100(vii) above). However whereas I can entirely see the relevance of this to the question as to whether the blood was defective within Article 6 (see paragraph 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 QC 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 per Croom-Johnson LJ at 769:

> *"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 Defendants' 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 paragraph 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 Article 7(e), establish that in respect of the period between 1 March 1988 and 1 March 1990, the introduction in the UK 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 Article 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 Article 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 Article 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 specific 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 (twenty four weeks) or twelve months (forty eight 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 £6006.10 for six months, and £11458.20 for twelve months: and of pegylated combination therapy as, respectively, £6631.10 and £12708.20. 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 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 paragraph 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.

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 QC 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 1988-9, 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 thirteen years, and it is, as will be seen, a disease with a potential duration of fifty 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 inter-relation 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 paragraph 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 paragraph 189(iv)(c), the median estimated duration of infection through to cirrhosis was thirty years. It is now estimated that, of those with chronic Hepatitis C, 20% (i.e. about two thirds of Category C) will develop cirrhosis in twenty years, and another 10% in thirty to fifty 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 150 million (I note that Dr Gane had earlier given an estimate of 300 million infected) and as 5 million 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 breast-feeding), 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 thirty 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 twenty to fifty 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 predicated 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 paragraph 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 twelve 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 a 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 paragraph 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, on the 'Quality of Life', using approved questionnaires. 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 QC 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;

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 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 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 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 QC:

> *"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, 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 illness."*

Then further in cross examination by Mr Underhill QC:

> *"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 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 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 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 – i.e. 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*). 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*

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 paragraph 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 QC 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 (29 July 1998), *Kemp & Kemp*, 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,

action, develop some serious disease or suffer some serious deterioration in his physical or mental condition". Pursuant to Part 41.2 of Civil Procedure Rules, 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 AER 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 Part 41.2 of the CPR 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 paragraph 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: e.g. 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*".

resilient, pessimistic, anxious or fearful, and the circumstances of the Claimant. Mr Brooke QC 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 paragraphs 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 QC'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: e.g. 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 QC.

214. Biopsies etc.

i) Mr Brooke QC 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 QC has taken me to examples in *Kemp & Kemp* of minor injuries, but I accept Mr Underhill QC'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 QC 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 & 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 QC, 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 QC 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, insofar 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 paragraph 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 paragraph 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 QC 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) e.g.:

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 paragraph 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 paragraph 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 QC did make reference in opening to the Law Reform (Personal Injuries) Act 1948, s2(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 (per Slade J at 635: *"I do not understand s2(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] 1QB 942, (CA) (per Lawton LJ at 957f: *"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 QC'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 QC, 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 QC'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 BCCI [1977] ICR 606. 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 girl-friends 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 inter-connection 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.

    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 fifty 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 QC, 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 QC 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 pre-requisite 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 Reyrolle [1976] ICR 253 at 261, was corrected by the judge in the Weekly Law Reports' report ([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 QC in which the claimant was not in employment at the time of trial, including Mitchell v Liverpool Area Health Authority (13.6.85 *Kemp & 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 County Council [1986] 1 AER 567). Such loss must be calculated "*in the round*" (Smith v Manchester Corporation itself [1974] 17 KIR 1 at 8) or "*plucked from the air*" (Moeliker per Stephenson LJ (1977) 1 WLR 132 at 144).

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 investigatable 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 QC 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 paragraph 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. Insofar 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 QC 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 – e.g. 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 paragraph 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, i.e. 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 paragraph 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 [1973] QB 942, Donnelly v Joyce [1974] QB 454), the central starting point is of course Housecroft v Burnett [1986] 1 AER 332. The seminal passages are those in the judgment of O'Connor LJ:

> *"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 costs'? 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 upon the facts of the case."*

The Claimants' Submissions

228. Mr Brooke QC 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 [1994] 5 Med LR 230 at 232, 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, a first instance decision of Morland J, reported only in *Kemp & Kemp* (A4-120), 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, 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 its love and support. Mr Brooke QC, 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 a sum of apparently more than the commercial rate was awarded to the Plaintiff's parents, in Housecroft 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 AER 854, a deduction equivalent to 14% was not disturbed by the Court of Appeal.

v) In Biesheuvel v Birrell [1999] PIQR Q40, Eady J at Q43 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 QC responds as follows:

i) The logic of Housecroft is quite clear, that the *"extreme solutions"* (full commercial costs on one hand and nothing on the other) are normally both inappropriate.

ii) Fish 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 at 461-2 *"the proper and reasonable cost of supplying those needs"*, in Housecroft itself per O'Connor LJ at 343e *"reasonable recompense to the relatives"* and in Hunt v Severs [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 GRO-A 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 GRO-A real and significant distress. Care and supervision have been required day and night. Not surprisingly through broken sleep, worry and anxiety Mr GRO-A has been fatigued and unable to concentrate and put as much into his business as he had done before GRO-A 's birth. Mrs GRO-A has been depressed and required medication ... Both* [experts] *found it difficult to suggest what was suitable recompense for Mr & Mrs GRO-A 's care for GRO-A at night, which involved putting her back to sleep several times a night, and most nights having to change her bedding when wet ... Miss GRO-A 's figure of £42,982, did not take into account night care. Both Miss GRO-A and Miss GRO-A 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 GRO-A '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 although the Court of Appeal left the Judge's award unaltered, O'Connor LJ said as follows: *"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 £4000. 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"*.

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 (CA) (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% for tax and national insurance, comes to about £82,000*".

230. I accept the submissions of Mr Underhill QC, 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, 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 plaintiff] *undoubtedly involves special skills over and above those normally possessed by Crossroads assistants or nursing auxiliaries*". In Petrovska v Mullings (13.8.99 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 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 QC's contention that, notwithstanding, or in the light of, the decision of the House of Lords in Wells v Wells [1999] 1 AC 345, and notwithstanding the absence of any exercise by the Lord Chancellor of his powers under s1 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 the case of Petrovska, 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 was not appealed, there has subsequently been a binding decision of the Court of Appeal in Warren v Northern General Hospital Trust [2000] PIQR Q284, 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 QC's submission, Mr Underhill QC indicated that he would have sought to adduce evidence in opposition to the belated evidence to be adduced by Mr Brooke QC. I indicated that there was no need for him to do so, as I rejected Mr Brooke QC'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 and more conclusively by the Court of Appeal in Warren.

ISSUE VI: THE SIX LEAD CASES

233. I turn to consider each of the six lead cases, and to resolve the outstanding issues of quantum with regard to each.

Mr S

234. Mr S is now 17. He gave evidence, as did his father and mother, with whom he lives, and his elder brothers, who have now left home. He was hospitalised with a head injury and a broken leg from a car accident when he was aged 7, and in the course of treatment for his injuries on or about 3 April 1991 he received a blood transfusion, which was infected with Hepatitis C virus. He was informed of his having been

infected in November 1995, as a result of the Defendant's Look-Back programme, referred to in paragraph 1 above. He tested positive by ELISA for Hepatitis C antibodies, but has always, as from the first PCR test in November 1995, tested PCR negative, and his ALT was normal. He is thus one of the 20% referred to in paragraph 191 above, who spontaneously cleared the virus. He had three negative PCR tests, and never required a biopsy, and by a letter of 16 March 1999 Professor Day wrote to confirm that *"he has completely cleared the virus and is therefore not at risk of chronic Hepatitis C"*. He has had no physical symptoms and has normal liver function, but he has been diagnosed by Dr Master, and confirmed by Professor Wessely, to have been suffering from an adjustment disorder for a three and a half year period, ending on receipt of Professor Day's letter. He has never been tested for genotype, and therefore it is unknown. His prognosis is excellent, and his worst case risk is of a 1% chance of developing some symptoms in more than thirty years: he must, of course, like all those who are opting for provisional damages, in any event be viewed on the basis that he will always remain in a condition short of activating any of the five triggers, for in that event (which in Mr S's case is wholly unlikely anyway) he could in any event apply for further damages: I direct, by agreement, that all five triggers apply to him. He received a letter dated 7 July 2000 from his consultant, after his last review which states: *"As always he is very well indeed. He is now 17 years old and we have been following up for five years because of Hepatitis C positive antibodies. In that time his Hepatitis C PCR has always been negative and his liver function tests have always been entirely normal. I repeated his blood tests again today and as before his liver function test and Hepatitis C PCR were negative. I think therefore that we can conclude that* [he] *has cleared his Hepatitis C and I have not arranged to review him again."*

235. The Issues. There are the following issues between the parties in Mr S's case. I propose in relation to all the Claimants not to record all the items of damage which have been agreed prior to the hearing or during the course of the trial, unless there is some particular relevance:

i) Quantum of general damages for PSLA by reference to the sub-categories of (a) infection simpliciter (b) adjustment order (c) vulnerability.

ii) Employment handicap.

iii) Gratuitous care.

iv) Follow-up costs.

236. PSLA

i) There is no suggestion in the case of Mr S that he has suffered from fatigue. His problem was rather the reverse, namely that he became aggressive, ill-tempered and moody. He was upset about being told about the infection, and, particularly in those days before quite as much was known about horizontal transmission, about the fact that it could be contagious: he was anxious about the precautions that he was told he had to take, which affected his relationship with his young nephew, and he was concerned about his future and about parenthood. He had a panic attack when he cut himself in a woodwork class at school and a teacher tried to help, and similarly, later, at his work when he cut his head. He was, until his final reassurance by Professor Day in March 1999,

fearful that the virus could flare up at any time. He suffered a certain amount of worry about telling people his condition; for example he was anxious about going away on holiday with a school friend without telling him or his parents about it, and an ex-girlfriend's mother was unpleasantly rude to him about his condition.

ii) It is, in my judgment, impossible in Mr S's case to differentiate, in assessing his total condition and his damages, what is categorised as the infection simpliciter from the adjustment disorder; for in his case the latter lasted through to the date when he was reassured, and in fact tied up with, or led to, the aggressive and other unacceptable behaviour which were the only outward symptoms he had, and which were plainly the external manifestations of his own internal concerns and worries. In effect, he had three years of bad behaviour, aggression and intolerance towards his parents and brothers. It seems to have affected his home life rather than his school time, for he did not absent himself from school, and although his school records indicate a distraction and a lack of co-operation and attention, with a number of reports for poor behaviour, it amounts to nothing that is much worse than one could expect of many teenage schoolboys. But at home he was very difficult: picking quarrels with his mother in particular, fighting with his brothers and his father and being totally unco-operative. Professor Wessely agreed that *"he developed what is best described as an adjustment disorder, associated with conduct and emotional disorder. I would agree that whilst many, perhaps even all, adolescents experience mood changes and argue with their parents, this was out of the ordinary and amounts to a recognised psychiatric disorder"*. His father, mother and brothers gave evidence of his unacceptable behaviour, of locking him into his room and of frequent temper tantrums and fraught discussions. I note also the breakages, whose cost has been accepted by the Defendants.

iii) I accept and find all that. However I also accept and find as follows:

a) He was advised by Dr Ryder that he did not need to adopt any different practices with regard to alcohol, or to sex, than he would otherwise do: that he was at no risk at all of sexual transmission.

b) It is not an easy life to be the youngest of three brothers, and it would seem they had been considerably better behaved teenagers than he, which was no doubt frequently pointed out to him, and they, and in particular the middle brother, Raymond, were not prepared to accept any cheek from him.

c) He was not as a result of his condition inhibited from playing football, which he continued to do as long as he wanted, although by the time he was fifteen he had ceased to be interested in playing for the local team and preferred other activities.

d) I do not put his relatively unsatisfactory school performance (which was reflected in similar comments even before his knowledge of his infection) down to his condition or his awareness of it.

e) Even after he had had the good news from Professor Day, and his adjustment order was at an end, he continued to be occasionally obstreperous and provocative at home. His middle brother was asked to carry out the somewhat difficult task of assessing *"what proportion of his total behaviour you think was due to his natural character?"* to which he answered: *"I would say at least 25-30% of him, of his cheekiness and everything, out of the whole proportion, but the rest of it was pure nastiness, I think."*

f) He is now able to put behind him not only the teenage years but also the fears which have now been totally resolved by the prognosis.

