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On behalf of the: Defendant
Witness: E A Robinson
Statement No:
Exhibits:
Dated: 18/01/2000
1998 A NO. 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:	**DR ELIZABETH ANGELA ROBINSON**
ADDRESS:	**National Blood Authority** **Oak House** **Reeds Crescent** **Watford** **Herts WD1 1WH**
OCCUPATION:	**Medical Director of the National Blood Authority**

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1. My full name is Dr Elizabeth Angela Robinson. I make this statement from my own knowledge and beliefs and I have reviewed the files disclosed from the Yorkshire Regional Transfusion Centre in Leeds ('YRTC'), for the purposes of making this statement.

2. I am currently National Medical Director of the National Blood Authority. I became a Consultant in Clinical Haematology and Blood transfusion at the Yorkshire Blood Transfusion Service ('YBTS'), based in Leeds, in 1976. *(At our meeting, I made a note that you were appointed Assistant General Manager of the RTC in Leeds in 1987 - was this correct?).* In 1988 I was appointed Chief Executive and Medical Director of YRTC. I had overall responsibility for the centre. Funding came from

the Yorkshire Regional Health Authority ('RHA') and I was accountable to the Chief Executive of the Regional Health Authority, *(name?)*. A copy of my CV summarising my career is attached.

Surrogate testing

3. I recall that I had clear views in the late 1980s that surrogate testing for ALT and anti-HBc was of little value in detecting donors who may be anti-HCV positive. This view derived from information provided to me by Dr Harold Gunson in his role as National Director, and from research which I had read, which included the study by Mijovic, Contreras and Barbara entitled 'Serum alanine aminotransferase (ALT) and *y*-glutamyltransferase (*y*-GT) activities in north London blood donors' (J Clin Pathol 1987; **40**; 1340 - 1344) (Leed 523 - 527) and the letter from Anderson, Contreras, Barbara and Mijovic entitled 'Surrogate testing for Non-A non-B hepatitis' printed in the Lancet on April 18 1987. (Leed 528) *(Dr Robinson these articles are on your files from the time - see file 2 , divider 5. Some parts have been underlined so appear to have been read. Are you content to say you would have read them?)*

4. I also received copies of research papers such as evaluations of ALT testing conducted by the SNBTS in November 1987 (Leed 171 - 193) and in August 1988 (Leed 166 - 170).

5. An example of my own experience, which contributed to my view that ALT testing was of little value, is that the bio-chemists at my RTC (*Dr Robinson, is this the correct job description for these staff? Can we identify the date? I cannot find a reference to this in our documents)* wished to identify a group of "normal" ALT samples so that these could be used as a control standard to which other ALT tests could be compared. Samples to be used for this purpose were collected from the plasmapheresis donors between December 1987 and January 1988 (*are you able to confirm the date*?) The samples taken in December 1987 showed that a high percentage of the donors had raised ALT levels, as did those taken in the week following the New Year celebrations. In our view/the researcher's view (?) this ALT was raised due to increased intake of alcohol over the Christmas and New Year period. When we took repeat tests later in January 1988, these did not show increased ALT. This example demonstrated the difficulty of obtaining "normal" ALT levels and also demonstrated the variability and the number of factors which

may affect this marker. *(Was a paper published on this experiment? If so, please give reference)*

6. I do not recall holding a particular view in respect of anti-HBc in relation to NANBH. I do recall however that my view, informed by the scientists at YRTC (*is this correct*?) was that anti-HBc was a non specific marker and therefore was not valuable as a test in isolation.

7. Had ALT testing on its own been introduced, or had ALT testing and anti-HBc testing together been introduced, I do not believe that this would have been of significant value in detecting donors who were ultimately found to be HCV antibody positive, and thereby reduced the rate of transfusion transmitted hepatitis.

8. Also, in late 1989, it was known that the commercial manufacturers were developing anti-HCV tests and with the prospect of such tests being available on the market in the near future, there was little point in commencing screening with surrogate tests which were known to have non-specific results.

9. I do recall that YRTC and other RTCs at the time were often short of blood, due to limited numbers of donors. Had non-specific surrogate marker results been used to exclude blood given by donors, this would have led to an even smaller supply of blood, and this was a serious consideration for the BTS. It is important that sufficient blood is always available to meet the demand from hospitals and users. *(Is it possible to expand on this? The point about requiring a constant supply of blood is an important one.)*

10. In addition, I would not have decided to commence surrogate testing at the YRTC without national advice from Dr Gunson and from the ACVSB. There was no pressure from the clinicians in my region, or from the RHA to introduce such tests, since they were generally considered to be non-specific.

