DRAFT

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From: Philip Hunt
Date: June 2000

cc: see attached

NATIONAL BLOOD AUTHORITY: HEPATITIS C LITIGATION PROPOSAL FOR AN OUT OF COURT SETTLEMENT

Issue

1. This note seeks your agreement to a proposed strategy for settling litigation brought against the National Blood Authority (NBA) by a group of people infected with hepatitis C (HCV) through blood transfusion between 1988 and 1991. The case is set for trial in October, and Counsel's advice is that at least some of the claimants are likely to succeed.

2. In developing a strategy, I have taken account of the fact that:

- the devolved administrations have similar litigation pending. A settlement here would therefore put pressure on them to follow suit. We need to agree a common UK approach, and I have already met Susan Deacon to discuss options;

- settling the litigation has presentational difficulties given that we are refusing financial assistance to haemophiliacs infected with HCV through blood products prior to 1985.

3. I am copying this note to Susan Deacon, Jane Hutt and George Howarth in case they have any comments on the proposal.

Timing

4. The case comes to trial in October and costs are mounting daily. An urgent decision is therefore needed, preferably so that this can be put to the Board of the NBA when they next meet on 27 June.

Key Facts

5. These are as follows:

(i) 113 people infected with HCV are seeking damages against the NBA. The trial of the six lead cases is due to start on 3 October 2000 and listed to last 3 months. The Department is not a party to the litigation;

(ii) the claimants were infected by blood transfused between 1 March 1988 and September 1991 when anti-HCV screening was introduced in the UK.

(iii) the case is being brought under the Consumer Protection Act 1987 (CPA) which allows for strict liability for production of a "defective" product (the definition of a product in the CPA is wide enough to include blood). The Court will need to

consider whether the blood which infected the claimants was defective within the meaning of the Act and whether NBA have a "state of the art" defence;

(iv) the hepatitis C virus was formally identified in May 1988. Only then did it become possible to develop a HCV-specific screening test, which became commercially available in December 1989. One of the questions the Court will need to decide is by what date screening ought reasonably to have been introduced by the NBA. It is almost certain that the Court will arrive at an earlier date than September 1991;

(v) the UK was, by some way, the last of the major developed countries to introduce universal screening for HCV in blood. The US licensed the new test and introduced screening in May 1990, and most European countries began screening the same year. Although there were good reasons for the delay in the UK – discussions on the cost/benefits of the new test, followed by trials – legal advice is that these are unlikely to stand up to serious scrutiny in court;

(vi) advice on the introduction of the HCV screening test in the UK was given by the Department's expert Advisory Committee on Virological Safety of Blood (ACVSB). In November 1990, following an evaluation of the test by the blood service, ACVSB recommended its introduction. However, shortly after this, a new second generation screening test become 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;

(vii) 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 HCV from May 1991 onwards, whilst the rest were not.

Likely Outcome of the Court Case: Advice from Counsel

6. The legal arguments presented by this case have not previously been tested in Court. Bearing this in mind, Counsel's advice is that there is an outside chance that *all* the claimants could succeed if they can convince the court on one of the following arguments:

(i) ***blood as a defective product***: because patients who receive blood do not expect it to be contaminated with a virus capable of causing serious illness, its safety was "not such as persons generally were entitled to expect" and was therefore defective within the meaning of the Act. Although Counsel thinks it unlikely that the Court would adopt such a crude approach, the claimants will push hard to have the issue taken to the European Court of Justice (they failed to persuade the judge to allow a pre-trial reference to the ECJ but will undoubtedly renew their attempts if the case goes to trial);

(ii) ***surrogate testing***: this is a test for general liver problems rather than one which specifically screens out HCV. The claimants will argue that surrogate testing would have substantially reduced the risk of HCV infection and should therefore have been introduced before the screening test became available. However, the

reliability of this form of testing was at all times controversial. It was introduced in some countries (eg Germany) with uncertain results but was eschewed by the UK and others. Surrogate testing would have led to a large number of false positives, seriously depleting the blood supply, and would not have made blood risk free: the risk would simply have been less. Counsel therefore doubts that a Court would rule that blood not subject to surrogate testing fell below the level of safety that persons generally were entitled to expect.

7. If these arguments fail, the Court will need to decide when it would have been reasonable for the UK to introduce screening. Counsel sees this as serious area of vulnerability for the reasons outlined in para 5(v)-(vii) above). It is hard to know what date the Court might plump for but, in Counsel's opinion, those claimants infected after May 1991 are "very likely to succeed" and there is "serious vulnerability" back to January 1991. However, it is possible that the Court may take an earlier date, and Counsel has suggested that the introduction of screening by the US in May 1990 might possibly be used as a benchmark.

Proposal for an Out of Court Settlement

8. Given this advice, I have been convinced by the arguments put forward by the NHS Litigation Authority, and the lawyers acting for them, that we should allow the NBA to settle this case out of court. This is because:

- 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. There would also be a precedent set by the Court as to the meaning of "defect" under the Consumer Protection Act which could impact on future litigation;

- a trial (starting October 2000) would involve a good deal of negative publicity; and

- considerable legal costs would be incurred – approximately £1m per side from now until the end of the trial.

9. My concern, however, has been around the terms of such a settlement. I want to ensure that there is a clear and defendable distinction between settlement of this litigation and our continued refusal to compensate haemophiliacs infected with HCV through blood products on the basis of non negligent harm.

