Lord Hunt

From: Charles Lister HSD2
Date: 26 March 2001

cc: see attached

HEPATITIS C LITIGATION: JUDGEMENT

Issue

1. The Judgement in the hepatitis C litigation against the National Blood Authority was delivered today. All 117 claimants have won damages. The Judgement also creates a very strict liability regime under the Consumer Protection Act 1987 and therefore has potentially major implications for the NBA and for the NHS as a whole.

Key Findings

2. The claims were brought under the Consumer Protection Act 1987 (CPA) which implemented the European Product Liability Directive 1985. The Judgement is 350 pages long and needs to be carefully assessed before we can be clear about the full implications. The Judge's main findings are:

- the public is entitled to expect that the blood that they receive will be 100% safe. His conclusion is that the knowledge of the medical profession is not relevant in determining the legitimate expectation of the public and nor is the fact that the defect could not have been avoided a relevant circumstance. Once the risk is known about, the product is defective even if the risk could not be identified in the particular product;

- there was a legitimate expectation that anti-hepatitis C screening of blood should have been introduced by 1 March 1990 *(screening for hepatitis C did not begin in the UK until September 1991);*

- there was a legitimate expectation that surrogate tests should have been introduced in the UK prior to 1 March 1988 *(these tests were not introduced in the UK because they are insufficiently specific).*

3. This creates a very strict liability regime that would apply to anything that falls within the definition of a product within the CPA. The question of whether other human organs and tissues are "products" would need to be tested in each case but the definition is very broad and could potentially cover almost anything – solid organs, bone marrow, stem cells etc. There is already a case involving transmission of hepatitis C via a heart due to heard later this year.

4. The Judge held that NBA is liable to all the claimants. A rough estimate of total preliminary damages (including those cases already settled out of court) is £4-4.5m. The claimants' costs of over £3m will also need to be paid. All claimants will be entitled to additional damages if they develop more serious symptoms in the coming years.

5. An Executive Summary of the Judgement, prepared by the solicitors acting for the NHSLA and NBA, is at Annex A.

Next Steps

6. We are meeting tomorrow with Counsel, the NHSLA and the solicitors acting for them to discuss the Judgement and, in particular, to consider possible grounds for an appeal and the pros and cons of doing so. One issue to consider is whether the Department can/should intervene as a party to any appeal.

7. We will seek Ministers views on the question of an appeal later in the week. There is a very tight deadline so a decision may be needed by Friday 30 March.

8. We also need to study the Judgement in detail to assess the wider implications for the Blood Service and for the NHS in general. For example, the Judge held that, because it was not known or accepted by society that blood carried a risk of hepatitis C infection, the legitimate expectation of the public was that blood was safe. In order to achieve public acceptance of the risk – and by implication avoid liability - the Judge considered that there would need to be, at the very least publicity and probably express warnings, and that even this might not be sufficient. This raises issues around educating the public on risk and the question of informed consent to blood transfusion or other treatment.

Media Interest

9. There has been a fair degree of media interest in the Judgement and we can expect plenty of coverage in tomorrow's press. For the moment, we are holding the line that we need time to assess the Judgement before commenting. The lines given to the media today are in the Rebuttal at Annex B.

Conclusion

10. You are invited to note the outcome of the trial. We will continue to keep you informed of developments and will provide further advice on the question of an appeal later in the week.

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Annex A

HEPATITIS C JUDGMENT - EXECUTIVE SUMMARY

The Judgment by Mr Justice Burton was delivered on Monday 26 March 2001.

- The trial concerned 117 Claimants infected with hepatitis C from blood transfusions since 1 March 1988 until September 1991. The claims were brought under the Consumer Protection Act 1987 ("CPA") which came into force on 1 March 1988 implementing the European Product Liability Directive ("the Directive").

- The claims were not brought in negligence. The CPA imposes strict liability on producers of defective products that cause injury. The case was the first significant case brought under the provisions of the CPA and tested the scope of the strict liability regime.

- The Judge held that the National Blood Authority was liable to all of the Claimants. Six selected lead cases were heard and damages were awarded in these cases. They set benchmark guidelines to value the other cases.

- Screening tests for hepatitis B had been introduced in December 1972 but it was known that there was another unidentified agent causing post transfusion hepatitis. It was called non-A non-B hepatitis. It was isolated by researchers in the US in Spring of 1988 and it became known as hepatitis C. A screening test for hepatitis C was developed and became commercially available in late 1989/early 1990. It was introduced as a screening test on 1 September 1991 in the United Kingdom.

- The Claimants' case was that pursuant to the CPA they were entitled to recover damages notwithstanding that the hepatitis C virus had not been identified in respect of some of the Claimants, and that no screening test was available for many of the Claimants and had not been introduced in the UK in respect of any of them.

- Prior to the commencement of the trial, the NBA decided not to contest that the screening test could have been introduced by 1 April 1991, and claims from infected patients subsequent to that date were settled (on a 90% basis).

- The CPA enacts the European Product Liability Directive, and consequently throughout the trial the provisions of the Directive, rather than the CPA were considered and the Judgment is based on the provisions of the Directive.