Development of anti-HCV tests and confirmatory tests

11. The Chiron test became available for research use only, but not for diagnostic purposes, in 1990 (Leed 108 - 124). After the first generation anti-HCV test became available from the manufacturers, various studies were undertaken to examine and

compare the validity of the results which were given by them. I received copies of such studies from both Dr Gunson as National Director and from Dr Peter Flanagan lead consultant in transfusion micro biology *(is this his correct title?)* at my centre. Details of the studies were circulated to RTDs with copies of the ACTTD Minutes, since the results would be presented at the Committee's meetings.

12. There were differences between the results produced by different manufacturer's kits (Leed 106, 407). These differences were confirmed in the data from SNBTS in November 1991 comparing the various tests (Leed 273 - 335)

13. A serious problem when the first generation test became available was the lack of confirmatory tests available (Leed 201 - 202). This meant that we would not have been able to verify whether positives obtained were true positives.

14. When confirmatory tests did become available, I recall that there were problems experienced with the RIBA 2 confirmatory tests. (Leed 8 - 9, 221-3, 421 - 426, 1285 - 1294)

15. We did not use PCR because it was extremely expensive as a confirmatory test (Leed 226). We did use PCR for indeterminate confirmatory results. The technology at the time meant that PCR tests gave inconsistent results and PCR could not therefore be used as a primary test and was only appropriate as a confirmatory test. Repeat reactives on the antibody test would be subjected to PCR if the results were indeterminate. *(Are there reference papers regarding the inconsistency of PCR at this time?)*

16. The YRTC initially asked John Craske's laboratory at the Manchester PHLS to conduct our confirmatory tests. This was a designated reference centre (Leed 392-393). Later in 1991, from early November, we used the PHLS in Leeds (Leed 271).

17. An eight week study of confirmatory testing took place in September and October 1991 *(I can't see that we have the outcome of this although it seems Leeds took part - see Dr Flanagan's letter to John Craske at page 271).*

18. Representatives from the manufacturers would have written to and visited the RTC and seen Dr Flanagan, who would then report to me regarding the development of

the tests (see eg. Leed 157 - 160, 3 - 46) The YRTC had established a familiarity with Ortho since we already used that company's equipment for other ELISA tests. (Leed 3 - 105). We did not have any Abbott equipment, and considered Organon and UBI to be newcomers in terms of HCV testing. We tended to avoid Abbott because the company tied laboratories to Abbott's IT which limited an RTC's flexibility to use other tests *(is this correct?)*.

19. Information developed within the Blood Transfusion Service regarding the two generations of antibody tests was disseminated in several ways. Information was distributed by Dr Gunson in the form of the minutes and papers of the ACTTD, the UKBTS's internal Committee which received information from members with expertise in all relevant areas.(see TTD refs at para 5 above). I would read the minutes on receipt from Dr Gunson and would pass these to Dr Flanagan and meet with him to discuss issues raised, including issues relating to the commencement of HCV screening. Dr Flanagan and I had meetings on a daily basis to discuss many issues in relation to the management of the RTC, and we would therefore have discussed this information at one of these meetings. I did not keep minutes or notes of such meetings.

20. Another way in which information and know-how was shared amongst the RTDs was by divisional meetings. I attended the meetings of the Northern Division, which were attended by the RTDs of the Liverpool, Manchester, Sheffield, Newcastle, Lancaster and Leeds RTCs (Leed 392 - 393). These meetings were chaired by Dr Douglas Lee, who at that time was the Medical Director of the Manchester and Lancaster RTCs. *(any minutes?)* The development of HCV testing was one of the topics discussed at these meetings. As far as I recall, these took place every quarter. Their purpose was to communicate and disseminate information, and to provide the heads of the RTCs with a forum in which issues could be raised, information obtained, and an opportunity provided to express opinions or challenge situations.

Responsibility towards donors

21. Throughout my time in the Blood Transfusion Service ('BTS'), I have always held a strong view that the BTS has clear obligations to its blood donors. If a positive result is obtained from a screening test undertaken on a donor's blood, in my view

one must inform the donor of this result. *(have you written any papers on this which we could quote?)*

22. I received the document prepared by Jack Gillon of the Scottish NBTS setting out a recommended procedure for the management of anti-HCV donors (Leed 693 - 706). I commented on aspects of this which I felt may need to be adapted to suit the circumstances of the YRTC and I favoured counselling of donors being undertaken by RTC staff if possible (Leed 707). (*were any adaptations made to the Gillon papers? I can't find any guidance on counselling donors which has been drafted specifically by the Yorkshire RTC.)*

