On behalf of the: Defendant
Witness: Peter Garwood
Statement No: 1
Exhibits:
Dated: March 2000
CASE NUMBER: 1998 - A- 458

IN THE HIGH COURT OF JUSTICE

QUEEN'S BENCH DIVISION

MR JUSTICE BURTON

RE: HEPATITIS LITIGATION

B E T W E E N : -

A AND OTHERS

Claimant

- and -

THE NATIONAL BLOOD AUTHORITY

Defendant

WITNESS STATEMENT OF:	**PETER ALEXANDER GARWOOD**
ADDRESS:	**National Blood Authority** **Brentwood Centre** **Crescent Drive** **Brentwood** **Essex CM15 8DP**
OCCUPATION:	**National Processing, Testing and Issue Director of the National Blood Authority**

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1. My full name is Peter Alexander Garwood. I make this statement from my own knowledge and beliefs.

2. I am currently National Processing, Testing and Issue (PTI) Director of the National Blood Authority. I became Scientific Director at the South Thames Blood Transfusion Centre in January 1991. In November 1994 I became Operations Director of the London and South East Zone. In August 1999 I was appointed National PTI Director. A copy of my CV is attached.

3. In my present position, I am now responsible for the effective management of the processing, testing, issue and tissue services activities on a national level. With formal planning measures fast and

efficient implementation of proposals can be achieved with the benefit of central assessment, review and devising of protocols.

4. By way of background to the Blood Centre where I was working at this time, I was Laboratory Manager, responsible for the different laboratories of the South London Regional Blood Transfusion Centre (SLRTC) until the end of 1990. There was a single centre at Tooting which served approximately 50 hospitals and covered a population of six million. 250,000 donations went through this centre and this was the largest centre in respect of such donation numbers by a considerable margin at the relevant period. There was also a small unit in Lewisham Hospital, which was subsequently moved to Hither Green Hospital and this centre collected 30,000 to 40,000 donations per year. The boundaries of other Regional Transfusion Centres matched the boundaries of the former Regional Health Authorities but there was no formal centre in South East Thames at the time. The SLRTC had to seek to meet the demands of all the hospitals in the South East and South West Thames area. The major NHS reforms that took place at this time were the trigger to get South East and South West Thames to examine the situation. The South Thames Blood Transfusion Service (STBTS) was created and a management structure was responsible for both Hither Green and Tooting. I became Scientific Director for both laboratories. A lot of re-organisation subsequently took place in STBTS throughout 1991 and onwards.

5. As Scientific Director of STBTS, I was very concerned with the practical steps necessary to introduce testing for the presence of antibodies to HCV. This can be seen from the proposal paper that I prepared in June 1991 (ST 40-43) and the Minutes of various meetings at the time such as the Strategy/Operations meeting on 1 July 1991 (ST 38). The following issues that I identify in this statement represent the main factors that required consideration but the importance of these issues would vary from centre to centre. For example, the overriding concerns in South Thames related to space and staff although other factors would have played a part as well.

6. When the STBTS were requested by the National Directorate to confirm the earliest date from which we could implement hepatitis C testing, there were therefore many different factors that influenced the suggested date that we put forward of 1 June 1991. In the Minutes (ST 21) the re-organisation of the laboratories is cited as well as the uncertainty over the length of the Gulf War and the fact that we were awaiting further proposals from the National Directorate.

7. As Scientific Director of the South Thames Blood Transfusion Centre I was involved in preparations for the introduction of anti-HCV screening between 1989 and 1991, at the South Thames Blood

Transfusion Centre. From my experience I am aware of the issues which needed to be considered in the implementation of a mandatory transfusion microbiology test in the early 1990s, and I discuss these below in order to demonstrate the logistical and time consequences that result.

8. At the time, all practical difficulties were overcome by the small teams at the different Regional Transfusion Centres. There were no central project teams at the time within the National Blood Transfusion Service. In different centres, these issues would be faced by laboratory managers, scientific directors, medical staff, technologists or managers. The lack of any central infra-structure was a factor that added to the time required to deal with the technical issues that I have identified. I believe that it is remarkable that the date of 1 September 1991 for the introduction of anti-HCV screening was achieved outside of any formal process.