iv) Vulnerability. I refer to my conclusions in paragraph 209 above. There was no suggestion but that Mr S is a perfectly resilient young man, now facing the future with confidence, as Dr Master and Professor Wessely agree. However Dr Master sought to promote his theory by ascribing vulnerability to him *"in statistical terms"* or *"all in a statistical sense"*. For the reasons I have given I do not accept this, and make no provision for vulnerability. Of course the fifth trigger is there for him, in the unlikely event that it is required.

v) I have been referred to authorities and references relating to quantum for my guidance by both parties. The Claimants, on this and other cases where an adjustment disorder is relevant, namely U and V, have referred to Ross (1991) *Kemp & Kemp* C4-058 (Master Topley), Waller (1993) *Kemp & Kemp* C4-051 (Judge Peppitt QC), Khan (1996) *Kemp & Kemp* C4-066/1 (Judge Altman), Watson (1998) *Kemp & Kemp* C4-049 (CICB), Long (1999) *Kemp & Kemp* 2000 C.L. 118 (CICB), and the CJD Litigation (unreported, 19/6/98) (Morland J). The Defendants have taken me to the fifth edition of the Judicial Studies Board ('JSB') Guidelines, updated in late 2000, since the June issue of *Kemp & Kemp,* relating to psychiatric damage. These important guidelines split up psychiatric damage into Severe Psychiatric Damage, Moderately Severe Psychiatric Damage, Moderate Psychiatric Damage, and Minor Psychiatric Damage, and set out material factors to illustrate the suggested categories and also broad bands for quantum (in relation to the last two categories, £3000 to £9500 and £750 to £3000). The Defendants suggest that Mr S's three year adjustment disorder falls within the last of the four categories. They also refer not only by reference to Mr S, but also the other lead cases, to Slimings (1992) *Kemp & Kemp* C4-111 (Scott Baker J), Evans (1992) *Kemp & Kemp* C4-109 (D. J. Evans) and Howell (1995) *Kemp & Kemp* C4-074 (D. J. MacMillan) and, with regard to the adjustment disorder, to Szulc (1995) *Kemp & Kemp* C4-113 (Judge Alton) and Carpenter (1997) *Kemp & Kemp* C4-114 (Judge Lorriston). I have also noted Rubens (1997) *Kemp & Kemp* L3-052 (Judge Peppitt QC). I invited the parties to put forward their suggested figures. The Claimants submit £10,000 for infection simpliciter plus £10,000 for adjustment disorder, namely a total of £20,000: the Defendants put forward £1000 for infection simpliciter plus £3000 for adjustment disorder, thus a total of £4000.

237. I have considered these cases and the parties' submissions. For the reasons I have given, I find it impossible in the case of Mr S to sever out infection simpliciter from adjustment disorder, as I have been invited to do. Apart from the adjustment disorder

and the behaviour exemplifying it, as to which I must obviously pay close regard to the JSB Guidelines, I take into account in addition the fact that Mr S was actually infected (rather than simply fearing he was infected as in GRO-A s, GRO-A and GRO-A), albeit that there was a lack of physical symptoms and a spontaneous clearance of the infection before he was aware of it; his anxiety and concerns; his embarrassment with his friends; and the fact that the adjustment disorder lasted three and a half years. My conclusion as to damages in total, and having looked in the round and paid regard to his good prognosis and the fact that (unlike in the CJD Litigation) the damages are provisional on the basis discussed, is a sum of £7000. If I had to split this sum, notwithstanding that the same underlying behaviour and symptoms relate to each of the aspects of the award, I would, with some reluctance, split it equally; but the total sum would better reflect the correct answer in respect of the whole period, effectively of three and a half years from discovery to total reassurance.

238. Employment Handicap. I refer to paragraph 222 above. The Claimants claim £2500 and the Defendants respond with nil. Mr S has been working in the catering trade now for some time, and without difficulty. He had filled in a health questionnaire before joining, which he did, after advice from his parents, without problems. He would like to be an estate agent, having worked for one on a work placement, and is in the process of applying. If he were to remain in catering, there is in fact no sufficient evidence from Mr Langman (rather the reverse, as appears in paragraph 222(ii) above) that this would create any difficulty, and, in any event, he will by then have a proven track record of working in the catering industry. Estate agency would seem to create no problems at all. The crux in any event so far as Mr S is concerned is that he spontaneously cleared the virus and has been PCR negative for five years. I can see no evidence of, nor grounds for inferring any risk on the labour market. I make no award.

239. Gratuitous Services. I refer to paragraph 231 above. I do not see any grounds in this case for not making a Housecroft deduction, which in this case the Defendants concede at 25%. In fact, by making a 25% deduction I suspect more is being paid than the commercial rate, simply by virtue of the fact that the commercial rate incorporates tax and national insurance at a percentage likely to work out at rather more than that. In any event, Mr S's parents are being recompensed for devoting more time and effort than can have been expected from normal parents, and that is why they are being paid at all. I agree with the Defendants that there is insufficient allowance, if payment were provided for in respect of one hour per day at the net commercial rate, for the fact that the behaviour with which they were dealing was to an extent that of an obstreperous teenager, overlaid by his disorder. His teenage years were a worse experience for them than those of either of his elder brothers, but I suspect that that is very often the position with the youngest of three boys, and, given the teenage character of Mr S, I conclude that there would have been a good deal of coping with tantrums and aggression in any event, as perhaps Raymond recognised. The fact that this is the case is further underlined by Mr S's continuing behaviour after March 1999, which I do not ascribe to his condition. That supports my conclusion that to allow for one hour per day throughout for coping with behaviour caused by the adjustment disorder would overcompensate, so that it falls to be reduced by the 25% allowance for which the Defendants contend; it also leads to my acceptance of the Defendants' contention that there should be no recovery after 31 March 1999. The rates are agreed, but they must be net of the Housecroft deduction. The figure, after the further allowance and disallowing the period after 31 March 1999, is £3512.25, which is the sum I award.

240. Follow-Ups. I refer to paragraph 214(ii). The cost of an annual follow-up is claimed. The Defendants discount the figure by 50%, to allow for the probability that there will not be an annual follow-up in respect of those, such as Mr S, who will have been PCR negative for many years. In his case there is the additional factor of the receipt of the letter of 25 July 2000, which I have set out in paragraph 234 above. I accordingly accept the Defendants' figure of £56.08, adopting the agreed multiplier.

Mr U

241. Mr U is now 32, and gave evidence. He has a wife, who also gave evidence, and two young children, with whom they live. He was infected in January 1991, while hospitalised with orthopaedic injuries after a road traffic accident. His infection is by genotype 3a. He also learnt of his infection as a result of the Look-Back programme, in March 1996, and tested PCR positive. He had biopsies in 1996 and 1998. He underwent Interferon monotherapy in 1996-7 over a period of nine months, and briefly responded, but soon thereafter reverted to PCR positive again. He had combination therapy for six months, starting in December 1998, which was successful. He is still PCR negative after tests in November 1999 and May and October 2000. He has therefore *cleared*, or has 'controlled', the virus: there is the very small risk that he may be one of the very exceptional cases who revert to positive, as discussed in paragraph 191 above, but, for the purpose of provisional damages, because of the existence of the first trigger, it must be assumed that he will not do so. He has no liver damage, as was made clear by the biopsies, and Dr Ryder put his worse case scenario as a 5% risk of liver disease in twenty years. Mr U described himself in evidence as '*back to 100%*'. He was diagnosed by Dr Master, and confirmed by Professor Wessely, to have had an adjustment disorder for a short period of two months from March to May 1996, immediately after the discovery of the infection, and a very short further transient period in May 1999. He too opted for provisional damages, and I so direct, with all five triggers applicable; so that he is to be assessed on the basis (as indeed is overwhelmingly likely to be the case, given his favourable prognosis) that he will remain short of the conditions there provided for.

242. The Issues

i) Quantification of General Damages for PSLA in the sub-categories of (a) infection simpliciter including fatigue. Adjustment disorder is agreed between the parties at £1000. As for vulnerability to future disorder, this is thus not a separate issue and in any event the 'Master theory' does not arise, and Professor Wessely's view, which I accept, was that Mr U would only be at risk of a further problem if it were to be that he had not cleared the virus, which he has (and/or the trigger(s) will provide for it): (b) the two biopsies: (c) the two Interferon treatments.

ii) Employment handicap.

iii) Insurance handicap.

iv) Gratuitous care, past and future.

v) Follow-up cost

243. PSLA

i) Mr U was devastated, as anyone would be, to learn of his infection. It affected his sleep and his appetite. He became lethargic and anxious about the fate of himself and his family. He was of course, until his second Interferon treatment, PCR positive, and he was very worried about his prognosis. His relations with his wife were affected by their worry about infection and they used contraception, although not always, as is clear from the conception of their second daughter in 1997. Like Mr S, he had a worrying time with a cut finger.

ii) His evidence about his fatigue and lethargy, which plainly arose from his inevitable stress and anxiety (and no doubt also during, and because of, his short adjustment disorder) has, I am satisfied, its limits however. He asserted that it was because of fatigue that he left his senior job with a courier firm, in respect of which he also made a claim for loss of earnings. After he had begun to be cross-examined about the latter topic, he abandoned his claim for loss of earnings; and I am satisfied that the reason he left the courier company was rather to further his business opportunity to work for, and soon after go into partnership in, a music business, which has substantially prospered. As a result of two promotions in the courier business, he was in fact doing much less manual work, if any at all; although he may have been labouring under a degree of 'middle management stress'. However it is clear that he was not driven to leave by the need of a break from work, due to fatigue, but rather went straight into his new business. In those circumstances I discount the evidence he has given about fatigue, although I accept the evidence, to which I refer below, that he, like others, suffered from tiredness during the period of his Interferon treatment.

iii) There is no doubt that he and Mrs U were worried about intimate relations. But this is now, it is hoped, resolved. With the benefit of advice to the effect referred to in paragraph 197 above, both of them are prepared to reconsider and readdress their concerns.

iv) His morale is now restored and, having been PCR negative for more than a year, he can put it all behind him. He was not back to his 'old self' in 1998 (no doubt because of the Interferon treatment to which I shall refer) but he is now '*100%*'. He confirmed too that "*the tiredness is not there any more, no lethargy any more*".

v) As to quantum in respect of infection simpliciter including fatigue, the parties refer to the same authorities. The Claimants put forward a sum of £12,500 for infection simpliciter and £2250 for fatigue, totalling £14,750: the Defendants £2500 for infection simpliciter, and nothing for fatigue.

vi) He had two biopsies as set out above, under local anaesthetic and without having to stay overnight. The site was sore, but he was not frightened. As for quantum in respect of the biopsies, I refer to what I have said in paragraph 214(i) above. The Claimants put forward £500 per biopsy (thus £1000 in all), and the Defendants £250 each, £500 in all.

vii) As to Interferon, he had two treatments, the first lasting nine months and the second six months. The side-effects were as discussed in paragraph 215 above.

He suffered flu-like symptoms, lost appetite and lethargy: on the second occasion also loss of weight and hair – both of which were restored after the treatment. He did not self-inject, and so his wife carried out his three-times weekly injection for him. He continued to work throughout both courses, and was reported contemporaneously as having coped very well with the first course. He confirmed in evidence that *"you tend to get used to it"* but he described it as *"horrible stuff"*. Although disappointed by the failure of the first course, I do not conclude on the evidence that such disappointment needs to be separately compensated (see paragraph 215 above). The second course too he managed to adjust to, by developing his strategy for minimising the problems. As for quantum in respect of the Interferon treatments, the same point applies as in respect of biopsies, namely the effect of its being only part of an overall condition; but of course their duration was considerably longer than a biopsy. The Claimants refer to a case which was, but it seems is no longer, in *Kemp & Kemp* called Ashworth v Jackson (March 24, 1970, CA) which is a case involving the accidental contraction of brucellosis by a 36-year old man producing disturbing and unpleasant symptoms over a period of five months: the Court of Appeal approved a figure of £200, which I am informed would now be equivalent to £1834. The Claimants put forward figures of £5000 in respect of the first treatment and £2500 in respect of the second, namely totalling £7500. The Defendants' figure is £1500 plus £1000, totalling £2500.