10. The main plank of our argument for refusing payment to haemophiliacs has been that heat treatment to eliminate HCV from blood products was introduced as soon as the technology was available. This is not true for the introduction of the screening test for HCV, and a financial settlement can be justified on that basis. However, we would start to run into difficulties if we include in the settlement those claimants infected before the screening test became commercially available.

11. I therefore propose that we ask NBA to offer to settle on all claimants infected after May 1990, the date the screening test was licensed and introduced in the US. This group would receive 100% of their claim. Those infected before that date would receive no payment. This would spilt the group of 113 as follows:

Group A: 68 claimants transfused subsequent to 2 May 1990

Group B: 45 claimants (including 3 where the date is unknown) – transfused prior to 2 May 1990.

The offer would need to be conditional on the 45 claimants (Group B) halting their action. The proposal would also require the payment of costs.

12. Given the overwhelming arguments in favour of settling, this way forward seems to me to offer the least hostages to fortune. However, we need to agree a fallback position should this offer be rejected.

Fallback Position

13. Given that 40% of the claimants would receive nothing, Group B may well decide that they have nothing to lose by continuing with the trial. Our options would then be as follows:

Option 1: settle with Group A (the stronger cases) without the precondition that Group B discontinue and be prepared to counter the arguments set out at para 6 (i) & (ii) above when the case comes to trial. This would make it easier to defend our position with the haemophiliacs, but at a price:

- the adverse publicity of the trial would not have been avoided, although it should be mitigated by demonstrating that we have settled the Group A cases. The Haemophilia Society would also inevitably leap on to the bandwagon to get their case aired again by the media;

- the considerable legal costs involved in a trial would not be significantly reduced;

- there is a real prospect of Group B cases being successfully defended but, given the uncertainties around interpretation of the Consumer Protection Act, it is possible that the Judge would conclude that blood was defective at some date prior to 2 May 1990 or conclude that the issue ought to be referred to the ECJ for a determination.

Option 2: Extend the scope of the settlement. This could be done in two stages:

Stage 1: Expand Group A so that it includes the 82 claimants infected after 1 January 1990 when the HCV screening test become commercially available. This would leave 31 claimants in Group B (as opposed to 45 in the initial offer) and would lessen the chances of this group continuing their legal action. By tying the offer into the availability of the screening test, it would also still preserve the clear distinction between claimants benefiting from this settlement and the haemophiliacs infected with HCV through blood products.

If this offer is rejected and the 31 signal their intention of continuing to trial, we have the choice of reverting to Option 1 or of proceeding to:

Stage 2: Agree a financial settlement for Group B. This would avoid the considerable downsides of Option 1, but would leave us more exposed with the haemophilia lobby. We could mitigate this exposure to some extent by offering Group B claimants a lower settlement than Group A in recognition that their case is not as strong. This could be worked out on a scale of discount depending on the date of infection, ranging from (say) 75% of the Group A payment for those infected in December 1989 down to a small ex-gratia sum for those infected before May 1988 (before HCV was even formally identified).

14. I am fairly comfortable with the fallback position at Option 2, Stage 1 but rather less so with Option 2, Stage 2. However, if the choice is between offering a settlement to Group B or allowing the case to go to trial, my reluctant conclusion is that Option 2, Stage 2 represents the lesser of two evils. The downside is that our arguments for refusing payments to the haemophilia lobby would be much harder to sustain. We would need to maintain the line that the two issues are quite separate - that the settlement was based on the best legal assessment of the outcome had the case gone to trial, and that the bulk of the settlement would only be available to the roughly 10% of those who go on to develop serious HCV-related illnesses (see paras 15 & 16 below).

Cost of the Settlement

15. The overwhelming majority of claimants have no symptoms. However, around 10% are likely to develop serious liver disease over the next 10-20 years and these cannot be identified in advance. The settlement will therefore need to be in two parts – an initial payment with a mechanism to award further payments to those who go on to develop serious illness.

16. Under the current proposal, each claimant in Group A would receive £33,000, with a further £275,000 for those who develop cirrhosis/liver cancer (these are current best estimates of the level of damages likely to be awarded by the courts). This gives approximate settlement costs of:

Initial Offer: £3m initially (3 of the Group A cases would recover damages on the basis of serious liver disease at this stage) with a further £1.1m needed over the next 10-20 years

First Fallback: £3.5m initially with a further £1.4m needed over the next 10-20 years.

17. Additional sums would be needed if it also proves necessary to settle on Group B.

18. The costs of the settlement would be met through the NHSLA's Existing Liabilities Scheme under which NBA pay and claim back their entitlement from the NHSLA. The NHSLA will have to find the money from their overall allocation for 2000/2001.

Conclusion

19. Are you content with my proposal that a settlement is offered on the following basis:

Initial offer: compensation paid to claimants infected after 2 May 1990 based on 100% of their claim on condition that the remaining (45) claimants discontinue.

First fallback: compensation paid to claimants infected after 1 January 1990 based on 100% of their claim on condition that the remaining (31) claimants discontinue.

Second fallback: compensation paid to (i) claimants infected after 1 January 1990 based on 100% of their claim (ii) claimants infected before 1 January 1990 on a sliding scale of discount from 75% of claim down to a small ex-gratia sum for those infected before May 1988.

20. If none of these offers are accepted (which is highly unlikely) I will come back to you with alternative strategies.

Philip Hunt

Copies:

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