9. **Availability of Suitable Validated Test Kits**

9.1 There is a precarious balance between the availability of blood donations and the demand for products derived from such donations. Stock levels were always a matter of great concern.

9.2 The use of a testing system that has a high repeat reactive rate (RRR) due to poor specificity would lead to an unacceptably high reject rate for blood donations leading to potentially dangerous low stock levels of red cells.

9.3 Without access to adequate confirmatory testing, this loss of product becomes cumulative, as donations from such unresolved "RRR" donors cannot be collected/used.

9.4 The use of a testing system that has a high initial reactive rate (IRR) would lead to a high repeat testing rate leading to unacceptable delays in the release of labile blood components. Running the screening test would produce initial reactives. From these initial reactives, repeat tests would be carried out two or three times. This produced the RRR. The repeating process itself would take time and resources in terms of people, tests and equipment. If the IRR was high then there would be more to do and the entire process would slow down.

9.5 Red cells have a shelf life of 35 days and platelet concentrates have a shelf life of five days. As was well-known to all RTC staff and hospital bloodbank staff, the NBTS was having some difficulties in meeting platelet needs. In London in particular, there was a very high need for labile blood components due to the very high demand from the teaching hospitals. A higher percentage of patients than elsewhere in the country were receiving treatment that required blood components to be available due to the number of teaching hospitals in the area. This

was a struggle already and the use of a testing system that had a high IRR and RRR would slow down the process even more and would have resulted in inadequate stocks on the shelves.

9.6 The validation of kits is not without difficulties. Even if a kit has been assessed centrally as being suitable, the kit must undergo an evaluation within the system used at each blood centre. Differences in handling, temperature, etc, may impact on the suitability of a kit. Assessment took place at each centre and it was therefore necessary to develop individual systems within each RTC.

10. Suitable Controls, Cut Offs Etc

10.1 Although manufacturers supply internal kit controls, it is good laboratory practice to incorporate external monitoring or cut off samples so as to ensure consistency and suitability. These might be provided by the National Institute for Biological Standards and Control or, if not available, may be internally prepared. Without the use of such additional controls there was a risk that there was an unacceptably high variation between batches of kits.

11. Confirmatory Testing Service

11.1 As discussed elsewhere, any transfusion microbiology test used for the screening of blood donations will test repeatedly reactive on a proportion of donors who are **not** carrying the infectious marker.

11.2 The exclusion from the blood supply of all repeat reactive donations will prevent the possible transmission of the infectious agent. However, if there are a significant number of unconfirmed positive donors (as a consequence of not having access to an adequate confirmatory testing service) this will have a cumulative effect on the availability of adequate supplies of blood components.

11.3 There will also be donor related difficulties as a consequence of "well" donors being worried by "false positive" results. This naturally has an unfortunate effect on individual donors but more significantly could affect the confidence and trust of donors in general. It was necessary to manage and effectively balance the care of donors, the question of resources in terms of both stock levels and funding, and the practical necessities of the process.

12. **Sampling Capacity**

12.1 Barcoded donor samples are processed by computer controlled samplers. These samplers read the identity of each sample prior to dispensing an accurate volume of serum into a particular well of a barcoded microplate/plate containing the active elements of the testing system.

12.2 The introduction of an additional mandatory test therefore extends the time taken to dispense all of the samples into all of the microplates/plates. For a particular blood centre, this extended sampling time could be unacceptably long (dependent upon the throughput at each centre, available equipment, current working arrangements, scheduling of donor sessions etc), in terms of having a detrimental effect upon supply levels.

12.3 Delays in the release of the results of all mandatory tests could impact on the availability of clinical products.

12.4 The introduction of an additional mandatory test could, therefore, necessitate the increase of sampling capacity, ie the purchase of additional computer controlled samplers.

13. **Testing Capacity**

13.1 Once accurate volumes of serum have been dispensed into particular wells of a barcoded microplate/plate containing the active elements of the testing system, the microplates/plates have to undergo processing. This processing involves the sequential addition of measured volumes of reagents (chemicals), incubation at defined temperatures for defined times and washing (removal of supernatants and resuspension in specified dilutents). This process may be repeated several times, leading to the generation of a "signal" (for enzyme immuno assays this would be the production of a colour).

