THE PENROSE INQUIRY

WITNESS STATEMENT – DR RUTHVEN MITCHELL

OCTOBER 2010

Issue in respect of which a statement is sought

The non-introduction in Scotland of surrogate testing for Non-A Non-B Hepatitis.

My responses to some of these questions are in my previous statements in response to Schedule 1, dated 26 August 2010.

Paragraphs 1 and 2

Consideration was given by the SNBTS to introduce surrogate tests for Non-A Non-B Hepatitis in the 1980's. Tests were again subject to rigorous evaluation in the West of Scotland Regional Transfusion Centre, supported by Dr Eddie Follett and Dr Dow at the Regional Reference Laboratory at Ruchill Hospital. Early in the 1980's, ALT testing had been used in some centres in the USA, with their different populations and different categories of blood donor. These tests were found not to be specific, giving a wide variety of result levels which did not relate to post-transfusion Hepatitis. NANB remained a diagnosis of exclusion. Similar results were found in the studies in my laboratories and, as I have already stated, there was a great deal of conflicting views throughout the world. Fortunately, the specific virus and the testing, which Dr Harvey Alter had predicted would never be found, was discovered, and this transformed the decision to start using tests which were satisfying the criteria of specificity, sensitivity and subsequent modification. The NIH consensus statement of January 1996 summarises many of these controversial issues.

Paragraph 3

I have no knowledge of why the English NANBH surrogate testing multicentre trial did not include Scotland, although at this time extensive testing was being done in Scotland. Test kits from manufacturers were obtained and used against samples from alleged Non-A Non-B patients within the Scottish Regional Transfusion Centres, with the help of the Regional Virus Laboratory at Ruchill. These included at risk patients, such as those with multiple transfusion history, those who were intravenous drug abusers and non-Hepatitic patients, as well as immuno compromised patients. The findings were reported to Regional Transfusion Centre Directors meetings by Dr Dow and Dr Follett.

Paragraph 4

These tests and subsequent work were done in Scotland after the meeting of 25 March 1986 which indicated that a suitable trial was desirable. The English study was commissioned by, I think, DHSS, but before it was completed the virus was cloned, and Scotland was eager to proceed with evaluating the available tests which were coming on the market. Toward the end of the 1980's, therefore, various groups were working hard to achieve the object of a specific robust sensitive test applicable to large scale screening in as short time as possible, and within reasonable costs. Information was freely exchanged within the United Kingdom and tests with the first, second and third generation kits provided by various manufacturers was progressed. Dr Dow and Dr Follett established very sensitive (RIBA) & PCR tests at Ruchill Virology Department which could be used for confirmatory testing for the various markers of the Hepatitis C virus. Accumulated archive test panels were of great value in carrying out these evaluations and I am sure Dr Dow will be able to provide some details of these if the laboratory records are available.

As the knowledge was accumulating from all sources, including English and Scottish studies, flowcharts were constructed for the handling of such donors found sensitive by these various tests. I am sure that Dr Dow will be able to advise on the details of the first, second and third generation tests for Non-A Non-B Hepatitis. Certainly any tests found to be reactive by any of the methods used would, of course, not be bankable but would be used to test the reliability, variability and reproducibility of each and every test.

Paragraph 5

SNBTS was updated on a regular basis on the comparative evaluation studies, and limited partial full scale testing was introduced in early 1991, when thousands of blood donors were screened to establish the Blood Transfusion Service's ability to undertake such an additional requirement on staff and resources. By this time Dr Dow was virtually full time at Ruchill. Staff worked on at extra times using kits supplied free of charge by manufacturers who were all anxious to have their kits in the market place. Around this time, most Regional Transfusion Centres in the UK were testing for HCV using a variety of tests and, if any reacted, donations were sent to the designated reference laboratories. Tests were revealing that some of the earlier tests were unable to detect some of the markers of the HCV virus and second and third generation tests were introduced. This took some time but, by the early 1990's, active steps were being taken to have resources provided for mass full scale screening. Records of these events may be held centrally.

