

DRAFT

Lord Hunt

From: Charles Lister HSD1

Date: July 1999

cc: see attached

NATIONAL BLOOD AUTHORITY: HEPATITIS C LITIGATION

Purpose

1. This submission sets out the background to this litigation and the current state of play and informs you of proposals, made to the NBA by the NHS Litigation Authority (NHSLA), for an out of court settlement. [This is the submission mentioned in Sheila Adam's minute of 21 July on haemophiliacs and HCV.]

Recommendation

2. The NBA Board are minded to take the NHSLA's advice and settle out of court those cases where they are advised that liability is beyond reasonable doubt. However, they are conscious that this may have wider policy implications for the Department and would value your views before taking a final decision. We have discussed this issue with the NHSLA, DH solicitors and members of the NBA Board and have come to the conclusion that the arguments in favour of settling this case far outweigh the disadvantages. We therefore recommend that you support the NBA Board's decision to settle. X

Timing

3. [The NHSLA have asked for a decision on the proposed settlement by Friday 6 August. New court rules require that out-of-court settlements are considered at all stages of litigation. Failure to do so when a settlement is possible can result in stiff financial penalties in costs at the end of the day. Your views are therefore sought by Tuesday 3 August to allow the NBA Board enough time to make a final decision before the 6 August deadline.]

Background

4. Around 120 people infected with Hepatitis C (HCV) through blood and blood products are seeking damages against the NBA. The claimants' case is that the blood service could have introduced a screening test for HCV earlier than September 1991 thus avoiding unnecessary transmission of infection. The case is due to be tried in October 2000.

5. The litigation is being handled by the NHS Litigation Authority and their solicitors, Davies Arnold Cooper (DAC).

Consumer Protection Act 1987

6. The case is being brought under the Consumer Protection Act 1987 (CPA) which allows for strict liability for production of a defective product. This is the first time that this Act has been used in a case involving human tissue/fluids so, although the Department is not a party to the case, we have taken a close interest in it because of the precedents that could be set. Last Autumn, DH took leading Counsel's advice and agreed that, for the purposes of this litigation only, blood and blood products could fall within the definition of "products" within the meaning of the CPA. Counsel's advice was that the courts would otherwise come to the same conclusion and that this formulation would avoid a legal precedent being set.

7. The claimants in the group action were infected with Hepatitis C between March 1988, when the Act came into force, and September 1991, when the HCV test was introduced nationally.

HCV Test

8. The question of whether the blood service could have introduced a HCV screening test earlier and, if so, how much earlier is complicated by a number of factors including arguments about the sensitivity and specificity of the tests available at various points in time. The claimants will, however, point to the fact that the US introduced a first generation screening test in June 1990, well over a year before the UK, and that most other European countries also introduced screening for HCV that year.

9. This same first generation screening test was evaluated by the blood service in England in late 1990. ACVSB (MSBT's predecessor) considered the results of the evaluation in November 1990 and recommended the introduction of the test for routine screening. However, shortly after this, a new second generation screening test became available and a decision was taken (by ACVSB backed by the Department) to halt the introduction of the first generation test and to evaluate the new one.

10. Trials of the new test took place from May 1991 in five regional blood transfusion centres. These centres continued to use the test until it was introduced across all 14 regions in September 1991. This led to a situation where between a third and a half of English blood donations were being screened for Hepatitis C from May 1991 onwards, whilst the rest were not.

11. Given these facts, Davies Arnold Coopers's advice to the NBA is that:

"...whilst there is a risk that liability will attach under the Consumer Protection Act in respect of all claims post March 1988, the liability exposure increases the later the date of the transfusion. Certainly there is considerable exposure for all transfusions subsequent to 1 January 1991. Indeed our view is that from May 1991 there is likely to be a finding of liability under the Act.

Pros and Cons of a Settlement

12. The arguments in favour of a settlement are:

- if the case comes to Court there is very likely to be a finding of liability against the NBA, at least for those claimants infected after May 1991;
- a trial (starting October 2000) would involve a good deal of negative publicity;
- considerable legal costs would be incurred – around £250,000 in the run up to the trial and a further £2m for the trial itself;
- the damages would be no greater now than after a trial and may even be less;
- there would be no finding by a judge that the Consumer Protection Act applies.

The disadvantages of doing a deal now are:

- if a settlement is reached it is likely that many new claimants will emerge (approximately 820 cases have been identified through a DH-sponsored look-back study). However, the same problem would occur if the claimants were successful in court;
- though a different issue, it may be confused with Hepatitis C and haemophilia issue, but again this would happen were it to go to trial.

Proposed Settlement

13. There are a number of ways in which a settlement could be worked out. This would be a matter for the NHSLA and DAC to negotiate with the claimants' solicitors, but the sum is likely to be of the order of £X. However, on the basis of

the legal advice offered, the NBA Board prefers a settlement on broadly the following lines:

- (a) a settlement made only in respect of those claimants whose claims are judged likely to succeed in court (currently estimated at around 20 claimants);
- (b) a two tier settlement with:
 - a provisional award to all claimants at (a);
 - a second payment awarded to those claimants who go on to develop Hepatitis C related illness (on current evidence, it is likely that some 90% of people with Hepatitis C will remain asymptomatic but 10% will develop cirrhosis or hepatocellular cancer after around 20 years).

The alternative would be to give all claimants at (a) a single, bigger award, but this would be over generous to the 90% or so who will remain asymptomatic and unfair to those who will go on to develop serious illness

Cost of the Settlement

13. [DN: to be added]

Wider Implications of a Settlement

14. We have consider whether settling now has any wider implications for:

Haemophiliacs and Hepatitis C: whether we can justify morally a financial settlement on the claimants but continue to refuse financial assistance to those who have not taken legal action (the 400 or so haemophiliacs still alive with HIV will also have HCV but will have signed an undertaking when they received their financial settlement not to take legal action on HIV or HCV). This is a difficult question, but we feel that the kind of limited settlement proposed (with payments only in respect of those likely to succeed in court) makes arguments for financial assistance easier to resist. The same issue would in any case arise if damages were awarded in court.

Other Litigation in the Pipeline: SOL have advised us that, because a decision to settle the Hepatitis C litigation out of court would be decided on

its own law and facts, it would not create a precedent for other litigation in the pipeline, such as that pending on vCJD.

Conclusion

15. The arguments in favour of the NBA Board agreeing to an out of court settlement in this case seem to us to be overwhelming. The disadvantages we have been able to identify would apply equally if the case went to trial and claimants were awarded damages, which we are advised would be the likely outcome.

16. Whatever we do, the outcome of this litigation is bound to be linked to the campaign for financial assistance for haemophiliacs with Hepatitis C. We would need to maintain the line that the two issues are quite separate, that the NBA had settled on only a small proportion of the claimants and that the bulk of the settlement would only be available to the roughly 10% of those who go on to develop Hepatitis C related illnesses.

17. In the light of this, are you content for the NBA to take forward arrangements for a settlement with the NHSLA?

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