244. As indicated above, the adjustment disorder is separately dealt with by the agreed sum of £1000, and I am not prepared, particularly in this case, to assess fatigue separately. I take into account that the knowledge of the infection lasted longer than it did in respect of Mr S, whose virus cleared spontaneously, although the adjustment disorder was far shorter in this case, and is being separately provided for. I note the favourable prognosis, the fatigue now cleared up and the fact that the periods with Interferon are also separately assessed: and again the fact that the damages are provisional. My figures are, for infection simpliciter (including fatigue) £5000: for the biopsies £250 each, and for the Interferon treatments £2000 for the first and £1500 for the second, totalling £9000. These sums, plus the agreed £1000 for the adjustment disorder, result in a total of £10,000 in aggregate, which I approve and award, and it is that total sum which falls to be compared with the figures awarded in the cases referred to in paragraph 236(v) above.

245. Employment Handicap. The Claimants put forward £5000: the Defendants nil. In the light of the factors that (i) Mr U had a successful job in the courier business which he left voluntarily (ii) he is now self-employed and is making a success of the music shop business, with an additional shop opened recently (iii) he is and will have continued to remain PCR negative, there is no evidence before me, nor inference that can be drawn, of any risk to him of loss of earning capacity by virtue of his condition. I make no award.

246. Insurance Handicap. The Claimants put forward £1500: the Defendants nil. He has prudently made his own insurance arrangements already, as he explained, including three policies with Allied Dunbar, and he has already remortgaged. In any event, the evidence from the agreed joint experts' report is that further cover is likely to be available to him, whether for five or fifteen years life cover, or five or fifteen years

critical illness protection, at normal rates: indeed Norwich Union have offered both, and accidental death cover, at a nil rating. I make no award.

247. Gratuitous Services. Mrs U has been a great support to Mr U. For the reasons given in paragraph 227 to 231 above however, I consider that insofar as she may be entitled to recompense in respect of time spent over and above that spent in ordinary course by a wife's support and companionship of her husband, there should be the Housecroft deduction, conceded by the Defendants to be 25%. As with others, the excess over what has been called 'wifely support' is not recognised by a wife being paid an excessive amount, but rather by her being paid at all, and there is no justification for more than the net commercial rate. The Defendants have however limited this recompense to the period of Mr U's actual adjustment disorder. I consider that Mrs U should also be recompensed in respect of her assistance during his periods of Interferon treatment, when she injected him and no doubt gave other additional support. My conclusion is of an extra one and a half hours per week for sixty five weeks at £4.80 per hour less 25%, namely £351 additional to the £123.12 conceded. I see no grounds whatever for allowing any further care in the future, in that he is back to 100%, and not likely to have any further treatment.

248. Follow-Up Cost. I refer to paragraph 214(i), and for the reasons there given it is right to discount, as the Defendants do, for the probability that there will not be annual check-ups at least for very long, and, in any event, as it is neither reasonable nor appropriate to provide for attendance by Mrs U. I agree with the Defendants' figures of £52.77 on the agreed multiplier.

Miss T

249. Miss T is now 20, and gave evidence. She lives with her parents, and her mother gave evidence: a statement was provided from one of her former teachers. She is now a legal secretary at a firm of solicitors, having been promoted in December 1999, after two years as office junior. She was infected on 16 February 1990 when, aged nine, she was given a blood transfusion during treatment for a kidney disease. She is genotype 4. She was identified by the Look-Back programme in September 1995, and tested PCR positive. She has had two biopsies, both under general anaesthetic, because she was fearful of them, in October 1995 and December 1997. She underwent combination therapy for a year, starting in May 1999, and tested PCR negative in April 2000, but reverted to PCR positive some three months later. She has had no physical symptoms, nor fatigue otherwise than during the Interferon treatment, when she suffered not only the 'usual' side-effects, but also from hypothyroidism, a risk from Interferon as appears in paragraph 205 above, which required to be separately, and successfully, treated by thyroxine. Her prognosis is very good, with no fibrosis and only minimal inflammation shown on the biopsies. Her worst case scenario, according to Dr Ryder, is that she may develop liver symptoms after twenty years, but more likely after more than fifty years: according to Dr Alexander the risk is "*close to zero*". She is agreed to be psychologically resilient, and has suffered from no disorder. She also opts for provisional damages, and I so direct, with all triggers applicable, save the first (she already being PCR positive).

250. The issues in her case are:

i) Quantification of general damages for PSLA in the sub-categories (a) infection simpliciter (b) biopsies and (c) the Interferon combination therapy.

ii) Whether she is to have further therapy, in say one year's time, in which case the agreed cost of pegylated combination therapy, if it has to be paid for, is, discounted, £12,340: but she claims additional general damages for the period of the treatment (also discounted).

iii) Employment handicap.

iv) Insurance handicap.

v) Follow-up costs and future biopsies.

251. Further Interferon. It is in my judgment essential first to decide, in the case of Miss T, whether I am satisfied that she should have, and recover in respect of, further, pegylated, combination therapy in one year's time, because this then sets in context some of her other claims. As for the Poynard predictive factors, referred to in paragraph 204 above, she is young, female and with no existing fibrosis, but she is genotype 4, which renders success in treatment somewhat less likely than in respect of genotypes 2 and 3, but more likely than genotype 1: and of course, although initially responding, which was in itself, as I understand it, a good sign, she relapsed to positive and was therefore unsuccessful, on the last occasion. She would not undergo combination therapy again, but was emphatic in evidence that she would be prepared to try a new course of treatment, such as the pegylated therapy. Dr Ryder would not be recommending her to undergo pegylated treatment, because, as he put it, *"she has very mild liver disease. There is no data in this situation to give her any realistic idea at the moment of what the chance would be ... The risk of progression without treatment ... in her case ... is very low"*. The factors against her having the therapy are clear, apart from Dr Ryder's own such view. The side-effects are likely to be unpleasant again, although it may be that they may be less worrying, not least because, with pegylated therapy, there is only need for one injection per week as opposed to three, and it appears to be the immediate effect of the injection which is the most difficult to cope with. There is a 90% chance of her suffering again from hypothyroidism, as she did before, and Dr Ryder considers that, this time, there would be a slightly greater than 50/50 chance that it would be permanent. She would certainly not like it at all if she had to have a biopsy, prior to the carrying out of any such treatment. However:

i) She knows the side-effects are likely to be unpleasant, and yet confirmed vigorously that she would still be prepared to try the treatment, even if they were worse than last time.

ii) She is prepared to take the risk of hypothyroidism, which in any event was controlled by thyroxine.

iii) Dr Ryder confirmed that, in fact, it would probably not be necessary to carry out a biopsy before further treatment: although he would feel slightly uncomfortable in not knowing where he was starting from, he would certainly be able to carry out further treatment without one, and I suspect that would certainly be so in the case of Miss T, where he is already satisfied as to her present condition, as set out above.

iv) She is plainly a very determined young lady, as indeed are her parents, as is clear from the endeavours they took to ensure that, notwithstanding initial

resistance, she was taken onto Professor Bassendine's trials on the last occasion.

It seems to me clear, as I shall set out below, that Miss T's only real surviving worry, but it is a very substantial one, is about vertical transmission, the possibility of transmitting the virus to a child if she became a mother. Quite apart from the smallness of that risk, which I have already addressed and shall refer to below, and the probability that in any event her concerns can be substantially if not wholly alleviated, I consider that, if further therapy were successful in rendering her PCR negative, that would remove the last hurdle to her self-assurance. I am satisfied that she will have the further therapy, and that it is reasonable that she should do so, and indeed that it may well be successful. It is clear that pegylated therapy is more likely to be successful than standard combination therapy; she was nearly successful last time, she will be very compliant with the treatment, unlike perhaps some patients, as Dr Alexander has recognised, and she is not a genotype 1. As for payment, I am sure in the light of the evidence that pegylated combination therapy will be licensed and available under the NHS, if not in the next few months then certainly by the time that Miss T undergoes the therapy in a year's time. However it seems to me clear that she would not come within the NICE Guidance, and that I cannot be at all sure that there would be any trials available to which she would be likely to be admitted without charge. Accordingly I award the £12340 sought.

252. PSLA.

i) As set out above, she has had no symptoms of fatigue resulting from her condition; her prognosis is very good, irrespective of the success of the further therapy; she may clear the virus as a result of such therapy and/or her prognosis may further improve; and in any event well before fifty years time it seems to me likely there will be a cure. She is, as has been pointed out, a very positive person. I cannot ascribe her scholastic under-achievement to her condition, not least in the light of her own very graphic description as to how it is that she found herself, as so many teenagers do, involved in a peer group for whom studying was not a priority: given the lack of psychological or physical symptoms which might explain it, and the fact that even prior to the diagnosis of her condition there is some sign of her lack of attention in school, any such suggestion cannot be supported. She is not inhibited by the slight restraint on her alcohol consumption, and is able, and has the energy, to go clubbing and dancing as she wishes. The only example of embarrassment caused to her by her condition, and it was obviously distressing, was in respect of requiring dental treatment: it seems to me that this should be urgently addressed by the professional body of dentists, so that dentists, too, can become sufficiently educated, such that it is to be hoped that such embarrassment will not recur. The real and central problem, as I see it, is her initial anger, and now her worry about the risks partially in respect of sexual transmission, but more centrally with regard to the possibility of vertical transmission. It is clear in fact that Miss T has had very little, if any, advice about this, namely a short discussion with Professor Bassendine about the small risk of transmission to a partner or child. Miss T's reaction is that a small risk is too much, and that before she went ahead to become pregnant she would have to feel certain about the position. I have already set out, in paragraph 197 above, what the real position appears to be, not only in relation to the very small risk of transmission, but

even with regard to the consequence to the baby even if such very small risk in fact ensued, not to speak of the ever improving methods of treatment available. However, at least at present, Miss T has this lingering worry, which will become more pressing as and when (still quite some way into the future) questions of possible parenthood become relevant, at least unless the further therapy, which I have allowed, renders her PCR negative. The Claimants put forward a figure of £20,000. The Defendants have put forward £5,000.

ii) As for the two biopsies, as I have set out they were both under general anaesthetic, because she was frightened about what was going to happen: indeed she worried for about two weeks before each biopsy, and found it difficult to sleep. As a result, she was required to stay in hospital the night before and the night after each biopsy. She had considerable pain for some time afterwards, and indeed after the second biopsy intended to return to work two days after the biopsy, but needed an extra day off because of the pain, missing the firm's Christmas dinner. The Claimants claim in respect of each biopsy £2000. The Defendants suggest £500 each.

iii) The Interferon lasted between May 1999 and May 2000, with self-injection three times per week. Her side-effects were headaches, pain on opening her eyes, loss of appetite, dizzy spells, muscle spasm, sore throat, fever, nosebleeds and weight loss and hair loss. The symptoms were primarily after each injection, which she carried out on a Tuesday, Thursday and Sunday, with the effect that she had no energy to go out on those evenings, with consequent detriment to her social life: but she was able to go to work, and indeed to go away on holiday. Her fatigue was exacerbated by the hypothyroidism which developed shortly before Christmas 1999, and continued through until it was completely controlled by thyroxine in January, whereafter both it and its symptoms resolved: but while she was affected by it she was totally lacking in energy, indeed such that she went to bed halfway through her own birthday party. Apart from the period of hypothyroidism, it is apparent that she became used to the side-effects, and coped reasonably well both at home and on holiday. When, shortly after the completion of the treatment, her PCR reverted to positive, she was disappointed, but said in evidence that she had always known that there was a 50/50 chance, and had prepared herself for the worst, and was not as upset as she had been when she was refused for the trials originally, because she had given it the best chance she could. The Claimants claim £7500 in respect of the twelve-month period combination therapy including the transient hypothyroidism: the Defendants suggest £3000.

iv) I have considered again the authorities, and all the circumstances and submissions. Apart from her very real anxiety about vertical transmission, to which I have referred above, her problems and symptoms have been very few; she indeed accepted that she had only been ill with the Hepatitis C while on the treatment and after biopsies, for which of course separate provision is being made, subject always to the overall figure. She has suffered, treatment apart, no fatigue and no adjustment disorder, being resilient and positive; but she continues, unless the further therapy is successful, as I trust and hope it will be, PCR positive, albeit with the very good prognosis, about which I am sure she would cease to worry, if only, and when, her worries about parenthood are either at an end or proved unnecessary. If they are not resolved, then

particularly in the event, and for the duration, of any pregnancy, they may obviously be acute. Those worries apart however, I am satisfied that her concerns, and indeed thoughts, about her Hepatitis C condition will gradually recede to the background, and certainly so if her therapy in a year's time is successful. I conclude that the proper figure for infection simpliciter, making due allowance for her concerns, is £12,500, to which I add £500 in respect of the first biopsy and £750 in respect of the second and, as the Interferon therapy was both longer than Mr U's and complicated and exacerbated by hypothyroidism, I award in respect of that £3500. The total figure, which I have already considered in the round in building it up, is £17,250. To this needs to be added future general damages in respect of the further therapy, which I have concluded she will and should have. This will again last twelve months because of her genotype 4 and her previous failure. There is the risk of hypothyroidism, and even permanent hypothyroidism to which I have referred. It is in my judgment likely to be less unpleasant in its side-effects than the previous therapy, simply because the injections will only be once a week. I conclude that the appropriate figure, after allowance for one year's accelerated discount, is £3250, making a total for general damages in all of £20,500, which I consider, having looked at it in the round, to be an appropriate aggregate figure.