Paragraph 6

The seeking of funding from SHHD was, I believe, based on the understanding that new tests for virus markers were becoming available and required full evaluation, and possible implementation, to enhance the required safety of the blood supply.

Paragraph 7

The decision in 1987 to seek funding from 1 April 1988 was based on the probability of having to do mass screening of volunteers using the tests then available. With the progress of time in the evaluations referred to earlier, it was clear that decisions based on non specific test information would not substantially improve the safety of donated blood, nor the handling of blood donors who were not unhealthy. They could present socioeconomic and psychological problems among the 5% of the non-remunerated population who volunteer for the benefit of others, whilst the other 95% of the population who do not volunteer would, if tested, reveal similar markers. My view and that of others was reported at the International Forum in Vox Sanguinis Volume 44 page 57. After my retrial I was invited to assist Australian solicitors concerning alleged HCV transmission and replied in August 1996 in these terms.

Paragraphs 8 and 9

Steps taken to introduce surrogate testing for Non-A Non-B Hepatitis were always subject to scientific evaluation of the known techniques available, taking account of the likely costs in time and energy and the outcome in terms of donor recruitment, acceptability, retention and use. The additional costs involved would be calculated at National Headquarters by the Finance Department based on the price of reagents and manpower required. I cannot recall the exact amounts but I am sure these would have been considered at the time.

Paragraph 10

Surrogate testing was not introduced in Scotland and elsewhere but was never abandoned as a desirable procedure. However, it was necessary to proceed with caution and accuracy for the benefit of patients and blood donors. I have already indicated in these notes that the use of reliable surrogate tests was slowly evolving in all national and international blood collecting agencies, not by a fear to adopt and adapt ideas, but to search for the true meaning and effect of all of these tests, which was not included until Chiron Type Tests were available.

Paragraph 11

Introduction of suitable surrogate tests in Scotland at the appropriate time would, in my view, reduce the possibility of Non-A Non-B Hepatitis, but by how much I cannot calculate because the early tests were unreliable and only later could it be said that HCV might be entirely eliminated from the blood supply if such a test were ever developed. It must be remembered that if there was any doubt concerning any donation, considerable care would be taken to avoid it entering the useable bank. It is also to be noted that the look back studies showed considerable uncertainty. It is stated in Journal of Hepatitis 11 September 2004 that about 40,000 positive HCV individuals exist in Scotland. In my laboratory from 30th May 1991 to 22nd July 1991, 23,644 new and repeat donations were tested and 0.11% were found and confirmed to be positive (1 in 954) by EIA testing, confirmed by RIBA and PCR, with no gender differences

Paragraph 12

If surrogate testing had been introduced in Scotland the deferral rate would have varied depending on which tests were being used. Many would have been deferred for no good reason and others for non-related findings. With a whole battery of tests, including look back and look forward in donation testing, then perhaps it would have been possible to arrive at a calculated amount for such Region. Such studies as look back and look forward were undertaken with considerable difficulty, and not found valuable because of lack of traceable data and the costs involved.

Paragraph 13

The paper in the Lancet of 13 June 1987 is based upon information I have already given throughout these notes. The letter involving the views of the Scottish Directors in the Lancet of 4 July 1987 again reiterates the need for funding a safe rapid specific sensitive and robust test or tests which would avoid the possible problems stated, including reluctance of manufacturers to co-operate in any comparative testing and evaluation of their test kits.

Paragraph 14

In the UK Transfusion Services Advisory Committee or the Transfusion Transmitted Diseases at their first meeting, I spoke about some very preliminary tests carried out in my department by way of showing the Scottish interest in familiarisation with the problems emerging in the world and the emergence of tests for the virus of NANBH. I do not have the file records of the tests referred to but the statement suggests to me that the tests may have been done to look at the number of ALT donors who were positive for anti Hbcore (HBc)which some considered to be a sign of chronic carriage of the Dane particle of Hepatitis B. Co-infection may occur with various viruses.

Statement of Truth

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

Signed.....

Dated.....2/2/2011.....