23. In the Yorkshire region, in the run up to the introduction of national HCV screening, we arranged that information and counselling from leading liver experts in the region would be available for donors. With my agreement, Dr Peter Flanagan wrote to consultant hepatologists and gastroenterologists in the region and asked them to confirm whether they would be willing to see and counsel donors who were identified as being anti HCV positive. Dr Flanagan also wrote to the Regional Health Authority to clarify the position regarding the funding to cover donor counselling and whether donors could be referred across district boundaries. He also wrote to all Directors of Public Health Districts served by the RTC in relation to the question of where donors in particular health districts should be referred and requesting the name of an appropriate person to whom confirmed HCV antibody positive donors should be referred (Leed 1243 - 1281).

24. After national screening had commenced, Dr Gunson asked for information about the way in which YRTC was handling donor counselling and Dr Flanagan responded, summarising our procedures for counselling and referral (Leed 710 - 712). The Centre developed its own standard letters to recall donors (Leed 716 - *this is a letter from Flanagan to Swinburne saying he encloses copies of the standard letters, but the letters themselves do not appear on the file. Would you be able to locate copies?)*

Information I received as RTD and reasons why it was important for all RTCs to act together as a national service

25. Although the centre was independent, in the sense that we were accountable only to the Regional Health Authority, I was very supportive of the Regional Transfusion Centres (RTCs) being part of the national co-ordinated blood transfusion service.

26. Although I did not serve on the ACTTD I used to receive the minutes of the ACTTD and was therefore aware of the deliberations of that Committee (see eg Leed 406 - 419, 430 - 455, 461 - 475, 485 - 491). I also received information regarding the policy decisions of the ACVSB, via the reports of Dr Harold Gunson to all the Regional Transfusion Directors ('RTDs').

27. In fulfilling the management objectives of the YRTC, I was guided by advice from Dr Harold Gunson as the National Director on issues which impacted on the national service, such as the safety of the blood. In particular I would have required exceptional circumstances to recommend that YRTC should act in a way contrary to the advice of the two Committees, the Advisory Committee on the Virological Safety of Blood ('ACVSB') and the Advisory Committee on Transfusion Transmitted Disease ('ACTTD'), which were considering the question of the introduction of HCV testing. It is highly improbable that the RHA would have allowed YRTC to act against the national consensus.

28. I received information and advice from Dr Gunson both formally and informally, by telephone and in writing. I did not keep telephone attendance notes. Telephone calls were usually to discuss issues relating to management and administration and not to provide me with core information.

29. Although there was no national authority which had control over the RTCs, I was very willing to liaise and act in accordance with Dr Gunson's advice to all RTCs, since I believed that it was important for donors and recipients of blood to be offered a nationally consistent service. In his role as National Director, Dr Gunson worked very hard to co-ordinate and manage the service across the country in a way which aimed to produce consistency of standards. He relied upon the willingness of each RTC to co-operate and liaise with his proposals and if an RTC decided to take a different course, Dr Gunson could not force them to follow the national policy nor could he penalise the RTC for acting unilaterally. *(This is a point we may want to review - Dr Gunson has not said this in terms in his statement, but I think it is an important point. Our evidence needs to be consistent)*

30. Information and views regarding NANBH and HCV were presented to the RTDs at annual symposia at which the Directors met, for instance the meeting in York in 1991. At this meeting I remember that Philip Mortimer and Jean Pierre Allain presented the current information available on hepatitis C *(is this correct? Expand : some directors attended some/ all meetings? Which ones went? How often were they? Was this the main forum for dissemination of ideas? We have been told by Dr Gunson that no minutes or documents were generated by these meetings. Can you recall if that is correct?).*

Decision by Newcastle RTC to commence screening unilaterally

31. Huw Lloyd, the RTD of the Newcastle RTC, also attended the Northern divisional meetings. I do not recall that he had expressed strong views at these meetings regarding the date on which national screening should be commenced and I certainly do not recall that he indicated to the meeting in March 1991 *(do we know if there was one at this date? Do you recall if you received minutes? I have not located them.)*) that he intended to commence screening in April 1991, separately to the rest of the BTS.

32. As I had been appointed RTD of the centre in 1988, between 1988 and 1991 I felt that I was a relatively junior Director in the NBTS. I felt it was appropriate to be guided by the advice of more senior members.