253. Employment handicap. Miss T is perfectly successful at present as a legal secretary, after her promotion, and her condition gives her no problems at all. She has previously had to complete two health questionnaires in respect of employment, which caused her no difficulty. The relevant problem is that she would like to become an air hostess, although she has not yet started making applications. Some enquiry has been made in general terms of airlines, and a not wholly unoptimistic response in very general terms has been received, at least from one airline, although that airline would require rather better educational qualifications than Miss T, at least at present, has, apparently a good conversational ability in a second language, which she does not have. It seems to me, in those circumstances, that she might well not be qualified as an air hostess in any event, at least without improving her qualifications, because I am not at the moment prepared to assume that other airlines would necessarily be less demanding, once it came to an interview. There is also the fact, as pointed out to her, that if indeed she would not be content with the office life, there are many jobs in travel that might be available other than being an air hostess. There is the further factor that the position may change for the better in any event, if next year's therapy is successful, and she becomes and remains PCR negative, and is able so to inform a potential employer. The Claimants seek as an uplift, or in any event, an ingredient, of a *Smith v Manchester* award, what they call 'loss of congenial employment'. But of course I have to be satisfied not only that there is a more than speculative chance of such a loss, but also that she would have attained the so called congenial employment in any event. They claim £7500, and the Defendants put forward £2000. Given the very broad brush nature of the *Smith v Manchester* jurisdiction in relation to quantification of the speculative loss, I am just prepared to say there is some evidence of a possible loss, and to value it at the figure put forward by the Defendants in the sum of £2000.

254. Insurance handicap. The Claimants put forward £3000, and the Defendants a nominal 'jury award' of £500. The likely result of any application now by Miss T for insurance would be deferral, as is the unanimous view of the experts; and in any event that makes absolute sense, not just because Miss T is neither of an age, nor certainly an

income, to consider such products now, but also because it must obviously make sense to wait until after the further therapy in a year's time, which may well be successful in causing her to clear the virus:

i) It is highly speculative as to whether Miss T would want to apply for any products at all, and certainly not for some time in any event.

ii) If the treatment were unsuccessful and/or she remains positive, then on the evidence she will still be able to obtain life insurance because of her good prognosis, even if at some loading. Miss V has of course been able to obtain such insurance at a loading, as referred to below. It can be concluded from Mr Purdy's report that Miss T might have paid £5 per month for a twenty five year mortgage protection which would, if she were to remain PCR positive, increase to perhaps £20 – an additional £180 per annum, and that there is a similar position in respect of critical illness cover, though I consider it unlikely that Miss T would have taken out the latter, in a relatively low paid occupation.

iii) If she were to become PCR negative as a result of successful treatment then, albeit not immediately but after a few years of continuing negativity, and certainly by the time she would be looking for insurance products (if she does), I am satisfied that, like Mr U, and Mr S, she would be likely to have no loading.

I am almost minded not to award anything 'plucked from the air' in respect of alleged insurance handicap, not least because (a) I am hopeful that her therapy will be successful; (b) I am confident that with her very good prognosis, even if she remained PCR positive, the insurance market will be sufficiently educated in due course to give her, when and if she were to apply at some stage in the future, a normal or near to normal rating. However I award £1000.

255. Follow-Ups and Biopsies. So far as follow-ups are concerned, the Claimants have provided for twice annually. I agree however that there should be the 50% discount for which the Defendants contend, both for the reasons set out in paragraph 214(ii) above, in the event that therapy were unsuccessful, and because of the possibility that it will be successful, and in any event by virtue of her very good prognosis. Consequently I award the discounted sum, at the agreed multiplier, of £432.90. As for future biopsies, the Claimants claim a sum (undiscounted) of £15,000, while the Defendants put forward a nominal sum of £100. I am sure that Miss T herself hopes that no further biopsies will be necessary, in the light of her dislike and fear of them. Once again the further therapy is relevant. I have already referred to Dr Ryder's view that a biopsy prior to such treatment would not be necessary, and I am satisfied that it will not be carried out. If her treatment were successful, then it is apparent that no further biopsies need to be provided for, as with the others who have *cleared* the virus. If it were unsuccessful, and she remained PCR positive, then too she would be unlikely to need a further biopsy, as appears in paragraph 214(ii) above; but additionally, with specific reference to Miss T, Dr Ryder gave evidence that it would be "*pretty doubtful about whether it would be worthwhile subjecting her to a biopsy*", even in five years. Once

we are looking beyond five years, then I am satisfied that, particularly given Miss T's own perfectly understandable reluctance, in the light of her very good prognosis, it will be considered that ultrasound may be sufficient, and/or that by that time non-invasive techniques would be in place, to which reference has already been made in paragraph 201 above. I accept the Defendants' £100.

Ms V

256. Ms V, who is 36, gave evidence, as did her mother. She lives with her partner, who also gave evidence, and their twin sons aged eleven and their daughter of five. In the course of the birth of the twins on GRO-C 1989 she became anaemic, and received a transfusion which was infected with Hepatitis C. She is infected with genotype 2a (or possibly 2b). She was lethargic for two months after the birth of her twins, and then recovered entirely. I am satisfied on the evidence that this did not result from her infection. She learnt of the infection through the Look-Back programme in November 1995, and tested PCR positive in December 1995. She has had three biopsies, on 3 April 1996, 18 December 1997 and 1 April 1998 (the last with ultrasound). She declined Interferon treatment for two inter-connected reasons: one that her condition was relatively mild and the other that she did not want at that stage to have the treatment, because she wished not to be rendered tired and lethargic by the side-effects, of which she was warned, when she had young children to look after. I quote from her Registrar's letter on 16 November 1998: "*We have discussed possible Interferon treatment in the past, but felt in view of the relatively low efficacy, together with quite considerable side-effects associated with treatment, that it would be very reasonable to defer any decision regarding the need for therapy, pending her more recent liver biopsy and pending possible improvements in anti-viral therapy, such as combination treatment*": and then again on 24 February 1999: "*she herself remains asymptomatic and not particularly keen on undergoing anti-viral therapy unless there is a good clinical indication. I have discussed this with her in the clinic today and my feeling is that, in the absence of any clear evidence of histological progression, there is no pressing need to undertake anti-viral therapy at present, as it may well be she is one of those patients who have a non-progressive form of liver insult related to their infection*". She agreed that effectively the position was that she was "*not enthusiastic, and they were not pushing it*". She thus remains PCR positive. Her prognosis is however very good. She has no fibrosis and it is, according to Dr Ryder, exceptionally unlikely that she will progress to significant fibrosis, whether in the short or medium term, and it is highly likely that she will never progress to cirrhosis. The worst case is CLD in more than twenty years. She has had no physical symptoms from her Hepatitis C condition. However she has been diagnosed by Dr Master, and confirmed by Professor Wessely, to be suffering from an adjustment disorder for a period which Professor Wessely originally estimated at two years in the light of his discussion with her, but was prepared in the event to accept, from Dr Master's view, may well have been as much as three and a half years. She was depressed during that period, although the most critical period was the two to three months after her diagnosis. She was very worried, with disturbed sleep, had a panic attack at work in April 1996, and had throughout a negative attitude, frequently tearful: Dr Master considered that an episode of weight loss and epigastric pain in 1996 was associated with her psychiatric condition. Her present outlook is however more positive, and she is feeling fit and well and she had a very good last report from her clinic in February 2000. She also opts for provisional damages, and I so direct, with all but the first trigger applicable,

and so she too must be deemed, as indeed is wholly likely to be the case, to remain short of any conditions provided for in the triggers.

257. The issues are as follows:

i) Quantification of general damages for PSLA in the sub-categories (a) infection simpliciter, (b) adjustment disorder (c) biopsies.

ii) Whether she is to have Interferon therapy in about six to seven years time when the children are older; in which case the agreed cost of pegylated combination therapy, together with agreed attendance by either her mother or her partner would be, discounted, £6870; but she also claims general damages for the period of the treatment (discounted).

iii) Employment handicap.

iv) Insurance handicap including loss to date.

v) Further biopsies.

258. Future Interferon Treatment. Once again it is sensible to decide first the question of whether it is, on the balance of probabilities, likely that she will have, and ought to be entitled to recover, in respect of further therapy. By reference to the Poynard predictive factors, Ms V is genotype 2, female and has, at any rate at present, no fibrosis. She mentioned in evidence intending to have the further therapy in some seven years time when her daughter was twelve. The parties appear to have agreed a somewhat complicated formula of discounted cost in relation to a period in six years time. In any event I conclude that, if Ms V is to have the treatment, she should have it earlier rather than later, because of Poynard's further predictive factor of age, namely that those under forty have the better chance. Ms V will be forty in four years time.

259. Do I conclude that it is likely that Ms V will have the treatment? There must be, given her previous history, a risk of her having Interferon-related depression (as appears from paragraph 205 above, there is estimated to be ordinarily a 15% risk), and, given the mildness of her disease and the very favourable prognosis she has, there is certainly no need for her to go through the treatment, not only with that risk but also with the other possible or probable side-effects suffered by the other lead Claimants, and apparent from the literature. On the other hand, she stands a good chance of *clearing* the virus, and told me in evidence that she was 80 to 90% sure that that was what she would do, having previously made the decision to defer it until her children were of an age that she could cope with it. In any event, it seems to me that in six years time it is highly possible not only that pegylated therapy will be more efficient in its results, giving her an even better chance of success, but even possible that, with ever improving treatments, a way might have been found of mitigating, or even avoiding, the side-effects, which will of course, in any event, as discussed in the case of Miss T, be less obtrusive, simply by virtue of there being only one injection per week in pegylated therapy, rather than three. I conclude that it is likely that she will have the treatment, that it is reasonable for her to do so, and indeed that the chances of success are very good, indeed are likely to be better than the 40% chance indicated by Dr Ryder, which was, as I take it, in any event, a reference to standard therapy. I shall return later to the sum to be awarded.

