SofS

Are you content to follow PS(L)'s advice at para 20. Cost £3m initially, £1m over 10-20 years.

URGENT DECISION

455/6/5

RESTRICTED - POLICY

Alan Milburn
Gisela Stuart

From: Philip Hunt
Date: 30 June 2000

cc: see attached

GRO-C: Stephen 30/6

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 significant 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 Bairbre de Brun 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.

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
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> ***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. If this happens, I propose that we extend the offer 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. This is crucial.

14. If this offer is rejected and the 31 Group B cases signal their intention of continuing to trial, we have a difficult choice between:

> **Option 1:** settle on the Group B cases as well as Group A, end the threat of legal action but risk exposure to 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); or
>
> **Option 2**: settle with Group A without the precondition that Group B discontinue their action and be prepared to counter the arguments set out at para 6 (i) & (ii) above when the case comes to trial.

15. Both options have potential downsides:

> **Option 1**: settling on the Group B claimants would place us under enormous political pressure to give a similar settlement to the haemophiliacs. Were we to do so, the cost would be considerable. There are currently 270 haemophiliacs

with severe liver disease as a result of hepatitis C infection. If we were to give them the same award as proposed in the out of court settlement (£275,000 each - see para 18 below) the immediate cost would be £75m. If we were to also give money to the remaining 3,000 haemophiliacs with HCV who don't have severe liver disease, the cost would be considerably in excess of this – perhaps a further £90m. We might also open the floodgates to demands for compensation from other groups inadvertently injured as a result of NHS treatment.

Option 2: also carries 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;

- 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 1 January 1990 or conclude that the issue ought to be referred to the ECJ for a determination. A decision in favour of the claimants would have implications for future policy on the screening of blood, putting NBA at risk of product liability if available blood screening tests are not introduced, regardless of the cost/benefit arguments or their impact on restricting the supply of blood to the NHS.

16. In my view, Option 1 is the least attractive because of the exposure to the haemophilia lobby. Given the likelihood of success in defending the Group B cases, I think we should be prepared to be robust and go for Option 2. I suggest, however, that if the proposed settlement and fallback offer are rejected, we seek a further opinion from Counsel on the likely outcome of a trail before making a final decision (we will by then have access to the evidence the claimants will be using to support their case).

Cost of the Settlement

17. 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.

18. 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

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

19. 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 are able to accommodate a settlement of this order within this year's cash limit for ELS payments.

Conclusion

20. Are you content with my proposal that:

(i) 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.

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

(ii) if these offers are rejected, the precondition that the 31 claimants discontinue is removed, and we allow the case to proceed to trial (subject to an assessment by Counsel of the likelihood of these cases being successfully defended).

Philip Hunt

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