13.2 The "signal" is then read and the strength of reaction compared with that of control samples incorporated into the test run.

13.3 Dependent upon the centre, the date and the assay, this additional processing may be undertaken manually or using an automated sample processor. Within STBTS, we used the introduction of anti-HCV microbiology testing as the spur to becoming far more automated.

13.4 Automated sample processors are computer controlled devices that undertake all of the necessary steps required by a particular test kit. This will include the reading of the final result and the determination of whether the test results on a particular microplate/plate are valid.

13.5 Such automated sample processors require adequate space and services. More staff would be required if manual processing were to be undertaken and while less staff would be involved in an automated system, there would still be a significant need for space. Hither Green was more heavily automated than most other centres at the time, including the one at Tooting. We took the view that automation would produce an improved quality of result.

13.6 Automated sample processors also need to be linked, electronically, to both the samplers (thus allowing the link between a well on a barcoded microplate/plate and a barcoded donation sample to be made) and to software that undertakes the interpretation of the test results generated.

14. Software

14.1 Computer software controls the samplers, the automated sample processors (if used), the integration of sample identification and test interpretation and the control of other aspects of the donation processing and testing.

14.2 Software used within the transfusion microbiology laboratory should be sufficiently flexible to allow the incorporation of an additional mandatory test with relatively little delay.

14.3 Core IT systems, however, may require significant changes prior to the implementation of an additional mandatory test.

14.4 The majority of core IT systems in use within the NBS during the early 1990's were commercial systems that required external suppliers to make the required changes. Such changes would need to be very carefully specified and subsequently acceptance tested.

14.5 Computer hardware may require changes. These could be as little as having additional communication ports installed to having to have an upgrade to disk capacity or processor capacity. The additional activities undertaken by the core computer system as a consequence of incorporating an additional mandatory test could be quite considerable. For some centres there could be an extensive lead-in time from the identification of the software needs to the necessary installation and operation.

15. **Trained Staff**

15.1 Additional staff may be required to undertake the additional mandatory test.

15.2 The need for staff, and their level of training, will be dependent upon whether automated sample processors are available or not. The less automation available then the more trained staff will be required.

15.3 Staff may be available to be redeployed from elsewhere within the blood centre or, more likely, will need to be recruited. Dependent upon the grade of staff required, the job market prevailing at the time, demographics etc, recruitment may be more or less difficult.

15.4 As I have already said, the issue of staffing was of great importance at STBTS at this time. This was one of the first issues that I addressed when I became Scientific Director for STBTS in January 1991. I was concerned about the difficulties in recruitment and retaining staff generally and in particular as regards the forthcoming introduction of anti-HCV screening tests. These considerations relating to staff had not resolved by the time of September 1991. As a result of the demographics of the South Thames area, there were many alternative jobs available at the various teaching hospitals.

16. **Space**

16.1 All of the additional equipment/staff will require additional space. This space may already be available but may not. The physical extension of transfusion microbiology testing laboratories requires sufficient time and discussion of availability of resources. Such work must not disrupt the pre-existing work flows as donors continue to donate and their samples continue to require testing to a suitable standard.

16.2 The space within STBTS was already inadequate before the needs of implementing anti-HCV screening became an issue. The screening programme however was clearly going to result in the need for a new test, new people and new equipment. As a result of the many changes that were taking place within the STBTS at this time, a new laboratory was built and double the existing space became available to us.

17. **Introduction of testing**

As can be seen from the proposal that I prepared in June 1991 (ST 40-43) there were numerous issues that I listed. I proposed that testing be underway by 1 August 1991 to allow time for staff training, de-bugging of protocols etc. It is impossible to introduce a highly complex procedure overnight and this lead-in period was to ensure that the difficulties had been identified, eliminated and that testing was established and routine. I believe that such a trial period was the only way that a centre could implement the start date of 1 September 1991.

I believe that the facts stated in this witness statement are true.

Signed: ..... Dated: .....