260. PSLA

i) Infection Simpliciter. Once again it is extremely difficult to extract the question of adjustment disorder out of the generality, but I shall endeavour to do so at the request of Mr Brooke QC. Nevertheless, it is right to say, as in the case of Mr S, that the reality is that the symptoms which might ordinarily be looked at as being part of infection simpliciter – anxiety, stress, upset, etc. – are in this case those which form the basis of Dr Master's conclusion of an adjustment disorder, and there is little to add, so far as general state of mind is concerned, for the purpose of assessing damages for infection simpliciter. She was certainly extremely upset by her discovery about the infection – and her panic attack in April 1996 was an obvious consequence. She was upset about the uncertainty: it appears that at one stage she was told that liver disease would be likely to onset within fifteen years of the infection (i.e. dating from 1989), which seemed worryingly close, and certainly is not the prognosis that she in fact has. She suffered what might be called 'social stigma', i.e. embarrassment and distress, in two respects, once when she felt upset in overhearing how junior doctors in an ultrasound department discussed their liver patients, and once, in particular, when her daughter's childminder declined to continue to look after her daughter in case her daughter (who had not at that stage been tested) turned out to have Hepatitis C, which she said might invalidate her insurance as a childminder. She has had a certain amount of worry about her relationship with her partner, becoming somewhat tentative towards him (although sexual relations did continue after a period, because she conceived in 1996). She confirmed that things were almost back to normal now between her and her partner; the one restraint she found was that she was still worried about kissing, but she has now been given complete reassurance by Dr Ryder that there is no risk in normal day-to-day activities such as kissing. So far as concerns the 1996 pregnancy, her evidence was that she was concerned about how her partner could cope with the three children if she became ill or indeed died. After a good deal of heart searching she had a termination. She said that, in her mind, the Hepatitis C was the *"deciding factor"*, but accepted that to have had the baby would in any event have been difficult, for a whole host of reasons, and she just did not know whether the same decision would have been made if she had not been infected with Hepatitis C. It is plain to me, having heard and considered all the evidence, that the reason for such termination was not her Hepatitis C condition, nor any fear of vertical transmission, but rather that with the other three children, a small house and a limited income, she did not feel able to cope. However what is equally plain is that the worry about Hepatitis C was a factor which featured in, perhaps exacerbated, a decision which would have been a difficult one for her to take in any event, even though I am satisfied that she would have made the same decision. On the other hand, be it adjustment disorder, or be it simply the worry in the back of the mind, it is equally plain that, not least because she has had no physical symptoms nor any fatigue resulting from the condition, she has got on with her life quite normally, once having made the decision to shelve the Interferon treatment. She has indeed looked after the three children, but in addition she has worked, and has not been off work as a result of the condition or indeed the adjustment disorder. She was working with Marks and Spencer when diagnosed: she disclosed her condition to them and had no problem as a result, and continued to work (save for food tastings) as a sales

assistant. Recently, and again it seems without difficulty both as to obtaining the new employment and in disclosing the position, as she has done, to her new employers, she changed jobs to one that was more satisfactory so far as the children's holidays were concerned (after qualifying in the meanwhile on a computer course), namely to become an IT support technician at a sixth form college. Although, because the court case is still going on, she feels that nothing has settled down at the moment, nevertheless, as set out above, she described herself as *'fine and healthy'*, and as having been so for some time, and she was thrilled at the very good prognosis which she has now understood.

ii) With regard to the adjustment disorder, Dr Master refers to her *"generally negative outlook,* [which] *persisted until about three to four months ago, when there was a gradual turn for the better. She thinks that the improvement is because in this period she has learned more about the illness and about her prognosis ... She understands now that the outlook is not as bad as she had feared"*. Professor Wessely concludes, and I accept, that *"as a result of learning that she has Hepatitis C the* [Claimant] *developed symptoms that are suggestive of an adjustment disorder. This was never very severe, in that she managed to keep working, but I agree was still sufficient to justify a psychiatric diagnosis"*. As for any question of continuing vulnerability, I have already indicated that I do not accept the 'Master theory': there is some pre-history which is relevant to Professor Wessely's 'hand of cards', such that, as he puts it in his report, *"she is* [not] *at any more increased risk of psychiatric disorder than before. Whatever it was that increased her vulnerability to psychiatric disorder, for example her genetic risk, remains true for the future should she again encounter adversity, but has not been increased by the adjustment disorder"*. For that reason, I ignore any question of vulnerability: but in any event, if there be in the future an adjustment disorder which can be shown to result from her Hepatitis C condition, directly or indirectly, then it may be that the fifth trigger would arise; but I must assume, for the purposes of assessment of provisional damages, that it will not so arise.

iii) The Claimants put forward figures for infection simpliciter of £12,500 and for adjustment disorder of £7500, totalling £20,000: the Defendants suggest £5000 and £3500, in the latter regard referring to the JSB Guidelines for moderate or minor psychiatric damage. Again both Counsel referred to the cases set out in paragraph 236(v) above.

iv) So far as the biopsies are concerned, the first of the three was under local anaesthetic and did not involve an overnight stay, but Ms V described it as the most pain she had ever experienced, far worse than childbirth (and she had had twins by forceps). The second was also by local anaesthetic, but on this occasion she stayed overnight (as it happened the biopsy was ineffective). On the third occasion she was particularly worried about it in anticipation as, given the fact that the second had been unsuccessful, she feared that she might have to go through it again, but in fact it was not a problem: again she had a local anaesthetic and stayed overnight. The Claimants put forward the sum of £3250 for the three biopsies (undifferentiated), while the Defendants put forward a total of £750, being £400 for the first, £200 for the second and £150 for the third.

v) I turn then to my conclusions as to quantum. It is clear that the adjustment disorder has not been a serious one, has not required any treatment, does not impact upon future vulnerability and has not affected the Claimant's ability to cope with her life and work. It is in my judgment in the lower bracket of the JSB Guidelines, although allowance must be made for the fact that it went on for up to three years. The Claimant has a Hepatitis C condition, but it is one that involves no physical symptoms, no fibrosis, a very good prognosis and a very good chance of clearing the virus. Nevertheless I take into account the fact that she has been worried about her relationship with her partner, about her future and that of her family if she were seriously ill (and she has not always been enabled to be as clear about the prognosis as she now is); it was a factor in the difficult decision of termination; she has suffered some embarrassment; and she is left, subject to the possibility of successful treatment, with a possible lifetime with the condition, albeit that it is unlikely that she will suffer any physical symptoms, and therefore her concerns should soon recede even further. I conclude that the appropriate figures are £3500 for the adjustment disorder and £6500 for the infection simpliciter, such that the total amounts to £10,000, added to which there will be £600, £300 and £350 for the three biopsies, totalling £1250. I conclude that the figure of £11,250 in aggregate is appropriate, and does not involve, or has taken into account, any overlap.

261. The Future Therapy. Although I am satisfied that by six years' time the pegylated Interferon therapy will be available on the National Health Service, since I do not conclude that Ms V will deteriorate during that period, I do not consider that she is likely to fall within the NICE Guidance, or the equivalent then in force, because, although I conclude that it is reasonable for her to have the treatment, I suspect that it will not be medically recommended. The question then arises as to whether she will have to pay for it. I am sure that there will be new treatments being developed. Dr Ryder confirmed that Ms V *"would undoubtedly fit within the criteria of many clinical trials of treatment"*. I propose to discount the figure of £6870 to £6250 to allow for the possibility that the treatment may be available otherwise than privately paid for. As for general damages in respect of her undergoing in the future the therapy, the Claimants seek a sum of £4530 which, as I understand it, is £5000 discounted. This does not seem to me to be an appropriate sum. The treatment is only a six month treatment (she being genotype 2 and without previous failure): as indicated above, the therapy may well have improved by six years time, but in any event it is only a one injection per week treatment: and the trigger would be there if there were a serious psychiatric condition triggered by the Interferon. I allow a figure of £1750, discounted by what I understand to be the appropriate multiplier of 0.8131, rounded up to £1450.

262. Future Biopsies. The Claimants put forward a figure of £5000 on the basis of continuing regular biopsies, but the Defendants submit a figure of £100, on the same basis as in relation to Miss T in paragraph 255 above. I reach the same conclusion as I did in relation to Miss T, by reference primarily to the matters set out in paragraph 214(ii). Ms V too will have, as I have concluded, therapy which will either be successful (no biopsies) or unsuccessful (no routine biopsies thereafter); and in any event even more so in the case of Ms V, where we are looking six years ahead, it is even more likely that non-invasive techniques will be the norm in lieu of a biopsy. I am sure that, as in the case of Miss T, a biopsy will be avoided in the case of Ms V if at all possible, and indeed I note that she was recently asked to attend for an ultrasound just to see the shape and size of her liver which, I am satisfied, given her

previous condition, will have raised no concerns, and will have been a perfectly satisfactory procedure. I am satisfied that the nominal sum of £100 is all that is appropriate.

263. Employment Handicap. The Claimants put forward £5000 and the Defendants deny that any sum is appropriate. As appears above, Ms V has successfully changed jobs recently without any problem. There is no evidence of any risk to her in the labour market. She has a very good prognosis, has revealed her condition to two employers without a problem and has a reasonably good chance of in due course *clearing* the virus in any event. I do not consider any award is appropriate.

264. Insurance Handicap. Ms V has already taken out life assurance, when she and her partner had the opportunity to buy their council house in late 1998/early 1999. The life cover that she obtained by way of mortgage protection was at a premium of £24.53 instead of £11.61, which it would have been but for her condition, an annual increase in premium of £155.04. It was taken out in respect of mortgage protection, and she and her partner have recently remortgaged, and obtained further life insurance by way of mortgage protection at a rated premium, such that she is currently paying £30.12 per month in all, instead of some £12.04, a 150% overall loading and an annual increased loading of £216.96. The Claimants claim, in addition to the excess premia paid to date in the sum of £284.24, which is admitted, a future loss of £216.96 per annum, at an agreed multiplier of 17.19, namely £3729.54. The agreed joint experts' report recites that Mr Purdy and Mr Brimblecombe agree that from the market she should be able to do better than the £30.12 she is currently paying, and that, if the policy is left in place for two to three years and her condition remains the same, a review at that stage should result in better underwriting terms, and a reduction in premium loading to 100%, rather than 150% as at present. The Defendants assert that both in respect of the duty of the Claimants to carry out reasonable mitigation of loss, and by virtue of a reasonable expectation of what is likely to occur, there should be a substantial discount in respect of this claim by virtue of (i) the fact that Ms V will be able, on that basis, to obtain more favourable terms, either from her existing insurers or from an alternative and/or (ii) what they refer to as the chance of her cure in the future, and improvement in the insurance market generally. The Claimants submit that Ms V should be under no obligation to reinsure, in case she put at risk the existing cover and/or by virtue of inconvenience and possible expense. I am satisfied that on both the two grounds put forward by the Defendants there should be a reduction. I conclude that there is an obligation to mitigate. As set out in paragraph 224(ii) and (iii) above, I am also of the view that the insurance market generally in relation to Hepatitis C, at least with regard to those, like Ms V, with a very good prognosis, will become more enlightened: and in any event, as set out above I am satisfied that Ms V has an extremely good chance of *clearing* the virus when, in six years time, she undertakes the therapy, as I have now been persuaded that she can, should and will; and she would then, if such occurred, be able to take advantage in due course of the nil rating, which, on the basis of the agreed joint report, is already available to Mr S, and will soon be available, insofar as relevant, to Mr U. I accept the figure of £2000.

265. In addition, the Claimants point to the fact that Ms V was, when granted life assurance cover by way of mortgage protection, refused the critical illness cover which she also sought. Ms Daniels has sought this cover from two companies, and in the course of the hearing renewed her application to one of them on a 'cushioned basis', but without success. Mr Purdy and Mr Brimblecombe agree however that it should be possible to

obtain in the market even at present, notwithstanding Ms Daniels' two failures, cover at a 150% loading, and, indeed, from Friends Provident and Swiss Re, at a 100% loading. On the basis of Mr Purdy's calculations in respect of Miss T, the effect of a 100% loading on a standard premium for a fifteen year critical illness policy might be an additional £10 per month, being £120 per annum. It is plain that we are not, in relation to Ms V, in the realms of the hypothetical, because she has actually sought critical illness cover, and at present only her partner is so covered, as a result of the refusal of it to her. I consider that it is appropriate to make an award in respect of future loss by way of insurance handicap, in relation to the loading in respect of critical illness cover; but it is clearly appropriate to make the same discounts, for the same reasons, as have been made in relation to the life assurance. The sensible course is for Ms V in any event to defer making any application until after the outcome of her further therapy. The Claimants claim an additional sum of £3000, in addition to the future loss in respect of life assurance, by virtue of insurance handicap with regard to the critical illness cover, but also possible handicap in respect of permanent health insurance and/or employee benefits. I consider the last item entirely hypothetical on the basis of the present evidence, and her employment and its prospects, and no mention was made by either her or her partner of any intention or desire or indeed ability to afford or consider permanent health insurance. The Defendants put forward a suggested figure of £200 to £500. I consider the appropriate sum by reference to the critical illness cover is £1000.