33. I offered support, by telephone call, to Dr Gunson as National Director at the time that I became aware that Newcastle had started screening unilaterally. This was following Huw Lloyd's letter to all RTDs in May 1991. I agreed with the views expressed by many RTDs that the decision taken by Dr Lloyd could be extremely damaging to the service across England (*how did you know at the time what these views were? Did RTDs telephone each other to discuss? Please expand.)*. I strongly believe that patients throughout England are entitled to receive the same standard of product and therefore believed it was necessary for all centres to commence screening at the same time. In my view it was important to start screening on the same date nationally because it is just and fair that all blood across the country should be to the same standard. This meant there would be no inequalities for patients.

Practical considerations to take into account in considering commencement of screening

34. It was necessary for us to purchase new equipment for the HCV test and I see from the contemporaneous documents that we purchased new Ortho equipment for this purpose (Leed 402 - 3).

35. We also had to recruit staff. The new staff would not have been given responsibility for this new test as this job would have been given to senior laboratory technicians who were familiar with screening tests, but the new staff were necessary to complete the tasks which these existing staff would have completed if their time was not being spent on the new screening test.

36. In relation to quality assurance issues, my staff were used to using ELISA tests for screening for other diseases. The biggest quality assurance issues were having an appropriate and agreed algorithm for dealing with repeat reactives, and at what point reactive tests should be referred to reference laboratories for confirmation. These were the subject of national discussion as Dr Gunson circulated the proposed algorithm and procedures so that all RTCs could comment on them. *(reference to be found)*

37. In relation to funding, as far as I recall my RTC did not experience difficulty in securing funding to commence HCV testing. I am aware that this is different to the experience of some other RTCs at this time (*in what way? How would you have known about other centres' funding difficulties at the time? Please expand.*). I was also aware that there were calls for central funding to cover this new test (Leed 386 - 389).

38. We assessed the financial implications of HCV testing for YRTC (Leed 376 - 385) in October 1989. In February 1991 Dr Gunson asked us not to conclude contracts with the manufacturers so that the Directorate could negotiate for the best prices on a national basis (Leed 400). I received information regarding the negotiated prices for HCV kits from the Procurement Directorate on 26 July 1991 (Leed 394 - 9). In February 1991 we investigated the cost of confirmatory testing (Leed 389) and the wider cost in the district (Leed 390 - 391) My RHA funded HCV testing in the

1991 financial year, and from April 1992 the price of testing was incorporated into product prices in accordance with the Department of Health's proposals (Leed 420).

39. Dr Flanagan took steps to put in place an appropriate system for counselling and referral of donors found to be HCV positive. This included writing to hepatologists in the region and asking them to agree to see donors who may be referred to them by the RTC.

40. As indicated above, arrangements were made for repeat reactive samples to be sent to John Craske at the Manchester PHLS for confirmatory testing. Later, we transferred this function to the PHLS in Leeds.

41. There was no pressure on the YRTC from clinicians within the region, including hepatologists who were treating patients with liver disease, or from the RHA, to introduce HCV screening of donated blood earlier than 1 September 1991.

Introduction of anti-HCV screening

42. On 22 January 1991, the eve of the Gulf War, Dr Gunson wrote to all RTDs notifying us that the Department of Health had agreed that routine testing of all blood donations for anti-HCV could commence. He stressed the need for a simultaneous commencement date across England and asked us to inform him of the earliest date when we could commence testing.

43. I replied on 24 January 1991 and informed him that the YRTC would be able to start screening at the beginning of May in preparation for a universal release of HCV tested product on the 1st June 1991, providing satisfactory arrangements had been agreed nationally. (E14 - *ref in Leeds files?*)

44. In fact YRTC commenced HCV screening on 20 May 1991 (*was it really this early? see page 356)* as part of the multi-centre trial assessing the second generation tests. The results up to 8 August at the YRTC were summarised (Leed 356 - 366). Later the YRTC results from June to November 1991 were summarised (Leed 205 - 215, 225 - 266, 367) This included a comparison of results from RIBA and Abbott tests. YRTC used the Ortho second generation EIA on all serum samples and referred samples were tested with the Abbott HCV second generation EIA and the Chiron

second generation RIBA HCV test. Indeterminate samples were further examined by the Abbott EIA supplemental assay.

45. I received the data collated from the SNBTS's results from HCV testing in November 1991. This compared the results of ELISA tests and confirmatory tests from the different manufacturers (Leed 273 - 335) (*How does this compare with Leeds data?*)

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

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

NOTE: conclusion of some sort needed. Also what about a section on responsibility towards recipients? The section on responsibility towards donors signals that any mention of recipients is missing. Please can you comment what your view would have been of the BTS's duty towards recipients?