- Article 6 of the Directive provides that a product is defective if it does not provide the safety that persons generally are entitled to expect. The Judge called this "the legitimate expectation" of the public. He decided that the public had a legitimate expectation that the blood transfused to them would not infect them with hepatitis C. The NBA had argued that given that the medical profession knew that there was a risk that blood transmitted hepatitis, the public could not have such a

legitimate expectation. The Judge concluded that the medical profession's knowledge was irrelevant. The NBA also contended that the Directive stated that in determining the legitimate expectation of the public "all circumstances" are taken into account and that "the avoidability" of the infection was such a circumstance. The Judge rejected this argument.

- The Judge concluded that blood infected by hepatitis C was a "non-standard product" and is to be compared with blood that is not so infected so that the public had a legitimate expectation of receiving non-infected blood. The Judge rejected the NBA's contention that the small risk that blood was infected with hepatitis C virus was a characteristic of all blood and one which was accepted by the public.

- Article 7(e) of the Directive provides a defence to a producer of a defective product, if the state of scientific and technical knowledge at the time that the product was put into circulation was such as not to enable the defect to be discovered ("the development risk defence"). The Judge rejected the NBA's defence of the claims under Article 7(e). He found that as soon as the risk of infection was known (as it was) then the defence was not available. He rejected the NBA's contention that the defence related to the particular product rather than products produced by the manufacturer generally.

- The above findings were sufficient to dispose of the case but the Judge went on to make factual findings in the event that his legal rulings were overturned on appeal. The principal question concerned the introduction of two "surrogate tests". Whilst not identifying NANBH directly they had been introduced in the United States as a means of reducing the risks of post transfusion hepatitis. Those tests were ALT and anti-HBc tests. The Judge found, contrary to the NBA's contention, that there was a legitimate expectation that the surrogate tests should have been introduced in the UK prior to 1 March 1988 and that accordingly blood not screened by these tests was defective. He rejected the development risk defence in respect of surrogate testing.

- Although the Judge concluded that the two surrogate tests used together would only have eliminated 40% of infected donations, the Judge rejected the NBA's contention that he should therefore conclude that damages should be assessed on the basis of "loss of a chance" of avoiding an infection, or denied entirely on the basis that the balance of probabilities was in any given case that the infection would not have been avoided. The Judge concluded that as there was a defect, and the remedy for defect is provided in the statute, rather than in common law, damages should be awarded without reduction to all of the Claimants injured by the defect.

- The Judge did however conclude that if he was wrong on his interpretation of the development risk defence, and an appeal Court concluded that it concerned "the particular product", rather than products in general, then, given his finding that surrogate tests would only pick up 40% of infected donations, on the balance of probabilities, the tests would not have picked up any particular infected donation, and therefore no damages would be recoverable for such Claimants infected prior to the date that there was a legitimate expectation of the introduction of the specific anti-hep C screening test.

- The Judge decided that the date when there was a legitimate expectation for the introduction of the anti-hep C screening test was 1 March 1990. (There are 33 claims prior to that date).

- The Judge assessed damages for the 6 lead Claimants. In the main, his assessments can be viewed as more in line with the submissions made by the NBA, rather than the Claimants, i.e. they are relatively modest. Provisional damages were awarded and further damages can be claimed if Claimants' medical conditions deteriorate in the future as a result of their infections.

- The Judge made some comments about the inappropriate confusion of the public between HIV and hepatitis C because of the use of the shorthand HCV, and expressed the hope that the disease would be called Hep C, rather than HCV in future, to avoid this confusion

Annex B

CHIP – Care and Health Information Portfolio

DH Depart of Heali

Rebuttal

HIGH COURT JUDGEMENT RULES IN FAVOUR OF HEPATITIS C SUFFERERS

Rebuttal - Media Centre

REBUTTAL DRAFT - NOT FOR PUBLIC RELEASE

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Issue:

The Hepatitis C litigation against the National Blood Authority (NBA) began at the Royal Courts of Justice on Tuesday 10 October.

The case was brought, under the Consumer Protection Act 1987, on behalf of 111 people infected with Hepatitis C through blood prior to the introduction of a blood screening test in September 1991. The Department of Health is not a party to the litigation.

Line to take:

Today's Judgement is very long and complex - A 350-page document. It would therefore be inappropriate for us to offer any comment until we have had a opportunity to assess it carefully.

The safety of the UK blood supply is widely acknowledged and verified through independent regulatory systems and audit. However almost every medical treatment or intervention is associated with some risk and blood transfusion is no exception. Keeping this risk to an acceptable minimum is part of the responsibility of the National Blood Service.

Blood transfusion saves the lives of thousands of people who need surgery, who have had serious accidents and a range of other serious conditions like cancer. We have taken active steps to encourage the better use of blood in the NHS and strive continuously to improve safety.

Recent SHOT (Serious Hazards of Transfusion) reports have demonstrated that blood transfusion in the UK is very safe and that it is becoming even safer with improving technology and clinical audit and that infection due to blood transfusion is now very rare.

The National Blood Service has put in place a number of precautionary measures to prevent transmission of viruses.

All blood for transfusion is tested for Hepatitis B, Hepatitis C, HIV and Syphilis. Every donation of blood has been tested for Hepatitis C since 1 September 1991. Since the mid 1980s the plasma used to manufacture blood products (such as clotting factors for haemophiliacs) has been treated to remove viruses such as Hepatitis B & C and HIV.

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