Mr W

266. Mr W, who is 72 on GRO-C, gave evidence: he was a coalminer until his retirement in 1984. He lives with his second wife. His children and step-children are grown up, and he has grandchildren and great grandchildren. He was infected on 3 May 1991, when he received a blood transfusion after a triple coronary artery bypass graft operation. He is infected with genotype 3a. He had two subsequent operations in 1995, successively a cholecystotomy and a laparotomy for gallstones, and then in December 1995 he was informed of his infection as a result of the Look-Back programme. He had three biopsies, on 28 March 1996, 3 July 1997 and 24 February 1999 (and an endoscopy in October 2000). He underwent Interferon treatment commencing on 3 June 1996, until 8 August 1997, but he did not respond and remained PCR positive: although he was an encouraging genotype, he did not bode well in relation to the other Poynard indicators, in being well over forty, male and suffering from severe fibrosis. That fibrosis, it is now agreed between Dr Ryder and Dr Alexander, has, at some stage after the last biopsy in February 1999, but prior to October 2000, progressed to cirrhosis, though still compensated. He suffered fatigue after the bypass, clearly consequent upon his heart condition and the operation, and never recovered his original energy levels, though he took up a part time driving job for a printing firm in about 1997, which he carried on until last October, stopping by agreement when he unfortunately drove through a red light: and he still does the gardening in his garden at home, from which he derives great pleasure, and takes his dog for short walks. The depression which affected him (not amounting to an adjustment disorder) is also ascribed by the experts to the cardiac condition and not to the diagnosis of Hepatitis C, which it antedated. He is inevitably now suffering from fatigue as a result of the deteriorating liver disease. In June 1999 he was diagnosed as suffering from diabetes, which he controls both with pills and diet, and there is an issue for me to resolve as to whether this was associated with the Hepatitis C condition. His prognosis so far as concerns his liver condition appears to be of something more than a 20% chance of

decompensated cirrhosis over five years and something less than 50% in ten years, though Dr Ryder, with all of whose opinions relating to the prognosis of Mr W Dr Alexander agrees, points out that his speed of progress from point of infection to cirrhosis was relatively quick, and that it is probable that the speed of progress to cirrhosis is likely to be a predictor of the speed of progress on to decompensated cirrhosis. Dr Ryder considers that by reference to the literature, and particularly to the paper by Fattovich (referred to in paragraph 189(iv)(d) above), Mr W has an 80% chance of surviving ten years by reference to his progressive liver disease alone: he is not a candidate for a liver transplant. Unfortunately however there are added complications. He had transient ischaemic attacks (mini-strokes) resulting in a diagnosis in June 1999 of atherosclerosis (furring up or blockage) of the carotid arteries, a similar process to that which had occurred in his coronary artery, leading to the bypass. It was found that he had bilateral carotid stenosis (narrowing) on the right side as to 68% and on the left 73%. Although he had had, as shown by an MRI scan, at some stage an old silent stroke on the left side of his brain, and had chronic lack of blood flow in both cerebral hemispheres, the mini-strokes had been caused by blood clots detaching themselves from his right artery, the one that was slightly less narrowed, and moving from there into the brain; and it was thus upon the right artery which Mr Hope carried out the carotid surgery. The surgery was major, but Mr Hope considered that the risk of future strokes was far greater than the operative risk. Mr Hope concluded that it was neither necessary nor sensible to operate on the left artery, and if it further narrows Mr W may be able to depend upon the newly cleaned out right artery, to its exclusion. However he concluded from the literature that Mr W has a stroke risk of 30% or more over five years, and increasing thereafter by at least 6% annually. As he further confirmed, the presence of the silent stroke is a warning that the condition of the arteries on the left hand side could cause a stroke at any time; there can be a stroke without any warning, or alternatively there can be a whole series of events that are what Mr Hope called a *"red card to the vascular surgeon"*, and it is simply chance whether such a clot as had detached itself from his right artery, and might similarly now do so from the left, would cause damage to the brain. In addition Mr W may still have arterial disease in his heart, and the prognosis for further cardiac disease is less good in his case than the norm for his age. As Dr Ryder stated, *"it is very difficult in someone of 71 with ischaemic heart disease and cerebrovascular disease to say what impact his liver disease is going to have on his survival"*. Mr W does not wish to seek provisional damages, but a final award.

267. The issues in this case are as follows:

i) Is the diabetes a consequence of the Hepatitis C condition?

ii) Will he have, and/or is he entitled to recover in respect of, further Interferon therapy in two years time?

iii) The quantification of general damages in respect of his Hepatitis C condition, after taking into account the matters which are not the subject matter of assessment, such as those caused by or connected to his cardiac and carotid problems.

iv) His future loss. It is common ground that he will not need any help with the gardening for two years. After that, the cost of providing a gardener is agreed at £1125 per annum. There is then a dispute. The Claimants say that Mr W has

a life expectancy of eight and a half years (although the figures which they have supplied to me appear only to provide for seven and a half) and the gardening, once started in two years' time, should last until his death, at a multiplier of 4.85 totalling £5459.46; care and attendance should start after three years, to be provided commercially at rates agreed by the two experts, and increasing each year in respect of the number of hours per week, over a postulated period of four and a half years, totalling (again on the figures provided by the Claimants), as discounted, £35,753.28. The Defendants deny that he is entitled to recover in respect of care at all, because he will not require any care due to his liver condition, but rather, if at all, due to his carotid and cardiac problems and/or will die from those problems, or simply from old age, before the need for care resulting from his liver condition arises.

268. Diabetes: The following is common ground:

i) Mr W was not suffering from diabetes in October 1994, when there was a normal glucose tolerance test taken. The issue between Dr Alexander and Dr Ryder is as to when the Claimant did at the earliest have diabetes, given its diagnosis in June 1999. No conclusion can be drawn about the position in 1997, when there was a serum glucose test, because it is agreed that, if the test was taken when Mr W was non-fasting, then it would be within the normal range, although Dr Alexander would have been suspicious, and might have wanted it followed up with further investigation, and there is no indication that it was taken when Mr W was fasting.

ii) Mr W's mother had diabetes and there was therefore a genetic or familial predisposition.

iii) The risk of diabetes increases with age.

269. Dr Alexander has made a particular study of the relationship between diabetes and Hepatitis C, and is the co-author, as set out in paragraph 189(iv)(d) above, of two of the relevant papers on the topic, which were studied in evidence. Dr Ryder also of course has extensive clinical experience. It was clear from their evidence, and the detailed discussion of the topic which occurred, both by consideration of the Caronia, Mason and Knobler articles, referred to in that sub-paragraph, and otherwise, that there is a particular connection between cirrhosis and diabetes, because cirrhosis appears to be an inhibitor of insulin and to cause glucose intolerance. If it was necessary for Mr W to have progressed to cirrhosis before he could contract diabetes, then, given that he had not progressed to cirrhosis by February 1999, the date of his third biopsy, that would give a very short time indeed for the development of diabetes. On the other hand it is clear from the literature, and indeed conceded by Dr Alexander, that there is also an association between diabetes and Hepatitis C and in particular that diabetes can be found in Hepatitis C sufferers before cirrhosis, namely, as appears from the Knobler article in particular, at the stage of advanced fibrosis, to which on any basis Mr W had progressed well before 1999, and that the risk of diabetes increases very significantly with the degree of fibrosis. The two rival contentions are summarised as follows: first by Dr Ryder:

> *"My view of the literature and of this particular case is that there are a number of factors which increase the risk of someone developing diabetes, and those would be their age,*

family history, the presence of Hepatitis C and advancing fibrosis in their liver. My view is that overall I feel that the evidence supports the fact that if one has a genetic predisposition ... to getting diabetes, and has Hepatitis C, it is much more likely actually to happen. If you translate that into do I think on the balance of probabilities the Hepatitis C caused his diabetes at an earlier stage than it would have done naturally, then I would say: yes. If you are saying that on the balance of probabilities, do I think the Hepatitis C is the cause of his diabetes per se, then I think it probably is, but I would completely accept that that is a very difficult judgment to make."

Dr Alexander's position he summarised as follows:

"The proportion of patients with a family history of diabetes who go on to develop non-insulin dependent diabetes exceeds any of the data for patients with early stage cirrhosis or stage 4 fibrosis, so on a balance of probabilities his genetics are more likely to have caused his non-insulin dependent diabetes mellitus than the Hepatitis C. If, of course, he had been at a more advanced stage of the cirrhosis, when the instance of diabetes rises to 50%, then I would argue it the other way round, but he is not, so I think on balance you would have to say that the genetics are the major factor."

Dr Alexander concluded his evidence, in answer to Mr Brooke QC:

"Q: I have put to you Dr Ryder's position and you still disagree with him

A: As it happens, I think Hepatitis C causes diabetes, but I think to say that in bald terms without the evidence being there is a big step to take ...

Q: ... I take it that you still disagree with him?

A: I do. I do not have the confidence that he has, I am afraid."

Reluctant as I am to tread into such an interesting dispute, I must do so. I conclude that, given the presence of the two important predisposing factors of family history and age, it is extremely likely that Mr W would have suffered from diabetes anyway. However I am satisfied that it is likely, on the balance of probabilities, that the progression to severe fibrosis caused by the Hepatitis C condition was the trigger, and thus caused an earlier onset of diabetes than would otherwise have occurred. All this fascinating dispute in the end has very little impact, however, on what I have to decide: for, first of all, in the light of my conclusion, it is probable that in a very few years Mr W would have had diabetes anyway, and secondly, as Dr Alexander pointed out, well managed, the diabetes is going to be the least of Mr W's problems. It is clear to me that it is being well managed, and is causing Mr W relatively little inconvenience. He is not having to inject himself, but is taking Metformin pills twice daily, he is monitored once a year by his GP (and takes his own readings) and,

because his wife is now used to cooking for him with Canderel, there is, as Mr W puts it, virtually no difference, now that she had got around to that way of doing it.

270. Further therapy. The case put forward is that Mr W would like to have a further course of Interferon therapy, in, say, two years, when he will be 74. The way it was put in evidence by him (in somewhat of a stark contrast to the way in which it was put by Ms V) was that he would want to do it, because it might make him better. He will of course be even further down the list by reference to Poynard's indicators than last time, with the additional contra-indicator that he will have failed previously, although he would now be receiving pegylated combination therapy. Dr Ryder put the chances at 5%, and does not recommend the treatment. Dr Alexander also advised against it, but in his case, in the light of Mr W's cardiac and carotid conditions (symptomatic heart disease and severe heart disease are listed as contra-indicators to such therapy in the International Consensus Statement), by virtue of his concern at the risk of hypotension resulting from the therapy. Dr Ryder did not put his opposition on that ground, he did not consider that a risk: and Mr Hope too had no concerns for his patient arising out of hypotension. The fact remains, however, that the expert for neither side recommends the treatment. Mr Brooke QC's Closing Submissions read, somewhat strikingly, as follows:

> *"It is probable that Mr W will undergo combination therapy with its complications, and the treatment is likely to fail."*

I am entirely clear that for a man in Mr W's state of health, indeed looking forward a further two years, when it is extremely likely that his cirrhosis will have progressed further (decompensated cirrhosis is also a contra-indication listed in the International Consensus Statement), it is quite inappropriate for him to have the burden of a further twelve months Interferon therapy. In two years time, he will be further down the line of what the Claimants themselves predict is only another eight and a half years, and, I anticipate, even less able to withstand the treatment, and certainly overwhelmingly likely to gain nothing whatever from it. Whatever the precise state of his cardiac or carotid condition and whatever the precise risk to him from the treatment, it is clear to me that he will not, and/or in any event should not, do it and should not recover for it, on one or other of the bases set out by me in paragraphs 217(i) and (ii) above.

271. Prognosis and Future Care. I refer to the detailed picture of Mr W and his future, as it appears from the medical evidence set out in paragraph 266 above. It is appropriate for me to set out my conclusions as to prognosis and life expectancy at this stage, although it in fact leads to the calculation of the future cost of care, because, to an extent, it impacts upon my conclusions as to general damages, which I set out below. I conclude, on the balance of probabilities, that, as indeed is common ground, the Claimant will have a further two years in which he will continue to be able to do his gardening and will not significantly deteriorate. He will then need the help of a gardener, for which both sides have made provision. After one year of such gardening help, I conclude he will need some attendance by a carer, because of a continuing deterioration in his liver condition, and the first year's agreed provision, as set out in an agreement between the parties, drawn from the care experts' reports, will then commence, of seven hours per week, to be discounted, because it will only start after the conclusion of three years from today. My conclusion, on the balance of probabilities, is that Mr W will not in the event die of the ever-deteriorating liver condition and of decompensated cirrhosis, but of a stroke which will become, as

indeed Mr Hope accepted, ever more likely as he gets older and indeed as his physical condition deteriorates. I conclude that, after the three years to which I have referred, he will live for a further four, and will die of a stroke before he enters into the fifth of the periods provided for in the care experts' report. Life expectancy is accordingly, in my judgment, seven years. His entitlement is to five years of gardening, deferred for two years, and to four years of increasing care, deferred for three. I leave it to the parties to calculate the appropriate sum on the basis of the agreed rates and the agreed hours and the relevant multiplier on the basis of 3% discount: and to calculate the sum for the agreed incidental costs of £98.80 per annum, also upon the basis of the relevant multiplier.

272. General Damages. This is a final award, and I am not asked to compartmentalise, so I must ensure that I take everything into account. I am satisfied that Mr W did not suffer from any symptoms, physical or mental, which in any way related to his Hepatitis C condition, until after his awareness of it in December 1995. Since then, he has had just over five unpleasant years. Although a number of the important features of that unpleasantness, such as depression and, until the recent onset of more severe fibrosis to which it can be ascribed, fatigue, and his hospitalisations, cannot be attributed to the Hepatitis C, nevertheless it has caused him to be anxious and angry and to face an uncertain future for himself and his family, and, more recently, to become fatigued very quickly: he has had three biopsies: he has undergone Interferon treatment for fourteen months, self-injecting, which he did not like, which caused him the 'usual' side-effects, such as, in his case, flu like symptoms for days at a time, skin problems and low moods. Apart from the Interferon, he has not suffered from physical symptoms as a result of the Hepatitis C, and he still, as can be seen, has been able to take a considerable amount of exercise, though he rests in the afternoon. He has had a somewhat earlier incidence of diabetes, with its attendant inconvenience and irritations. His prognosis from his liver condition is of progressive deterioration over the rest of his life, without hope of a transplant, and in some two years he will not be able to do his beloved gardening. The period to come, as Mr W progresses towards decompensated cirrhosis, is likely to bring to him the same discomfort and debilitation as it brought to Mrs X, without the saving grace of her transplant.

273. The Claimants claim £40,000 for general damages: the Defendants put forward £10,000. I must bear in mind that, included in whatever figure I decide for general damages in total, there must be allowed some £3250 for the three biopsies and the fourteen month Interferon treatment, in order that Mr W should not suffer as compared with the others from non-compartmentalisation of his damages. A number of authorities have been drawn to my attention by both sides in relation to Mr W and Mrs X. At this stage I mention only those which may have some bearing on both, and leave aside for a moment those which were only specifically relied upon in relation to the case of Mrs X. The relevant decisions were those in Baker (1985) *Kemp & Kemp* F3-013 (Jupp J), Re M. J. [a provisional award] (1987) *Kemp & Kemp* L3-051 (CICB)), James (1996) *Kemp & Kemp* F2-033 (Judge Stephenson), Glendinning (1997) *Kemp & Kemp* F2-040 (Morland J), Sutcliffe (1997) *Kemp & Kemp* F2-035/1 (Dyson J), Snell (1998) *Kemp & Kemp* F2-037/1 (CA) and H (1998) 1999 CL 211 (CICB). The important distinctions between this case and all of those stem not simply from the age of Mr W, because a number of the asbestosis cases there referred to related to claimants in their seventies. They comprise also the relative shortness of the time during which Mr W has suffered as a result of the condition, namely five years to date and now his remaining life expectancy, a total of some twelve years, compared

with, for example, the thirty years or more of the life of the claimant in H: and, crucially, the impact of the other conditions affecting Mr W. Albeit that for the future, as from about two years time at any rate, the most significant effect upon his daily life will come from his liver disease, it has not yet been his major problem, and I have concluded that he is most likely to die of his carotid or cardiac conditions, with one or other of which he has had to live for many years. I conclude that the appropriate figure to award for general damages, to include the accelerated diabetes, is £27,000.

Mrs X

274. Mrs X is now 56, and gave evidence. She lives with her husband of 36 years, who also gave evidence; and has three grown-up children, two sons, and a daughter, who is a staff nurse, who also gave evidence, and six grandchildren. She was infected on 6 June 1990, while undergoing a laparotomy for a cystic mass in the ovary. Her infection is by genotype 2(b). She had a subsequent cholecystectomy in October 1991. It appears that, in her case, the progress of the disease was very speedy, and by summer 1994 she was suffering from fatigue and nausea, sufficient to make her consult her GP, and, after blood tests, she was diagnosed in August 1994 as infected with Hepatitis C; and after a biopsy on 7 September 1994 she was confirmed as suffering from cirrhosis, which of course explained the symptoms of lethargy and fatigue. She underwent Interferon treatment between 27 March and 11 September 1995, but the virus did not respond, no doubt due to her age and the advanced stage of her liver disease, and she remained PCR positive. She collapsed on two occasions in late 1994, feeling dizzy and nauseous; once on arrival at work, when she was admitted to hospital for three days, where they tried unsuccessfully some fourteen times to give her a lumbar puncture, leaving her back '*black and blue*'; and once when she was out shopping with her daughter. She was a GRO-C, which involved some shifting and lifting, as well as considerable management skills, as the branch, under her control, increased in size and in turnover, and in importance to the business. By September 1995 however, she felt simply unable to carry on the job, and retired on the grounds of ill-health on 1 October 1995. She had a holiday for six weeks in the United States, when, probably because she had finished the Interferon treatment which had, as with the other Claimants, caused her unpleasant side-effects, she felt better. From then on, however, her condition gradually deteriorated, as she suffered from stomach pain, swelling in the stomach and ankles, dizziness, nausea and breathlessness, and found herself more and more confined to bed. In 1996 an endoscopy confirmed the advanced stage of her liver disease, and, by December 1998, she had developed fluid retention, and her condition gave her doctors such cause for concern, by reference to the decompensation of her cirrhosis and to her life expectancy, which they then estimated at less than four months, that she was referred for a transplant assessment. She and her husband, who took early retirement from his job as an electricity meter reader at the end of August 1996, in order to spend more time with and look after her, waited, ever more anxiously, for the availability of a suitable donor, hoping every time the telephone rang that it would be the hospital. On 28 February 1999 a transplant opportunity was available, and she had the operation, remaining in the hospital for approximately four weeks before she was discharged home: she took at least three months to recover from the surgery. The operation was entirely successful, and since then her condition has greatly improved. She is still prevented from doing heavy work such as gardening, or picking up heavy pans when cooking, or holding bags or selecting heavy articles when shopping, accompanied by her husband and her daughter.

275. Although her tiredness and fatigue is much improved, she still has to have a nap most days, but Dr Ryder is clear that a major inhibition to her recovering her full energy has been the immuno-suppressant drugs, which she has been required to take since the transplant, and the quantum of the drugs, and in particular of Tacrolimus, has recently been reduced, specifically in order to give her what he called a *"further benefit in terms of her energy level"*. Dr Master has described her as in his view having had a 'personality change' since the transplant, which he puts down also to the immuno-suppressant drugs. I prefer Professor Wessely's description, who agrees that *"there has been a slight change in her personality since the liver transplant, in that she has become more irritable, which was not present prior to the surgery, and must be either a post-surgical sequela, or a side-effect of immuno-suppression"*. She has, in contrast to her temperament before the transplant, since it been *'volcanic'* on occasion; though much I think may be ascribed to the fact that, since her improvement in health, she has found herself becoming irritable with her husband's well-intentioned efforts to continue what he had been doing for her when she did not have her strength. In his words: *"after the transplant she was obviously a lot better than what she was before, and I still find myself* [taking over and talking for her] *which irritated her ... and I think this was where a lot of the volatile nature came in now and again. I found it very difficult to adjust after ... I have more time on my hands, and I found I was still trying to do the same things* [for her as I had done previously] *and I used to get under her feet"*.

276. It appears to be common ground among the experts that the reduction in immuno-suppressant drugs is likely to benefit the Claimant, not only in respect of her tiredness, but also in respect of her irritability and volatility. She herself considers that her energy levels are a great deal better than they were in 1994/1995 before she stopped work, and probably back to what they were when she first consulted her GP in the summer of 1994. As she put it *"as time is going on it is ... getting better and better"*. She has, it seems to me, effectively returned to life, like Lazarus, from the very edge of death. She of course remains PCR positive, such that, as set out in paragraph 195 above, there is a certainty of reinfection of the new liver. However, Dr Ryder makes clear that she has normal liver function, that she is unlikely to be in the category of patients who develop accelerated Hepatitis C post-transplantation, and that *"the most likely outcome is that her life expectancy may be modestly reduced compared with a member of the population of similar age and gender who did not acquire Hepatitis C and require a liver transplant"*. In the words of one of the doctors who reported upon her soon after the transplant *"this lady is doing brilliantly"*: she did in evidence feel she was doing brilliantly, and she confirmed that she is definitely *"approaching* [the future] *with some pleasure"*. In any event she seeks only provisional damages. She is thus deemed not to develop cirrhosis, or indeed liver cancer (or, as to which the risks are in any event all but non-existent, extra-hepatic complications or late acute rejection of the transplant) during her life time, and I direct the applicability to her of the last three triggers, not of course the first two, as she is already PCR positive, and has had the compensated cirrhosis prior to her transplant.

277. The issues in her case are as follows:

i) A global provisional award of general damages for PSLA, which is not sought to be sub-categorised.

ii) Gratuitous care by Mr X (there is, as will be seen, no issue about gratuitous care provided by their daughter).

iii) Future and past loss: trips to town (the recovery of Mrs X's loss of earnings past and future to aged 65 and loss of pension etc is agreed, and thus not in issue): save that as to pension loss there is a surviving and unexplained difference of 38p (at a multiplier of 10.87), for which the parties will be best advised to toss a coin.

iv) Insurance handicap.

278. PSLA. The following issues arise to be taken into account, against the background which I have set out in paragraphs 271 to 273 above.

i) As there appears, Mrs X suffered from tiredness, pain and discomfort and gradual debilitation from 1994, as her liver disease deteriorated, and tiredness also during her Interferon treatment; and of course exhaustion prior to the transplant, of the kind graphically described by Dr Alexander, when, as discussed in paragraph 207 above, he differentiates the fatigue complained of by many patients, including liver patients, arising from their knowledge of their condition and the accompanying stress and worry, from the *"overwhelming exhaustion one sees with cirrhosis ... a clear sleep reversal. These patients are not fatigued; they are exhausted, and exhaustion of that nature is in my view an indication for a liver transplant. But it is quite different from the symptoms that people describe in the earlier stage of the disease"*. Subsequent to her transplant, there has then been the fatigue which has, it is now clear, been caused, or caused primarily, by the immuno-suppressant drugs, and is hopefully now being alleviated, and in due course even eliminated. Together with that, of course, has been the irritability or volatility which has not only upset her family – though they have, as she confirmed, been prepared to make allowances – but inevitably upset her also.

ii) Of course right from the beginning, when she, wrongly, thought that she had cancer, and continuing up to the transplant and the waiting for the telephone call, she suffered from inevitable fear and anxiety, although she has coped with this by virtue of her *"very positive outlook on life, always ... very good at dealing with adversity"*: her religious faith has assisted considerably, and she made a pilgrimages to Lourdes in 1995 and 1997. She has suffered from sleeplessness, which has resulted in her moving into a different bedroom from her husband, but that too Dr Ryder considers will probably get better.

iii) She gave up her job, which she loved, and has not been able to return to it, or indeed to any employment, and she has less of a relationship with her grandchildren than she would have liked, because of her inability to expend as much energy upon them. She has had dietary constraints, because of the immuno-suppressant drugs, although, because she can still go out to eat at her favourite restaurant, which makes special arrangements for her, this has not been any real problem to her, and in any event Dr Ryder has advised that she need not be so concerned. The need to cut down or eliminate alcohol has not caused her a problem, because she has, it seems, *"never been much of a drinker"*. She has been more concerned about any possible inhibition on travelling on holiday with her husband, because travel is something she and he

love. The problem is not travel insurance, for she has obtained it, nor the ability to travel physically, because she has been able to go recently on holiday in Spain with her husband for two weeks, but what she believes to be a problem in relation to going any country where vaccination or injections are necessary. Once again Dr Ryder has advised that *"she does not need to worry as much as she does about these sorts of things, the vaccinations, eating various foods and so on. Those should not apply to her. There are some vaccines that have to be avoided by anyone who is immuno-suppressed ... for most of these there is an alternative and there are actually very few live vaccines used, so for the majority of people this is not really a major issue"*. She has been upset from time to time by what has loosely been described, as discussed in paragraphs 219 to 220 above, as 'stigma'. Her employers, fellow employees and family have all been very supportive (except briefly for one sister-in-law, who was soon put right) but she has experienced ignorant, and hence hurtful, reactions from people she has met on holiday, and from the family of an ex-girlfriend of her son.

iv) So far as concerns what one might call the medical side, for which, as with Mr W, allowance must be made even in the absence of compartmentalisation, there was a biopsy in September 1994 for which she had to stay in overnight, but which she said did not particularly hurt (similarly perhaps therefore to Mr U). Although she has not had any further biopsies since, it would seem likely that she will, as in the case of other transplant patients, have to have an occasional biopsy thereafter, although in her case it may well be that the non-invasive techniques will be in place and available. There were the unsuccessful attempts at a lumbar puncture in October 1994, to which I have referred. As to the Interferon treatment, she described it as *"horrible"*. She was very much of a *"mustn't grumble"* kind of a person, and therefore did not make a great deal of fuss about it to her medical advisers during the course of it, but she did feel unwell, and, like the other Claimants, (and again perhaps similarly to Mr U) she had such uncomfortable side-effects as flu-like symptoms, fatigue, pain and swelling, and in her case also halitosis, although this may have been more a symptom of the underlying condition, as her liver deteriorated. Like others, because the injections were three times weekly and the symptoms appear to have followed closely upon them, she had *"peaks and troughs"* during the week. As for the transplant operation itself it was of course painful and it left scars, although these in fact only cause her any embarrassment when she is in a swimming pool changing room.

v) She is now left with a residual fear of going out alone, no doubt because of the two incidents in 1994. I have every confidence, and conclude, that this will soon pass, given the kind of person she is, and as her personality returns even more to normal. As for her continuing inability to carry out the heavy work in the house and the gardening, that is resolved by the agreed care provision by nine hours per week to deal with the domestic chores.

279. The Claimants claim a sum of £80,000 for PSLA: the Defendants propose £20,000. I have looked at the cases referred to in paragraph 273 above, and in relation to Mrs X, the Defendants add the following: Aloni (1982) *Kemp & Kemp* A3-009 (Judge Lipfriend), Mitchell (1989) *Kemp & Kemp* E3-001 (Judge Bates), Read (1991) *Kemp & Kemp* A3-008 (CICB), Routledge (1992) *Kemp & Kemp* E3-002 (Otton J), Re G

(1998) *Kemp & Kemp* B2-007/1 (CICB) and Curi v Colina (1998) *Kemp & Kemp* B2-008/1 (CA), to which I made reference in paragraph 212 above. The purpose of the Defendants in referring me to those decisions was to contrast the amounts that were there awarded to Claimants with very much more serious injuries and consequences, including paraplegics, with the sum of £80,000 which the Claimants have put forward, so as to indicate that that sum is wholly excessive. The Court of Appeal in Curi v Colina, for example, approved, while describing it as *"not a generous award"*, general damages, which, as up-dated, would be £64,000, given by way of final award to a claimant of 22 with very serious injuries and a long deteriorating prognosis over a full life expectancy. This, and the other cases, would suggest a sum considerably lower than the Claimants' figure; particularly given that the sum to be awarded to Mrs X is by way of provisional damages, and that she now has both a relatively favourable prognosis and, not by virtue of any substantial attenuation of it as a result of her condition but simply by virtue of her seniority in years, a much shorter life expectancy. I have looked again in particular at the Claimants' cases of James (updated as £42,000), Glendinning (updated as £29,000), Sutcliffe (updated as £34,000) and Snell (the Court of Appeal decision, updated to £33,000: described by the C.A. as the *"top end of the permissible bracket"*). Given the pleasingly positive outcome for Mrs X, but making full allowance for her seven or so miserable years, her escape from death and her relative disability to come, my figure is £45,000.

280. Gratuitous Services. There is agreement between the parties as to the amount of hours, and the rates, on the basis of past and future care (after exclusion of the period when Mrs X was in hospital), if it is to be recovered at commercial rates. The Claimants however seek (i) recovery of Mr X's lost earnings, pension and tax-free sum from his past employment, amounting to substantially more than the commercial rate (ii) that in respect of Mr X's gratuitous services, although not those given by their daughter, if he is to be remunerated by reference to the commercial rate, there should be no Housecroft deduction. I refer to paragraphs 227 to 231 above. The circumstances in which Mr X gave up his job were described by him in his witness statement as follows: *"Whereas I had been* [her] *companion and partner, I became her carer. As her condition deteriorated prior to the transplant, she became so fatigued that she could only manage to wash and dress herself. As I have indicated,* [most of] *the domestic chores were done by me ... However the demands placed on my time became too great with my full time job, so I took early retirement in 1996 ... Once I had ceased working, caring for* [Mrs X] *and looking after our home became a central part of my life, and in a sense filled the void left by my retirement from my job"*. They did not consider the possibility of employing anyone to do the domestic chores as an alternative: *"it never came into the equation because there were other factors involved, not just the hours involved. It was other factors like being with my wife and giving her support and also we did not know how long we had got together"*. Mrs X explained that she would not have wanted *"a stranger to come in and do the chores ... I needed my husband's support at that time and I needed him to be there ... just to give me a cuddle or to talk to when I needed some support"*. What he did then, Mrs X makes clear, was perform most of the household chores, the cooking, the housekeeping and the shopping: although he also helped her in and out of the bath, as she became weaker. In fact, the consensus from the two experts, after they had considered all the evidence as to past care, was that, when Mr X gave up work in August 1996, the hours per week that he was giving by way of gratuitous care, for which he would, on the usual principles, be entitled to be reimbursed, were only seven, rising to eleven in 1997 and fifteen in 1998. The time when he gave virtually

full time care (estimated at 26 hours per week, over and above what could normally be expected of a husband) was the period in April and May 1999, when Mrs X returned from hospital.

281. Mr X was obviously very supportive, and still is. However it seems to me clear that, even if there were any leeway, or any exceptional circumstances, that could be allowed for within the authorities which I have considered in full in paragraphs 227 to 231 above, there is nothing on the facts of this case which could so qualify. In Lamey, relied upon by Mr Brooke QC, not only were the services obviously exceptional, but the experts themselves confirmed that they should be valued at more than the commercial rate, because they amounted to more than the commercial carer would do. There is no such evidence here in relation to the housework performed by Mr X. His emotional support was obviously invaluable to Mrs X, but it could and would have been given in any event, had a stranger been employed to carry out the chores. I can see no ground either for going above the Housecroft ceiling or for awarding more than the net commercial rate, or rather, given that, as I have indicated, it is in any event probable that, by only making a 25% deduction, more than the net commercial rate is in fact being paid, for reaching any other conclusion than that the Defendants' 25% reduction should be made.

282. Trips to town. It is claimed by the Claimants that in respect of the period from 1 January 1994 to 1 October 2000 Mrs X should be entitled to recover the cost of three trips per week by car because of her Hepatitis C illness: and there is also a claim for recovery of three such trips per week continuing for the rest of her life expectancy, on the basis of a whole life multiplier of 18.58. When asked about whether there were three such trips, she answered "*probably, yes*". Plainly of course it can only be a rough estimate. However, quite apart from whether such period is justified in starting as early as January 1994, when no complaint of fatigue was made to her doctor until June 1994, it is apparent to me that there can be no justification for such a case while she was still continuing to work; indeed she explained in evidence how, from time to time, she would pop out to the butcher or the chemist after her own shop closed. In respect of the period after she retired and was at home, it is apparent that, particularly as she became more and more confined to bed, it was her daughter and her husband who did the shopping. Indeed this was one of the household chores which she said that Mr X took over. I conclude that the broad-brush response by the Defendants, to allow for an average of one visit per week throughout the claimed period is realistic, if not generous. However, so far as the period since her operation is concerned, clearly in the early weeks she would have been too ill to go out at all. Now it is the case that her husband or her daughter takes her shopping, and she chooses the articles, while her companion loads the shopping bag. That relates to what one might call the 'weekly big shop'. However she says, as referred to in paragraph 278(v) above, that she is nervous of going out alone, and so there will be other occasions when, even though she might not need help for heavy lifting, she would need assistance in going into town. As set out above, I am confident that this fear will be transient. I would allow two trips per week in respect of the period starting in June 1999, when I suspect she began to be up and about again after the transplant, and lasting through to June 2002; but thereafter I conclude that, as in relation to the period from January 1994 through to January 1999, the Defendants' proposal of one trip per week is appropriate, and no more: I shall leave it to Counsel for the parties to calculate the correct sum in respect of one trip per week from 1 January 1994 to 31 December 1998, none from 1 January

1999 to 31 May 1999, two from 1 June 1999 to 31 May 2002, and thereafter, at the relevant multiplier, of one trip per week for the future.

283. Insurance handicap. The Claimants suggest 'a maximum of £500'. Clearly there is no evidence of any detriment or loss to the Claimant in respect of life insurance or other products, no suggestion that but for the condition she would have applied for any, and certainly now, at age 56, no intention or opportunity to do so. The only point which is raised relates to travel insurance. I have referred to this in paragraph 223(iv) above. Mr & Mrs X have been on holiday this year in Spain and, after making full disclosure, received unconditional travel cover from the Prudential without any addition to the premium, and Mrs X confirmed that she would be able to obtain international insurance on the same basis, if her destination were other than Spain. On the evidence before me, and upon the basis of my belief and presumptions about the travel insurance market, and certainly in the absence of any evidence from experts to the contrary, I see no case made, by way of evidence or inference, of a risk of loading of premiums. I make no award.

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 Part 41.2(2) of the CPR, and containing the triggers for provisional damages which I have set out in paragraph 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.

LIST OF ERRATA TO

A AND OTHERS

V

THE NATIONAL BLOOD AUTHORITY AND OTHERS

1. Para 8: '... subsequently developed, ...'
2. Para 108 (i): '... introduced in the United Kingdom by 1 March 1988'
3. Para 114 to have a new heading: 'The Rest of the World' (also to be inserted into Table of Contents)
4. Para 114(iv): '... useful as a surrogate marker of NANBH ...'
5. Para 129(i): '... for anyone infected with Hepatitis B who might escape ...'
6. Para 143: 'March 1991 (not before March) in left hand column; remove '('all 'not before' March)' in right hand column
7. Para 158(vii): '... it would appear that, at any rate ...'
8. Para 158(ix): '... RIBA 2 ...'
9. Para 189: '... there were of course particular witnesses ...'
10. Para 193: '... symptom; the others being 'anicteric' ...'
11. Para 204(iv): remove 'a' before 'male gender'
12. Para 206: '... in his published study, using approved questionnaires, ...'
13. Para 207: '... sufferers:'
14. Para 214(ii)(b): '... covered by a trigger), ...'
15. Para 217(iii): '... circumstances, ...'
16. Para 221(iii): '... [1977] ...'
17. Para 228(ii): remove 'its' before 'love'
18. Para 229(i): '... on the one hand ...'
19. Para 238: '... inferring, ...'
20. Para 252(iv): (A) '... longer than Mr U's, ...'
    (B) '... permanent hypothyroidism, ...'
21. Para 259: '... not only highly possible ...'
22. Para 277(iii): remove ')' after 'issue': insert after 'coin'.
23. Para 278: remove 'a' before 'pilgrimages'
24. Para 279: '... claimants ...'